As confidentially submitted to the U.S. Securities and Exchange Commission on May 22, 2018 as Amendment No. 1 to the confidential submission dated April 2, 2018.

**Registration No. 333-**

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

FORM S-1

**REGISTRATION STATEMENT** 

UNDER THE SECURITIES ACT OF 1933

### Aquestive Therapeutics, Inc. (Exact Name of Registrant as Specified in its Charter)

Delaware

(State or Other Jurisdiction of Incorporation or Organization)

2834 (Primary Standard Industrial Classification Code Number)

82-3827296 (I.R.S. Employer Identification Number)

30 Technology Drive Warren, NJ 07059 (908) 941-1900

(Address, Including Zip Code, and Telephone Number, Including Area Code, of Registrant's Principal Executive Offices)

> John T. Maxwell **Chief Financial Officer** Aquestive Therapeutics, Inc.

Aquestive Therapeutics, Inc. 30 Technology Drive Warren, NJ 07059 (908) 941-1900 (Name, Address, Including Zip Code, and Telephone Number, Including Area Code, of Agent for Service)

With copies to:

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Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this registration statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, as amended (the "Securities Act"), check the following box. o

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Securities Exchange Act of 1934.

Large accelerated filer o Accelerated filer o Smaller reporting company o Non-accelerated filer ⊠ Emerging Growth Company (Do not check if a smaller

reporting 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 to Section 7(a)(2)(B) of the Securities Act. o

CALCULATION OF REGISTRATION FEE

Title of Each Class of	Proposed Maximum	Amount of
Securities to be Registered	Aggregate Offering Price <sup>(1)</sup>	Registration Fee <sup>(2)</sup>
Common Stock, par value \$0.001 per share	\$	\$

Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(o) under the Securities Act and includes the offering price of shares (1)that the underwriters have the option to purchase to cover over-allotments.

Calculated pursuant to Rule 457(o) under the Securities Act based on an estimate of the proposed maximum aggregate offering price and includes the offering (2)price of shares that the underwriters have the option to purchase to cover over-allotments.

The Registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment that specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act or until the registration statement shall become effective on such date as the U.S. Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

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

**Preliminary Prospectus** 

Subject to Completion, dated May 22, 2018

Shares



### Aquestive Therapeutics, Inc. Common Stock

### **\$** Per Share

This is the initial public offering of our common stock. We are offering shares of our common stock. The initial public offering price of our common stock is expected to be between \$ and \$ per share.

Prior to this offering, there has been no public market for our common stock. We have applied for listing of our common stock on the Nasdaq Global Market under the symbol "AQST".

We are an "emerging growth company" as defined by the Jumpstart Our Business Startups Act of 2012 and, as such, we have elected to comply with certain reduced public company reporting requirements for this prospectus and future filings.

#### Investing in our common stock involves risks. See "Risk Factors" beginning on page 11.

	Per Sha	are Total	
Initial public offering price	\$	\$	
Underwriting discount <sup>(1)</sup>	\$	\$	
Proceeds, before expenses, to Aquestive Therapeutics, Inc.	\$	\$	

(1) We refer you to "Underwriting" beginning on page 151 of this prospectus for additional information regarding underwriting compensation.

To the extent that the underwriters sell more than shares of common stock, the underwriters have the option to purchase up to an additional shares from us at the initial public offering price less the underwriting discount.

Neither the Securities and Exchange Commission nor any state securities commission has approved of anyone's investment in these securities, or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The underwriters expect to deliver the shares of common stock to the purchasers on or about , 2018.

Joint Book-Running Managers

### **BMO Capital Markets**

Co-Lead Managers

**JMP Securities** 

**RBC Capital Markets** 

Wedbush PacGrow

Prospectus dated ,

, 2018.

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

We own various U.S. federal trademark registrations and applications, and unregistered trademarks and service marks, including "Aquestive Therapeutics" and our corporate logo. Solely for convenience, trademarks and trade names referred to in this prospectus, including logos, artwork and other visual displays, may appear without the ® or ™ symbols. We do not intend our use or display of other companies' trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

Additionally, throughout this document we use the proposed brand names of Libervant and Sympazan, which have been approved by the FDA on a preliminary basis, when referring to AQST-203 and AQST-120, respectively, despite both product candidates having yet to receive marketing approval from the FDA. All references in this prospectus to Libervant and Sympazan refer only to our product candidates and are not meant to imply FDA approval of the product candidates or their proposed brand names.

#### **PROSPECTUS SUMMARY**

This summary highlights information contained in other parts of this prospectus. Because it is only a summary, it does not contain all of the information that you should consider before investing in shares of our common stock and it is qualified in its entirety by, and should be read in conjunction with, the more detailed information appearing elsewhere in this prospectus. Before investing in our common stock, you should carefully read this entire prospectus, including our consolidated financial statements and the related notes thereto and the information set forth under the sections titled "Risk Factors," "Special Note Regarding Forward-Looking Statements" and "Management's Discussion and Analysis of Financial Condition and Results of Operations," in each case included in this prospectus. Unless the context requires otherwise, references in this prospectus to "Aquestive," "the Company," "we," "us" and "our" refer to Aquestive Therapeutics, Inc. The consolidated financial statements included subsidiary.

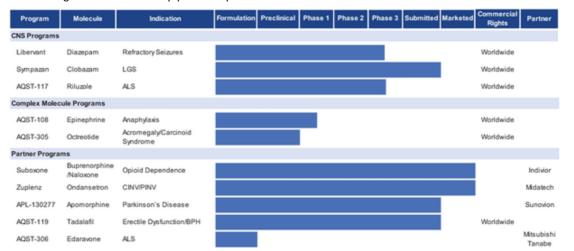
#### Overview

We are a specialty pharmaceutical company focused on identifying, developing and commercializing differentiated products to address unmet medical needs. We have a late-stage proprietary product pipeline focused on the treatment of diseases of the Central Nervous System, or CNS. We believe that the characteristics of these patient populations and shortcomings of available treatment options create opportunities for the development and commercialization of meaningfully differentiated medicines. Our most advanced proprietary product candidates, which we intend to commercialize ourselves, include (i) Libervant (the preliminary brand name for AOST-203), a buccally, or inside of the cheek, administered soluble film formulation of diazepam for the treatment of recurrent epileptic seizures, for which we expect to submit a New Drug Application, or NDA, in 2018; (ii) Sympazan (the preliminary brand name for AQST-120), an oral soluble film formulation of clobazam for the treatment of seizures associated with a rare, intractable form of epilepsy known as Lennox-Gastaut Syndrome, or LGS, for which we submitted an NDA in October 2017 and have been assigned an August 31, 2018 Prescription Drug User Fee Act, or PDUFA, date, which is the date the U.S. Food and Drug Administration, or FDA, expects to complete its review of our NDA, and (iii) AQST-117. an oral soluble film formulation of riluzole for the treatment of Amvotrophic Lateral Sclerosis, or ALS, for which we expect to submit an NDA in 2018. We have also developed a proprietary pipeline of complex molecule products addressing large market opportunities beyond CNS indications, which include (i) AQST-108, a sublingual film formulation of epinephrine for the treatment of anaphylaxis, for which we expect to begin additional Phase 1 trials in 2018 and (ii) AOST-305, a buccal film formulation of octreotide for the treatment of acromegaly and neuroendocrine tumors, for which we expect to begin human proof of concept trials in 2018.

In addition to these product candidates, we have a portfolio of commercialized and development-stage partnered products. These products include Suboxone, a sublingual film formulation of buprenorphine and naloxone, which is the market leader for the treatment of opioid dependence. We manufacture all of our partnered and proprietary products at our FDA and Drug Enforcement Administration, or DEA, inspected facilities and anticipate that our current manufacturing capacity is sufficient for commercial quantities of our products and product candidates currently in development. We have produced over 1.2 billion doses of Suboxone in the last four years. Our products are developed using our proprietary PharmFilm technology and know-how. Our patent portfolio currently comprises at least 200 issued patents worldwide, of which at least 40 are U.S. patents, and more than 75 pending patent applications worldwide.

#### **Our Product Portfolio and Pipeline**

The following table outlines our pipeline of product candidates:



#### Proprietary CNS Product Portfolio

We have initially focused our proprietary product pipeline on certain difficult to treat CNS diseases. Our PharmFilm technology allows us to develop medicines that offer non-invasive delivery, customized suitability for patients with dysphagia, or trouble swallowing, can be administered without water and ensure consistent therapeutic dosing. We believe that these characteristics will allow us to achieve the desired patient outcomes, while potentially reducing the total cost of patient care.

The most advanced assets within our proprietary CNS portfolio are as follows:

- Libervant a buccally, or inside of the cheek, administered soluble film formulation of diazepam, a
  benzodiazepine used as a rescue therapy for breakthrough epileptic seizures and an adjunctive therapy for
  use in recurrent convulsive seizures. We are developing Libervant as an alternative to Diastat (diazepam
  rectal gel), the current standard of care rescue therapy for patients with epilepsy, which as a rectal gel, is
  invasive, inconvenient, and difficult to administer. Libervant is currently completing its final clinical trials. We
  expect to submit an NDA for Libervant in 2018.
- **Sympazan** an oral soluble film formulation of clobazam, a benzodiazepine used as an adjunctive therapy for seizures associated with LGS. We are developing Sympazan as an alternative to Onfi (clobazam), currently available in either tablet form or liquid suspension. LGS patients often have difficulty swallowing pills and large volume suspensions leading to uncertain and inconsistent dosing and increasing the burden of care, particularly for patients that may be combative or resistant to treatment. In clinical trials, Sympazan has demonstrated bioequivalence to Onfi. We submitted an NDA for Sympazan in October 2017 and were given a PDUFA date of August 31, 2018. If approved by the FDA, we anticipate launching Sympazan by the end of 2018.
- AQST-117 an oral soluble film formulation of riluzole, a small molecule glutamate antagonist used as an adjunctive therapy in the treatment of ALS, which has been shown to slow disease progression, increase lifespan and improve quality of life. However, because ALS patients typically have difficulty swallowing, tablet administration is challenging. We are developing AQST-117 as an alternative to Rilutek (riluzole), which is currently available only in tablet form in order to achieve an easier, more reliable and accurate dosing. This may allow patients to continue therapy even after their ability to swallow has become compromised. AQST-117

addresses these treatment obstacles because it is mucoadhesive and dissolves easily on the tongue without the need for water and without a substantial increase in salivary flow. In clinical trials, AQST-117 has demonstrated bioequivalence to Rilutek. We expect to submit an NDA for AQST-117 in 2018.

In March 2018, we received interim data from our adult Epilepsy Monitoring Unit, or EMU, clinical study for Libervant. The study consists of two treatment arms designed to compare the pharmacokinetics, or PK, of Libervant in subjects with epilepsy in the interictal condition, when they are not experiencing seizures, versus the ictal/peri-ictal condition, when they are experiencing seizures. Through February 2018, 12 subjects had completed the study across the two treatment arms. This represents 40% of the 30 subjects needed to complete the study. Preliminary analysis of the data indicates the following:

- A 12.5mg dose of Libervant administered during an interictal, or non-seizure, state and without regard to food (n=12 patients) provided appropriate maximal plasma concentrations of diazepam (Cmax) within 60 minutes of administration (Tmax). Furthermore, similar Cmax and Tmax levels were obtained during dosing in a peri-ictal state. We believe these results successfully demonstrate that Libervant is adequately absorbed into the blood stream regardless of whether it is applied during a seizure or normal state.
- Observed plasma levels of diazepam in patients with epilepsy were lower than plasma levels in healthy volunteers at the same dose level. This is consistent with the effects of multiple concomitant anti-epileptic drugs, or AEDs, which interact with diazepam and are commonly used by these patients.
- Based on these data, we currently anticipate that a 12.5mg dose of Libervant will be equivalent to a 17.5mg dose of Diastat. As a point of reference, our 12.5mg Libervant in patients with epilepsy had a similar Cmax to a 12.5mg dose of Diastat given to healthy volunteers with no exposure to AEDs. We believe this confirms our ability to provide an efficacious dose of Libervant at a lower dose level than Diastat.

We are in the process of requesting a face-to-face meeting with the FDA where these data, along with other clinical data, will be presented. We believe the interim data support our view that, upon the completion of our adult EMU study, we will have the necessary supporting data to submit a marketing application to the FDA.

#### Proprietary Complex Molecule Portfolio

We are utilizing our technology and know-how to target large market opportunities by developing orallyadministered complex molecule therapies as alternatives to invasively-administered standard of care injectable therapeutics. We currently have two active complex molecule programs in clinical development, which are:

- AQST-108 a sublingual film formulation of epinephrine for the treatment of anaphylaxis, a severe and potentially life-threatening allergic reaction. Epinephrine is the standard of care in the treatment of anaphylaxis and is currently administered via intramuscular injection. The current market leader is EpiPen, a single-dose, pre-filled epinephrine automatic injection device. As a result of its administration via intramuscular injection, many patients and their caregivers are reluctant to use currently available products, resulting in increased hospital visits and overall cost of care to treat anaphylactic events. We are designing AQST-108 to be the first non-injectable form of epinephrine used to treat anaphylaxis.
- **AQST-305** a sublingual film formulation of octreotide, a small peptide that has a similar pharmacological profile to natural somatostatin, for the treatment of acromegaly, as well as severe diarrhea and flushing associated with carcinoid syndrome. Acromegaly is a hormone disorder that results from the overproduction of growth hormone in middle-aged adults. Octreotide is the standard of care for the treatment of acromegaly. The current market leader, Sandostatin (octreotide injectable suspension), is administered via deep subcutaneous or intramuscular injections once a month. This monthly treatment regimen can result in loss of

efficacy towards the end of the monthly treatment cycle. We are developing AQST-305 as a non-invasive, pain-free alternative to Sandostatin to reduce treatment burden, healthcare costs and the potential loss of efficacy over the treatment cycle.

#### Partnered Products

Our portfolio also includes products and product candidates that we have partnered, or will seek to partner, for commercialization. In the year ended December 31, 2017, our partnered product portfolio generated over \$1 billion in revenue for our partners, resulting in \$66.9 million in revenue to us. Our key partnered products include:

- Suboxone a sublingual film formulation of buprenorphine and naloxone that is marketed in the United States and internationally for the treatment of opioid dependence. Suboxone was launched in 2010 in partnership with Reckitt Benckiser Pharmaceuticals, Inc., who was later succeeded to in interest by Indivior, Inc. Suboxone is the most prescribed branded product in its category with approximately 60% market share.
- **APL-130277** a sublingual film formulation of apomorphine, a dopamine agonist in development to treat episodic off-periods in Parkinson's disease. APL-130277 is being developed as a sublingual alternative to injectable apomorphine. Sunovion Pharmaceuticals, Inc., or Sunovion, our partner and sponsor of APL-130277, submitted an NDA to the FDA on March 29, 2018.

#### PharmFilm - Our Oral Film Technology

We developed our PharmFilm technology to provide meaningful clinical and therapeutic advantages over other existing dosage forms and, in turn, to improve the lives of patients and caregivers.

PharmFilm is comprised of proprietary polymer compositions that serve as film formers to hold active pharmaceutical ingredients, or APIs, and excipients in place. Proprietary and patent-protected compositions, formulation and manufacturing techniques and technology are employed to ensure that the API is distributed uniformly throughout the film and that target absorption levels are achieved. Our proprietary technology and manufacturing process ensures that PharmFilm can be engineered to fit a variety of target product profiles in order to best address the unmet patient need present within specific disease states. PharmFilm, which is similar in thickness and size to a postage stamp, can be administered via buccal, sublingual or lingual oral delivery.

We believe the innovative nature of our PharmFilm drug delivery platform has the potential to offer a number of meaningful advantages to patients, caregivers and physicians compared to current standard of care therapies, including:

- preferred alternative to more invasive drugs such as injection;
- faster onset of action;
- · direct absorption into the bloodstream reducing or avoiding "first pass" effects in the liver;
- reduced gastrointestinal, or GI, side effects;
- positive dosing outcomes, especially for patients with physical (*e.g.*, dysphagia) or psychological barriers to other methods of drug administration;
- stable, durable, portable and quick-dissolving (with or without water);
- customizable delivery routes for tailored PK profiles (buccal, sublingual or lingual); and
- customizable taste profiles.

#### **Our Management Team**

Our management team is a critical component to the development of our business model and the execution of our strategy. We are led by executives with an average of over 17 years of relevant senior leadership experience, including developing and commercializing branded and generic pharmaceuticals at large multinational pharmaceutical companies such as Johnson & Johnson, GlaxoSmithKline PLC and Novartis AG. Our team has significant experience in commercialization of pharmaceutical products, translational science, drug evaluation, clinical development, regulatory affairs and business development.

#### **Our Strategy**

We are a patient-centric pharmaceutical company developing and commercializing products that address unmet needs and improve the lives of patients and their caregivers. We focus on developing medicines for patient populations suffering from the shortcomings of available treatment options, which can create an opportunity for differentiated medicines. Our pipeline is initially focused on developing treatments for CNS diseases, as well as orally administered complex molecules that we believe can be alternatives to invasively-administered standard of care therapies. Our strategy leverages our global intellectual property portfolio, know-how, demonstrated research and development capabilities and proprietary manufacturing platform.

To achieve these goals, our strategy includes the following key elements:

- advance our late stage proprietary portfolio of CNS product candidates to solve critical healthcare problems and make a meaningful improvement in the lives of patients and caregivers;
- scale our commercial platform to maximize the value of our proprietary product candidates;
- exploit our technology and know-how to develop oral versions of more complex injectable drugs to address unmet patient needs;
- continue to identify product opportunities within CNS and other markets to expand our proprietary product pipeline;
- acquire products or establish partnerships to develop and market products utilizing new chemical entities; and
- continue to expand and solidify our intellectual property portfolio for our products, product candidates and manufacturing processes.

#### **Risks Associated with Our Business**

Our business is subject to numerous risks, as more fully described in the section entitled "Risk Factors" immediately following this prospectus summary. You should read these risks before you invest in our common stock. We may be unable, for many reasons, including those that are beyond our control, to implement our business strategy.

These risks include, but are not limited to, the following:

- we have incurred significant losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future and may never achieve or maintain profitability;
- even if this offering is successful, we will need substantial additional capital to fund our operations, which
  may not be available on acceptable terms, if at all;
- our level of indebtedness and significant debt service obligations could constrain our ability to invest in our business and make it more difficult for us to fund our operations;
- we are dependent upon the commercial success of Suboxone and other licensing activities to generate revenue for the near future;
- we have never directly commercialized a product candidate and we may lack the necessary expertise, personnel and resources to successfully commercialize any of our products that receive regulatory approval on our own or together with collaborators;
- our commercial success depends upon attaining significant market acceptance of our products and product candidates, if approved, among patients, physicians, pharmacists and the medical community;
- if we are unable to achieve and maintain coverage and adequate reimbursement for our products or product candidates, if approved, their commercial success may be severely hindered;
- if the FDA does not conclude that our product candidates satisfy the requirements for the 505(b)(2) regulatory approval pathway, or if the requirements for approval of any of our product

candidates under Section 505(b)(2) are not as we expect, the approval pathway for our product candidates will likely take significantly longer, cost significantly more and encounter significantly greater complications and risks than anticipated, and in any case may not be successful;

- if we are unable to obtain or protect intellectual property rights related to any of our product candidates, we
  may not be able to compete effectively in our market; and
- we rely on third parties to conduct our preclinical studies and clinical trials. If these third parties do not
  successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain
  regulatory approval for or commercialize our product candidates and our business could be substantially
  harmed.

#### **Corporate Information**

We were originally formed in Delaware in January 2004 and until December 31, 2017, we conducted our business through MonoSol Rx, LLC, a Delaware limited liability company, or MonoSol. From the period of organization through October 31, 2017, our predecessor was a limited liability company, or LLC, treated as a partnership for income tax purposes. From November 1, 2017 through December 31, 2017, MonoSol elected to be taxed as a C corporation. On January 1, 2018, MonoSol converted from a Delaware LLC into a Delaware corporation pursuant to a statutory conversion and changed its name to Aquestive Therapeutics, Inc. In a corporate reorganization conducted following the conversion of MonoSol into a Delaware corporation, the holders of units of MonoSol contributed their interests in MonoSol to Aquestive Partners, LLC, or APL, in exchange for identical interests in APL and following such exchange APL became the parent and sole stockholder of Aquestive Therapeutics, Inc. Upon consummation of this offering, our shares held by APL will be distributed to the holders of interests in APL in exchange for such interests, and APL will be liquidated. Except as disclosed in this prospectus, the consolidated financial data and other financial information included in this prospectus are those of MonoSol prior to the conversion into Aquestive Therapeutics, Inc.

Our principal executive office is located at 30 Technology Drive, Warren, New Jersey 07059, and our telephone number is (908) 941-1900. Our corporate website address is www.aquestive.com. Information contained on or accessible through our website is not a part of this prospectus, and the inclusion of our website address in this prospectus is an inactive textual reference only.

#### Implications of Being an Emerging Growth Company

We are an "emerging growth company," as defined in Section 2(a) of the Securities Act of 1933, as amended, or the Securities Act, as modified by the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. As such, we are eligible to take advantage of 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 have our internal control over financial reporting audited by our independent registered public accounting firm pursuant to Section 404(b) of the Sarbanes-Oxley Act of 2002;
- being permitted to present only two years of audited financial statements and only two years of related Management's Discussion and Analysis of Financial Condition and Results of Operations;
- 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 have taken advantage of some of the reduced reporting burdens in this prospectus and may take advantage of additional exemptions in the future. Accordingly, the information contained herein may be different than the information provided by other public companies. We do not know if some investors will

find our shares less attractive as a result of our utilization of these or other exemptions. The result may be a less active trading market for our shares and our share price may be more volatile.

In addition, Section 107 of the JOBS Act also provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. In other words, an "emerging growth company" can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. As an emerging growth company, we have elected to take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards and, as a result, we will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for public emerging growth companies.

We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the consummation of this offering, (b) in which we have total annual gross revenue of at least \$1.07 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeded \$700.0 million as of the last day business day of our most recently completed second fiscal quarter, and (2) the date on which we have issued more than \$1.0 billion in non-convertible debt during the prior three-year period. Please note any references herein to "emerging growth company" shall have the meaning associated with it in the JOBS Act.

Т	IE OFFERING				
Shares of common stock offered by us	shares				
Shares of common stock to be outstanding after this offering	shares				
Over-allotment option to purchase additional shares	shares				
Use of proceeds	We estimate that the net proceeds from this offering will be \$ million, or approximately \$million if the underwriters exercise their over-allotment option in full, assuming an initial public offering price of \$per share (the mid-point of the price range set forth on the cover page of this prospectus), after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. We intend to use the net proceeds from this offering, together with our existing cash and cash equivalents and cash generated from existing partnerships, (i) to fund pre-launch commercialization investments for our epilepsy products, Libervant and Sympazan, as well as AQST-117, (ii) to fund the commencement of our clinical trials for our complex molecules AQST-108 and AQST-305, (iii) to identify our new pipeline candidates in epilepsy and other CNS diseases, and (iv) for general corporate purposes, including working capital and capital expenditures. See "Use of Proceeds" on page <u>54</u> .				
Proposed Nasdaq Global Market symbol	"AQST"				
Risk factors	You should read the "Risk Factors" section of this prospectus for a discussion of certain of the factors to consider carefully before deciding to purchase any shares of our common stock.				
The number of shares of our common stock to be common stock outstanding as of March 31, 2018 (on					
<ul> <li>shares of common stock issuable immediately prior to the consummation of this offering pursuant to the automatic exercise of warrants to purchase shares of our common stock at an exercise price of \$0.01 per share granted to Perceptive (as defined below), or the Perceptive Warrants; but excludes:</li> </ul>					
• shares of common stock reserved for 2018 Plan.	future issuance under our 2018 Equity Incentive Plan, or the				
Unless otherwise indicated, all information conta	ined in this prospectus assumes:				
a for reverse stock split of our c	ommon stock effected on , 2018;				
<ul> <li>the distribution of shares of our common sto APL and the subsequent liquidation of APL is</li> </ul>	ck held by APL to its members in exchange for their interests in upon consummation of this offering;				
no exercise by the underwriters of their optic and	on to purchase an additional shares of our common stock;				
no issuance or exercise of stock options or a	any other warrants on or after March 31, 2018.				

#### SUMMARY CONSOLIDATED FINANCIAL DATA

The following table summarizes our historical financial data as of, and for the periods ended on, the dates indicated. We have derived the statements of operations data for the years ended December 31, 2017 and 2016 from our audited consolidated financial statements included elsewhere in this prospectus. The accompanying unaudited interim consolidated financial statements are prepared in conformity with accounting principles generally accepted in the United States ("U.S. GAAP") and with Article 10 of Regulation S-X for interim financial reporting. The statements of operations data for the three months ended March 31, 2018 and 2017 and the balance sheet data as of March 31, 2018 have been derived from our unaudited interim consolidated financial statements included elsewhere in this prospectus and have been prepared in accordance with generally accepted accounting principles in the United States on the same basis as the annual audited consolidated financial statements and, in the opinion of management, the unaudited data reflects all adjustments, consisting only of normal recurring adjustments, necessary for the fair presentation of the financial information in those statements. Our historical results are not necessarily indicative of the results that may be expected in the future, and results from our interim period may not necessarily be indicative of the results of the entire year or any future period. The summary of our financial data set forth below should be read together with our consolidated financial statements, and the related notes thereto and "Selected Consolidated Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" appearing elsewhere in this prospectus.

		Year Ended December 31,		Three Months Ended March 31,				
		2017		2016		2018		2017
(In thousands, except per membership interest and per share data)						(una	udite	ed)
Consolidated Statements of Operations and Comprehensive Income (Loss):								
Revenues	\$	66,918	\$	51,785	\$	23,411	\$	16,436
Costs and expenses:								
Manufacture and supply		19,820		16,378		5,636		4,184
Research and development		22,133		15,450		4,901		5,343
Selling, general and administrative		25,078		20,804		7,569		6,128
Total costs and expenses		67,031		52,632		18,106		15,655
Operating (loss) income		(113)		(847)		5,305		781
Other expenses:								
Interest expense		(7,707)		(6,143)		(1,927)		(1,818)
Loss on extinguishment of debt		—		(757)		—		—
Loss on impairment of investment		_		(1,006)		_		_
Change in fair value of warrant		(1,123)		(750)		697		(420)
Other income (expense)				(99)		24		
Net (loss) income before income taxes		(8,943)		(9,602)		4,099		(1,457)
Income taxes								
Net (loss)income		(8,943)		(9,602)		4,099		(1,457)
Dividends on redeemable preferred interests		(2,480)		(2,342)				(613)
Net income (loss) attributable to shares of common stock / members' interests		(11,423)		(11,944)		4,099		(2,070)
Comprehensive (loss) income	\$	(11,423)	\$	(11,944)	\$	4,099	\$	(2,070)
Net income per share/ net (loss) per membership interest	\$	(0.09)	\$	(0.10)	\$	0.02	\$	(0.02)

	Year E Decemb		Three Months Ended March 31,			
	2017	2016	2018	2017		
(In thousands, except per membership interest and per share data)			(una	audited)		
Weighted-average number of shares of common stock / membership interests outstanding—basic and diluted	121,228,353	118,785,104	186,061,577	121,228,353		
Unaudited pro forma net income (loss) <sup>(1)</sup>	\$ (8,943)		\$ (14,801)	)		
Unaudited pro forma net income (loss) per share of common stock	\$ (0.04)		\$ (0.06)	)		
Unaudited pro forma weighted-average number of shares of common stock outstanding used to compute net loss per share of common stock <sup>(1)</sup>	246,768,153		246,768,153			
			As of March 31, 2	2018		
		Actual	Pro <u>Forma<sup>(1)</sup></u> (unaudited)	Pro Forma As Adjusted <sup>(2)(3)</sup>		
Balance Sheet Data:			(			
Cash and cash equivalents		\$ 16,488	\$ 16,488			
Working capital <sup>(4)</sup>		14,349	6,949			
Total assets		46,082	46,082			
Total debt		45,965	45,965			
Accumulated deficit		(115,994)	(134,894)			
Total stockholders' deficit		(22,396)	(22,820)			

(1) The pro forma column reflects the charge of \$18.9 million for the termination of the Performance Unit Plan, effective January 1, 2018. Also included is the conversion of the warrant liability of \$6,976 as an addition to additional paid-in capital and a reduction of the warrant liability.

(2) The pro forma as adjusted column reflects the pro forma adjustments discussed above and the sale of shares of our common stock in this offering at an assumed initial public offering price of \$ per share, the midpoint of the price range set forth on the cover page of this prospectus, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

(3) Each \$1.00 increase (decrease) in the assumed initial public offering price of \$ per share, the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) each of cash and cash equivalents, working capital, total assets and total stockholders' equity on a pro forma as adjusted basis by approximately \$ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each 1.0 million increase (decrease) in the number of shares offered by us would increase (decrease) each of cash and cash equivalents, working capital, total assets and total stockholders' equity on a pro forma as adjusted basis by approximately \$ million, assuming that the number of shares offered by us would increase (decrease) each of cash and cash equivalents, working capital, total assets and total stockholders' equity on a pro forma as adjusted basis by approximately \$ million, assuming that the assumed initial public offering price remains the same, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. The pro forma as adjusted information discussed above is illustrative only and will be adjusted based on the actual initial public offering price and other terms of this offering determined at pricing.

(4) Working capital is defined as current assets less current liabilities. See our financial statements for additional information regarding our current assets and current liabilities.

#### **RISK FACTORS**

An investment in shares of our common stock involves a high degree of risk. You should carefully consider the following information about these risks, together with the other information appearing elsewhere in this prospectus, before deciding to invest in our common stock. The occurrence of any of the following risks could have a material adverse effect on our business, financial condition, results of operations and future growth prospects. In these circumstances, the market price of our common stock could decline, and you may lose all or part of your investment.

#### Risks Related to Our Financial Condition and Need for Additional Capital

### We have incurred significant losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future and may never achieve or maintain profitability.

We have a limited operating history. To date, we have focused primarily on developing a broad product portfolio and have obtained regulatory approval for two of our products: Suboxone, the first sublingual film product for the treatment of opioid dependence, and Zuplenz, the first approved prescription oral soluble film for the prevention of chemotherapy-induced, radiotherapy-induced, and postoperative nausea and vomiting. Some of our product candidates will require substantial additional development time and resources before we would be able to receive regulatory approvals, implement commercialization strategies and begin generating revenue from product sales. We may not generate significant revenue from sales of our product candidates in the near term, if ever. We have incurred losses of \$8.9 million and \$9.6 million for the years ended December 31, 2017 and 2016, respectively. As of March 31, 2018, we had an accumulated deficit of \$116.0 million from inception.

We have devoted most of our financial resources to product development. To date, we have financed our operations primarily through the sale of equity and debt securities and from revenues from certain partnerships we have entered into with respect to our products. The size of our future net losses will depend, in part, on the rate of future expenditures and our ability to generate revenue. To date, only two of our products, Suboxone and Zuplenz, have been commercialized, and if our product candidates are not successfully developed or commercialized, or if revenue is insufficient following marketing approval of such product candidates, we will not achieve profitability and our business may fail.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to fully predict the timing or amount of our expenses, but we expect to continue to incur substantial expenses, which we expect to increase as we expand our development activities and product portfolio. Some of the expenses we expect to continue to incur include:

- conducting clinical trials of our product candidates;
- seeking regulatory approval for any of our product candidates that successfully complete clinical development;
- commercialization activities, including product sales, marketing, manufacturing and distribution, for our products, if approved;
- maintaining, expanding and protecting our intellectual property portfolio;
- · acquiring or in-licensing new technologies or development-stage or approved products;
- adding clinical, scientific, operational, financial and management information systems and personnel, including
  personnel to support our product development and potential future commercialization efforts and to support our
  transition to being a public company; and
- experiencing any delays or encountering any issues with any of the above, including, but not limited to, failed trials, complex results, safety issues or other regulatory challenges.

As a result of the foregoing, we expect to continue to incur significant and increasing losses and negative cash flows for the foreseeable future, which may increase compared to past periods.

# Even if this offering is successful, we will need substantial additional capital to fund our operations, which may not be available on acceptable terms, if at all. If we are unable to raise capital when needed, we may need to significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates.

Our operations have consumed substantial amounts of cash. We had \$16.5 million in cash and cash equivalents as of March 31, 2018. Currently, our cash equivalents have a maturity of three months or less. We have no committed sources of capital and our borrowing capability under our loan agreement, or the Loan Agreement, with Perceptive Credit Opportunities Fund, LP, or Perceptive, is fully drawn.

We believe that the net proceeds from this offering, combined with our existing cash and cash equivalents and expected revenue from our partnered product activities, will be sufficient to fund our operations at least through the next 24 months of operations, including our planned investments in the pre-launch commercialization of our late stage CNS product candidates, research and development investments in our complex molecule product pipeline candidates, capital expenditures and investments in new product candidates in epilepsy and other CNS diseases. We have based this estimate on assumptions that could change, and we could utilize our available financial resources sooner than we currently expect. We expect to continue to spend substantial amounts to commercialize our epilepsy products, Libervant and Sympazan, our ALS product, AQST-117, and our other proprietary product candidates. Based on our current operating budget and business plan, we will need to raise substantial additional financing by various means, including, among others, through public or private equity or debt financings, third-party funding, marketing and distribution arrangements, as well as other collaborations, strategic alliances and licensing arrangements, or any combination of these approaches. Our existing resources may not be adequate to permit us to complete clinical development of our product candidates or fund our operations over the longer term. We may need to secure significant additional resources to complete such development and to support our continued operations. We are exploring a variety of funding alternatives, including both dilutive and non-dilutive financing options and strategic partnerships.

Our estimate of the period of time through which our financial resources will be adequate to support our operations is based on assumptions that may prove to be wrong, and we could deplete our available capital resources sooner than we currently expect. In addition, our operating plan and budget could change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned, whether through public or private equity or debt financings, third-party funding, marketing and distribution arrangements, as well as other collaborations, strategic alliances and licensing arrangements, or any combination of these approaches.

We have historically relied upon sales of Suboxone and Zuplenz, our two commercialized partnered products, milestone payments, fees from co-development and research services, fees from licensed proprietary technologies and patent rights, and royalties based on specified product sales, together with private sales of equity or debt securities, to fund our operations. Delays in obtaining funding could adversely affect our ability to develop and commercially introduce products, if approved, and cause us to be unable to comply with our obligations. Even if we believe we have sufficient capital for our current or future operating plans, we may seek additional capital if market conditions are favorable or if we have specific strategic considerations. Any additional capital raising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our current and future product candidates.

Our ability to obtain additional financing will be subject to a number of factors, including market conditions, our operating performance and investor sentiment. If we are unable to raise additional capital when required or on acceptable terms, we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates, restrict our operations or obtain funds by entering into agreements on unattractive terms, which would likely have a material adverse effect on our business, stock price and our relationships with third parties with whom we have business relationships, at least until additional funding is obtained. If we do not have sufficient funds to continue operations, we could be required to seek bankruptcy protection or other alternatives that would likely result in our stockholders losing some or all of their investment in us.

## We may sell additional equity or incur debt to fund our operations, which may result in dilution to our stockholders, including purchasers of shares of common stock in this offering, and impose restrictions on our business.

We do not have any committed external source of funds other than potential milestone payments and royalties under certain of our collaboration agreements. Until such time, if ever, as we can generate sufficient revenue to fully fund our operations, we may seek additional capital through a public or private equity or debt financings, third-party funding, marketing and distribution arrangements, as well as other collaborations, strategic alliances and licensing arrangements, or any combination of these approaches. 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 may include liquidation or other preferences that adversely affect your rights as a stockholder. Debt financings may be coupled with an equity component, such as warrants to purchase shares of our common stock, which could also result in dilution of existing stockholders' ownership. The incurrence of indebtedness would result in increased fixed payment obligations and could also result in certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to conduct our business and may result in liens being placed on our assets and intellectual property. If we were to default on such indebtedness, we could lose such assets and intellectual property.

If we raise additional funds through collaborations, or strategic alliance, marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, product candidates or future revenue streams or grant licenses on terms that are not favorable to us.

### Even if we are able to generate revenues from our operations in the future, our revenues and operating income could fluctuate significantly.

Even if we are able to generate future revenues, our operating income, and results may vary significantly from yearto-year and quarter-to-quarter. Variations may result from, among other factors:

- the timing of FDA or any other regulatory authority approvals;
- the timing of process validation for particular product candidates;
- the timing of product launches and market acceptance of such products launched;
- changes in the amount we spend to research, develop, acquire, license or promote new product candidates;
- the outcome of our research, development and clinical trial programs;
- serious or unexpected health or safety concerns related to our product candidates;
- the introduction of new products by others that render our product candidates obsolete or noncompetitive;
- · our ability to maintain selling prices and gross margins on our product candidates;
- our ability to comply with complex governmental regulations applicable to many aspects of our business;
- changes in coverage and reimbursement policies of health plans and other health insurers, including changes to Medicare, Medicaid and similar government healthcare programs;
- · increases in the cost of raw materials used to manufacture our product candidates;
- manufacturing and supply interruptions, including product rejections or recalls due to failure to comply with manufacturing specifications;
- · timing of revenue recognition related to our collaboration agreements;
- our ability to protect our intellectual property and avoid infringing the intellectual property of others; and
- the outcome and cost of possible litigation with third parties.

### Our level of indebtedness and significant debt service obligations could constrain our ability to invest in our business and make it more difficult for us to fund our operations.

We have, and after the consummation of this offering will continue to have, substantial debt and substantial debt service obligations. At March 31, 2018, we had an aggregate principal amount of \$50.0 million of outstanding indebtedness. In the future, we may need to borrow additional funds.

Because of our indebtedness:

- we may have difficulty satisfying our obligations with respect to our existing indebtedness including the repayment of such indebtedness;
- we may have difficulty obtaining financing in the future for working capital, capital expenditures, acquisitions or other purposes;
- we will need to use a substantial portion of our available cash flow to pay interest and principal on our debt, which will reduce the amount of money available to finance our operations and other business activities;
- we may be more vulnerable to general economic downturns and adverse industry conditions;
- if cash flows from product sales are insufficient to satisfy our obligations with respect to our existing
  indebtedness, we may be forced to sell assets or seek additional capital, which we may not be able to
  accomplish on favorable terms, if at all;
- we could be limited in our flexibility in planning for, or reacting to, changes in our business and in our industry in general;
- · we could be placed us at a competitive disadvantage compared to our competitors that have less debt;
- our failure to comply with the financial and other restrictive covenants in our debt instruments which, among
  other things, require us to maintain specified financial covenants and limit our ability to incur debt and sell
  assets, could result in an event of default that, if not cured or waived, could have a material adverse effect on
  our business or prospects; and
- our tangible and intangible assets, including our intellectual property are subject to first priority liens and may be used to satisfy our outstanding debt.

We intend to satisfy our current and future debt service obligations with our existing cash and cash equivalents. However, we may not have sufficient funds, and may be unable to arrange for additional financing, to pay the amounts due under our Loan Agreement or any other debt instruments we may enter into. Failure to make payments or comply with other covenants under our existing credit facility or such other debt instruments could result in an event of default and acceleration of amounts due, which could have a material adverse effect on our business, financial condition and results of operations.

### We are dependent upon the commercial success of Suboxone and other licensing activities to generate revenue for the near future.

Although we are in the process of testing and developing proprietary product candidates and may seek to acquire rights in other approved drugs, we anticipate that our ability to generate revenue and to become profitable in the near future will depend upon the continued commercial success of our only approved partnered products, Zuplenz and Suboxone, as well as our other licensing and partnered development activities. There is no assurance that we will become commercially successful. If Zuplenz and Suboxone are not commercially successful, we cannot continue to generate licensing revenues and we have not received approval for any other of our product candidates, we may not be able to generate any royalties or product revenue, as the case may be, for those products or proprietary our product candidates at all. Moreover, any delay or setback in the development of any product candidate could materially adversely affect our business and cause the price of our common stock to fall.

Additionally, we are currently named as a defendant in litigation brought against us and Indivior. Such litigation involves allegations that defendants engaged in conduct intended to interfere with the introduction of generic drug products based on our product, Suboxone, to the marketplace. The Company

denies any wrongdoing and is defending that litigation, but depending on the outcome of the litigation, whether or not any remedies are entered against us or Indivior and, if so, what those remedies are, it could affect our ability to recognize revenues from Suboxone. For more information, please see the section titled "Business – Legal Proceedings." Moreover, any delay or setback in the development of any product candidate could materially adversely affect our business and cause the price of our common stock to fall.

#### **Risks Related to Commercialization of Our Products and Product Candidates**

### We cannot be certain that we will be able to successfully develop our product candidates or obtain regulatory approval for our product candidates.

We currently have nine product candidates in clinical development. Our business depends primarily on the successful clinical development, regulatory approval and commercialization of our product candidates. Before our product candidates can be marketed, the FDA and other comparable foreign regulatory agencies must approve our NDA or comparable regulatory submissions. Even after successful completion of clinical testing, there is a risk that the FDA may request further information from us, disagree with our findings or otherwise undertake a lengthy review of our submission. Even if the FDA approves our NDA, we may be unable to successfully commercialize our product candidates.

It is possible that the FDA will not approve any application that we may submit or our product candidates may not obtain appropriate regulatory approvals necessary for us to commence clinical trials for our product candidates. Any delay or failure in obtaining required approvals could have a material adverse effect on our business. This process can take many years and will likely require the expenditure of substantial resources beyond the proceeds we currently have on hand.

Even if we obtain approval from the FDA and comparable foreign regulatory authorities for our current and future product candidates, any approval might contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, or may be subject to burdensome post-approval study or risk management requirements. If we are unable to obtain regulatory approval, or any approval contains significant limitations, we may not be able to obtain sufficient funding or generate sufficient revenue to continue the development of that product candidate or any other product candidate that we may in-license, develop or acquire in the future.

## We have never directly commercialized a product candidate and we may lack the necessary expertise, personnel and resources to successfully commercialize any of our products that receive regulatory approval on our own or together with collaborators.

We have relied on our third-party collaborators to commercialize our products, Suboxone and Zuplenz. Thus, we do not have direct experience in commercializing a product candidate. To achieve commercial success of our product candidates, if any are approved, we will have to develop our own sales, marketing and supply capabilities or outsource these activities to a third party.

Factors that may affect our ability to commercialize our product candidates on our own include: recruiting and retaining adequate numbers of effective sales and marketing personnel, obtaining access to or persuading adequate numbers of physicians to prescribe our product candidates and other unforeseen costs associated with creating an independent sales and marketing organization. Developing a sales and marketing organization requires significant investment and resources, is time-consuming and could delay the launch of our product candidates. We may not be able to build an effective sales and marketing organization in the United States or other key global markets. We also intend to enter into strategic partnerships with third parties to commercialize our product candidates outside of the United States. We may have difficulty establishing relationships with third parties on terms that are acceptable to us, or in all of the regions where we wish to commercialize our products, or at all. If we are unable to build our own distribution and marketing capabilities or to find suitable partners for the commercialization of our product candidates, we may have difficulties generating revenue from them.

### Our commercial success depends upon attaining significant market acceptance of our products and product candidates, if approved, among patients, physicians, pharmacists and the medical community.

It is possible that we may not complete development of our product candidates or obtain regulatory approval. Even if we do complete development and obtain regulatory approval for our product candidates, our product candidates may not gain market acceptance among patients, physicians, pharmacists, the medical community or third-party payors, which is critical to commercial success. Market acceptance of our products and any product candidate for which we receive approval depends on a number of factors, including:

- the timing of market introduction of the product candidate as well as competitive products;
- the clinical indications for which the product candidate is approved;
- the potential and perceived advantages of such product candidate over alternative treatments;
- favorable pricing and the availability of coverage and adequate reimbursement by third-party payors and government authorities;
- relative convenience and ease of administration;
- any negative publicity related to our or our competitors' products that include the same active ingredient;
- the prevalence and severity of adverse side effects, including limitations or warnings contained in a product's FDA-approved labeling; and
- the effectiveness of sales and marketing efforts.

Even if a potential product displays a favorable efficacy and safety profile in clinical trials, market acceptance of the product will not be known until after it is launched. If our products or product candidates, if approved, fail to achieve an adequate level of acceptance by physicians, nurses, pharmacists, patients and the medical community, we will be unable to generate significant revenues, and we may not become or remain profitable.

# Adverse side effects or other safety risks associated with our product candidates could delay or preclude approval, cause us to suspend or discontinue clinical trials, abandon product candidates, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.

Undesirable side effects that may be caused by our product candidates could result in the delay, suspension or termination of clinical trials by us, our collaborators, the FDA or other regulatory authorities for a number of reasons. For example, to date, patients treated with Libervant have experienced drug-related side effects including somnolence, or a state of strong desire for sleep, or sleeping for unusually long periods. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of these or other side effects. In such an event, our clinical trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. If we elect or are required to delay, suspend or terminate and our ability to generate product revenues from any of these product candidates will be delayed or eliminated. Any of these occurrences may harm our business, prospects, financial condition and results of operations significantly.

## We could incur substantial costs and disruption to our business and delays in the launch of our product candidates if our competitors and/or collaborators bring legal actions against us, which could harm our business and operating results.

We cannot predict whether our competitors or potential competitors, some of whom we collaborate with, may bring legal actions against us based on our research, development and commercialization activities, as well as any product candidates or products resulting from these activities, claiming, among



other things, infringement of their intellectual property rights, breach of contract or other legal theories. If we are forced to defend any such lawsuits, whether they are with or without merit or are ultimately determined in our favor, we may face costly litigation and diversion of technical and management personnel. These lawsuits could hinder our ability to enter the market early with our product candidates and thereby hinder our ability to influence usage patterns when fewer, if any, of our potential competitors have entered such market, which could adversely impact our potential revenue from such product candidates. Some of our competitors have substantially greater resources than we do and could be able to sustain the cost of litigation to a greater extent and for longer periods of time than we could. Furthermore, an adverse outcome of a dispute may require us: to pay damages, potentially including treble damages and attorneys' fees, if we are found to have willfully infringed a party's patent or other intellectual property rights; to cease making, licensing or using products that are alleged to incorporate or make use of the intellectual property of others; to expend additional development resources to reformulate our products or prevent us from marketing a certain drug; and to enter into potentially unfavorable royalty or license agreements in order to obtain the rights to use necessary technologies. Royalty or licensing agreements, if required, may be unavailable on terms acceptable to us, or at all.

### Guidelines and recommendations published by government agencies can reduce the use of our product candidates.

Government agencies promulgate regulations and guidelines applicable to certain drug classes which may include our products and product candidates that we are developing. Recommendations of government agencies may relate to such matters as usage, dosage, route of administration and use of concomitant therapies. Regulations or guidelines suggesting the reduced use of certain drug classes which may include our products and product candidates that we are developing or the use of competitive or alternative products as the standard of care to be followed by patients and healthcare providers could result in decreased use of our product candidates or negatively impact our ability to gain market acceptance and market share.

### We face significant competition from other specialty pharmaceutical and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.

The specialty pharmaceutical industry is intensely competitive and subject to rapid and significant technological change. We expect to have competitors both in the United States and internationally, including major multinational pharmaceutical companies, biotechnology companies and universities and other research institutions. Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. As a result, these companies may obtain regulatory approval more rapidly than we are able and may be more effective in selling and marketing their products as well. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis drug products or drug administration technologies that are more effective or less than product candidate that we are currently developing or that we may develop. In addition, our competitors may file citizen petitions with the FDA in an attempt to persuade the FDA that our products, or the clinical studies that support their approval, contain deficiencies. Such actions by our competitors could delay or even prevent the FDA from approving any NDA that we submit under Section 505(b)(2).

We believe that our ability to successfully compete will depend on, among other things:

- the efficacy and safety of our products and product candidates, including as relative to marketed products and product candidates in development by third parties;
- the time it takes for our product candidates to complete clinical development and receive marketing approval;
- the ability to maintain a good relationship with regulatory authorities;
- · the ability to commercialize and market any of our product candidates that receive regulatory approval;
- the price of our products, including in comparison to branded or generic competitors;
- whether coverage and adequate levels of reimbursement are available under private and governmental health insurance plans, including Medicare;
- · the ability to protect intellectual property rights related to our products and product candidates;
- the ability to manufacture on a cost-effective basis and sell commercial quantities of our products and product candidates that receive regulatory approval; and
- acceptance of any of our products and product candidates that receive regulatory approval by physicians and other healthcare providers.

If our competitors market products that are more effective, safer or less expensive than our product candidates, or that reach the market sooner than our product candidates, we may enter the market too late in the cycle and may not achieve commercial success. In addition, the biopharmaceutical industry is characterized by rapid technological change. Because we have limited research and development capabilities, it may be difficult for us to stay abreast of the rapid changes in each technology. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Technological advances or products developed by our competitors may render our technologies or product candidates obsolete, less competitive or not economical.

### If we are unable to achieve and maintain coverage and adequate reimbursement for our products or product candidates, if approved, their commercial success may be severely hindered.

Our ability to commercialize our product candidates successfully will depend in part on the extent to which coverage and adequate reimbursement are available for our product candidates, once approved, from third-party payors, including governmental healthcare programs such as Medicare and Medicaid, commercial health insurers and managed care organizations, and how quickly we obtain such coverage and reimbursement, if we are able to obtain it at all. Third-party payors determine which medications they will cover and establish reimbursement levels. Reimbursement decisions by third-party payors depend upon a number of factors, including each third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- appropriate and medically necessary for the specific condition or disease;
- cost effective; and
- neither experimental nor investigational.

Obtaining coverage and reimbursement approval for our product candidates from third-party payors may be a time consuming and costly process that could require us to provide supporting scientific, clinical and cost-effectiveness data, including results from expensive pharmacoeconomic studies, beyond the data required to obtain marketing approval, to each third-party payor. There is no guarantee that we will be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement.

Third-party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement for medical products and services. Third-party payors may deny reimbursement for covered products if they determine that a medical product was not used in accordance with third-party payor coverage policies, such as required procedures for cost-effective diagnosis methods and other conditions that must be met before the third-party payor will provide coverage for use of a

product. For example, insurers may establish a "step-edit" system that requires a patient to first use a lower price alternative product prior to becoming eligible for reimbursement of a higher price product. Third-party payors also may refuse to reimburse for drugs, procedures and devices deemed to be experimental, or that are prescribed for an unapproved indication. In addition, third-party payors may also limit coverage to specific products on an approved list, or formulary, which might not include all of the FDA-approved products for a particular indication. Further, some third-party payors are the challenging the prices charged for medical products and may impose price controls or require that drug companies provide them with predetermined discounts from list prices.

The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Levels of reimbursement may also decrease in the future, and future legislation, regulation or reimbursement policies of third-party payors may adversely affect the reimbursement available for and the pricing of our product candidates, once approved, which in turn, could negatively impact the demand for our product candidates. If patients are not adequately reimbursed for our product candidates, they may reduce or discontinue purchases of it, which would result in a significant shortfall in achieving revenue expectations and negatively impact our business, prospects and financial condition.

# Our relationships with customers, physicians, and third-party payors will be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, health information privacy and security laws, and other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

Healthcare providers, physicians and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, principal investigators, consultants, customers and third-party payors may subject us to various federal and state fraud and abuse laws and other health care laws, including, without limitation, the federal Anti-Kickback Statute, the federal civil and criminal false claims laws and the law commonly referred to as the Physician Payments Sunshine Act and regulations promulgated thereunder. These laws will impact, among other things, our clinical research program and our proposed sales, marketing and educational programs. In addition, we may be subject to patient privacy laws by both the federal government and the states in which we conduct or may conduct our business. The laws that will affect our operations include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, in return for the purchase, recommendation, leasing or furnishing of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand, and prescribers, purchasers and formulary managers on the other. The Patient Protection and Affordable Care Act, as amended, or the PPACA, amended the intent requirement of the federal Anti-Kickback Statute. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it;
- federal civil and criminal false claims laws, including, without limitation, the False Claims Act, and civil
  monetary penalty laws which prohibit, among other things, individuals or entities from knowingly presenting, or
  causing to be presented, claims for payment or approval from Medicare, Medicaid or other government payors
  that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay
  money to the federal government. The PPACA provides, and recent government cases against pharmaceutical
  and medical device manufacturers support, the view that federal Anti-Kickback Statute violations and certain
  marketing practices, including off-label promotion, may implicate the False Claims Act;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit a person from knowingly and willfully executing a scheme or making false or fraudulent statements to defraud any healthcare benefit program, regardless of the payor (*e.g.*, public or private);

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization on entities subject to the rule, such as health plans, health care clearinghouses and certain health care providers, and their respective business associates who provide services involving the creation, use or disclosure of HIPAA protected health information;
- federal transparency laws, including the federal Physician Payments Sunshine Act, which is part of the PPACA, that require certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to: (i) payments or other "transfers of value" made to physicians and teaching hospitals; and (ii) ownership and investment interests held by physicians and their immediate family members, with such information being made publicly available through a searchable website;
- state and foreign law equivalents of each of the above federal laws; state laws that require manufacturers to
  report information related to payments and other transfers of value to physicians and other healthcare
  providers, marketing expenditures, or pricing information; state laws that require pharmaceutical companies to
  comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance
  guidance promulgated by the federal government or to adopt compliance programs as prescribed by state laws
  and regulations, or that otherwise restrict payments that may be made to healthcare providers; and state and
  local laws that require the registration of pharmaceutical sales representatives; and
- state and foreign laws that govern the privacy and security of health information in some circumstances, many
  of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating
  compliance efforts.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws.

It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, contractual damages, reputational harm and the curtailment or restructuring of our operations.

The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance and/or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements.

## Recently enacted and future healthcare reform legislation or regulation may increase the difficulty and cost for us and any future collaborators to obtain marketing approval of and commercialize our product candidates and may adversely affect the prices we, or they, may obtain and may have a negative impact on our business and results of operations.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other

things, prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability, or the ability of any future collaborators, to profitably sell any products for which we, or they, obtain marketing approval. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we, or any future collaborators, may receive for any approved products.

In March 2010, President Obama signed into law the PPACA. Among the provisions of the PPACA of importance to our business, including, without limitation, our ability to commercialize and the prices we may obtain for any of our product candidates and that are approved for sale, are the following:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs, although this fee does not apply to sales of certain products approved exclusively for orphan indications;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- expansion of manufacturers' rebate liability under the Medicaid Drug Rebate Program by increasing the minimum rebate for both branded and generic drugs and revising the definition of "average manufacturer price," or AMP, for calculating and reporting Medicaid drug rebates on outpatient prescription drug prices and extending rebate liability to prescriptions for individuals enrolled in Medicare Advantage plans;
- addition of more entity types eligible for participation in the Public Health Service the 340B drug pricing program, or the 340B program;
- established the Medicare Part D coverage gap discount program by requiring manufacturers to provide a 50% point-of-sale-discount off the negotiated price of applicable brand drugs to eligible beneficiaries during their coverage gap period as a condition for the manufacturers' outpatient drugs to be covered under Medicare Part D; the Bipartisan Budget Act of 2018, or BBA, among other things, increased the manufacturer's subsidy under this program from 50% to 70% of the negotiated price, beginning in 2019;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and
- established the Center for Medicare and Medicaid Innovation within CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. For example, beginning April 1, 2013, Medicare payments for all items and services, including drugs and biologics, were reduced by 2% under the sequestration (*i.e.*, automatic spending reductions) required by the Budget Control Act of 2011, as amended by the American Taxpayer Relief Act of 2012. Subsequent legislation, including the BBA, extended the 2% reduction, on average, to 2027, subject to additional Congressional action. Sequestration may result in additional reductions in Medicare and other healthcare funding and, if we obtain regulatory approvals, may otherwise affect the prices we may obtain for our product candidates or the frequency with which our product candidates may be prescribed or used if approved. Additional changes that may affect our business include the expansion of new programs such as Medicare payment for performance initiatives for physicians under the Medicare Access and CHIP Reauthorization Act of 2015, or MACRA, which will be fully implemented in 2019. At this time, it is unclear how the introduction of the Medicare quality payment program will impact overall physician reimbursement.

Further, legislative changes to or regulatory changes under the PPACA remain possible and appear likely in the 115th U.S. Congress and under the Trump administration. The nature and extent of any legislative or regulatory changes to the PPACA, including repeal and replacement initiatives, are uncertain at this time. It is possible that the PPACA repeal and replacement initiatives, if enacted into law, could ultimately result in fewer individuals having health insurance coverage or in individuals having insurance coverage with less generous benefits. While Congress has not passed repeal legislation, the Tax Cuts and Jobs Act of 2017, or the TCJA, which was recently signed into law by President Trump, includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the PPACA 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." In addition, the BBA, among other things, amends the PPACA, starting January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut nole." The scope of potential future legislation to modify or repeal and replace the PPACA provisions is highly uncertain in many respects. We continue to evaluate the potential impact of the PPACA and its possible repeal or replacement on our business.

The costs of prescription pharmaceuticals in the United States have also been the subject of considerable discussion in the United States, and members of Congress and the administration have stated that they will address such costs through new legislative and administrative measures. This focus has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. 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. While any proposed measures will require authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures are increasingly passing legislation and implementing 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.

We expect that these and other healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved drug. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our drugs. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

The pricing of prescription pharmaceuticals is also subject to governmental control outside the United States. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost effectiveness of our product candidates to other available product candidates. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our ability to generate revenues and become profitable could be impaired.

#### Comprehensive tax reform legislation could adversely affect our business and financial condition.

On December 22, 2017, the TCJA was enacted. The TCJA is major tax legislation that, among other things, contains significant changes to corporate taxation, including reducing the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%; limiting the tax deduction for interest expense; limiting the

deduction for net operating losses and eliminating net operating loss carrybacks, in each case, for losses arising in taxable years beginning after December 31, 2017 (though any such tax losses may be carried forward indefinitely); eliminating certain requirements of the PPACA, including the individual mandate; and modifying or repealing many business deductions and credits, including reducing the business tax credit for certain clinical testing expenses incurred in the testing of certain drugs for rare diseases or conditions generally referred to as "orphan drugs". We continue to examine the impact this tax reform legislation may have on our business. However, the effect of the TCJA on us and our affiliates, whether adverse or favorable, is uncertain and may not become evident for some period of time. You are urged to consult your tax adviser regarding the implications of the TCJA on an investment in our common stock.

## Even though we have obtained orphan drug designation for Libervant and AQST-117 in the United States, we may not obtain or maintain orphan drug exclusivity for these or other product candidates, and we may not obtain orphan drug designation or exclusivity for any of our other product candidates or indications.

Regulatory authorities in some jurisdictions, including the United States, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the United States.

Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA from approving another marketing application for the same drug for the same disease for seven years. Orphan drug exclusivity may be lost if the FDA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. Orphan drug designation must be requested before submitting an application for marketing approval.

We obtained orphan drug designation in the United States for Libervant for the treatment of selected, refractory patients with epilepsy who are on stable regimens of antiepileptic drugs, or AED, and who require intermittent use of diazepam to control bouts of increased seizure activity, or acute repetitive seizures, and for AQST-117 for the treatment of amytrophic lateral sclerosis, or ALS. A company that first obtains FDA approval for a designated orphan drug for the designated rare disease or condition receives orphan drug marketing exclusivity for that drug for the designated disease for a period of seven years in the United States. This orphan drug exclusivity prevents the FDA from approving another application to market a drug containing the same active moiety for the same orphan indication, except in very limited circumstances, including when the FDA concludes that the later drug is safer, more effective or makes a major contribution to patient care. In addition, a designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation.

Even though we have received orphan drug designation for Libervant and for AQST-117, we may not be the first to obtain marketing approval for the orphan-designated indication due to the uncertainties associated with developing product candidates. For example, other pharmaceutical companies developing diazepam have obtained orphan drug designation for their product candidates for an acute repetitive seizures indication using other routes of administration, such as intranasal and subcutaneous. While there can be no assurance, we believe that our Libervant is further along in development than these other companies' versions of diazepam. However, if any of these other pharmaceutical companies obtains approval of an NDA for its formulation of diazepam for the management of acute repetitive seizures before we are able to receive approval of Libervant for the same indication, we would be barred from marketing Libervant in the United States during the seven-year orphan drug exclusivity period, unless we could demonstrate that Libervant is clinically superior to the approved diazepam product. In addition, in order to obtain our own period of marketing exclusivity, we would need to demonstrate that Libervant is clinically superior to any other diazepam products approved for the same indication, including Diastat.

Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties can be approved for the same condition or a drug with the same active moiety can be approved for a different

indication. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process. In addition, even if we intend to seek orphan drug designation for other product candidates or indications, we may never receive such designations or obtain orphan drug exclusivity.

#### **Risks Related to Our Reliance on Third Parties**

# We rely on third parties to conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

We have relied upon and plan to continue to rely upon third-party contract research organizations, or CROs, to monitor and manage data for our preclinical and clinical programs. We rely on these parties for execution of our preclinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on the CROs does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with FDA laws and regulations regarding current good clinical practice, or GCP, which are also required by the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities in the form of International Conference on Harmonization, or ICH, guidelines for all of our products in clinical development. Regulatory authorities enforce GCP through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable GCP, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under the current good manufacturing practice, or cGMP, regulations. While we have agreements governing activities of our CROs, we have limited influence over their actual performance. In addition, portions of the clinical trials for our product candidates are expected to be conducted outside of the United States, which will make it more difficult for us to monitor CROs and perform visits of our clinical trial sites and will force us to rely heavily on CROs to ensure the proper and timely conduct of our clinical trials and compliance with applicable regulations, including GCP. Failure to comply with applicable regulations in the conduct of the clinical trials for our product candidates may require us to repeat clinical trials, which would delay the regulatory approval process.

Some of our CROs have an ability to terminate their respective agreements with us if, among other reasons, it can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors or if we are liquidated. If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. In addition, our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our preclinical and clinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. Consequently, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase substantially and our ability to generate revenue could be delayed significantly.

Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

## We rely on limited sources of supply for our thin film foil, and any disruption in the chain of supply may impact production and sales and cause delay in developing and commercializing our Proprietary PharmFilm Technology product candidates.

We currently have relationships with only one third party for the manufacture of our thin film foil. Because of the unique equipment and process for manufacturing our thin film foil, transferring manufacturing activities for our foil to an alternate supplier would be a time-consuming and costly endeavor, and there are only a limited number of manufacturers that we believe are capable of performing this function for us. Switching thin film foil suppliers may involve substantial cost and could result in a delay in our desired clinical and commercial timelines. If any of our thin film foil manufacturers breaches or terminates their agreements with us, we would need to identify an alternative source for the thin film foil manufacture and supply of foil to us for the purposes of our development and commercialization of the applicable products. Identifying an appropriately qualified source of alternative thin film foil supply for any one or more of these product candidates could be time consuming, and we may not be able to do so without incurring material delays in the development and commercialization of our product candidates, which could harm our financial position and commercial potential for our products. Any alternative thin film foil vendor would also need to be gualified through an NDA supplement which could result in further delay. The FDA or other regulatory agencies outside of the United States may also require additional studies if we appoint a new manufacturer for supply of our product candidates that differs from the manufacturer used for clinical development of such product candidates. For our other product candidates, we expect that only one supplier will initially be qualified as a vendor with the FDA. If supply from the approved vendor is interrupted, there could be a significant disruption in commercial supply.

These factors could cause the delay of clinical trials, regulatory submissions, required approvals or commercialization of our product candidates, cause us to incur higher costs and prevent us from commercializing them successfully. Furthermore, if our suppliers fail to deliver the required commercial quantities of components and active pharmaceutical ingredient on a timely basis and at commercially reasonable prices, and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, our clinical trials may be delayed or we could lose potential revenue.

# We rely on third parties to manufacture active pharmaceutical ingredients, or API, for our product candidates, and we intend to rely on third parties to manufacture the API for any other approved products. The commercialization of any of our products could be stopped, delayed or made less profitable if those third parties fail to provide us with sufficient quantities of API or fail to do so at acceptable quality levels or prices or fail to maintain or achieve satisfactory regulatory compliance.

We currently rely, and expect to continue to rely, on third parties to manufacture API for our product candidates, and control only certain aspects of their activities.

Any of these third parties may terminate their engagements with us at any time. If we need to enter into alternative arrangements, it could delay our proprietary product candidate programs and commercialization activities. Our reliance on these third parties reduces our control over these activities but does not relieve us of our responsibility to ensure compliance with all required legal, regulatory and scientific standards and any applicable trial protocols. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our studies in accordance with regulatory requirements or our stated study plans and protocols, we will not be able to complete, or may be delayed in completing, clinical trials required to support future regulatory submissions and approval of our product candidates.

Our products and product candidates are highly reliant on very complex sterile techniques and personnel aseptic techniques. The facilities used by our third-party API manufacturers to manufacture our products and product candidates must maintain a compliance status acceptable to the FDA or other applicable regulatory authorities pursuant to inspections that will be conducted after we submit our NDA to the FDA. If any of our third-party API manufacturers cannot successfully manufacture material that conforms to our specifications and the applicable regulatory authorities' strict regulatory requirements, or pass regulatory inspection, they will not be able to secure or maintain regulatory approval for the manufacturing facilities. In addition, we have no control over the ability of third-party API manufacturers to maintain adequate quality control, quality assurance and qualified personnel. Further, as we scale up



manufacturing of our product candidates and conduct required stability testing, product, packaging, equipment and process-related issues may require refinement or resolution in order for us to proceed with our planned clinical trials and obtain regulatory approval for commercialization of our product candidates. In the future, for example, we may identify impurities in the product manufactured for us for commercial supply, which could result in increased scrutiny by the regulatory agencies, delays in our clinical program and regulatory approval, increases in our operating expenses, or failure to obtain or maintain approval for our product candidates. If the FDA or any other applicable regulatory authority does not approve these facilities for the manufacture of our products or if they withdraw any such approval in the future, or if our suppliers or third-party manufacturers decide they no longer want to manufacture our products, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our products or product candidates.

More generally, API manufacturers of pharmaceutical products often encounter difficulties in production, particularly in scaling up and validating initial production. These problems include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing, shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. Additionally, our API manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If our manufacturers were to encounter any of these difficulties, or otherwise fail to comply with their contractual obligations, our ability to make product candidates available for clinical trials and development purposes or to further commercialize any of our product candidates in the United States would be jeopardized. Any delay or interruption in our ability to meet commercial demand may result in the loss of potential revenues and could adversely affect our ability to gain market acceptance for approved products. In addition, any delay or interruption in the supply of clinical trial supplies could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials completely. Additionally, if supply from one approved API manufacturer is interrupted, there could be a significant disruption in commercial supply. Regulatory agencies may also require additional studies if a new manufacturer is relied upon for commercial production. Switching manufacturers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines.

The occurrence of any of these factors could have a material adverse effect on our business, results of operations, financial condition and prospects.

### The design, development, manufacture, supply, and distribution of our product candidates is highly regulated and technically complex.

All entities involved in the preparation of therapeutics for clinical trials or commercial sale, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in late-stage clinical trials must be manufactured in accordance with cGMP and equivalent foreign standards. These regulations govern manufacturing processes and procedures (including record keeping) and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of adventitious agents or other contaminants, or to inadvertent changes in the properties or stability of our product candidates that may not be detectable in final product testing. The development, manufacture, supply, and distribution of our other product candidates, is highly regulated and technically complex. We, along with our third-party providers, must comply with all applicable regulatory requirements of the FDA and foreign authorities.

We, or our API and component manufacturers, must supply all necessary documentation in support of our regulatory filings for our product candidates on a timely basis and must adhere to the FDA's good laboratory practices, or GLP, and cGMP regulations enforced by the FDA through its facilities inspection program, and the equivalent standards of the regulatory authorities in other countries. Any failure by our third-party API or component manufacturers to comply with cGMP or failure to scale-up manufacturing processes, including any failure to deliver sufficient quantities of product candidates in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval of any of our product candidates. Our facilities and quality systems and the facilities and quality systems of some or all of our third-party API and component manufacturers must also pass a pre-approval inspection for compliance with the applicable



regulations as a condition of regulatory approval of our product candidates or any of our other potential products. In addition, the regulatory authorities in any country may, at any time, audit or inspect a manufacturing facility involved with the preparation of our product candidates or our other potential products or the associated quality systems for compliance with the regulations applicable to the activities being conducted. If these facilities and quality systems do not pass a pre-approval plant inspection, FDA approval of our product candidates, or the equivalent approvals in other jurisdictions, will not be granted.

Regulatory authorities also may, at any time following approval of a product for sale, inspect our manufacturing facilities or those of our third-party suppliers or contractors. If any such inspection identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly and/or time-consuming for us or a third party to implement and that may include the temporary or permanent suspension of a clinical trial or commercial sales or the temporary or permanent closure of a facility. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business. If we or any of our third-party API or component manufacturers fail to maintain regulatory compliance, the FDA can impose regulatory sanctions including, among other things, refusal to approve a pending NDA for a new drug product or revocation of a pre-existing approval. As a result, our business, financial condition and results of operations may be materially harmed.

### We may not be successful in establishing development and commercialization collaborations, which could adversely affect, and potentially prohibit, our ability to develop our product candidates.

Because developing pharmaceutical products, conducting clinical trials, obtaining regulatory approval, establishing manufacturing capabilities and marketing approved products are expensive, we are exploring collaborations with third parties outside of the United States that have more resources and experience. For example, we are exploring selective partnerships with third parties for development and commercialization of our product candidates outside of the United States. We may, however, be unable to advance the development of our product candidates in territories outside of the United States, which may limit the market potential for this product candidate.

In situations where we enter into a development and commercial collaborative arrangement for a product candidate, we may also seek to establish additional collaborations for development and commercialization in territories outside of those addressed by the first collaborative arrangement for such product candidate. There are a limited number of potential partners, and we expect to face competition in seeking appropriate partners. If we are unable to enter into any development and commercial collaborations and/or sales and marketing arrangements on acceptable terms, if at all, we may be unable to successfully develop and seek regulatory approval for our product candidates and/or effectively market and sell future approved products, if any, in all of the territories outside of the United States where it may otherwise be valuable to do so.

# We may not be successful in maintaining development and commercialization collaborations, and any partner may not devote sufficient resources to the development or commercialization of our product candidates or may otherwise fail in development or commercialization efforts, which could adversely affect our ability to develop certain of our product candidates and our financial condition and operating results.

Even if we are able to establish collaborative arrangements, any such collaboration may not ultimately be successful, which could have a negative impact on our business, results of operations, financial condition and prospects. If we partner with a third party for development and commercialization of a product candidate, we can expect to relinquish some or all of the control over the future success of that product candidate to the third party. It is possible that a partner may not devote sufficient resources to the development or commercialization of our product candidate or may otherwise fail in development or commercialization efforts, in which event the development and commercialization of such product candidate could be delayed or terminated and our business could be substantially harmed. In addition, the terms of any collaboration or other arrangement that we establish may not prove to be favorable to us or may not be perceived as favorable, which may negatively impact the trading price of our common

stock. In some cases, we may be responsible for continuing development of a product candidate or research program under a collaboration, and the payment we receive from our partner may be insufficient to cover the cost of this development. Moreover, collaborations and sales and marketing arrangements are complex and time consuming to negotiate, document and implement, and they may require substantial resources to maintain.

We are subject to a number of additional risks associated with our dependence on collaborations with third parties, the occurrence of which could cause our collaborative arrangements to fail, including that:

- we may be required to undertake the expenditure of substantial operational, financial and management resources;
- we may be required to issue equity securities that would dilute our stockholders' percentage of ownership;
- we may be required to assume substantial actual or contingent liabilities;
- strategic collaborators could terminate the arrangement or allow it to expire, which would delay the development and may increase the cost of developing our product candidates;
- business combinations or significant changes in a strategic collaborator's business strategy may affect a strategic collaborator's willingness or ability to complete its obligations under any arrangement; and
- strategic collaborators could decide to move forward with a competing product candidate developed either independently or in collaboration with others, including our competitors.

Additionally, conflicts may arise between us and our partners, such as conflicts concerning the interpretation of clinical data, the achievement of milestones, the interpretation of financial provisions or the ownership of intellectual property developed during the collaboration. For example, we are largely dependent on Indivior, which holds the global commercialization rights to our approved product, Suboxone. During the three months ended March 31, 2018 and the year ended December 31, 2017, Indivior represented 97% and 88% of our total revenue, respectively. If any such conflicts were to arise with Indivior or any other partner, such partner could act in its own self-interest, which may be adverse to our interests. Any such disagreement between us and a partner could result in one or more of the following, each of which could delay or prevent the development or commercialization of our product candidates and harm our business:

- reductions in the payment of royalties or other payments we believe are due pursuant to the applicable collaborative arrangement;
- actions taken by a partner inside or outside our collaboration which could negatively impact our rights or benefits under our collaboration; and
- unwillingness on the part of a partner to keep us informed regarding the progress of its development and commercialization activities or to permit public disclosure of the results of those activities.

#### **Risks Related to Our Business Operations and Industry**

### Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on the principal members of our executive team listed under "Management" located elsewhere in this prospectus, the loss of whose services may adversely impact the achievement of our objectives. Any of our executive officers could leave our employment at any time, as all of our employees are "at will" employees. Recruiting and retaining other qualified employees for our business, including scientific and technical personnel, will also be critical to our success. There is currently a shortage of skilled executives in our industry, which is likely to continue. As a result, competition for skilled personnel is intense and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical

companies for individuals with similar skill sets. In addition, failure to succeed in clinical studies may make it more challenging to recruit and retain qualified personnel. The inability to recruit key executives or the loss of the services of any executive or key employee might impede the progress of our development and commercialization objectives.

#### Under applicable employment laws, we may not be able to enforce covenants not to compete.

Certain of our executive officers' employment agreements include covenants not to compete. These agreements prohibit our employees, if they cease working for us, from competing directly with us or working for our competitors for a limited period. We may be unable to enforce these agreements or may not be able to enforce these agreements to their full extent under applicable law. If we cannot demonstrate that such an interest will be harmed, we may be unable to prevent our competitors from benefiting from the expertise of our former employees and our competitiveness may be diminished.

### We will need to expand our organization, and we may experience difficulties in managing this growth, which could disrupt our operations.

Our company has been rapidly growing and we expect to continue to grow over the next several years. As our company matures, we expect to expand our employee base to increase our managerial, scientific and engineering, operational, sales, marketing, financial and other resources and to hire more consultants and contractors. Future growth would impose significant additional responsibilities on our management, including the need to identify, recruit, maintain, motivate and integrate additional employees, consultants and contractors. Also, our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Future growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of our existing or future product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and/or grow revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize our product candidates, if approved, and compete effectively will depend, in part, on our ability to effectively manage any future growth.

### Our products, if approved, may give rise to potential product liability, and, if successful claims are brought against us, we may incur substantial liability.

As a specialty pharmaceutical company, we operate in a market that is subject to risk of liability. To our knowledge, we are not currently subject to any product liability suits. However, the sales of our approved products and for any product candidates for which we obtain marketing approval and the use of our product candidates in clinical trials (if any), exposes us to the risk of product liability claims alleging adverse effects from such products or product candidates. Product liability claims might be brought against us by consumers, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our product candidates. Any liability claims could have a material adverse effect on our business, financial position, results of operations and future growth prospects. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- impairment of our business reputation;
- withdrawal of clinical study participants;
- · costs due to related litigation;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants;
- the inability to commercialize our product candidates; and
- · decreased demand for our product candidates, if approved for commercial sale.

#### We may not be able to maintain insurance coverage, and our existing or any future insurance policies or our own resources will not sufficiently cover claims for damages that we may receive in the future.

Our business exposes us to potential product liability and other liability risks that are inherent in clinical development, manufacturing, marketing and use of human therapeutic products. It is generally necessary for us to secure certain levels of insurance as a condition for the conduct of clinical trials and any sale or use of our products. We have taken out product liability insurance with respect to all clinical trials and ongoing trials performed to date for which we were responsible (*i.e.*, in respect of our internal product pipeline). Further, we may seek to expand our insurance coverage if we obtain marketing approval for any of our internal product candidates or if other risks related to our business increase.

Our current product liability insurance coverage may not be sufficient to reimburse us for any expenses or losses we may suffer. Insurance coverage is becoming increasingly expensive and in the future we may not be able to maintain insurance coverage at an acceptable cost to us or in sufficient amounts to protect us against losses due to liability. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated adverse effects. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business.

## We rely significantly on information technology and any failure, inadequacy, interruption or security lapse of that technology, including any cybersecurity incidents, could harm our ability to operate our business effectively.

Despite the implementation of security measures, our internal computer systems and those of third parties with which we contract are vulnerable to damage from cyber-attacks, computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. System failures, accidents or security breaches could cause interruptions in our operations, and could result in a material disruption of our product development and clinical activities and business operations, in addition to possibly requiring substantial expenditures of resources to remedy. The loss of product development or clinical trial data could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and our development programs and the development of our product candidates could be delayed.

#### Business interruptions could delay us in the process of developing our product candidates.

Our headquarters are located in Warren, New Jersey and we have manufacturing facilities in Portage, Indiana. If we encounter any disruptions to our operations at these sites or one were to shut down for any reason, including by fire, natural disaster, such as a hurricane, tornado or severe storm, power outage, systems failure, labor dispute or other unforeseen disruption, then we may be prevented from effectively operating our business. Our coverage for natural disasters may be somewhat limited for floods or earthquakes and we may not carry sufficient business interruption insurance to compensate us for losses that may occur. Any losses or damages we incur could have a material adverse effect on our business operations.

## Our employees, principal investigators, consultants and commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of fraud or other misconduct by our employees, principal investigators, consultants and commercial partners. Misconduct by these parties could include failure to:

- comply with FDA regulations or the regulations applicable in other jurisdictions;
- provide accurate information to the FDA and other regulatory authorities;
- · comply with healthcare fraud and abuse laws and regulations in the United States and abroad;
- report financial information or data accurately; or
- disclose unauthorized activities to us.

In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct also could involve the improper use of information obtained in the course of clinical trials or interactions with the FDA or other regulatory authorities, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from government investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of significant civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of noncompliance with these laws, contractual damages, reputational harm and the curtailment or restructuring of our operations, any of which could have a negative impact on our business, financial condition, results of operations and prospects.

### Our research and development activities could be affected or delayed as a result of possible restrictions on animal testing.

Certain laws and regulations require us to test our product candidates on animals before initiating clinical trials involving humans. Animal testing activities have been the subject of controversy and adverse publicity. Animal rights groups and other organizations and individuals have attempted to stop animal testing activities by pressing for legislation and regulation in these areas and by disrupting these activities through protests and other means. To the extent the activities of these groups are successful, our research and development activities may be interrupted, delayed or become more expensive.

### Our operations involve hazardous materials and we and third parties with whom we contract must comply with environmental laws and regulations, which can be expensive and restrict how we do business.

As a specialty pharmaceutical company, we are subject to environmental and safety laws and regulations, including those governing the use of hazardous materials. The cost of compliance with health and safety regulations is substantial. Our business activities involve the controlled use of hazardous materials. Our research and development activities involve the controlled storage, use and disposal of hazardous materials, including the components of our product candidates and other hazardous compounds. We and manufacturers and suppliers with whom we may contract are subject to laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. In some cases, these hazardous materials and various wastes resulting from their use are stored at our and our manufacturers' facilities pending their use and disposal. We cannot eliminate the risk of accidental contamination or injury from these materials, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. We cannot guarantee that the safety procedures utilized by third-party manufacturers and suppliers with whom we may contract will comply with the standards prescribed by laws and regulations or will eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and U.S. federal and state or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. We do not currently carry biological or hazardous waste insurance coverage. In the event of an accident or environmental discharge, we may be held liable for any consequential damage and any resulting claims for damages, which may exceed our financial resources and may materially adversely affect our business, results of operations and prospects, and the value of our shares.

#### **Risks Related to Government Regulation**

### Changes in law, including as a result of recent presidential administration changes, could have a negative impact on the approval of our product candidates.

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. For example, certain policies of the Trump administration may impact our business and industry. Namely, the Trump administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. Notably, on January 23, 2017, President Trump ordered a hiring freeze for all executive departments and agencies, including the FDA, which prohibited the FDA from filling employee vacancies or creating new positions. While freeze has since been lifted, any additional freezes could result in delays in FDA's responsiveness or in its ability to review submissions or applications, issue regulations or guidance, or implement or enforce regulatory requirements in a timely fashion or at all. Moreover, on January 30, 2017, President Trump issued an Executive Order, applicable to all executive agencies, including the FDA, which requires that for each notice of proposed rulemaking or final regulation to be issued in fiscal year 2017, the agency shall identify at least two existing regulations to be repealed, unless prohibited by law. These requirements are referred to as the "two-for-one" provisions. This Executive Order includes a budget neutrality provision that requires the total incremental cost of all new regulations in the 2017 fiscal year, including repealed regulations, to be no greater than zero, except in limited circumstances. For fiscal years 2018 and beyond, the Executive Order requires agencies to identify regulations to offset any incremental cost of a new regulation. In interim guidance issued by the Office of Information and Regulatory Affairs within OMB on February 2, 2017, the administration indicates that the "two-for-one" provisions may apply not only to agency regulations, but also to significant agency guidance documents. It is difficult to predict how these requirements will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose constraints on FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

Further and more recently, President Trump has suggested that he plans to seek repeal of all or portions of the PPACA, and he has indicated that he wants Congress to replace the PPACA with new legislation. Risks related to the ongoing efforts of the Trump administration with respect to the repeal or repeal and replacement of elements of the PPACA are described above under the heading "Recently enacted and future healthcare reform legislation or regulation may increase the difficulty and cost for us and any future collaborators to obtain marketing approval of and commercialize our product candidates and may adversely affect the prices we, or they, may obtain and may have a negative impact on our business and results of operations." We cannot predict whether other legislative changes will be adopted, if any, or how such changes would affect the pharmaceutical industry generally.

# If the FDA does not conclude that our product candidates satisfy the requirements for the 505(b)(2) regulatory approval pathway, or if the requirements for approval of any of our product candidates under Section 505(b)(2) are not as we expect, the approval pathway for our product candidates will likely take significantly longer, cost significantly more and encounter significantly greater complications and risks than anticipated, and in any case may not be successful.

We intend to seek FDA approval through the 505(b)(2) regulatory pathway for each of our product candidates described in this prospectus. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, added Section 505(b)(2) to the Federal Food, Drug, and Cosmetic Act, or FDCA. Section 505(b)(2) 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.

If the FDA does not allow us to pursue the 505(b)(2) regulatory pathway for our product candidates as anticipated, we may need to conduct additional clinical trials, provide additional data and information and meet additional standards for regulatory approval. If this were to occur, the time and financial resources required to obtain FDA approval for our product candidates would likely substantially increase. Moreover, the inability to pursue the 505(b)(2) regulatory pathway could result in new competitive products reaching the market faster than our product candidates, which could materially adversely impact

our competitive position and prospects. Even if we are allowed to pursue the 505(b)(2) regulatory pathway for a product candidate, we cannot assure you that we will receive the requisite or timely approvals for commercialization of such product candidate.

In addition, notwithstanding the approval of a number of products by the FDA under Section 505(b)(2) over the last few years, certain competitors and others have objected to the FDA's interpretation of Section 505(b)(2). We expect that our competitors will file citizens' petitions with the FDA in an attempt to persuade the FDA that our product candidates, or the clinical studies that support their approval, contain deficiencies. If the FDA's interpretation of Section 505(b)(2) is successfully challenged, the FDA may be required to change its Section 505(b)(2) policies and practices, which could delay or even prevent the FDA from approving any NDA that we submit under Section 505(b)(2).

## Clinical development is a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results. Failure can occur at any stage of clinical development.

Clinical testing, even when utilizing the 505(b)(2) pathway, is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process, even with active ingredients that have previously been approved by the FDA as safe and effective. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later stage clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials.

Our product candidates are in various stages of development, from early stage to late stage. Clinical trial failures may occur at any stage and may result from a multitude of factors both within and outside our control, including flaws in formulation, adverse safety or efficacy profile and flaws in trial design, among others. If the trials result in negative or inconclusive results, we or our collaborators may decide, or regulators may require us, to discontinue trials of the product candidates or conduct additional clinical trials or preclinical studies. In addition, data obtained from trials and studies are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may delay, limit or prevent regulatory approval. For these reasons, our future clinical trials may not be successful.

We do not know whether any future clinical trials we may conduct will demonstrate consistent or adequate efficacy and safety to obtain regulatory approval to market our product candidates. If any product candidate for which we are conducting clinical trials is found to be unsafe or lack efficacy, we will not be able to obtain regulatory approval for it. If we are unable to bring any of our current or future product candidates to market, our business would be materially harmed and our ability to create long-term stockholder value will be limited.

# Delays in clinical trials are common and have many causes, and any delay could result in increased costs to us and could jeopardize or delay our ability to obtain regulatory approval and commence product sales. We may also find it difficult to enroll patients in our clinical trials, which could delay or prevent development of our product candidates.

We may experience delays in clinical trials of our product candidates. Our planned clinical trials may not begin on time, have an effective design, enroll a sufficient number of patients or be completed on schedule, if at all. Our clinical trials can be delayed for a variety of reasons, including:

- inability to raise or delays in raising funding necessary to initiate or continue a trial;
- delays in obtaining regulatory approval to commence a trial;
- delays in reaching agreement with the FDA on final trial design;
- imposition of a clinical hold for safety reasons or following an inspection of our clinical trial operations or trial sites by the FDA or other regulatory authorities;
- delays in reaching agreement on acceptable terms with prospective CROs and clinical trial sites, or failure by such CROs to carry out the clinical trial at each site in accordance with the terms of our agreements with them;

- delays in obtaining required institutional review board, or IRB, approval at each site;
- difficulties or delays in having patients complete participation in a trial or return for post-treatment follow-up;
- clinical sites electing to terminate their participation in one of our clinical trials, which would likely have a detrimental effect on subject enrollment; or
- time required to add new clinical sites.

If initiation or completion of our planned clinical trials is delayed for any of the above reasons or other reasons, our development costs may increase, our regulatory approval process could be delayed and our ability to commercialize and commence sales of our product candidates could be materially harmed, all of which could have a material adverse effect on our business.

In addition, identifying and qualifying patients to participate in clinical trials of our product candidates is critical to our success. The timing of our clinical trials depends on the speed at which we can recruit patients to participate in testing our product candidates as well as completion of required follow-up periods. We may not be able to identify, recruit and enroll a sufficient number of patients, or those with required or desired characteristics or to complete our clinical trials in a timely manner. Patient enrollment is and completion of the trials is affected by factors including:

- severity of the disease under investigation;
- design of the trial protocol;
- size of the patient population;
- eligibility criteria for the trial in question;
- perceived risks and benefits of the product candidate under trial;
- proximity and availability of clinical trial sites for prospective patients;
- availability of competing therapies and clinical trials;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians; and
- ability to monitor patients adequately during and after treatment.

## Our products or product candidates may cause adverse effects or have other properties that could delay or prevent their regulatory approval or limit the scope of any approved label or market acceptance, or result in significant negative consequences following marketing approval, if any.

As with many pharmaceutical and biological products, treatment with our products or product candidates may produce undesirable side effects or adverse reactions or events. Although the nature of our products or product candidates as containing active ingredients that have already been approved means that the side effects arising from the use of the active ingredient or class of drug in our products or product candidates is generally known, our products or product candidates may still cause undesirable side effects. These could be attributed to the active ingredient or class of drug or to our unique formulation of such products or product candidates, or other potentially harmful characteristics. Such characteristics could cause us, our IRBs, clinical trial sites, the FDA or other regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay, denial or withdrawal of regulatory approval, which may harm our business, financial condition and prospects significantly.

Further, if any of our products cause serious or unexpected side effects after receiving market approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw their approval of the product or impose restrictions on its distribution;
- the FDA may require implementation of a Risk Evaluation and Mitigation Strategy, or REMS;



- regulatory authorities may require the addition of labeling statements, such as warnings or contraindications;
- we may be required to change the way the product is administered or conduct additional clinical studies;
- we could be sued and held liable for harm caused to patients; or
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product or product candidate and could substantially increase the costs of commercializing our products and product candidates.

## The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. To date we have obtained regulatory approval for two products in the United States, but it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval in the United States or other jurisdictions.

Our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree that our changes to branded reference drugs meet the criteria for the 505(b)(2) regulatory pathway or foreign regulatory pathways;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective or comparable to its branded reference product for its proposed indication;
- the results of any clinical trials we conduct may not meet the level of statistical significance required by the FDA
  or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- we or third-party API or component manufacturers with which we may contract may be unable to maintain a compliance status acceptable to the FDA or comparable foreign regulatory authorities or the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes identified in our marketing application; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may change significantly in a manner rendering our clinical data insufficient for approval.

This lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our product candidates, which would harm our business, results of operations and prospects significantly.

In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could harm the commercial prospects for our product candidates.

We have limited experience using the 505(b)(2) regulatory pathway to submit an NDA or any similar drug approval filing to the FDA, and we cannot be certain that any of our product candidates will receive regulatory approval. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approvals to market one or more of our product candidates, our revenue will be dependent, to a significant extent, upon the size of the markets in the territories for which we gain regulatory approval. If the markets for patients or indications that we are targeting are not as significant as we estimate, we may not generate significant revenue from sales of such products, if approved.

## The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses.

If we are found to have improperly promoted off-label uses of our products or product candidates, if approved, we may become subject to significant liability. Such enforcement has become more common in the industry. The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, such as our product candidates, if approved. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. If we receive marketing approval for our product candidates for our proposed indications, physicians may nevertheless use our products for their patients in a manner that is inconsistent with the approved label, if the physicians personally believe in their professional medical judgment it could be used in such manner. However, if we are found to have promoted our products for any off-label uses, the federal government could levy civil, criminal and/or administrative penalties, and seek fines against us. The FDA or other regulatory authorities could also request that we enter into a consent decree or a corporate integrity agreement, or seek a permanent injunction against us under which specified promotional conduct is monitored, changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

## Our business is subject to extensive regulatory requirements and our approved product and product candidates that obtain regulatory approval will be subject to ongoing and continued regulatory review, which may result in significant expense and limit our ability to commercialize such products.

Even after a product is approved, we will remain subject to ongoing FDA and other regulatory requirements governing the labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, import, export, record-keeping and reporting of safety and other post-market information. The holder of an approved NDA is obligated to monitor and report adverse events, or AEs, and any failure of a product to meet the specifications in the NDA. 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. Advertising and promotional materials must comply with FDA rules and are subject to FDA review, in addition to other potentially applicable federal and state laws. In addition, the FDA may impose significant restrictions on the approved indicated uses for which the product may be marketed or on the conditions of approval. For example, a product's approval may contain requirements for potentially costly post-approval studies and surveillance to monitor the safety and efficacy of the product, or the imposition of a REMS program.

The holder of an NDA is subject to payment of user fees and adherence to commitments made in the NDA. A manufacturer is also subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMPs. If we or a regulatory agency discovers previously unknown problems with a product, such as AEs of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions relative to that product or the manufacturing facility, including requiring product recall, notice to physicians, withdrawal of the product from the market or suspension of manufacturing.

If we or our products or product candidates or our manufacturing facilities fail to comply with applicable regulatory requirements, a regulatory agency may:

- issue warning letters or untitled letters asserting that we are in violation of the law;
- impose restrictions on the marketing or manufacturing of the product;
- seek an injunction or impose civil, criminal and/or administrative penalties, damages, assess monetary fines, require disgorgement, consider exclusion from participation in Medicare, Medicaid and other federal healthcare programs and require curtailment or restructuring of our operations;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- · refuse to approve a pending NDA or supplements to an NDA submitted by us;
- seize product; or
- refuse to allow us to enter into government contracts.

Similar post-market requirements may apply in foreign jurisdictions in which we may seek approval of our products. Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize our products and generate revenues.

In addition, the FDA's regulations, policies or guidance may change and new or additional statutes or government regulations in the United States and other jurisdictions may be enacted that could prevent or delay regulatory approval of our product candidates or further restrict or regulate post-approval activities. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from pending or future legislation or administrative action, either in the United States or abroad. If we are not able to achieve and maintain regulatory compliance, we may not be permitted to market our products and/or product candidates, which would adversely affect our ability to generate revenue and achieve or maintain profitability.

## We are required to obtain regulatory approval for each of our products in each jurisdiction in which we intend to market such products, and the inability to obtain such approvals would limit our ability to realize their full market potential.

In order to market products outside of the United States, we must comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. However, the failure to obtain regulatory approval in one jurisdiction may adversely impact our ability to obtain regulatory approval in another jurisdiction. Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and costs for us and require additional non-clinical studies or clinical trials which could be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approval in international markets is delayed, our target market will be reduced and our ability to realize the full market potential of our products will be harmed.

## If we fail to develop, acquire or in-license other product candidates or products, our business and prospects will be limited.

Our long-term growth strategy is to develop and commercialize a portfolio of product candidates in addition to our existing product candidates. We may also acquire or in-license early to mid-stage new chemical entities, or NCEs. Although we have internal research and development capacity that we believe will enable us to make improvements to existing compounds or active ingredients, we do not have internal



drug discovery capabilities to identify and develop entirely new chemical entities or compounds. As a result, our primary means of expanding our pipeline of product candidates is to develop improved formulations and administration methods for existing FDA-approved products and/or select and acquire or in-license product candidates for the treatment of therapeutic indications that complement or augment our current targets, or that otherwise fit into our development or strategic plans on terms that are acceptable to us. Developing new formulations of existing products or identifying, selecting and acquiring or in-licensing promising product candidates requires substantial technical, financial and human resources expertise. Efforts to do so may not result in the actual development, acquisition or in-license of a particular product candidate, potentially resulting in a diversion of our management's time and the expenditure of our resources with no resulting benefit. If we are unable to add additional product candidates to our pipeline, our long-term business and prospects will be limited.

#### **Risks Related to Our Intellectual Property**

## If we are unable to obtain or protect intellectual property rights related to any of our product candidates, we may not be able to compete effectively in our market.

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our products and our product candidates. The issuance, scope, validity, enforceability, strength and commercial value of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own or in-license may fail to result in issued patents with claims that cover the products, if approved, or product candidates in the United States or in foreign countries or territories. If this were to occur, early generic competition could be expected against our products, if approved, and our product candidates in development. There may be relevant prior art relating to our patents and patent applications which could invalidate a patent or prevent a patent from issuing based on a pending patent application. In particular, because the active pharmaceutical ingredients in many of our product candidates have been on the market as separate products for many years, it is possible that these products have previously been used offlabel in such a manner that such prior usage would affect the validity of our patents or our ability to obtain patents based on our patent applications.

The patent prosecution process is expensive and time-consuming. We or our licensors may not be able to prepare, file and prosecute all necessary or desirable patent applications for a commercially reasonable cost or in a timely manner or in all jurisdictions. It is also possible that we or our licensors 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. Moreover, depending on the terms of any future in-licenses to which we may become a party, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology in-licensed from third parties. Therefore, these patents and patent applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our drug development and reformulation processes that involve proprietary know-how, information or technology that is not covered by patents. Although we generally require all of our employees to assign their inventions to us, and all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed or that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret. In addition, others may independently discover our trade secrets and

proprietary information. For example, the FDA is considering whether to make additional information publicly available on a routine basis, including information that we may consider to be trade secrets or other proprietary information, and it is not clear at the present time how the FDA's disclosure policies may change in the future, if at all. If we are unable to prevent material disclosure of the non-patented intellectual property related to our technologies to third parties, and there is no guarantee that we will have any such enforceable trade secret protection, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition.

### We may enjoy only limited geographical protection with respect to certain patents and we may not be able to protect our intellectual property rights throughout the world.

Filing and prosecuting patent applications and defending patents covering our products, if approved, or product candidates in all countries throughout the world would be prohibitively expensive. Competitors may use our and our licensors' technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we and our licensors have patent protection, but enforcement rights are not as strong as that in the United States or Europe. These products may compete with our products or product candidates, and our and our licensors' patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

In addition, we may decide to abandon national and regional patent applications before grant. The examination of each national or regional patent application is an independent proceeding. As a result, patent applications in the same family may issue as patents in some jurisdictions, such as in the United States, but may issue as patents with claims of different scope or may even be refused in other jurisdictions. It is also quite common that depending on the country, the scope of patent protection may vary for the same product candidate or technology.

The laws of some jurisdictions do not protect intellectual property rights to the same extent as the laws or rules and regulations in the United States and Europe, and many companies have encountered significant difficulties in protecting and defending such rights in such jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in other jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing as patents, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. Furthermore, while we intend to protect our intellectual property rights in our expected significant markets, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our product candidates. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate, which may have an adverse effect on our ability to successfully commercialize our product candidates in all of our expected significant foreign markets. If we or our licensors encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished and we may face additional competition from others in those jurisdictions.

Some countries also have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, some countries limit the enforceability of patents against government agencies or government contractors. In those countries, the patent owner may have limited remedies, which could materially diminish the value of such patents. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired.

### Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

Our ability to obtain patents is highly uncertain because, to date, some legal principles remain unresolved, there has not been a consistent policy regarding the breadth or interpretation of claims allowed in patents in the United States and the specific content of patents and patent applications that are necessary to support and interpret patent claims is highly uncertain due to the complex nature of the relevant legal, scientific and factual issues. Changes in either patent laws or interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection. For example, on September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The United States Patent and Trademark Office, or USPTO, has developed new and untested regulations and procedures to govern the full implementation of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, only became effective in March 2013. The Leahy-Smith Act has also introduced procedures making it easier for third parties to challenge issued patents, as well as to intervene in the prosecution of patent applications. Finally, the Leahy-Smith Act contains new statutory provisions that still require the USPTO to issue new regulations for their implementation and it may take the courts years to interpret the provisions of the new statute.

The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce existing patents or patents that we might obtain in the future. Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce existing patents or patents that we may obtain in the future. Accordingly, it is too early to tell what, if any, impact the Leahy-Smith Act will have on the operation of our business and the protection and enforcement of our intellectual property. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. An inability to obtain, enforce and defend patents covering our proprietary technologies would materially and adversely affect our business prospects and financial condition.

Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. For example, if the issuance to us, in a given country, of a patent covering an invention is not followed by the issuance, in other countries, of patents covering the same invention, or if any judicial interpretation of the validity, enforceability, or scope of the claims in, or the written description or enablement, in a patent issued in one country is not similar to the interpretation given to the corresponding patent issued in another country, our ability to protect our intellectual property in those countries may be limited. Changes in either patent laws or in interpretations of patent laws in the United States and other countries may materially diminish the value of our intellectual property or narrow the scope of our patent protection.

### We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our patents or the patents of any potential licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. For example, beginning in August 2013, we filed patent infringement lawsuits against six generic companies in the U.S. District Court for the District of Delaware for the approval by the

FDA of generic versions of Suboxone Sublingual Film in the United States. Of these, cases against two of the six generic companies have been resolved. We are also seeking to enforce our patent rights in multiple cases as further described in the section titled "Business — Legal Proceedings."

In an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing.

Interference proceedings provoked by third parties or brought by us may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our collaborators or licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States.

As described in the section titled "Business — Legal Proceedings," several of our issued patents are involved in litigations. In addition to the challenges we face in those litigations, a number of our issued patents are or have been involved in administrative proceedings, such as reexamination and *inter partes* review at the USPTO and opposition at the EPO. We cannot be certain that all claims of the challenged patents will be upheld or that the challenged patents will be found infringed. We may lose any of the challenged patents entirely, or we may have to amend the scope of claims to the extent which may be considered insufficient to cover our products or product candidates. If any of those scenarios were to occur, we might lose our competitive advantage in our market, and our business could be materially affected.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock. For more information, please see the subsection "Patent-Related Litigation" under the section titled "Business – Legal Proceedings."

# The patents and patent applications that we have covering our products and product candidates are limited to specific formulations and manufacturing processes, and our market opportunity for our products and product candidates may be limited by the lack of patent protection for the active ingredients and by competition from other formulations and manufacturing processes, as well as administration methods that may be developed by competitors.

We have obtained, and continue to seek to obtain patent protection for our manufacturing technology, drug administering technology and our products and product candidates, including specific formulations and manufacturing processes, which may not be as effective as composition of matter coverage in preventing work-arounds by competitors. As a result, generic products that do not infringe the claims of our issued patents covering formulations and processes are, or may be, available while we are marketing our products. Competitors who obtain the requisite regulatory approval will be able to commercialize products with the same active ingredients as our products or product candidates so long as the competitors do not infringe any process, use or formulation patents that we have developed for our products or product candidates, subject to any regulatory exclusivity we may be able to obtain for our products.

The number of patents and patent applications covering products containing the same active ingredient as our products or product candidates indicates that competitors have sought to develop and may seek to commercialize competing formulations that may not be covered by our patents and patent

applications. The commercial opportunity for our products or product candidates could be significantly harmed if competitors are able to develop and commercialize alternative formulations of our products or product candidates that are different from ours and do not infringe our issued patents covering our products or use of our products.

# Suboxone and Zuplenz have been approved by the FDA, and we anticipate that other product candidates will be approved by the FDA in the future. As additional products of ours are on the market, one or more third parties may also challenge the patents that we control covering our products, which could result in the invalidation or unenforceability of some or all of the relevant patent claims of our issued patents covering our products.

Suboxone and Zuplenz have been approved by the FDA, and we anticipate that other product candidates will be approved by the FDA in the future. Once our products are on the market, one or more third parties may challenge the patents that we control covering our products in court or the USPTO, which could result in the invalidation or unenforceability of some or all of the relevant patent claims of our issued patents covering our products.

If we or one of our licensing partners initiated legal proceedings against a third party to enforce a patent covering one of our products or product candidates, the defendant could counterclaim that the patent covering our product or product candidate is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are common, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post grant review, and equivalent proceedings in foreign jurisdictions (*e.g.*, opposition proceedings). Such proceedings could result in revocation of or amendment to our patents in such a way that they no longer cover our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our patent counsel and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Such a loss of patent protection could have a material adverse impact on our business.

## Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and/or applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our owned and licensed patents and/or applications and any patent rights we may own or license in the future. We rely on our outside counsel or our licensing partners to pay these fees due to non-U.S. patent agencies. The USPTO and various non-U.S. government patent agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply and we are also dependent on our licensors to take the necessary action to comply with these requirements with respect to our licensed intellectual property. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment or lapse of the patents or patent applications, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market and this circumstance could harm our business.

Our drug development strategy relies heavily upon the 505(b)(2) regulatory pathway, which requires us to certify that we do not infringe upon third-party patents covering approved drugs. Such certifications typically result in third-party claims of intellectual property infringement, the defense of which will be costly and time consuming, and an unfavorable outcome in any litigation may prevent or delay our development and commercialization efforts which would harm our business.

Litigation or other proceedings to enforce or defend intellectual property rights are often complex in nature, may be very expensive and time-consuming, may divert our management's attention from other aspects of our business and may result in unfavorable outcomes that could adversely impact our ability to launch and market our product candidates, or to prevent third parties from competing with our products and product candidates.

There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions and inter party reexamination proceedings before the USPTO. Numerous United States and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we and our collaborators are developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties.

In particular, our commercial success depends in large part on our avoiding infringement of the patents and proprietary rights of third parties for existing approved drug products. Because we utilize the 505(b)(2) regulatory pathway for the approval of our products and product candidates, we rely in whole or in part on studies conducted by third parties related to those approved drug products. As a result, upon filing with the FDA for approval of our product candidates, we will be required to certify to the FDA that either: (1) there is no patent information listed in the FDA's Orange Book with respect to our NDA; (2) the patents listed in the Orange Book have expired; (3) the listed patents have not expired, but will expire on a particular date and approval is sought after patent expiration; or (4) the listed patents are invalid or will not be infringed by the manufacture, use or sale of our proposed drug product. When we submit a paragraph IV certification to the FDA, a notice of the paragraph IV certification must also be sent to the patent owner once our 505(b)(2) NDA is accepted for filing by the FDA. The third party may then initiate a lawsuit against us to defend the patents identified in the notice. The filing of a patent infringement lawsuit within 45 days of receipt of the notice automatically prevents the FDA from approving our NDA until the earliest of 30 months or the date on which the patent expires, the lawsuit is settled, or the court reaches a decision in the infringement lawsuit in our favor. If the third party does not file a patent infringement lawsuit within the required 45-day period, our NDA will not be subject to the 30-month stay.

In addition to paragraph IV litigation noted above, third-party owners of patents may generally assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, formulations or methods of manufacture related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending or subsequently filed patent applications which may later result in issued patents that may be infringed by our products or product candidates. If any third-party patents were held by a court of competent jurisdiction to cover aspects of our product candidates, including the formulation, any method or process involved in the manufacture of any of our product candidates, any molecules or intermediates formed during such manufacturing process or any other attribute of the final product itself, the holders of any such patents may be able to block our ability to commercialize our product candidates unless we obtain a license under the applicable patents, or until such patents expire. In either case, such a license may not be available on commercially reasonable terms or at all.

Parties making claims against us may request and/or obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates on a temporary or permanent basis. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or



more licenses from third parties, pay royalties or redesign our infringing products or manufacturing processes, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such licenses would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research, manufacture clinical trial supplies or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize one or more of our product candidates, which could harm our business significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against our products or product candidates, resulting in either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties.

### We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

We employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of our employees' former employers or other third parties. We may also be subject to claims that former employers or other third parties have an ownership interest in our patents. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and even if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees.

## We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We may also be subject to claims that former employees, collaborators or other third parties have an ownership interest in our patents or other intellectual property. We may be subject to ownership disputes in the future arising, for example, from conflicting obligations of consultants or others who are involved in developing our product candidates and companion diagnostic. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

#### Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business or permit us to maintain our competitive advantage. The following examples are illustrative:

- others may be able to make products that are similar to our products or product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed;
- we or any potential future licensors or might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own or have exclusively licensed may be held invalid or unenforceable as a result of legal challenges by our competitors;
- issued patents that we own or have exclusively licensed may not provide coverage for all aspects of our products or product candidates in all countries;



- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- · we may not develop additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

Should any of these events occur, they could significantly harm our business, results of operations and prospects.

#### Risks Related to this Offering and Ownership of Our Common Stock

## No public market for our common stock currently exists, and a public market may not develop or be liquid enough for you to sell your shares quickly or at market price.

Prior to this offering, there has not been a public market for our common stock. If an active trading market for our common stock does not develop following this offering, you may not be able to sell your shares quickly or at the market price. An inactive market may also impair our ability to raise capital to continue to fund operations by selling shares of our common stock and may impair our ability to acquire other companies or technologies by using our common stock as consideration. The initial public offering price of our common stock will be determined by negotiations between us and representatives of the underwriters, and may not be indicative of the market prices of our common stock that will prevail in the trading market.

## The market price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our common stock in this offering.

The market price of our common stock is likely to be volatile. The stock market in general and the market for biopharmaceutical or pharmaceutical companies in particular, has experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, you may not be able to sell your common stock at or above the initial public offering price. The market price for our common stock may be influenced by many factors, including:

- sales of our approved products;
- · results of clinical trials of our current and any future product candidates or those of our competitors;
- the success of competitive drugs or therapies;
- · regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to our current and any future product candidates or clinical development programs;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- our inability to obtain or delays in obtaining adequate drug supply for any approved drug or inability to do so at acceptable prices;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including patent or stockholder litigation;
- variations in our financial results or those of companies that are perceived to be similar to us;



- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions; and
- the other factors described in this "Risk Factors" section.

## Our quarterly operating results may fluctuate significantly, and these fluctuations could cause our stock price to decline.

We expect our operating results to be subject to quarterly, and possibly annual fluctuations. These fluctuations could cause our stock price to decline. Our net loss and other operating results will be affected by numerous factors, including:

- whether the FDA requires us to complete additional, unanticipated studies, trials or other activities prior to approving any of our current and future product candidates, which would likely delay any such approval;
- our execution of other collaborative, licensing or similar arrangements and the timing of payments we may make or receive under these arrangements;
- variations in the level of expenses related to our future development programs;
- any product liability or intellectual property infringement lawsuit in which we may become involved;
- regulatory developments any of our other current and future product candidates, or the product candidates of our competitors; and
- if any of our current or future product candidates receive regulatory approval, the level of underlying demand for such product candidate and wholesaler buying patterns.

If our quarterly or annual operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly or annual fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially.

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

As of , our executive officers, directors, 5% or greater stockholders and their affiliates beneficially own approximately % of our voting stock. Based upon the assumed number of shares to be sold in this offering as set forth on the cover page of this prospectus, upon the closing of this offering, that same group will beneficially own % of our outstanding voting stock. Bratton Capital Management L.P., which controls certain of our approximately major stockholders, has beneficial ownership of approximately % of our common stock as of . Therefore. even after this offering these stockholders will have the ability to influence us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders, acting together, may be able to control elections of directors, amendments of our organizational documents or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may believe are in your best interest as one of our stockholders.

## If securities analysts do not publish research or reports about our business or if they publish negative evaluations of our stock, the price of our stock could decline.

The trading market for our common stock will rely, in part, on the research and reports that industry or financial analysts publish about us or our business. We do not currently have, and may never obtain, research coverage by industry or financial analysts. If no, or few, analysts commence coverage of us, the trading price of our stock would likely decrease. Even if we do obtain analyst coverage, if one or more of the analysts covering our business downgrade their evaluations of our stock, the price of our stock could decline. If one or more of these analysts cease to cover our stock, we could lose visibility in the market for our stock, which in turn could cause our stock price to decline.



## We may incur substantial costs relating to "excess parachute payments" under Sections 280G and 4999 of the Internal Revenue Code of 1986, as amended.

We entered into employment agreements with Keith J. Kendall, our Chief Executive Officer, and A. Mark Schobel, our Chief Innovation and Technology Officer, pursuant to which they are each entitled to receive an additional tax indemnification payment, or a "gross-up" payment, if the payments and benefits under their respective employment agreements or any other benefits plans and programs trigger excise tax liability under Sections 280G and 4999 of the Internal Revenue Code of 1986, as amended, or the Code for "excess parachute payments." Under Sections 280G and 4999 of the Code, the excise tax is triggered by change in control-related payments that equal or exceed three times Mr. Kendall's or Mr. Schobel's, as applicable, average annual taxable compensation over the five calendar years preceding the change in control. The excise tax equals 20% of the amount of the payment in excess of one times Mr. Kendall's or Mr. Schobel's, as applicable, average taxable compensation over the preceding five calendar year period (*i.e.*, the excess parachute payments). We may not take a federal tax deduction for Mr. Kendall's and/or Mr. Schobel's excess parachute payments.

If an "excess parachute payment" is made to Mr. Kendall and/or Mr. Schobel, we would incur substantial costs related to a change in control of the Company due to the gross-up payment and the lost federal tax deduction for Mr. Kendall's and/or Mr. Schobel's excess parachute payments.

## We are an "emerging growth company," and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies," including exemption from compliance with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in this prospectus and our periodic reports and proxy statements, and exemptions from the requirements of holding a non-binding advisory vote on executive compensation. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of this offering, (b) in which we have total annual gross revenue of at least \$1.07 billion, or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds \$700 million as of the last day business day of our most recently completed second fiscal quarter, and (2) the date on which we have issued more than \$1.0 billion in non-convertible debt during the prior three-year period.

Even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company," which would allow us to take advantage of many of the same exemptions from disclosure requirements including exemption from compliance with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may 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.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. As an emerging growth company, we have elected to take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards and, as a result, we will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for public emerging growth companies.

## 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. In addition, any testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act, or the subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our consolidated financial statements or identify other areas for further attention or improvement. 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.

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

As a public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act, as well as rules subsequently implemented by the SEC, and Nasdaq have imposed various requirements on public companies. In July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that required the SEC to adopt additional rules and regulations in these areas such as "say on pay" and proxy access. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact (in ways we cannot currently anticipate) the manner in which we operate our business. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain our current levels of such coverage.

### If you purchase our common stock in this offering, you will incur immediate and substantial dilution in the book value of your shares.

Investors purchasing common stock in this offering will pay a price per share that substantially exceeds the pro forma as adjusted book value (deficit) per share of our tangible assets after subtracting our liabilities. As a result, investors purchasing common stock in this offering will incur immediate dilution of \$ per share, based on an assumed initial public offering price of \$ per share (the mid-point of the price range set forth on the cover page of this prospectus) and our pro forma as adjusted net tangible book value (deficit) as of March 31, 2018. For more information on the dilution you may suffer as a result of investing in this offering, see "Dilution."

This dilution is due to the substantially lower price paid by our investors who purchased shares prior to this offering as compared to the price offered to the public in this offering and the exercise of stock options potentially granted to our employees. The exercise of any of these options if granted would result in additional dilution. As a result of the dilution to investors purchasing shares in this offering, investors may receive significantly less than the purchase price paid in this offering, if anything, in the event of our liquidation.

## Sales of a substantial number of shares of our common stock in the public market by our existing stockholders could cause our stock price to fall.

Sales of a substantial number of shares of our common stock by our existing stockholders, including shares issued to employees and directors in respect of the intended termination of our Performance Unit Plans, or PUP Plans, in the public market or the perception that these sales might occur, could depress



the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that such sales may have on the prevailing market price of our common stock.

Substantially all of our existing stockholders are subject to lock-up agreements with the underwriters of this offering that restrict the stockholders' ability to transfer shares of our common stock for at least 180 days after the date of this prospectus. The lock-up agreements limit the number of shares of common stock that may be sold immediately following the public offering. Subject to certain limitations, including sales volume limitations with respect to shares held by our affiliates, substantially all of our outstanding shares prior to this offering will become eligible for sale upon expiration of the lock-up period, as calculated and described in more detail in the section of this prospectus entitled "Shares Eligible for Future Sale." In addition, shares issued or issuable upon exercise of options and warrants vested as of the expiration of the lock-up period will be eligible for sale at that time. Sales of stock by these stockholders could have a material adverse effect on the trading price of our common stock.

Certain holders of our securities are entitled to rights with respect to the registration of their shares under the Securities Act, subject to the 180-day lock-up arrangement described above. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

## Future issuances of our common stock or rights to purchase our common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall.

While we currently do not have any options outstanding, we intend to adopt a new equity incentive plan and, following consummation of this offering, we intend to grant options to purchase shares of our common stock or other forms of equity compensation to our employees and directors. We intend to register all shares of common stock that we may issue under our stock-based compensation plans. Once we register these shares, they can be freely sold in the public market upon issuance, subject to any applicable lock-up agreements and the restrictions imposed under Rule 144 under the Securities Act, which may cause our stockholders to experience additional dilution.

## We have broad discretion in the use of the net proceeds from this offering and may not use them effectively.

Our management will have broad discretion in the application of the net proceeds, including for any of the purposes described in the section of this prospectus entitled "Use of Proceeds," and you will not have the opportunity as part of your investment decision to assess whether the net proceeds are being used appropriately. Because of the number and variability of factors that will determine our use of the net proceeds from this offering, their ultimate use may vary substantially from their currently intended use. The failure by our management to apply these funds effectively could harm our business. Pending their use, we may invest the net proceeds from this offering in short-term, investment-grade, interest-bearing securities. These investments may not yield a favorable return to our stockholders.

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

We have incurred substantial losses since inception and do not expect to become profitable in the near future, if ever. Under the newly enacted federal income tax law, to the extent that we continue to generate taxable losses in 2018 and in future years, such unused losses will carry forward to offset future taxable income, if any, but our deductibility of such losses in a future year is generally limited to 80% of taxable income. Furthermore, under Section 382 of the Code, if a corporation undergoes an "ownership change," generally defined as a greater than 50% 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 further limited. We believe that, with our initial public offering, we may have triggered an "ownership change" limitation. In addition, we may experience ownership changes in the future as a result of subsequent shifts in our stock ownership, including an ownership change as a result of the combined effect of our initial

public offering and future equity offerings. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards to offset United States federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us.

## We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock.

We have never declared or paid any cash dividend on our common stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to the appreciation of their stock.

## Provisions in our certificate of incorporation and bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire us or increase the cost of acquiring us, even if doing so would benefit our stockholders or remove our current management.

Some provisions of our charter documents and Delaware law may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our stockholders and may prevent attempts by our stockholders to replace or remove our current management. These provisions include:

- authorizing the issuance of "blank check" preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval;
- limiting the removal of directors by the stockholders;
- creating a classified board of directors;
- establishing a supermajority stockholder vote requirement for amending certain provisions of our amended and restated certificate of incorporation, or certificate of incorporation, or our amended and restated bylaws, or bylaws;
- prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders;
- eliminating the ability of stockholders to call a special meeting of stockholders; and
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted upon at stockholder meetings.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management. In addition, we are subject to Section 203 of the Delaware General Corporation Law, which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with an interested stockholder for a period of three years following the date on which the stockholder became an interested stockholder, unless such transactions are approved by our board of directors. This provision could have the effect of delaying or preventing a change of control, whether or not it is desired by or beneficial to our stockholders. Further, other provisions of Delaware law may also discourage, delay or prevent someone from acquiring us or merging with us.

## Our bylaws designate 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 employees.

Our bylaws provide that, subject to limited exceptions, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, any action asserting a claim against us arising pursuant to any provision of the Delaware General Corporation Law, our certificate of incorporation or our bylaws, any action to interpret, apply, enforce or determine the validity of our certificate of incorporation or our bylaws

or any other action asserting a claim against us that is governed by the internal affairs doctrine. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of our certificate of incorporation described above. This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and employees. Alternatively, if a court were to find these provisions of our certificate of incorporation 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 and financial condition.

#### SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus and the documents incorporated by reference herein contain forward-looking statements. The forward-looking statements are contained principally in the sections entitled "Prospectus Summary," "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Business." These forward-looking statements involve a number of risks and uncertainties. We caution readers that any forward-looking statement is not a guarantee of future performance and that actual results could differ materially from those contained in the forward-looking statement. These statements are based on current expectations of future events. Such statements include, but are not limited to, statements about future financial and operating results, plans, objectives, expectations and intentions, costs and expenses, interest rates, outcome of contingencies, financial condition, results of operations, liquidity, cost savings, objectives of management, business strategies, success of competing drugs, financing, potential growth and market opportunities, product pipeline, clinical trial timing and plans, clinical and regulatory pathways for our development programs, the achievement of clinical and commercial milestones, the advancement of our technologies and our proprietary, co-developed and partnered products and product candidates, and other statements that are not historical facts. In some cases, you can identify these statements by terms such as "anticipate," "believe," "could," "estimate," "expects," "intend," "may," "plan," "potential," "predict," "project," "should," "will," "would" or the negative of those terms, and similar expressions.

These forward-looking statements are based on the current beliefs and expectations of our management with respect to future events and are subject to significant risks and uncertainties. If underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results may differ materially from current expectations and projections. We discuss many of these risks in greater detail under the heading "Risk Factors." Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. Given these uncertainties, you should not place undue reliance on these forward-looking statements, which speak only as of the date made.

All subsequent written or oral forward-looking statements attributable to us or any person acting on our behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this section. We do not undertake any obligation to release publicly any revisions to these forward-looking statements to reflect events or circumstances after the date of this prospectus supplement or to reflect the occurrence of unanticipated events, except as may be required under applicable United States securities law. If we do update one or more forward-looking statements, no inference should be drawn that we will make additional updates with respect to those or other forward-looking statements.

You should read this prospectus and the documents that we reference in this prospectus and have filed as exhibits to the registration statement, of which this prospectus is a part, completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of the forward-looking statements in this prospectus by these cautionary statements.

#### MARKET AND INDUSTRY DATA

Certain market and industry data included in this prospectus were obtained from independent third-party surveys, market research, publicly available information, reports of governmental agencies and industry publications and surveys. All of the market and industry data used in this prospectus involve a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. Although we are responsible for all of the disclosure contained in this prospectus and we believe the information from the industry publication and other third-party sources included in this prospectus is reliable, such information is inherently imprecise. The industry in which we operate is subject to a high degree of uncertainty and risk due to a variety of factors, including those described in the section titled "Risk Factors." These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties and by us.

#### USE OF PROCEEDS

We estimate that we will receive net proceeds of approximately \$ million (or approximately \$ million if the underwriters' option to purchase additional shares is exercised in full) from the sale of the shares of common stock offered by us in this offering, based on an assumed initial public offering price of \$ per share (the mid-point of the price range set forth on the cover page of this prospectus), and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

A \$1.00 increase (decrease) in the assumed initial public offering price of \$ per share (the mid-point of the price range set forth on the cover of this prospectus) would increase (decrease) the net proceeds to us from this offering by approximately \$ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, an increase (decrease) of shares in the number of shares offered by us, as set forth on the cover of this prospectus, would increase (decrease) the net proceeds to us by \$ million, assuming the assumed initial public offering price of \$ per share (the mid-point of the price range set forth on the cover of this prospectus) remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The principal purposes of this offering are to obtain additional capital to support our operations, to create a public market for our common stock and to facilitate our future access to the public equity markets. We intend to use the net proceeds of this offering, together with our existing cash and cash equivalents and cash generated from existing partnerships, as follows:

- approximately \$ million to fund pre-launch commercialization investments for our late-stage epilepsy products, Libervant and Sympazan, as well as our ALS product candidate, AQST-117;
- approximately \$ million to fund the commencement of our clinical trials for our complex molecules AQST-108 and AQST-305;
- approximately \$ million to identify our new pipeline candidates in CNS diseases and other therapeutic categories and indications; and
- the remainder for general corporate purposes, including working capital and capital expenditures.

We believe that the net proceeds from this offering, combined with the revenue from partnered product activities and our existing cash and cash equivalents, will be sufficient to fund our operations at least through the next 24 months, including the investments identified above. Our expected use of net proceeds from this offering represents our current intentions based upon our present plans and business condition, which could change in the future as our plans and business conditions evolve. As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the net proceeds to be received upon the consummation of this offering, or the amounts that we will actually spend on the uses set forth above. The amounts and timing of our actual use of the net proceeds will vary depending on numerous factors, including our ability to obtain additional financing, the progress, cost and results of our proprietary commercialized product candidate programs, including our planned clinical trials, and whether we are able to enter into future collaborative arrangements. As a result, our management will have broad discretion in the application of the net proceeds, and investors will be relying on our judgment regarding the application of the net proceeds from this offering.

Our strategic plan includes the intent to expand our portfolio of product candidates through business development with a focus on CNS and other diseases where patients are significantly underserved by current medicines. Consequently, we might also devote more resources to other potential drug candidates in our pipeline or we might identify and develop other drug candidates not yet in our pipeline. We believe opportunities may exist from time to time to expand our current business through acquisitions or in-licenses of complementary companies, medicines or technologies. While we have no existing agreements, commitments or understandings for any specific future acquisitions or in-licenses at this time, we may use a portion of the net proceeds for these purposes.

Pending their use, we plan to invest the net proceeds from this offering in short- and intermediate-term, interestbearing obligations, investment-grade instruments, certificates of deposit or direct or guaranteed obligations of the United States government.

#### **DIVIDEND POLICY**

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings to support our operations and finance the growth and development of our business. We do not intend to pay cash dividends on our common stock for the foreseeable future. Any future determination related to our dividend policy will be made at the discretion of our board of directors and will depend upon, among other factors, our results of operations, financial condition, capital requirements, contractual restrictions, business prospects and other factors our board of directors may deem relevant.

#### CAPITALIZATION

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

- on an actual basis;
- on a pro forma basis to give effect to: (i) conversion of PUPs and valuation thereof to shares of common stock; and (ii) conversion of Perceptive Warrants outstanding into shares of common stock; and
- on a pro forma as adjusted basis to give further effect to our issuance and sale of stock offered in the offering, assuming an initial public offering price of \$ per share (the mid-point of the price range set forth on the cover of this prospectus), after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

The pro forma as adjusted information below is illustrative only and our capitalization following the closing of this offering will be adjusted based on the actual initial public offering price and other terms of this offering determined at pricing. You should read this table together with our audited consolidated financial statements and the related notes appearing elsewhere in this prospectus, the sections entitled "Selected Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and other financial information contained in this prospectus.

	As of March 31, 2018							
	Pro Forma As <u>Actual</u> Pro Forma Adjusted <sup>(1)</sup>							
(In thousands, except share and per share data)	(unaudited)							
Cash and cash equivalents	<u>\$ 16,488</u> <u>\$ 16,488</u> <u>\$</u>							
Long-term debt	45,965 45,965							
Stockholders' equity:								
Common stock, \$0.001 par value per share: Authorized 350,000,000 shares; 186,061,577 shares issued and outstanding at March 31, 2018; authorized 350,000,000 shares; 246,768,153 issued and outstanding, pro forma; authorized shares; and shares issued and outstanding, pro forma as adjusted	186 247							
Additional paid-in capital	93,412 111,827							
Accumulated deficit	(115,994) (134,894) —							
Total stockholders' deficit	(22,396) (22,820) —							
Total capitalization	<u>\$ 23,569</u> <u>\$ 23,145</u> <u>\$</u>							

<sup>(1)</sup> A \$1.00 increase (decrease) in the assumed initial public offering price of \$ per share (the mid-point of the price range set forth on the cover page of this prospectus) would increase (decrease) each of cash, additional paid-in capital, total stockholders' (deficit) equity and total capitalization by approximately \$ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase (decrease) of shares in the number of shares we are offering would increase (decrease) cash, additional paid-in capital, total stockholders' (deficit) equity and total capitalization by approximately \$ million, assuming the assumed initial public offering price remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

The table above includes the following:

- shares of common stock issuable immediately prior to the consummation of this offering pursuant to the automatic exercise of the Perceptive Warrants; but excludes
- shares of common stock reserved for future issuance under the 2018 Plan.

#### DILUTION

If you invest in our common stock in this offering, your interest will be diluted immediately to the extent of the difference between the initial public offering price per share of our common stock and the pro forma as adjusted net tangible book value per share of our common stock upon consummation of this offering. Dilution results from the fact that the initial public offering price is substantially in excess of the book value per share attributable to the existing stockholders for the presently outstanding stock.

Our historical net tangible book value (deficit) in our common stock as of March 31, 2018 was approximately \$(22.6) million, or \$(0.09) per share of common stock. Our historical net tangible book value (deficit) is the amount of our total tangible assets less our liabilities and preferred stock which is not included within equity. Net historical tangible book value (deficit) per share is our historical net tangible book value (deficit) divided by the number of shares of common stock outstanding as of March 31, 2018. Our pro forma net tangible book value (deficit) as of March 31, 2018 was approximately \$\_\_\_\_\_ million, or \$\_\_\_\_\_ per share of common stock. Pro forma net tangible book value (deficit) gives effect to the conversion of all of our outstanding preferred units and common units into an aggregate of

shares of our common stock, assuming an initial public offering price of \$ per share (the mid-point of the range set forth on the cover of this prospectus).

Pro forma as adjusted net tangible book value is our pro forma net tangible book value (deficit), plus the effect of the sale of shares of our common stock in this offering at an assumed initial public offering price of \$ per share (the mid-point of the range set forth on the cover of this prospectus), and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. This amount represents an immediate increase in pro forma as adjusted net tangible book value of \$ per share to our existing stockholders, and an immediate dilution of \$ per share to new investors participating in this offering.

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

Assumed initial public offering price per share	\$
Historical net tangible book value (deficit) per share as of March 31, 2018	\$ (0.09)
Pro forma decrease in net tangible book value per share as of March 31, 2018, attributable to pro forma transactions and other adjustments described above	_
Pro forma net tangible book value per share as of March 31, 2018	
Increase in pro forma net tangible book value per share attributable to new investors participating in this offering	_
Pro forma as adjusted net tangible book value per share after this offering	—
Dilution in net tangible book value per share to new investors participating in this offering	\$

The dilution information discussed above is illustrative only and will change based on the actual initial public offering price and other terms of this offering determined at pricing. A \$1.00 increase (decrease) in the assumed initial public offering price of \$ per share (the mid-point of the price range set forth on the cover page of this prospectus) would increase (decrease) the pro forma as adjusted net tangible book value (deficit) per share after this offering by per share and the pro forma dilution per share to investors participating in this offering would be approximately \$ per share, assuming that the number of shares offered by us, as set forth on the cover page of approximately \$ this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. A share increase in the number of shares offered by us, as set forth on the cover of this prospectus, would increase the pro forma as adjusted net tangible book value (deficit) per share after this offering by approximately \$ and the pro forma dilution per share to investors participating in this offering would be approximately \$ , assuming the assumed initial public offering price of \$ per share (the mid-point of the price range set forth on the cover of this prospectus) remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, a share decrease in the number of shares offered by us, as set forth on the cover of this prospectus, would decrease the pro forma as adjusted net tangible book value (deficit) per share after this offering by approximately \$ and the pro forma

dilution per share to investors participating in this offering would be approximately \$, assuming the assumed initial public offering price of \$ per share (the mid-point of the price range set forth on the cover of this prospectus) remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

If the underwriters exercise their option in full to purchase additional shares of our common stock in this offering, the pro forma as adjusted net tangible book value will increase to \$ per share, representing an immediate increase to existing stockholders of \$ per share and an immediate dilution of \$ per share to new investors participating in this offering.

The following table summarizes, as of March 31, 2018, on a pro forma as adjusted basis as described above, the total number of shares of common stock purchased from us on an as converted to common stock basis, the total consideration paid or to be paid, and the average price per share paid or to be paid by existing stockholders and by new investors in this offering at an assumed initial public offering price of \$ per share (the mid-point of the price range set forth on the cover page of this prospectus), before deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. As the table below shows, investors participating in this offering will pay an average price per share substantially higher than our existing stockholders paid.

			Total considera		
	Shares p Number	urchased Percent	Amount (in thousands)	Percent	Average price per share
Existing stockholders before this offering	Number	%	<u> </u>	%	
Investors participating in this offering					
Total		100%	\$	100%	

Each \$1.00 increase (decrease) in the assumed initial public offering price of \$ per share (the mid-point of the price range set forth on the cover page of this prospectus) would increase (decrease) the total consideration paid by investors participating in this offering and total consideration paid by all stockholders by \$ million and, in the case of an increase, would increase the percentage of total consideration paid by new investors by percentage points and, in the case of a decrease, would decrease the percentage of total consideration paid by new investors by percentage points, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same.

Similarly, each share increase (decrease) in the number of shares offered by us, as set forth on the cover page of this prospectus, would increase (decrease) the total consideration paid by investors participating in this offering and total consideration paid by all stockholders by \$ million, and, in the case of an increase, would increase the percentage of total consideration paid by new investors by percentage points and, in the case of a decrease, would decrease the percentage of total consideration paid by new investors by percentage points, assuming the assumed initial public offering price remains the same.

If the underwriters exercise their option to purchase additional shares in full in this offering, the number of shares of common stock held by existing stockholders will be reduced to % of the total number of shares of common stock to be outstanding after this offering, and the number of shares of common stock held by investors participating in this offering will be further increased to , or % of the total number of shares of common stock to be outstanding after this offering.

The foregoing discussion is based on shares of common stock outstanding as of March 31, 2018, assuming an initial public offering price of \$ (the mid-point of the range set forth on the cover of this prospectus) and includes:

- shares of common stock issuable immediately prior to the consummation of this offering pursuant to the automatic exercise of the Perceptive Warrants; but excludes
- shares of common stock reserved for future issuance under our 2018 Plan.

New investors will experience further dilution if any new options are issued and exercised under our equity incentive plans or we issue additional shares of common stock, other equity securities or convertible debt securities in the future.

#### SELECTED CONSOLIDATED FINANCIAL DATA

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

The following tables set forth our financial data for and as of the years ended December 31, 2017 and 2016, all of which has been derived from our audited consolidated financial statements appearing elsewhere in this prospectus. The accompanying unaudited interim consolidated financial statements are prepared in conformity with accounting principles generally accepted in the United States ("U.S. GAAP") and with Article 10 of Regulation S-X for interim financial reporting. The statements of operations data for the three months ended March 31, 2018 and 2017 and the balance sheet data as of March 31, 2018 have been derived from our unaudited interim consolidated financial statements included elsewhere in this prospectus and have been prepared in accordance with generally accepted accounting principles in the United States of America on the same basis as the annual audited consolidated financial statements and, in the opinion of management, the unaudited data reflects all adjustments, consisting only of normal recurring adjustments, necessary for the fair presentation of the financial information in those statements. Our historical results are not necessarily indicative of the results that may be expected for any period in the future and results from our interim period may not necessarily be indicative of the results of the entire year or any future period.

		Year E Decem					Three Months Ended March 31,		
		2017		2016		2018		2017	
(In thousands, except per membership interest and per share data)									
Consolidated Statements of Operations and Comprehensive Income (Loss):									
Revenues	\$	66,918	\$	51,785	\$	23,411	\$	16,436	
Costs and expenses:									
Manufacture and supply		19,820		16,378		5,636		4,184	
Research and development		22,133		15,450		4,901		5,343	
Selling, general and administrative		25,078		20,804		7,569		6,128	
Total costs and expenses		67,031		52,632		18,106		15,655	
Operating (loss) income		(113)		(847)		5,305		781	
Other expenses:									
Interest expense		(7,707)		(6,143)		(1,927)		(1,818)	
Loss on extinguishment of debt		_		(757)		_		_	
Loss on impairment of investment				(1,006)		_		_	
Change in fair value of warrant		(1,123)		(750)		697		(420)	
Other (expense) income				(99)		24			
Net (loss) income before income taxes		(8,943)		(9,602)		4,099		(1,457)	
Income taxes		_		_		_			
Net income (loss)		(8,943)		(9,602)		4,099		(1,457)	
Dividends on redeemable preferred interests		(2,480)		(2,342)		_		(613)	
Net income (loss) attributable to shares of common stock / members' interests		(11,423)		(11,944)		4,099		(2,070)	
Comprehensive (loss) income	\$	(11,423)	\$	(11,944)	\$	4,099	\$	(2,070)	
Net income / Net (loss) per membership / shareholder interest	\$	(0.09)	\$	(0.10)	\$	0.02	\$	(0.02)	
Weighted-average number of shares of common stock / membership interests outstanding — basic and diluted	•	121,228,353	•	118,785,104	Ŧ	186,061577	•	121,228,353	
Unaudited pro forma net loss <sup>(1)</sup>	\$	(8,943)			\$	(14,801)			
Unaudited pro forma net loss per share of common stock $^{(1)}$	\$	(0.04)			\$	(0.06)			
Unaudited pro forma weighted-average number of shares of common stock outstanding used to compute net loss per share of common stock $^{(1)}$		246,768,153				246,768,153			

(1) See Note 2 of our notes to the unaudited interim financials statements included elsewhere in this prospectus for an explanation of the method used to calculate the pro forma net loss, net loss per share and the weighted-average number of shares used in the computation of the per share amounts

		As of December 31,			As of M 2																																																																																														
		2017 2016		2017 2016		2017 2016		2017 2016		2017 2016		2016		2016		2016		2016		2016		2016		2016		2016		2016		2016		2016		2016		2016		2016		2016		2016		2016		2016		2016		2016		2016		2016		2016		2016		2016		2016		2016		2016		2016		2016		2016		2016		2016		2016		2016		2016		2016		2016		2016		2016		2016		017 2016		Actual	F	Pro Forma <sup>(1)</sup>	Pro Forma As Adjusted <sup>(2)(3)</sup>
(In thousands)											(u	naudited)																																																																																							
Balance Sheet Data:																																																																																																			
Cash and cash equivalents	\$	17,379	\$	9,209	\$	16,488	\$	16,488																																																																																											
Working capital <sup>(4)</sup>		12,813		12,526		14,349		6,949																																																																																											
Total assets		43,116		39,389		46,082		46,082																																																																																											
Total debt		45,507		38,650		45,965		45,965																																																																																											
Accumulated deficit	(1	120,093)	(2	108,670)	(	(115,994)		(134,894)																																																																																											
Total members' / stockholders' deficit		(68,596)		(57,197)		(22,396)		(22,820)																																																																																											

(1) The pro forma column reflects the charge of \$18.9 million for the termination of the Performance Unit Plan, effective January, 2018. Also included is the conversion of the warrant liability of \$6,976 as an addition to additional paid-in capital and a reduction in the warrant liability.

(2) The pro forma as adjusted column reflects the pro forma adjustments discussed above and sale of shares of our common stock in this offering at an assumed initial public offering price of \$ per share, the midpoint of the price range set forth on the cover page of this prospectus, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

(3) Each \$1.00 increase (decrease) in the assumed initial public offering price of \$ per share, the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) each of cash and cash equivalents, working capital, total assets and total stockholders' equity on a pro forma as adjusted basis by approximately \$ million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each 1.0 million increase (decrease) in the number of shares offered by us would increase (decrease) each of cash and cash equivalents, working capital, total assets and total stockholders' equity on a pro forma as adjusted basis by approximately \$ million, assuming that the number of shares offered by us would increase (decrease) each of cash and cash equivalents, working capital, total assets and total stockholders' equity on a pro forma as adjusted basis by approximately \$ million, assuming that the assumed initial public offering price remains the same, and after deducting underwriting discounts and commissions and estimated offering expenses and total stockholders' equity on a pro forma as adjusted basis by approximately \$ million, assuming that the assumed initial public offering price remains the same, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. The pro forma as adjusted information discussed above is illustrative only and will be adjusted based on the actual initial public offering price and other terms of this offering determined at pricing.

(4) Working capital is defined as current assets less current liabilities. See our consolidated financial statements for additional information regarding our current assets and current liabilities.

## 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 consolidated financial statements and the related notes appearing at the end of this prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. You should read the "Risk Factors" section of this prospectus for a discussion of important factors that could cause actual results to 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 specialty pharmaceutical company focused on identifying, developing and commercializing differentiated products to address unmet medical needs. We have a late-stage proprietary product pipeline focused on the treatment of CNS diseases. We believe that the characteristics of these patient populations and shortcomings of available treatment options create opportunities for the development and commercialization of meaningfully differentiated medicines. Our most advanced proprietary product candidates, which we intend to commercialize ourselves, include (i) Libervant, a buccal soluble film formulation of diazepam for the treatment of recurrent epileptic seizures, for which we expect to submit an NDA in 2018; (ii) Sympazan, an oral soluble film formulation of clobazam for the treatment of seizures associated with a rare, intractable form of epilepsy known as LGS, for which we submitted an NDA in October 2017 and have been given an August 31, 2018 PDUFA date, and (iii) AQST-117, an oral soluble film formulation of riluzole for the treatment of Amyotrophic Lateral Sclerosis, or ALS, for which we expect to submit an NDA in 2018. We have also developed a proprietary pipeline of complex molecule-based products addressing large market opportunities beyond CNS indications, which include (i) AQST-108, a sublingual film formulation of epinephrine for the treatment of anaphylaxis, for which we expect to begin additional Phase 1 trials in 2018 and (ii) AQST-305, a buccal film formulation of concept trials in 2018.

In addition to these product candidates, we have a portfolio of commercialized and development-stage partnered products. These products include Suboxone, a sublingual film formulation of buprenorphine and naloxone, which is the market leader for the treatment of opioid dependence. We manufacture all of our partnered and proprietary products at our FDA- and DEA-inspected facilities and anticipate that our current manufacturing capacity is sufficient for commercial quantities of our products and product candidates currently in development. We have produced over 1.1 billion doses of Suboxone in the last four years and over three billion commercial doses or dose equivalents for all customers since 2008. Our products are developed using our proprietary PharmFilm technology and know-how. Our patent portfolio currently comprises at least 200 issued patents worldwide, of which at least 40 are U.S. patents, and more than 75 pending patent applications worldwide.

We were originally formed in Delaware in January 2004 and until December 31, 2017, we conducted our business through MonoSol Rx, LLC, a Delaware limited liability company, or MonoSol. From the period of organization through October 31, 2017, our predecessor was a limited liability company, or LLC, treated as a partnership for income tax purposes. From November 1, 2017 through December 31, 2017, MonoSol elected to be taxed as a C corporation. On January 1, 2018, MonoSol converted from a Delaware LLC into a Delaware corporation pursuant to a statutory conversion and changed its name to Aquestive Therapeutics, Inc. In a corporate reorganization conducted following the conversion of MonoSol into a Delaware corporation, the holders of units of MonoSol contributed their interests in MonoSol to Aquestive Partners, LLC, or APL, in exchange for identical interests in APL and following such exchange APL became our parent and sole stockholder. Aquestive Therapeutics, Inc., our current corporate form, was formed effective on January 1, 2018 via the conversion of MonoSol Rx, LLC to, a Delaware corporation. As part of this conversion our charter approved the authorization of 25,000 shares of common stock and 5,000 shares of common stock were issued and outstanding as of March 31, 2018. As of March 31, 2018 our shares were 100% owned by APL. On April 16, 2018, we terminated our performance unit plans, or the PUP Plans, and as a result, we accelerated the vesting of any unvested



performance units and issued non-voting shares of common stock to the holders of our performance units in order to compensate the such holders of record on January 1, 2018. In April 2018, our board of directors approved a Certificate of Amendment to the Certificate of Incorporation in order to: (i) increase the authorized number of capital stock from 25,000 to 350,000,000 shares, (ii) authorize the issuance of non-voting common stock, and (iii) to effect a stock split of shares of our common stock. For purposes of our unaudited interim consolidated financial statements, the stock split has been presented as if it has occurred on January 1, 2018. Upon consummation of this offering, our shares held by APL will be distributed to the holders of interests APL in exchange for such interests, and APL will be liquidated.

We generated revenue of \$23.4 million and \$16.4 million for the three months ended March 31, 2018 and 2017, respectively, and \$66.9 million and \$51.8 million in 2017 and 2016, respectively, largely from commercial products marketed by our partners that generated manufacturing and supply revenues, and licensing, royalty and co-development and research fees. Suboxone, which was launched in 2010, was our first partnered pharmaceutical product to be commercialized, and we have multiple other partner relationships that contribute significantly to our revenue and future revenue opportunities from partnered products.

In 2013, we made a strategic decision to develop our own pipeline of proprietary pharmaceutical products and to pursue commercialization of these products. We expect revenues from these development efforts to start being realized in 2019, subject to applicable regulatory approval. Substantial investments have been made since 2013 in the development of our proprietary pipeline. We expect to continue these investments and invest in pre-launch commercialization initiatives throughout 2018 and 2019 in advance of the planned commercial launches of our CNS products. A portion of these development and commercialization investments has been funded by partner-related revenues, which we expect to continue. In addition, we have funded our activities with a \$50.0 million senior credit facility with Perceptive (as defined below) (see Liquidity and Capital Resources), and equity investments, most of which were made prior to 2009.

As of March 31, 2018, we had \$16.5 million in cash and cash equivalents. As a result of our investments in product development and recent investments in pre-launch commercialization initiatives, as of March 31, 2018, we had an accumulated deficit of \$116.0 million. We recorded net income of \$4.1 million and a net loss of \$1.5 million for the three months ended March 31, 2018 and 2017, respectively. For the years ended December 31, 2017 and 2016, we recorded net losses of \$8.9 million and \$9.6 million respectively.

We expect to continue to incur net losses for the next few years as we pursue the development and commercialization of our proprietary product candidates. Our net losses may fluctuate significantly from period to period, depending on the timing of our planned clinical trials and expenditures on our other research and development and commercial development activities. We expect our expenses will increase substantially over time as we:

- fund commercialization investments for our epilepsy products, Libervant and Sympazan, and our ALS product, AQST-117;
- continue clinical development of our complex molecules, AQST-108 and AQST-305;
- identify new pipeline candidates in CNS diseases and other indications; and
- fund working capital requirements and possible capital expenditures as a result of the launch of proprietary products and related growth.

Our business has been financed through a combination of revenue from partnered product activities, equity investments from our stockholders and debt proceeds from our credit facilities. In addition to proceeds from this offering, we may require additional financing to execute our business strategy.

We believe that the net proceeds from this offering, combined with our existing cash and cash equivalents and expected revenue from our partnered product activities, will be sufficient to fund our operations at least through the next 24 months of operations, including our planned investments in the pre-launch commercialization of our late stage CNS product candidates, research and development investments in our complex molecule product pipeline candidates, capital expenditures and investments

in new product candidates in epilepsy and other CNS diseases. We have based this estimate on assumptions that could change, and we could utilize our available financial resources sooner than we currently expect. The key assumptions underlying this estimate include:

- the costs necessary to successfully complete our development efforts of our proprietary product candidates;
- · continued revenue from our partnered products at levels similar to or above recent years' results;
- the levels and timing of revenues and costs of commercialization of our late stage CNS product candidates; and
- the infrastructure costs to support a public company.

We have no committed sources of additional capital. We may attempt to raise additional capital due to favorable market conditions or other strategic considerations even if we have sufficient funds for planned operations. Until we become profitable, if ever, we may need to raise additional capital in the future to further the development and commercialization of our epilepsy products, Libervant and Sympazan, our ALS product, AQST-117, and our other product candidates. We may seek to obtain additional financing in the future through the issuance of our common stock, through other public or private equity or debt financings, through collaborations or partnerships with other companies or other means, if available. We may not be able to raise additional capital on terms acceptable to us, or at all, and any failure to raise capital as and when needed could compromise our ability to execute on our business plan and cause us to delay or curtail our operations until such funding is received. To the extent that we raise additional funds by issuance of equity securities, our stockholders may experience dilution, and debt financings, if available, may involve restrictive covenants or may otherwise constrain our financial flexibility. To the extent that we raise additional funds through collaborative arrangements, it may be necessary to relinquish some rights to our intellectual property or grant licenses on terms that are not favorable to us. In addition, payments made by potential collaborators or licensors generally will depend upon our achievement of negotiated development and regulatory milestones. Failure to achieve these milestones may harm our future capital position.

#### **Financial Operations Overview**

#### Revenues

Our revenues to date have been earned from partnered pipeline and marketed product activities. These activities generate revenues in three primary categories: co-development and research fees, license and royalty revenue and manufacturing and supply revenue.

#### Co-development and Research Fees

We work with our partners to co-develop pharmaceutical products. In this regard, we earn fees through performance of specific tasks, activities, or completion of stages of development defined within a contractual arrangement with the relevant partner. The nature and extent of these performance obligations, broadly referred to as milestones or deliverables, are usually dependent on the scope and structure of the project as contracted, as well as the complexity of the product and the specific regulatory approval path necessary for that product.

#### License and Royalty Revenue

Once a viable product opportunity is identified from our co-development and research activities with our partners, we may out-license to our partners the rights to utilize our intellectual property related to their marketing of such products globally. As a result, we earn revenue from up-front license fees received under such license, development and supply agreements. We also may earn royalties based on our partners' sales of products that use our intellectual property that are marketed and sold in the countries where we hold royalty rights pursuant to such arrangements.

#### Manufacture and Supply Revenue

Currently, we produce two of our partners' pharmaceutical products: Suboxone and Zuplenz. We are the exclusive manufacturer for these products. We manufacture based on receipt of purchase orders from our partners, and our partners accept delivery of these orders at shipping point. As a result, we record



revenues when product is shipped and title passes to the customers. Our partners are responsible for all other aspects of commercialization of these products.

We expect future revenue from partnered activities to increase based on growing production volumes of partnered products, new product development with partners, and additional licensing of our intellectual property.

As we commercialize our proprietary CNS product candidates, beginning with Libervant and Sympazan, subject to regulatory approval, we expect to directly sell our products to consumers in the United States, resulting in an additional source of revenue which will be referred to as Product Sales, net. Additionally, we may choose to select a collaborator to commercialize our product candidates in certain markets outside of the United States. To date, we have not generated any revenues from product sales.

#### **Costs and Expenses**

Our costs and expenses are primarily the result of the following activities: generation of partnered revenues; development of our pipeline of proprietary product candidates; selling, general and administrative, including pre-launch commercialization efforts related to our CNS product candidates, intellectual property development and maintenance, and corporate management functions; and interest on our corporate borrowings. We primarily record our costs and expenses in the following categories:

#### Manufacture and Supply Costs and Expenses

Manufacture and supply costs and expenses are comprised of costs and expenses related to manufacturing our proprietary dissolving film products for our marketed partnered pharmaceutical products and for clinical trial batches of our proprietary and partnered product candidates, including raw materials, direct labor and fixed overhead principally in our Portage, Indiana facility. Our material costs include the costs of raw materials used in the production of our proprietary dissolving film and primary packaging materials. Direct labor costs consist of payroll costs (including benefits) of employees engaged in production activities. Fixed overhead principally consists of indirect payroll, facilities rent, utilities and depreciation for production machinery and equipment.

Our manufacture and supply costs and expenses are impacted by our customers' supply requirements; costs of production, which includes raw materials, which we purchase at market prices and production efficiency (measured by the cost of a salable unit) which can increase or decrease based on the amount of direct labor and materials required to produce a product and the allocation of fixed overhead, which is dependent on the levels of production.

We expect our manufacture and supply costs and expenses to increase over the next several years as we commercialize and begin to market, following regulatory approval, our product candidates, including Libervant and Sympazan, our ALS product candidate, AQST-117, and our other product candidates. Additionally, we expect to incur increased costs associated with hiring additional personnel to support the increased manufacturing and supply costs arising from our commercialization of these products and product candidates. As such, we expect our manufacturing and supply costs and expenses to increase as our product candidates receive regulatory approval and can be commercialized both in and outside the United States.

#### Research and Development Expenses

Research and development expenses primarily consist of:

- employee-related expenses, including salaries, benefits, and travel expense;
- external research and development expenses incurred under arrangements with third parties, such as contract research organizations, investigational sites and consultants;
- · the cost of acquiring, developing and manufacturing clinical study materials; and
- costs associated with preclinical and clinical activities and regulatory operations.

We expense research and development costs as incurred.

Clinical development timelines, likelihood of success and total costs vary widely. We do not currently track our research and development costs or our personnel and related costs on an individual product

basis. Furthermore, we use our research and development resources, including employees and proprietary dissolving film technology, across multiple drug development and other programs. As a result, we cannot state precisely the costs incurred for each of our research and development programs of our product candidates.

We expect our research and development expenses to increase over the next several years as we continue to implement our business strategy, expanding our research and development efforts, seeking regulatory approvals for any product candidates that successfully complete clinical trials, accessing and developing additional product candidates, and costs associated with hiring additional personnel to support our research and higher development efforts. In addition, product candidates in later stages of clinical development generally incur higher development costs that those in earlier stages of clinical development, primarily attributable to the increased size and duration of later-stage clinical trials. As such, we expect our research and development expenses to increase as our product candidates advance into later stages of clinical development, and as we add new candidates to our pipeline.

#### Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of salaries, benefits and other related costs for executive, finance, selling and operational personnel. Other significant costs include facility and related costs not otherwise included in research and development expenses such as: professional fees for legal, consulting, tax and accounting services; insurance; selling; market research; advisory board and key opinion leaders; depreciation; and general corporate expenses.

Historically, our selling, general and administrative expenses have been focused primarily on partnered selling activities and corporate management functions. However, costs related to commercialization of our CNS product candidates began in the second half of 2017 and are expected to accelerate in 2018, as we approach planned commercial launches. In addition, our general and administrative costs will increase as a public company, including costs related to additional personnel and accounting, audit, legal, regulatory and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, director and officer insurance costs, and investor and public relations costs.

#### Interest Expense

Interest expense consists of interest expense related to the Loan Agreement. Our interest is subject to changes in one-month LIBOR, and represents a monthly cash payment obligation. This debt facility is discussed in more depth in Liquidity and Capital Resources.

#### Other Expense

Other expense consists of non-cash changes in the fair value of the Perceptive Warrants issued to Perceptive in connection with the Loan Agreement, loss on extinguishment of debt and loss on disposal of investment in Midatech.

#### **Results of Operations**

#### Comparison of the Three Months Ended March 31, 2018 and 2017

We recorded revenue of \$23.4 million and \$16.4 million in the three months ended March 31, 2018 and March 31, 2017, respectively, generating net income of \$4.1 million and a net loss of \$1.5 million for each of those quarters, respectively.

The following discussion of our results of operations explains the material drivers of these results of operations.

#### Revenues

The following table sets forth our revenue data for the periods indicated.

	ths Ended h 31,	Cha	nge	
(In thousands, except %)	2018	2017	\$	%
Manufacture and supply revenue	\$ 11,560	\$ 10,155	\$1,405	14%
License and royalty revenue	9,500	5,223	4,277	82%
Co-development and research fees	2,351	1,058	1,293	122%
Revenues	\$ 23,411	\$ 16,436	\$6,975	42%

Our revenue increased 42% from \$16.4 million in 2017 to \$23.4 million in 2018.

Manufacture and supply revenue increased approximately 14% from \$10.2 million in 2017 to \$11.6 million in 2018 due to higher volume demand attributable to Suboxone and Zuplenz product sales.

License and royalty revenue increased 82% from \$5.2 million in 2017 to \$9.5 million in 2018. This increase was primarily related to license fees on our partnered products Suboxone and APL-130277, and royalties on Suboxone and Zuplenz. License fees were higher in 2018 as a result of the timing of milestones in these agreements, and royalties rose year-over-year on higher product sales volumes. License fees are milestone driven and may fluctuate significantly from quarter-to-quarter.

Co-development and research fees rose 122% from \$1.1 million in 2017 to \$2.4 million in 2018. These fees are highly dependent on the timing of partnered product research and development activities and related milestones, and may fluctuate significantly quarter-to-quarter.

#### Expenses:

The following table sets forth our expense data for the periods indicated:

		nths Ended ch 31,	Chan	ge
(In thousands, except %)	2018	2017	\$	%
Manufacturing and supply	\$ 5,636	\$ 4,184	\$ 1,452	35%
Research and development	4,901	5,343	(442)	(8)%
Selling, general and administrative	7,569	6,128	1,441	24%
Interest	1,927	1,818	109	6%
Other	(721)	420	(1,141)	NM%

Manufacturing and supply costs and expenses increased 35% from \$4.2 million in 2017 to \$5.6 million in 2018, driven by an increase in related partnered product volumes.

Research and development expenses decreased 8% from \$5.3 million in 2017 to \$4.9 million in 2018 primarily due to timing of expenses for direct project costs associated with our CNS product candidates (Libervant and AQST-117) and early clinical trial activity for our complex molecule product candidate AQST-108. Below is a depiction of research and development expenses by type of cost for each period presented:

	Three Months	Three Months Ended					
in 000's	2018		2017				
Clinical Trials	\$ 2,364	\$	3,054				
Labor - R&D staff	1,118	)	1,302				
Miscellaneous R&D	1,419		987				
Total	\$ 4,901	\$	5,343				

Selling, general and administrative expenses increased 24% from \$6.1 million in 2017 to \$7.6 million in 2018 primarily due to initial investments in our commercialization capabilities in preparation for the expected launch of Libervant, Sympazan and AQST-117. These higher costs included personnel, external

consultants and other resources that enabled us to establish the key commercial functions such as sales and marketing, market access and medical affairs. We also have added additional personnel and other external resources to prepare our company for going public.

Interest expense increased 6% from \$1.8 million in 2017 to \$1.9 million in 2018 as a result of a longer period of outstanding borrowings in 2018 compared to 2017 as the \$5.0 million borrowing was outstanding for all the 2018 while in 2017 the borrowing was outstanding for a few days, along with higher interest rates year-over-year. Our interest expense is subject to adjustment based on one-month LIBOR.

Other (income) expenses decreased, principally due to the change in fair value of warrants. The decrease in expense associated with the fair value of the warrants in March 31, 2018 is attributable to our performance of a valuation prepared in accordance with the AICPA Practice Aid, Valuation of Privately-Held Company Equity Securities Issued as compensation, and evaluated as part of its fair value exercise using best available information.

#### Comparison of Years Ended December 31, 2017 and 2016

We recorded revenue of \$66.9 million and \$51.8 million in 2017 and 2016, respectively, generating net losses of \$8.9 million and \$9.6 million for each of those years, respectively.

The following discussion of our results of operations explains the material drivers of these results of operations.

#### Revenues

The following table sets forth our revenue data for the periods indicated.

						Chang	je																				
	1	2017 2016		2016		2016		2016		2016		2016		2016		2016		2016		2016		2016		2016		\$%	
(In thousands, except %)																											
Manufacture and supply revenue	\$	40,092	\$	37,324	\$	2,768	7%																				
License and royalty revenue		23,133		11,320		11,813	104%																				
Co-development and research fees		3,693		3,141		552	18%																				
Revenues	\$	66,918	\$	51,785	\$	15,133	29%																				

Our revenue increased 29% from \$51.8 million in 2016 to \$66.9 million in 2017. This increase came primarily from increases in license and royalty revenue, followed by an increase in manufacturing and supply revenue.

Manufacture and supply revenue increased approximately 7% from \$37.3 million in 2016 to \$40.1 million in 2017 due to higher volume demand attributable to Suboxone product sales and the launch of Zuplenz in late 2016.

License and royalty revenue increased 104% from \$11.3 million in 2016 to \$23.1 million in 2017. This increase was primarily related to license fees on our partnered products Suboxone and APL-130277, and royalties on Suboxone and Zuplenz. License fees were higher in 2017 as a result of the timing of milestones in these agreements, and royalties rose year-over-year on higher product sales volumes. License fees are milestone driven and may fluctuate significantly from quarter-to-quarter.

Co-development and research fees rose 18% from \$3.1 million in 2016 to \$3.7 million in 2017. These fees are highly dependent on the timing of partnered product research and development activities and related milestones, and may fluctuate significantly quarter-to-quarter.

Expenses:

The following table sets forth our expense data for the periods indicated:

				Chang	je	
		2017		2016	 \$	%
(In thousands, except %)						
Manufacturing and supply	\$	19,820	\$	16,378	\$ 3,442	21%
Research and development		22,133		15,450	6,683	43%
Selling, general and administrative		25,078		20,804	4,274	21%
Interest		7,707		6,143	1,564	25%
Other		1,123		2,612	(1,489)	(57%)

Manufacturing and supply costs and expenses increased 21% from \$16.4 million in 2016 to \$19.8 million in 2017, driven by an increase in related partnered product volumes.

Research and development expenses increased 43% from \$15.5 million in 2016 to \$22.1 million in 2017 primarily due to increased direct project costs associated with our CNS product candidates (Libervant, Sympazan and AQST-117) and early clinical trial activity for our complex molecule product candidate AQST-108. The primary reason for the increases in costs was due to additional clinical studies of epilepsy patients at EMUs related to Libervant. Below is a depiction of research and development expenses by type of cost for each period presented:

	<u> </u>	Year Ended December 31					
in 000's		2017		2016			
Clinical Trials	\$	10,486	\$	2,401			
Labor - R&D staff		5,114		4,872			
Regulatory Submission Costs & Support		2,330		1,377			
All Other R&D		4,202		6,800			
Total	\$	22,133	\$	15,450			

Selling, general and administrative expenses increased 21% from \$20.8 million in 2016 to \$25.1 million in 2017 primarily due to initial investments in our commercialization capabilities in preparation for the expected launch of Libervant, Sympazan and AQST-117. These higher costs included personnel, external consultants and other resources that enabled us to establish the key commercial functions such as sales and marketing, market access and medical affairs. We also have added additional personnel and other external resources to prepare our company for going public.

Interest expense increased 25% from \$6.1 million in 2016 to \$7.7 million in 2017 as a result of higher borrowings in 2017 compared to 2016, along with higher interest rates year-over-year. Our interest expense is subject to increases based on one-month LIBOR.

Other expenses decreased by 57% in 2017 compared to 2016, principally due to the change in fair value of warrants of \$0.4 million, offset by one-time expense items in 2016 related to the \$1.0 million loss on impairment of our Midatech investment, \$0.8 million loss on the extinguishment of debt and \$0.1 million of other expenses in the 2016 period that did not occur in 2017.

#### Liquidity and Capital Resources

#### Sources of Liquidity

Since our inception in January 2004, we have incurred significant losses and as of March 31, 2018, we had an accumulated deficit of \$116.0 million. We have funded our operations primarily with equity and debt financings and milestone and royalty payments from our collaboration partners. Through March 31, 2108, we received net proceeds from debt and equity issuances of \$125.6 million as follows:

- \$50.0 million of these proceeds are from debt facilities further described below; and
- \$75.6 million of these proceeds are from equity financings, with most of these proceeds received in 2008 and prior years.

We generate revenue from partnered products and related activities, but the costs to generate these revenues and the costs and expenses of our proprietary CNS and complex molecule development programs and related commercialization efforts have resulted in the deficit we have accumulated since our inception.

We had \$16.5 million in cash as of March 31, 2018. We have no committed sources of capital and our borrowing capability under the Loan Agreement is fully drawn.

# Credit Agreement and Guaranty

On August 16, 2016, we entered into a Credit Agreement and Guarantee with Perceptive, which we amended on May 21, 2018, or, as so amended, the Loan Agreement. At closing, we borrowed \$45.0 million under the Loan Agreement and were permitted to borrow up to an additional \$5.0 million within one year of the closing date based on achievement of a defined milestone. In March 2017, we met our performance obligations under the terms of the Loan Agreement and received the remaining \$5.0 million available to us under the Loan Agreement. Proceeds under the Loan Agreement were used to repay an existing debt obligation of \$37.5 million, with the balance available for general corporate purposes. The loan from Perceptive will mature on August 16, 2020, however, following the consummation of this offering, the maturity date will be automatically extended to December 16, 2020. The loan bears interest, payable monthly, at one-month LIBOR or 2% plus 9.75%, subject to a minimum rate of 11.75%. The loan is interest-only through December 2018.

Additionally, pursuant to the Loan Agreement, as amended, commencing on May 1, 2019, seven monthly principal payments are due in the amount of \$550 thousand. Thereafter, monthly principal payments in the amount of \$750 thousand are due through the maturity date (as extended), at which time the full amount of the remaining outstanding loan balance is due. Our tangible and intangible assets are subject to first priority liens to the extent of the outstanding debt. Other significant terms include financial covenants, change of control triggers and limitations on additional indebtedness, asset sales, acquisitions and dividend payments. The Loan Agreement contains certain financial covenants, which include (1) a minimum liquidity requirement pursuant to which we must maintain a monthly cash balance of \$4.0 million at all times and (2) a minimum revenue requirement pursuant to which on a quarterly basis (calculation date) we must maintain minimum revenues for the twelve consecutive months ended prior to the calculation date. Further, under the Loan Agreement, as amended, we are allowed, subject to Perceptive's consent, to monetize the royalty and fees associated with APL-130277 and, in connection with such monetization Perceptive has agreed to release liens related to these royalties and fees.

As of March 31, 2018, we were compliant with all financial and other covenants under the Loan Agreement.

In addition, at closing, Perceptive received the Perceptive Warrants to purchase shares of our common stock representing 4.5% of our fully diluted common stock on an as converted basis. The Perceptive Warrants have certain rights and preferences including anti-dilution adjustments so that, upon exercise, they will represent 4.5% of our fully diluted common stock on an as converted basis, subject to dilution for certain financing transactions including the issuance of shares upon termination of our PUP Plans.

The Loan Agreement originally contained a requirement that we make a mandatory prepayment in the amount of 25% of the net cash proceeds to us upon consummation of our initial public offering; however, as amended, upon consummation of this offering such requirement shall not apply.

# **Cash Flows**

The following table provides information regarding our cash flows for the three months ended March 31, 2018 and 2017:

(In thousands)	2018		2017	
Net cash provided by operating activities	\$	785	\$	3,908
Net cash used in investing activities		(259)		(657)
Net cash (used in) provided by financing activities		(1,417)		5,024
Net (decrease) increase in cash and cash equivalents	\$	(891)	\$	8,275

# Net Cash Provided by Operating Activities

Net cash provided by operating activities for the three months ended March 31, 2018 was \$0.8 million, and was primarily attributed to net income of \$4.1 million that was offset by \$4.1 million of changes in operating assets and liabilities that had the effect of providing cash in 2018 and \$0.8 million in non-cash charges such as depreciation, amortization, amortization of debt issuance costs and discounts and changes in warrant valuation. Net cash provided by operating activities for the three months ended March 31, 2017 was \$3.9 million, and was primarily attributed to our \$1.5 million net loss and \$3.6 million of changes in operating assets and liabilities that had the effect of providing cash in 2017, offset by \$1.8 million in non-cash charges such as depreciation, amortization, amortization of debt issuance costs and changes in warrant valuation.

# Net Cash Used in Investing Activities

Net cash used in investing activities for the three months ended March 31, 2018 was attributable to capital expenditures for property, plant and equipment. We expect our capital expenditures to increase in future periods as we launch additional proprietary and partnered products, and as we make additional investments in corporate infrastructure mostly related to information technology investments, and we expect to fund these additional investments with cash from operations.

# Net Cash (Used in) Provided by Financing Activities

Net cash used in financing activities for the three months ended March 31, 2018 represents payments related to this offering offset in part by debt issuance costs. Net cash provided by financing activities for the three months ended March 31, 2017 represents the proceeds of \$5.0 million from the Loan Agreement.

The following table provides information regarding our cash flows for the years ended December 31, 2017 and 2016:

(In thousands)	 2017		2016	
Net cash provided by (used in) operating activities	\$ 5,824	\$	(8,175)	
Net cash (used in) provided by investing activities	(2,068)		190	
Net cash provided by financing activities	 4,414		5,689	
Net increase (decrease) in cash and cash equivalents	\$ 8,170	\$	(2,296)	

# Net Cash Provided by (Used in) Operating Activities

Net cash provided by operating activities for the year ended December 31, 2017 was \$5.8 million, and was primarily attributed a net loss of \$8.9 million that was offset by \$7.9 million of changes in operating assets and liabilities that had the effect of providing cash in 2017 and \$6.9 million in non-cash charges such as depreciation, amortization, amortization of debt issuance costs and discounts. Net cash used in operating activities for the year ended December 31, 2016 was \$8.2 million, and was primarily attributed to our \$9.6 million net loss and \$6.3 million of changes in operating assets and liabilities that had the effect of using cash in 2016, offset by \$7.7 million in non-cash charges such as depreciation, amortization, impairment of investment, amortization of debt issuance costs and loss on extinguishment of debt and changes in warrant valuation.

## Net Cash (Used in) Provided by Investing Activities

Net cash used in investing activities for the year ended December 31, 2017 was attributable to capital expenditures for property, plant and equipment. Net cash provided by investing activities for the year ended December 31, 2016 was attributable to proceeds from the sale of an investment in Midatech offset by capital expenditures for property, plant and equipment. We expect our capital expenditures to increase in future periods as we launch additional proprietary and partnered products, and as we make additional investments in corporate infrastructure mostly related to information technology investments, and we expect to fund these additional investments with cash from operations.

# Net Cash Provided by Financing Activities

Net cash provided by financing activities for the year ended December 31, 2017 represents the proceeds of \$5.0 million from the Loan Agreement, offset by debt issuance costs. Net cash provided by financing activities for the year ended December 31, 2016 represents the proceeds from the Loan Agreement of \$45.0 million, offset by the paydown of \$37.5 million of existing debt and early debt extinguishment costs along with debt issuance costs on the Loan Agreement.

## **Funding Requirements**

We believe that the net proceeds from this offering, combined with our existing cash and expected revenue from our partnered product activities, will be sufficient to fund our operations at least through the next 24 months of operations, including our planned investments in the pre-launch commercialization of our late stage CNS product candidates, research and development investments in our complex molecule product pipeline candidates, capital expenditures and investments in new product candidates in epilepsy and other CNS diseases. We have based this estimate on assumptions that could change, and we could utilize our available financial resources sooner than we currently expect. The key assumptions underlying this estimate include:

- the costs necessary to successfully complete our development efforts of our proprietary product candidates;
- continued revenue from our partnered products at levels similar to or above recent years' results;
- · the levels and timing of revenues and costs to commercialize our late stage CNS product candidates; and
- the infrastructure costs to support being a public company.

We have no committed sources of additional capital. We may attempt to raise additional capital due to favorable market conditions or other strategic considerations even if we have sufficient funds for planned operations. Until we become profitable, if ever, we may need to raise additional capital in the future to further the development and commercialization of our epilepsy products, Libervant and Sympazan, our ALS product, AQST-117, and our other product candidates. We may seek to obtain additional financing in the future through the issuance of our common stock, through other public or private equity or debt financings, third-party funding, marketing and distribution arrangements, as well as other collaborations, strategic alliances and licensing arrangements, or any combination of these approaches. We may not be able to raise additional capital on terms acceptable to us, or at all, and any failure to raise capital as and when needed could compromise our ability to execute on our business plan and cause us to delay or curtail our operations until such funding is received. To the extent that we raise additional funds by issuance of equity securities, our stockholders may experience dilution, and debt financings, if available, may involve restrictive covenants or may otherwise constrain our financial flexibility. To the extent that we raise additional funds through collaborative arrangements, it may be necessary to relinquish some rights to our intellectual property or grant licenses on terms that are not favorable to us. In addition, payments made by potential collaborators or licensors generally will depend upon our achievement of negotiated development and regulatory milestones. Failure to achieve these milestones may harm our future capital position.

If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate our research and development programs, or reduce our planned commercialization efforts. We also may be required to evaluate partnering aspects of our proprietary product candidate programs that we currently plan to self-commercialize.

We expect to incur significant additional costs to support the obligations of a public company to various regulatory agencies, to investors and in order to comply with certain legislation and regulations, such as the Sarbanes-Oxley Act of 2002. These expenditures will include the costs of additional employees with specific skills and experiences such as SEC reporting or internal controls as well as additional costs to outside service providers such as audit, tax and legal fees.

## **Contractual Obligations and Commitments**

Our contractual obligations relate to our debt agreement and operating leases for our facilities. The following table sets forth a summary of our contractual obligations as of March 31, 2018:

Contractual Obligations (In thousands)	Total	Less than one year		One to three years		Four to five years		After five years	
Perceptive debt principal and interest	\$ 63,047	\$	7,590	\$	55,457	\$	—	\$	_
Operating lease obligations	4,575		1,204		2,829		542		_
Total contractual obligations	\$ 67,622	\$	8,794	\$	58,286	\$	542	\$	

### **Operating Lease Obligations**

We have entered into various lease agreements for production and research facilities and offices. Most leases contain renewal options. Certain leases contain purchase options and require us to pay for taxes, maintenance and operating expenses. All of our leases are classified as operating leases.

# Production and Research Facilities, Portage, Indiana

We lease our current production facilities in Portage, Indiana, which house certain research and development offices and current good manufacturing practices, or cGMP, manufacturing operations. The leases contain an option to purchase the facility at any time during the lease term and/or a right of first refusal to purchase the facility. In October 2017, we extended the lease in our 8,400-square-foot facility (Melton) such that it will expire in March 2023. Our second facility, a 73,000-square-foot facility (Ameriplex), has a lease, as amended, that extends through September 30, 2022 and contains a renewal option that could extend the lease through September 30, 2026.

# Office and Research Facilities, Warren, New Jersey

We lease our 16,454 square-foot headquarters and principal laboratory facility in Warren, New Jersey. Through various amendments and extensions, the lease extends through February 28, 2020.

## **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.

# Quantitative and Qualitative Disclosures about Market Risk

Our exposure to market risk due to changes in interest rates relates primarily to the increase or decrease in the amount of interest expense from fluctuations in one-month LIBOR associated with the Loan Agreement. For each 1% increase in one-month LIBOR in excess of 2%, our annual interest expense would increase by approximately \$0.5 million. Our cash and cash equivalents are maintained in FDIC protected accounts with no exposure to material changes in interest rates. We do not purchase, sell or hold derivatives or other market risk sensitive instruments to hedge interest rate risk or for trading purposes.

## **Critical Accounting Policies and Estimates**

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of the consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses. On an ongoing basis, we evaluate our estimates and judgments. We base our estimates on historical experience and on various other assumptions that we believe are 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.

Our significant accounting policies are more fully described in Note 1 to our consolidated financial statements appearing elsewhere in this prospectus. We believe that the following accounting policies relating to revenue recognition, research and development expenses, inventory valuation and impairment of long-lived assets are most critical to aid you in fully understanding and evaluating our reported financial results.

### **Revenue Recognition**

Our principal source of revenue is currently derived from marketed products out-licensed to our partners. In the future, as our proprietary product candidates are approved, an additional revenue category will be product sales, net.

Revenues include the sale of our two commercialized partnered products, fees from co-development and research services, fees from licensed proprietary technologies and patent rights, and royalties based on specified product sales. Related contractual arrangements may include up-front payments, milestone payments linked to specified performance obligations, fixed monthly payments, or payments due for delivered products or services. Contracts may also include multiple-element arrangements. These are evaluated to identify deliverables and separate units of accounting. Deliverables generally represent obligations to provide analytical or testing services and reports, licenses for the use of intellectual property, manufactured products, or other performance obligations. Pursuant to FASB ASC Topic 605, *Revenue Recognition*, revenue is recognized when there is persuasive evidence of an agreement, title has passed or delivery has occurred, the price is fixed or determinable, and collection is reasonably assured.

We may enter into licensing, development and supply agreements that contain multiple deliverables. Under the provisions of FASB ASC Subtopic 605-25, *Revenue – Multiple Deliverables, Accounting for Revenue Arrangements with Multiple Deliverables*, we will evaluate whether these deliverables constitute separate units of accounting. A deliverable qualifies as a separate unit of accounting when the item delivered to the customer has standalone value and, if there is a general right of return for the items delivered to the customer, delivery or performance of the undelivered elements is considered probable and substantially in our control. Revenue from such arrangements is recognized when we have substantially completed our obligations under the terms of the arrangement and our remaining involvement is inconsequential and perfunctory. If we have significant continuing involvement under such an arrangement, fees are recognized over the estimated performance period. We recognize revenue derived from milestone payments for its research and development activities upon the achievement of specified milestones if (i) the milestone is substantive in nature, the achievement of the milestone was not reasonably assured at the inception of the agreement and achievement is linked to our performance, (ii) consideration earned relates to past and complete performance and (iii) the milestone payment is nonrefundable. Payments received in excess of amounts earned are classified as deferred revenue until earned.

### Inventory Valuation

Inventories are stated at the lower of cost or net realizable value. Cost is determined on a first-in, first-out basis. Inventory includes the cost of materials, production labor and overhead. We regularly review our inventories for impairment and reserves are established when necessary. We manufacture to specific orders and do not generally manufacture for inventory or take inventory risk for finished goods and therefore believe it unlikely that significant adjustments for inventory obsolescence will take place. However, the FDA and other regulatory authorities may take action regarding certain active pharmaceutical ingredients that may cause raw material or packaging inventories to become non-usable. If our estimates for excess or obsolete inventory and its potential utility are less favorable than those projected, additional inventory reserves may be required.

# Impairment of Long-Lived Assets

In accordance with the Subsections of FASB ASC Subtopic 360-10, *Property, Plant and Equipment – Overall*, longlived assets, such as property and equipment and intangible assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. That carrying value is considered unrecoverable if it exceeds the sum of the undiscounted cash flows expected from the use and eventual disposition of the asset.

As a result of management's evaluation of the recoverability of the carrying value of long-lived assets subject to ASC 360-10, no impairment charges were recorded for the three months ended March 31, 2018 and 2017 and for the years ended December 31, 2017 and 2016. If these estimates or their related assumptions change the fair value of these assets in the future, we may be required to record additional impairment charges.

## Warrant Liability

We classify the Perceptive Warrants as a liability on our balance sheets as they are free-standing financial instruments that may require us to transfer assets upon exercise. The Perceptive Warrants were initially recorded at fair value on date of grant, and are subsequently remeasured to fair value at each balance sheet date. Changes in fair value of the Perceptive Warrants are reported in Other Expense in the statement of operations and comprehensive loss.

Pursuant to the terms of the Perceptive Warrants, the holder thereof has the right to purchase shares of our common stock, which will be automatically exercised immediately prior to the consummation of this offering. The Perceptive Warrants have certain rights and preferences including anti-dilution adjustments so that, upon exercise, they will represent 4.5% of our fully diluted common stock on an as converted basis, subject to dilution for certain financing transactions including the issuance of shares upon termination of our PUP Plans.

### **Research and Development Costs**

We expense costs associated with research and development activities as incurred. Research and development expenses include (i) employee-related expenses, including salaries, benefits, travel and share-based compensation expense, (ii) external research and development expenses incurred under arrangements with third parties, such as contract research and contract manufacturing organizations, investigational sites and consultants, (iii) the cost of acquiring, developing and manufacturing clinical study materials; and (iv) costs associated with preclinical and clinical activities and regulatory operations.

Research and development costs reflect costs for our internal proprietary research and development projects as well as costs incurred under arrangements with third parties from which we generate co-development and research fees.

# Income Taxes

On December 22, 2017, the TCJA was enacted into law which overhauled the Internal Revenue Code of 1986, as amended, to revitalize our nation's economy. One significant aspect of this new legislation was to lower the U.S. Corporate tax rate from 35% to 21%. The tax reform legislation did not have a material impact on our provision for income taxes for the year ended December 31, 2017 due to the valuation allowance against our net deferred tax assets. From the period January 1, 2017 through October 31, 2017 and all of 2016, we were a Delaware limited liability company treated as a partnership for income tax purposes. From November 1, 2017 through December 31, 2017, we elected to be taxed as a C corporation. On January 1, 2018, we converted into a Delaware corporation and incorporated as Aquestive Therapeutics, Inc.

Income taxes are recorded in accordance with FASB ASC Topic 740 Income Taxes, or ASC 740, which provides for deferred taxes using an asset and liability approach. Income taxes have been calculated on a separate tax return basis. Certain of our activities and costs have been included in the tax returns filed by our predecessor company, MonoSol LLC. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases using enacted tax rates in effect for the year in which the differences are expected to affect taxable income. Tax benefits are recognized when it is more likely than not that a tax position will be sustained during an audit. Valuation allowances are provided if based upon the weight of available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

We account for uncertain tax positions in accordance with the provision of ASC 740. When uncertain tax positions exist, we recognize the tax benefit of tax provisions to the extent that the benefit of tax



positions to the extent that the benefit will more likely than not be realized. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position, as well as consideration of the available facts and circumstances. To date, we have not had any significant uncertain tax positions.

# Share-Based Payments

We have historically issued share-based payments pursuant to the terms of our Performance Unit Plans, or PUP Plans prior to terminating such plans in April 2018. The cost of employee services received in exchange for equitybased awards is determined based on FASB ASC Topic 718, *Compensation – Stock Compensation* using the grantdate fair value of the awards. Under our PUP Plans, all outstanding equity-based payments are to be recognized as an expense based on their fair value at the measurement date, which approximates our current estimated business enterprise value. Recognition of compensation expense is delayed until achievement of specified performance conditions can be considered probable. At the time that all contingencies are satisfied, the performance units granted to both employees and consultants will be reflected as liability-classified instruments based on the application of FASB ASC Topic 718.

We are a private company with no active public market for our common stock. Prior to this offering, the fair value of our performance units issued to our PUP Plans' participants was estimated on the date of grant by our board of directors. In order to determine the fair value of our performance units, our board of directors considered, among other things, timely valuations of our business enterprise value prepared by a qualified and independent third-party valuation firm in accordance with the guidance provided by the American Institute of Certified Public Accountants Practice Guide, Valuation of Privately-Held-Company Equity Securities Issued as Compensation, or the Practice Aide. Given the absence of a public trading market for our common units, our board of directors exercised reasonable judgment and considered a number of objective and subjective factors to determine the best estimate of the fair value of the performance units, including (i) our business, financial condition and results of operations, including related industry trends affecting our operations; (ii) our forecasted operating performance and projected future cash flows; (iii) the illiquid nature of our common stock; (iv) liquidation preferences and other rights and privileges of our Preferred units; (v) market multiples of our most comparable public peers and (vi) market conditions affecting our industry.

There are significant judgments and estimates inherent in the determination of the fair value of our performance units and common stock. These judgments and estimates include assumptions regarding our future operating performance, the time to completing an IPO or other liquidity event and the determinations of the appropriate valuation methods. If we had made different assumptions, our equity-based compensation expense, net loss and net loss per share of common stock could have been significantly different.

No compensation cost was recorded in 2017 and prior years because it was not probable that the specified performance conditions under the PUP Plans would be achieved and payments would be made.

In connection with our conversion from a Delaware limited liability company to a Delaware corporation, we received board of director approval and PUP Plan A participant approval to terminate the PUP Plans on April 16, 2018 effective January 1, 2018. At termination, we accelerated the vesting of any unvested performance units and issued 60.7 million shares of non-voting common stock to compensate the performance unit holders of record on January 1, 2018. We determined the compensation expense associated with the termination of the PUP Plans and the issuance of shares of non-voting common stock by engaging a valuation consultant to prepare an estimate of our enterprise value and the fair value of each series of our capital stock and equity instruments as of the date of termination. Such valuation yielded value of \$0.19 per share of non-voting common stock after considering the nature of these shares and the enterprise value of the business. The valuation utilized for this purpose was developed in accordance with the Practice Aide. The shares of non-voting common stock will be automatically converted into voting common stock upon consummation of this offering.

In accordance with guidance ASC 718, *Compensation* — *Stock Compensation*, we will record a charge to earnings of approximately \$11.5 million in the second quarter of 2018 to reflect the compensation cost associated with the issuance of non-voting common stock to compensate the

performance unit holders of record on January 1, 2018. Additionally, pursuant to the provisions of the termination of the Plans, we elected to pay the withholding tax on behalf of the performance unit holders and will record an additional liability and compensation cost in the second quarter of 2018 of approximately \$7.4 million. Our aggregate charge related to this transaction will be \$18.9 million.

## **Recent Accounting Pronouncements**

Refer to Note 2. "Summary of Significant Accounting Policies" in the accompanying notes to our consolidated financial statements appearing elsewhere in this prospectus for a discussion of recent accounting pronouncements.

# **JOBS Act**

On April 5, 2012, the Jumpstart Our Business Startups Act, or the JOBS Act, was enacted. The JOBS Act provides that, among other things, an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. As an emerging growth company, we have elected to take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards and, as a result, we will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for public emerging growth companies.

In addition, we intend to rely on the other exemptions and reduced reporting requirements provided by the JOBS Act. Subject to certain conditions set forth in the JOBS Act, if as an "emerging growth company" we intend to rely on such exemptions, we are not required to, among other things, (i) provide an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act of 2002, (ii) provide all of the compensation disclosure that may be required of non-emerging growth public companies under the Dodd-Frank Wall Street Reform and Consumer Protection Act, and (iii) disclose certain executive compensation-related items such as the correlation between executive compensation and performance and comparisons of the Chief Executive Officer's compensation to median employee compensation. These exemptions will apply for a period of five years following the consummation of this offering or until we no longer meet the requirements of being an emerging growth company, whichever is earlier.

### BUSINESS

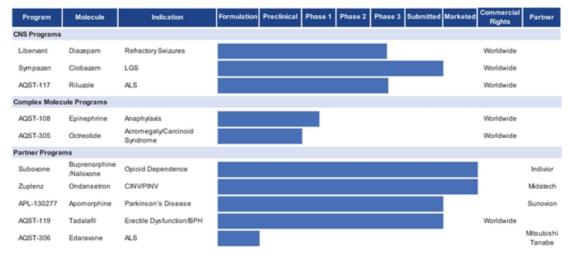
# Overview

We are a specialty pharmaceutical company focused on identifying, developing and commercializing differentiated products to address unmet medical needs. We have a late-stage proprietary product pipeline focused on the treatment of diseases of the Central Nervous System, or CNS. We believe that the characteristics of these patient populations and shortcomings of available treatment options create opportunities for the development and commercialization of meaningfully differentiated medicines. Our most advanced proprietary product candidates, which we intend to commercialize ourselves, include (i) Libervant, a buccal soluble film formulation of diazepam for the treatment of recurrent epileptic seizures, for which we expect to submit a New Drug Application, or NDA, in 2018; (ii) Sympazan, an oral soluble film formulation of clobazam for the treatment of seizures associated with a rare, intractable form of epilepsy known as Lennox-Gastaut Syndrome, or LGS, for which we submitted an NDA in October 2017 and have been given an August 31, 2018 Prescription Drug User Fee Act, or PDUFA, date, which is the date the U.S. Food and Drug Administration, or FDA, expects to complete its review of our NDA, and (iii) AOST-117, an oral soluble film formulation of riluzole for the treatment of Amyotrophic Lateral Sclerosis, or ALS, for which we expect to submit an NDA in 2018. We have also developed a proprietary pipeline of complex molecule products addressing large market opportunities beyond CNS indications, which include (i) AQST-108, a sublingual film formulation of epinephrine for the treatment of anaphylaxis, for which we expect to begin additional Phase 1 trials in 2018 and (ii) AQST-305, a buccal film formulation of octreotide for the treatment of acromegaly and neuroendocrine tumors, for which we expect to begin human proof of concept trials in 2018.

In addition to these product candidates, we have a portfolio of commercialized and development-stage partnered products. These products include Suboxone, a sublingual film formulation of buprenorphine and naloxone, which is the market leader for the treatment of opioid dependence. We manufacture all of our partnered and proprietary products at our FDA and Drug Enforcement Agency, or DEA, inspected facilities and anticipate that our current manufacturing capacity is sufficient for commercial quantities of our products and product candidates currently in development. We have produced over 1.2 billion doses of Suboxone in the last four years. Our products are developed using our proprietary PharmFilm technology and know-how. Our patent portfolio currently comprises at least 200 issued patents worldwide, of which at least 40 are U.S. patents, and more than 75 pending patent applications worldwide.

#### **Our Product Portfolio and Pipeline**

The following table outlines our pipeline of product candidates:



# Proprietary CNS Product Portfolio

We have initially focused our proprietary product pipeline on certain difficult to treat CNS diseases. Our PharmFilm technology allows us to develop medicines that offer non-invasive delivery, customized suitability for patients with dysphagia, or trouble swallowing, can be administered without water and ensure consistent therapeutic dosing. We believe that these characteristics will allow us to achieve the desired patient outcomes, while potentially reducing the total cost of patient care.

The most advanced assets within our proprietary CNS portfolio are as follows:

- Libervant a buccally, or inside of the cheek, administered soluble film formulation of diazepam, a
  benzodiazepine used as a rescue therapy for breakthrough epileptic seizures and an adjunctive therapy for use
  in recurrent convulsive seizures. We are developing Libervant as an alternative to Diastat (diazepam rectal
  gel), the current standard of care rescue therapy for patients with epilepsy, which as a rectal gel, is invasive,
  inconvenient, and difficult to administer. As a result, a large portion of the patient population does not receive
  adequate treatment or foregoes treatment altogether. We believe that Libervant will enable a larger share of
  patients to receive more appropriate treatment by providing consistent therapeutic dosing in a non-invasive and
  innovative treatment form for epileptic seizures. Libervant is currently completing its final clinical trials. We
  expect to submit an NDA for Libervant in 2018.
- **Sympazan** an oral soluble film formulation of clobazam, a benzodiazepine used as an adjunctive therapy for seizures associated with LGS. We are developing Sympazan as an alternative to Onfi (clobazam), currently available in either tablet form or liquid suspension. LGS patients often have difficulty swallowing pills and large volume suspensions leading to uncertain and inconsistent dosing and increasing the burden of care, particularly for patients that may be combative or resistant to treatment. We believe that Sympazan will address these treatment obstacles because it is mucoadhesive, dissolves rapidly in existing saliva and is swallowed along with a patient's natural saliva production, and therefore cannot be easily spit out. In clinical trials, Sympazan has demonstrated bioequivalence to Onfi. We submitted an NDA for Sympazan in October 2017 and were given a PDUFA date of August 31, 2018. If approved by the FDA, we anticipate launching Sympazan by the end of 2018.
- **AQST-117** an oral soluble film formulation of riluzole, a small molecule glutamate antagonist used as an adjunctive therapy in the treatment of ALS, which has been shown to slow disease progression, increase lifespan and improve quality of life. However, because ALS patients typically have difficulty swallowing, tablet administration is challenging. We are developing AQST-117 as an alternative to Rilutek (riluzole), which is currently available only in tablet form in order to achieve an easier, more reliable and accurate dosing. This may allow patients to continue therapy even after their ability to swallow has become compromised. AQST-117 addresses these treatment obstacles because it is mucoadhesive and dissolves easily on the tongue without the need for water and without a substantial increase in salivary flow. In clinical trials, AQST-117 has demonstrated bioequivalence to Rilutek. We expect to submit an NDA for AQST-117 in 2018.

# Proprietary Complex Molecule Portfolio

We are utilizing our technology and know-how to target large market opportunities by developing orallyadministered complex molecule therapies as alternatives to invasively-administered standard of care injectable therapeutics. We currently have two active complex molecule programs in clinical development. The first is focused on the oral delivery of the hormone epinephrine. The second is focused on the delivery of a peptide known as octreotide. Octreotide would be the first peptide delivered orally using our technology and may create other opportunities for peptides and biologics.

The two active programs in our complex molecule portfolio are:

• **AQST-108** – a sublingual film formulation of epinephrine that we are developing for the treatment of anaphylaxis, a severe and potentially life-threatening allergic reaction. Epinephrine is the standard of care in the treatment of anaphylaxis and is currently administered via intramuscular injection. The current market leader is EpiPen, a single-dose, pre-filled automatic injection



device. As a result of its administration via intra-muscular injection, many patients and their caregivers are reluctant to use currently available products, resulting in increased hospital visits and overall cost of care to treat anaphylactic events. We are designing AQST-108 to be the first non-injectable form of epinephrine used to treat anaphylaxis. We believe that, as a result of its sublingual administration, AQST-108 will improve patient compliance and lower the total cost of care. AQST-108 has shown promising results in one human proof of concept trial. We are currently optimizing the formulation for Phase 1 trials, which we expect to begin in 2018.

• AQST-305 – a sublingual film formulation of octreotide, a small peptide that has a similar pharmacological profile to natural somatostatin, for the treatment of acromegaly, as well as severe diarrhea and flushing associated with carcinoid syndrome. Acromegaly is a hormone disorder that results from the overproduction of growth hormone in middle-aged adults. Octreotide is the standard of care for the treatment of acromegaly. The current market leader, Sandostatin, is administered via deep subcutaneous or intramuscular injections once a month. This monthly treatment regimen can result in loss of efficacy towards the end of the monthly treatment cycle. We are developing AQST-305 as a non-invasive, pain-free alternative to Sandostatin to reduce treatment burden, healthcare costs and the potential loss of efficacy over the treatment cycle. AQST-305 has shown promising preclinical results. We initiated a development program to demonstrate human proof-of-concept and expect to dose the first patient in 2018.

## Partnered Products

Our portfolio also includes products and product candidates that we have partnered, or will seek to partner, for commercialization. In the year ended December 31, 2017, our partnered product portfolio generated over \$1 billion in revenue for our partners, resulting in \$66.9 million in revenue to us. Our key partnered products and products that we intend to partner include:

- Suboxone a sublingual film formulation of buprenorphine and naloxone that is marketed in the United States
  and internationally for the treatment of opioid dependence. Suboxone Sublingual Film was launched in
  partnership with Indivior Inc., or Indivior, in 2010. Suboxone Sublingual Film is the most prescribed branded
  product in its category and is the first sublingual film product for the treatment of opioid dependence with
  approximately 60% market share despite multiple competitors, including alternative dosing formulations. We
  are the sole supplier and manufacturer of Suboxone Sublingual Film. In the past four years, we have produced
  over 1.1 billion doses of Suboxone.
- **APL-130277** a sublingual film formulation of apomorphine, which is a dopamine agonist in development to treat episodic off-periods in Parkinson's disease. APL-130277 is being developed as a sublingual alternative to injectable form of apomorphine. We licensed intellectual property for APL-130277 to Cynapsus Therapeutics, a company that was acquired by Sunovion Pharmaceuticals Inc., or Sunovion. APL-130277 has successfully completed Phase 3 clinical studies. Sunovion, our partner and sponsor of APL-130277, submitted an NDA to the FDA on March 29, 2018.

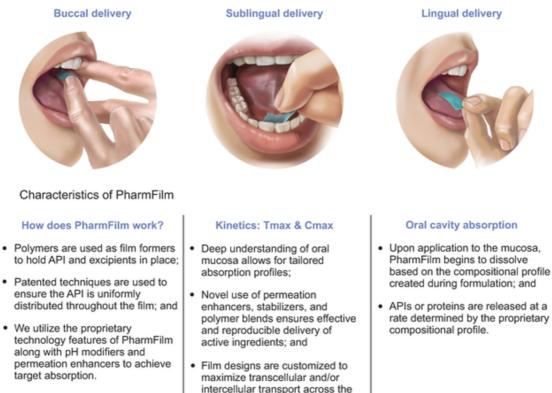
# PharmFilm – Our Oral Film Technology

We are the worldwide leader in oral film drug delivery and manufacturing. We supply more than 95% of the world's oral films for prescription pharmaceutical use, and we have the capability to produce more than one billion commercial doses a year. We developed our PharmFilm technology to provide meaningful clinical and therapeutic advantages over other existing dosage forms and, in turn, to improve the lives of patients and caregivers. PharmFilm is protected by our patent portfolio, which currently comprises at least 200 issued patents worldwide, of which at least 40 are U.S. patents, and more than 75 pending patent applications worldwide. Several of the patents in this intellectual property portfolio are utilized in each of our proprietary pipeline products. We are continuing to develop additional intellectual property and know-how related to the applications and engineering of PharmFilm alone or in combination with other technologies to create product capabilities that have compelling value propositions.

PharmFilm is comprised of proprietary polymer compositions that serve as film formers to hold active pharmaceutical ingredients, or APIs, and excipients in place. Proprietary and patent-protected



compositions, formulation and manufacturing techniques and technology are employed to ensure that the API is distributed uniformly throughout the film and that target absorption levels are achieved. Our proprietary technology and manufacturing process ensures that PharmFilm can be engineered to fit a variety of target product profiles in order to best address the unmet patient need present within specific disease states. PharmFilm, which is similar in thickness and size to a postage stamp, can be administered via buccal, sublingual or lingual oral delivery.



We believe the innovative nature of our PharmFilm drug delivery platform has the potential to offer a number of meaningful advantages to patients, caregivers and physicians compared to current standard of care therapies, including:

- preferred alternative to more invasive drugs such as injection;
- faster onset of action;
- direct absorption into the bloodstream reducing or avoiding "first pass" effects in the liver;

buccal mucosa.

- reduced gastrointestinal, or GI, side effects;
- positive dosing outcomes, especially for patients with physical (e.g., dysphagia) or psychological barriers to other methods of drug administration;
- stable, durable, portable and quick-dissolving (with or without water);
- customizable delivery routes for tailored pharmacokinetic, or PK, profiles (buccal, sublingual or lingual); and
- customizable taste profiles.

We chose to initially focus our development efforts on the CNS market because we believe the application of PharmFilm is particularly valuable and relevant to patients suffering from certain CNS

disorders where there are unmet patient needs or shortcomings in current standards of care. We believe there remains significant opportunity to develop additional products in the CNS market. Additionally, our know-how and proprietary position have broad application beyond CNS, and we plan to explore the applications of PharmFilm in other disease areas.

## **Our Management Team**

Our management team is a critical component to the development of our business model and the execution of our strategy. We are led by executives with an average of over 17 years of relevant senior leadership experience, including developing and commercializing branded and generic pharmaceuticals at large multinational pharmaceutical companies such as Johnson & Johnson, GlaxoSmithKline PLC and Novartis AG. Additionally, our team has significant experience in commercialization of pharmaceutical products, translational science, drug evaluation, clinical development, regulatory affairs and business development. Our management team is supervised and supported by a board of directors with expertise in finance, strategy, medicine and drug development.

# **Our Strategy**

We are a patient-centric pharmaceutical company developing and commercializing products that address unmet needs and improve the lives of patients and their caregivers. We focus on developing medicines for patient populations suffering from the shortcomings of available treatment options, which can create an opportunity for differentiated medicines. Our pipeline is initially focused on developing treatments for CNS diseases, as well as orally administered complex molecules that we believe can be alternatives to invasively-administered standard of care therapies. Our strategy leverages our global intellectual property portfolio, know-how, demonstrated research and development capabilities and proprietary manufacturing platform.

To achieve these goals, our strategy includes the following key elements:

- Advance our late stage proprietary portfolio of CNS product candidates to solve critical healthcare
  problems and make a meaningful improvement in the lives of patients and caregivers. We have three
  proprietary CNS product candidates for which we have completed or are approaching NDA submission. These
  product candidates address treatment challenges associated with epilepsy and ALS. We have submitted an
  NDA to the FDA and were given a PDUFA date of August 31, 2018 for Sympazan. We expect to submit NDAs
  for Libervant and AQST-117 in 2018.
- Scale our commercial platform to maximize the value of our proprietary product candidates. In order to
  maximize the value of our proprietary product candidates, we plan to self-commercialize our late stage CNS
  and other proprietary product candidates through a dedicated and focused commercial organization. We have
  built expertise in marketing, sales, payor and market access management and medical affairs in anticipation of
  multiple product launches starting in 2018. Based on overlapping prescriber call points for our initial CNS
  product candidates, we believe an efficient and dedicated sales force can effectively cover the vast majority of
  targeted prescribers.
- Exploit our technology and know-how to develop oral versions of more complex injectable drugs to
  address unmet patient needs. Based on promising preclinical and early clinical results, we intend to continue
  to develop oral transmucosal versions of epinephrine and octreotide, products that are currently available only
  in injectable form. We believe the success of these efforts may lead to additional high value opportunities in
  developing oral transmucosal versions of some proteins, peptides and other complex molecule drugs, which
  have historically been administered by means other than oral intake, such as injection or infusion.
- Continue to identify product opportunities within CNS and other markets to expand our proprietary product pipeline. We intend to identify additional product candidates that provide clinical differentiation and solve unmet needs. In the CNS space, we will leverage our

relationships with key stakeholders including patients, caregivers, key opinion leaders and patient advocacy groups to identify new product opportunities. Additionally, we will continue to evaluate other therapeutic areas, indications and products where our expertise and know-how can create differentiation and value.

- Acquire products or establish partnerships to develop and market products utilizing new chemical entities. We intend to continue to strategically expand our product portfolio by developing products that incorporate new chemical entities to treat disorders with high unmet need. For example in August 2017, we entered into a partnership with Mitsubishi Tanabe relating to edaravone, a treatment for ALS currently marketed only in injectable form.
- Continue to expand and solidify our intellectual property portfolio for our products, product candidates and manufacturing processes. Our robust global intellectual property portfolio is a significant source of competitive advantage, the strength of which has been demonstrated through multiple successful patent defenses. We have built a two-tier patent estate consisting of composition-of-matter and method of manufacture patents and patent applications. We intend to expand our intellectually property estate as we advance our PharmFilm and other technologies and as we develop new and existing product candidates.

## **Market Overview**

## **CNS Market**

CNS diseases affect the brain or spinal cord, and cause neurological and psychiatric disorders. Driven by an increase in mental health awareness and an aging population, the global market for therapeutics indicated for CNS disorders was estimated by EvaluatePharma to be \$80 billion in 2017, with anticipated growth to \$96 billion by 2022.

## Epilepsy

Epilepsy is a chronic CNS disorder characterized by recurrent seizure activity. There are approximately 3.4 million people in the United States suffering from epilepsy. According to IQVIA, antiepileptic medications generated sales of \$4.4 billion in the United States in 2017. The direct (medical) and indirect (lost wages and productivity) annual costs associated with epileptic patients in the United States are estimated to be approximately \$15.5 billion.

Epilepsy treatment regimens typically consist of chronic and acute management therapies. Chronic medicines are used on a daily basis to suppress seizure activity. Approximately 1.2 million of those 3.4 million people suffering from epilepsy will continue to suffer with breakthrough seizures and require an acute (rescue) management strategy. Patients are routinely prescribed antiepileptic drugs, or AEDs, as "maintenance" therapy to control chronic seizure activity. Most AEDs specifically target neuronal excitation or neuronal inhibitory pathways. There are currently more than 20 AEDs approved for use in the United States, and therapeutic choice depends on the epileptic syndrome being considered. Patients are routinely prescribed benzodiazepines as "rescue" therapy for the management of acute seizure emergencies.

Rescue therapies are administered as needed in the event of an acute seizure to rapidly terminate seizure activity. One of the most effective benzodiazepines currently available for the treatment of acute seizures is diazepam. Diazepam is currently marketed as Diastat, a product administered rectally. Although Diastat is the preferred drug prescribed by physicians, due to its rectal administration, Diastat presents a particular challenge for patients. As a result, only approximately 100,000 patients out of 1.2 million sufferers currently use this therapy. The remaining sufferers either pursue less effective treatments or forego treatment altogether.

There are multiple epileptic syndromes including LGS, which is a rare, intractable form of epilepsy and affects approximately 55,000 patients in the United States. Patients with LGS are often drug resistant, predisposing them to recurrent seizures, and are typically prescribed a combination of antiepileptic medications, which often includes clobazam. Clobazam is currently marketed under the brand name Onfi and is available in both a tablet and suspension formulation. Onfi generated combined sales revenue of \$753 million with more than 475,000 prescriptions filled in 2017, and is expected to lose patent protection in October 2018.

We are developing our lead product candidates, Libervant and Sympazan, to reduce the burden associated with administering both chronic and rescue therapies, thereby improving patient compliance and lowering the overall cost to the healthcare system for epileptic patients.

### Amyotrophic Lateral Sclerosis

ALS is a progressive neurodegenerative disease affecting nerve cells responsible for controlling voluntary muscle movement. Patients suffering from ALS have progressive degeneration of motor neurons, which ultimately leads to death, primarily due to respiratory failure. Diagnosis of ALS typically occurs between the ages of 40 and 60, with more than 13,000 patients diagnosed in the U.S. each year, which corresponds to a prevalence of four cases per 100,000 people. According to IQVIA<sup>1</sup>, ALS medications generated sales of \$62 million in the U.S. in 2017.

There are currently no treatments available that reverse the damage caused by ALS. However, there are two treatment molecules that have been shown to slow disease progression, riluzole marketed as Rilutek and edaravone marketed as Radicava. According to IQVIA, the combined market for riluzole generated over 62,000 prescriptions and sales of \$7 million in 2017.

In addition to therapeutics aimed at slowing disease progression, patients are often prescribed multiple medications and receive additional therapies, including breathing care, physical therapy, occupational therapy, speech therapy, nutritional support, and psychological and social support, to ease the burden of the disease.

As a result of the degenerative muscle function associated with ALS, patients eventually lose the ability to swallow. Because riluzole may slow disease progression and delay the need for a tracheotomy, dysphagia represents a barrier to treatment for many of these patients. We are developing AQST-117 to allow patients to remain on riluzole therapy for extended periods of time, delaying the need for procedures like tracheotomies, prolonging the quality of life for those patients and lowering the overall cost of treatment.

## **Other Therapeutic Areas**

In addition to products to treat CNS conditions, we are developing a number of product candidates in other therapeutic areas, such as anaphylaxis and acromegaly to create differentiated medicines to address unmet needs.

## Anaphylaxis

Anaphylaxis is a systemic allergic reaction caused by a wide range of allergen exposure, estimated to affect one in 50 people in the United States. Anaphylaxis typically occurs quickly once allergen exposure has occurred, and if untreated, can lead to death via airway restriction. According to IQVIA<sup>1</sup>, anaphylaxis treatments generated sales of \$1.7 billion in the U.S. in 2017.

Treatment of anaphylaxis typically consists of an intramuscular injection of epinephrine administered at the earliest opportunity, followed by additional intramuscular or intravenous injections as needed. While generic versions of epinephrine are currently available, they are provided as a vial of medication administered via syringes. Due to the inconvenience of this dosing mechanism, a branded form of epinephrine known as the EpiPen, which utilizes a proprietary auto-injector device administered through a deep intramuscular injection, dominates the market. In addition, recent manufacturing issues that resulted in injector malfunctions have led to significant patient concern regarding the reliability of auto-injectors. According to IQVIA<sup>1</sup>, branded and generic versions of epinephrine auto-injectors generated over 3.8 million prescriptions and combined gross sales of \$1.5 billion in 2017. EpiPen, which is marketed by Mylan, represents over 74% of the current market on a prescription volume basis.

Proper dosing and the ability to effectively administer epinephrine in a timely, reliable manner is critical for patients experiencing anaphylaxis. However, the inability to administer complex molecules via oral administration has limited the development of treatments that have the potential to provide significant patient benefit. We designed AQST-108 to offer a more convenient and cost effective oral form of epinephrine as an alternative to the current standard of care.

<sup>1 (</sup>IQVIA FIA Audit, NPA Audit, ChannelDynamics 02/2012 - 01/2018, Extracted 03/2018)



# Acromegaly

Acromegaly is a hormone disorder that results from the overproduction of growth hormone in middle-aged adults. The condition is typically caused by a benign tumor present in the pituitary gland that excretes excessive amounts of growth hormone and leads to exaggerated bone growth over time. Due to the gradual progression of the disorder, patients are often not diagnosed for years. The prevalence of acromegaly is estimated to be 78 cases per million people, indicating approximately 25,000 diagnosed patients within the United States. According to IQVIA<sup>2</sup>, acromegaly treatments generated sales of \$1.2 billion in the United States in 2017.

Depending on the placement and size of the tumor, patients may be eligible for endoscopic transnasal transsphenoidal surgery, a procedure in which pituitary tumors are removed through the nose and sphenoid sinus. However, surgeons may be unable to completely remove the tumor, leading to persistently elevated growth hormone levels post-surgery. The standard of care for post-surgery patients includes the use of somatostatin analogues to lower production or block the action of growth hormones. The somatostatin analogues currently available, octreotide and lanreotide, are administered by deep subcutaneous or intramuscular injections once a month, or subcutaneous injections three times daily.

The market leading product for acromegaly is octreotide, which is marketed as Sandostatin LAR by Novartis, and is administered monthly via depot injections. According to IQVIA<sup>2</sup>, Sandostatin generated over 49,000 prescriptions and sales of \$843 million in 2017.

Ease of administration has been identified as an unmet patient need within this market, with at least one other company pursing an oral formulation of octreotide. Our PharmFilm formulation has the potential to reduce treatment burden and healthcare costs for patients, and improve clinical differentiation.

## **Proprietary CNS Product Candidates**

# Libervant (Diazepam)

# Product Overview

Libervant is a buccal soluble film formulation of diazepam in development as a rescue therapy for patients with epilepsy who are already taking antiepileptic medications, and who require occasional use of diazepam to control bouts of increased seizure activity. We expect to submit an NDA for Libervant in 2018. Libervant has been granted orphan drug designation and has been granted fast track designation.

# Limitations of Current Therapies

Approximately 1.2 million of the 3.4 million people suffering from epilepsy will continue to suffer with breakthrough seizures and require an acute (rescue) management strategy. Many patients who suffer from severe epilepsy and experience refractory or breakthrough seizures are managed sub-optimally with current therapies, and in some cases chose not to be prescribed any therapies due to the limitations of the currently marketed rectal product. The standard of care therapy, Diastat, is particularly difficult to administer and presents challenges for both patients and caregivers. Difficulties associated with rectal administration of Diastat include patient dignity and respect, inaccurate dosing due to leakage of rectal gel, invasiveness of treatment, inconvenience, time required to administer the drug, and ability of non-primary caregivers to effectively administer Diastat in the event a primary caregiver is not present. As a result of these challenges, only about 250,000 doses of Diastat are prescribed per year, despite a much larger population of patients suffering from epilepsy who would potentially benefit from a rescue therapy.

Additionally, there is a population of epilepsy patients who do not achieve adequate blood plasma concentration of diazepam following administration of Diastat. We refer to these patients as Diastat "non-responders". Although this population represents a relatively small portion of the market, these patients are similarly underserved, and are currently prescribed therapies that are considered less effective than Diastat.

## Our Solution

We are developing Libervant as an alternative to Diastat. As an easily administered buccal film product that quickly dissolves when applied to the buccal mucosa, Libervant has a rapid onset of action

<sup>2 (</sup>IQVIA FIA Audit, NPA Audit, ChannelDynamics 02/2012 - 01/2018, Extracted 03/2018)

and provides a consistent therapeutic dosing. We believe Libervant has the potential to address many of the dosing and administration issues facing patients who are currently prescribed Diastat and to become the standard of care therapy for patients. Libervant also uses less diazepam to achieve desired treatment results. We believe Libervant has the potential to expand the population of epilepsy patients who are prescribed rescue therapies to include high functioning teens and adults who otherwise chose not to use Diastat and instead manage their symptoms with extra maintenance doses of their oral therapies before or after they experience a seizure. An oral product with fast onset of action could be a better rescue therapy option to these patients. In market research studies we have performed, patients, caregivers, and physicians have all indicated high receptivity to an oral alternative to Diastat.

We also believe that Libervant has the potential to be effective in the Diastat "non-responders" population. In studies to date, Libervant has shown consistent blood plasma concentrations in volunteers that did not obtain expected diazepam levels using Diastat.

# Clinical Development

Our clinical trials were designed under a Section 505(b)(2) pathway in consultation with the FDA, and included a dose proportionality study in healthy adults designed to demonstrate dose proportional blood plasma levels for Libervant at 5, 10 and 15 mg doses, a pivotal bioavailability study in healthy adults designed to compare the PK and demonstrate bioavailability of Libervant to Diastat, two food effect studies, adult and pediatric Epilepsy Monitoring Unit (EMU) studies in patients with epilepsy designed to compare the PK of Libervant in subjects with epilepsy in the interictal condition (when they are not experiencing seizures) versus the ictal/peri-ictal condition (when they are experiencing seizures), and a long-term safety study in children, adolescents and adults to assess the safety and tolerability of chronic intermittent use of Libervant by examining any pathological changes in the oral mucosa and gustatory cavity.

Our pivotal bioavailability study comparing the pharmacokinetic profile of a 15mg dose of Libervant to a 20mg dose of Diastat when administered to healthy volunteers in a fasted state showed that patients treated with a 15mg dose of Libervant achieved both a higher Cmax and a faster Tmax when compared to patients treated with a 20mg dose of Diastat. Additionally, all subjects treated with Libervant achieved significant blood levels (defined as a Cmax of 100 ng/mL of diazepam or greater for the top dose level). Two subjects administered the 20mg dose of Diastat (identified as subjects #7 and #9) only reached peak concentrations of 25 ng/mL and 15 ng/mL respectively. Both of these subjects have been labeled as 'non-responders' since their peak concentrations were below 100 ng/mL. Both subjects were administered four different dosages of diazepam: a 15mg dose of Libervant and 5mg, 12.5mg, and 20mg doses of Diastat. In both subjects the pharmacokinetic profiles for all three doses of Diastat were consistent with a typical Diastat non-responder. In contrast, both patients achieved diazepam blood levels following administration of Libervant that were in-line with the overall mean diazepam concentrations achieved across all Libervant dosings in this study. Based on these results, we believe Libervant has the potential to provide meaningful benefit to these "non-responders."

In March 2018, we received interim data from our adult EMU clinical study for Libervant. Through February 2018, 12 subjects had completed the study across the two treatment arms. This represents 40% of the 30 subjects needed to complete the study. Preliminary analysis of the data indicates the following:

- A 12.5mg of Libervant administered during an interictal, or non-seizure, state and without regard to food (n=12 patients) provided appropriate maximal plasma concentrations of diazepam (Cmax) within 60 minutes of administration (Tmax). Furthermore, similar Cmax and Tmax levels were obtained during dosing in a peri-ictal state. We believe these results successfully demonstrate that Libervant adequately absorbed into the blood stream regardless of whether it is applied during a seizure or normal state.
- Observed plasma levels of diazepam in patients with epilepsy were lower than plasma levels in healthy volunteers at the same dose level. This is consistent with the effects of multiple concomitant AEDs, which interact with diazepam and are commonly used by these patients.

Based on these data, we currently anticipate that a 12.5mg dose of Libervant will be equivalent to a 17.5mg dose of Diastat. As a point of reference, our 12.5mg Libervant in patients with epilepsy had a similar Cmax to a 12.5mg dose of Diastat given to healthy volunteers with no exposure to AEDs. We believe this confirms our ability to provide an efficacious dose of Libervant at a lower dose level than Diastat.

Based on our interactions with the FDA to date, we believe the data generated in this study represent a critical step in supporting approval of Libervant. We believe the comparability between the two dosing states will be viewed positively during our upcoming interactions with the FDA.

We are in the process of requesting a face-to-face meeting with the FDA where these data, along with other clinical data, will be presented. We believe the interim data support our view that, upon the completion of our adult EMU study, we will have the necessary supporting data to submit a marketing application to the FDA.

# Sympazan (Clobazam)

# Product Overview

Sympazan is an oral soluble film formulation of clobazam, a benzodiazepine that is used as an adjunctive therapy for seizures associated with LGS. We submitted an NDA to the FDA in October 2017 and were given a PDUFA date of August 31, 2018. If approved by the FDA, we anticipate launching Sympazan by the end of 2018.

# Limitations of Current Therapies

Patients with LGS are often drug resistant, predisposing them to recurrent seizures, and are typically prescribed a combination of antiepileptic medications, which often includes branded clobazam. Clobazam is currently marketed by Lundbeck under the brand name Onfi and is available in both a tablet and suspension formulation.

Medication administration is perceived to be a significant unmet need for LGS caregivers and patients. Approximately 30-40% of LGS patients experience dysphagia making more traditional administration routes a significant burden on the patient. Additionally, some patients refuse to swallow tablets due to physical limitations of the disease, behavioral or compliance issues. While some caregivers will crush the tablets to make dosing easier or use a suspension formulation that is squirted into the mouth, these methods do not always ensure that the patient receives the full, correct dose. Further, suspension dosage forms require significant volume, often result in an unpleasant taste and can be easily spit out by non-compliant patients.

# Our Solution

We are developing Sympazan to offer patients a well-known antiepileptic medication in a formulation that could improve ease of use, dosing completeness and tolerability. We believe that Sympazan offers advantages over other clobazam dosage forms in patients with LGS. Specifically, we have developed Sympazan as a mucoadhesive, rapidly dissolving, easy to swallow film that cannot be easily spit out by non-compliant patients once placed in the mouth. We also believe that Sympazan alleviates the concerns of excessive volume and unpalatable taste associated with traditional suspension dosage forms, as well as alleviating the burden of care, potentially for patients that may be combative or resistant to treatment. We believe a significant market opportunity exists for a form of clobazam with these advantages. In various comparison studies of Sympazan, physicians, caregivers and patients have expressed a preference for our soluble film formulation over traditional forms of clobazam.

# **Clinical Development**

Our clinical development of Sympazan has followed the 505(b)(2) regulatory pathway. Beginning in 2016 we conducted three clinical trials studying Sympazan in LGS. The first two studies were both pilot studies that evaluated the pharmacokinetic profile of low and high doses of Sympazan to comparative levels of Onfi. The final study, our definitive pivotal study, compared the pharmacokinetic profile of a 20mg

dose of Sympazan to a 20mg dose of Onfi when administered to healthy volunteers in a fasted state. We believe that the data from our pivotal study demonstrated bioequivalence to the reference listed drug Onfi. We submitted an NDA to the FDA, including the data from our study, with a target indication of LGS in October 2017. This NDA has a PDUFA date of August 31, 2018.

Additionally, given the broad applicability of the molecule and strong prescriber preference across a range of indications, we may develop and submit Sympazan for approval in additional indications in the future.

# AQST-117 (Riluzole)

## Product Overview

AQST-117 is an oral soluble film formulation of riluzole, a small molecule glutamate antagonist used as an adjunctive therapy in the treatment of ALS, which has been shown to slow disease progression, increase lifespan and improve quality of life. AQST-117 has been granted orphan drug designation.

# Limitations of Current Therapies

ALS is a neurodegenerative disorder that involves gradual breakdown of motor neurons leading to muscle weakness, disability, and ultimately death. The U.S. prevalence of ALS is 4 cases per 100,000 persons, though higher prevalence rates are seen among specific age and ethnic groups. Disease progression leads to muscle atrophy, including loss of ability to swallow. Riluzole is currently marketed by Covis Pharma under the brand name Rilutek and has been subject to generic competition since June 2013 and is currently available in a tablet formulation.

As a result of the degenerative muscle function associated with ALS, patients eventually lose the ability to swallow. Dysphagia represents a barrier to treatment for many of these patients, with medication administration resulting from dysphagia representing a significant unmet need for ALS caregivers and patients. The longer patients are able to remain on riluzole therapy, which has been shown to slow the progression of ALS, more invasive and costly treatments, such as tracheotomies, can be delayed, thus improving patients' quality of life.

## Our Solution

We have developed AQST-117 as an alternative to the existing riluzole therapy (Rilutek), which is currently available only in tablet form. AQST-117 allows ALS patients, who suffer dysphagia as a core symptom of their progressing disease, to achieve more reliable and accurate dosing and to continue therapy even after their ability to swallow is compromised. We believe this improved administration may lead to improved outcomes in ALS patients.

## Clinical Development

We have completed a pilot PK and pivotal PK study for AQST-117. In addition we have completed a food effect study. All of these studies have successfully shown bioequivalence to the reference listed drug, Rilutek. We are currently conducting a swallowing study in approximately 25 subjects with ALS. We compared pharmacokinetic profile of a 50mg dose of riluzole oral soluble film, or ROSF, with a 50mg dose of Rilutek (riluzole) tablets when administered to healthy volunteers in a fasted state. We believe that ROSF, which has demonstrated bioequivalence to Rilutek can fulfill a critical need for ALS patients, due to its ability to be administered twice daily without the need for water. Based on our interactions with the FDA, we believe that the completion of these studies may represent the final data required for the submission of an NDA to the FDA via the 505(b)(2) pathway. We expect to submit an NDA for AQST-117 in the treatment of ALS in the second half of 2018.

## **Proprietary Complex Molecule Candidates**

# AQST-108 (Epinephrine)

# Product Overview

AQST-108 is a sublingual film formulation of epinephrine that we are developing for the treatment of anaphylaxis, a severe and potentially life-threatening allergic reaction. AQST-108 is currently in Phase 1 clinical development, and we expect to initiate another Phase 1 study with an optimized formulation of AQST-108 in the middle of 2018.

## Limitations of Current Therapies

Anaphylaxis is a severe systemic allergic reaction that can be triggered by certain foods, insect stings, certain medications and latex, among other allergens. Signs and symptoms of anaphylaxis typically occur within seconds or minutes of exposure and may include low blood pressure, skin rash or itching, constriction of the airway and difficulty breathing and nausea and vomiting. If not treated immediately, anaphylaxis can lead to death due to airway restriction or cardiac arrest. Anaphylaxis affects an estimated one in fifty people in the United States across a range of allergens.

The standard of care for anaphylaxis is epinephrine, a non-selective adrenergic agonist, which is administered via intramuscular injection. Because anaphylaxis can progress quickly, the ability to administer a reliable and accurate dose of epinephrine as quickly as possible following a reaction is critical for patient recovery and survival. Epinephrine typically comes in a single-dose, pre-filled automatic injection device, or an auto-injector. People with known allergies and who are at risk for anaphylaxis are advised to carry an auto-injector with them at all times and self-administer at the first signs of an anaphylactic reaction. The EpiPen and similar products are inconvenient to transport and many patients and caregivers dislike injections as a delivery method. Additionally, injector malfunction issues and user administration errors may prevent successful and timely dosing which can result in danger to patients.

## Our Solution

We are developing AQST-108 as an alternative to the currently marketed intramuscular injections. We believe there is a market opportunity for a non-injectable, easier to administer product with a fast onset of action. A product with this profile would enable patients to conveniently and rapidly self-administer a reliable and accurate dose of epinephrine during an anaphylactic reaction, which we believe would result in greater patient compliance. We believe AQST-108 has the potential to reduce the treatment burden currently associated with intramuscular injections and may lower costs to the healthcare system associated with anaphylaxis, such as hospitalizations due to inaccurate or untimely dosing.

## **Clinical Development**

We have conducted proof-of-concept studies to demonstrate our ability to deliver epinephrine via a non-invasive sublingual film. We evaluated AQST-108 in two dose escalation studies, each with six patients, in which there were no severe adverse events. In addition, we completed a Phase 1 near-term 3-way crossover study in healthy male subjects comparing the pharmacokinetic profile of 30mg dose of epinephrine sublingual soluble film to EpiPen intramuscular injection (0.3mg epinephrine) when administered to healthy volunteers. We believe that this proof of concept study in man provides proof of our ability to deliver epinephrine via the oral cavity.

Based on the results of the Phase 1 study, we are optimizing the formulation of AQST-108. We are currently testing our new formulation in preclinical studies and expect to initiate a second Phase 1 study with the new formulation in the second half of 2018. Upon the completion of our second Phase 1 study, we plan on requesting a pre-IND meeting with the FDA to discuss our clinical development program.

## AQST-305 (Octreotide)

#### Product Overview

AQST-305 is a sublingual film formulation of octreotide, an 8 amino acid peptide that has a similar pharmacological profile to natural somatostatin, for the treatment of acromegaly. We initiated a development program to demonstrate human proof-of-concept in December 2017 and expect to dose the first patient in the middle of 2018.

## Limitations of Current Therapies

Acromegaly is a hormone disorder that results from the overproduction of growth hormone in middle-aged adults. The condition is typically caused by a benign tumor present in the pituitary gland that excretes excessive amounts of growth hormone and leads to exaggerated bone growth over time.

First-line treatment of acromegaly usually involves surgery to remove the tumor. Some patients are not eligible for surgery depending on the placement and size of the tumor, and in some cases, surgery does not completely remove the tumor, leading to persistently elevated growth hormone levels. The standard of care for post-surgery patients includes the chronic use of somatostatin analogues to lower production or block the action of growth hormones. The somatostatin analogues currently on the market, octreotide and lanreotide, are administered by deep subcutaneous or intramuscular injections once a month, which are invasive and painful and can represent a treatment burden for patients. Such treatment burdens associated with the somatostatin analogues currently on the market include injection site reactions, sub-optimal symptom control and adverse emotional impact. We believe there is a market opportunity for a non-injectable, easier to administer product that delivers a reliable and consistent dose of octreotide.

## Our Solution

We have designed AQST-305 for twice daily administration, which we believe will reduce the burden of monthly depot intramuscular injections and address the potential loss of efficacy over the treatment life cycle with currently marketed products. AQST-305 can be administered by the patient, rather than having to receive monthly injections in a physician's office. Additionally, because AQST-305 is administered twice-daily, patients will receive a consistent dose of octreotide and will not need to be concerned with the potential loss of efficacy that may otherwise result when receiving only a monthly dosage administered via injection. We believe AQST-305 will reduce the burden for patients who are looking for a non-invasive, pain-free, easier to administer product.

## **Clinical Development**

We have conducted five preclinical studies in animal models to date, which have demonstrated initial positive results compared to Sandostatin.

We initiated a development program to demonstrate human proof-of-concept in December 2017 and expect to dose the first patient in the middle of 2018. Upon the completion of the proof-of-concept study, we plan to conduct formulation optimization work and progress to a Phase 1 study.

### Partnered Products and Product Candidates

# Suboxone (Buprenorphine and Naloxone)

Suboxone is a sublingual film formulation of buprenorphine and naloxone. Buprenorphine and naloxone are opioid antagonists that, when combined, are effective for treating opioid addiction. Suboxone reduces the potential for abuse and improves safety, clinical differentiation, dissolution, taste and texture for patients suffering from opioid addiction. According to the American Society of Addiction Medicine, drug overdose is the leading cause of accidental death in the United States, with opioid addiction driving this epidemic. Opioid dependence is estimated to affect more than two million people in the United States. Patients overcoming opioid addiction can experience painful withdrawal symptoms, which can be mitigated with the use of opioid antagonists.

Suboxone Sublingual Film was launched in partnership with Indivior in 2010 to treat opioid dependence pursuant to a commercial agreement. Indivior has an exclusive worldwide license to this product. Suboxone Sublingual Film is the market leader for buprenorphine based opioid abuse disorder treatment, capturing approximately 60% of total prescriptions in 2017, despite generic competitors. In the last four years, over 1.2 billion doses have been delivered to patients. We are the sole and exclusive manufacturer of Suboxone Sublingual Film worldwide for Indivior. See "Material Agreements – Commercial Exploitation Agreement with Indivior."

## Zuplenz (Ondansetron)

Zuplenz is an oral soluble film formulation of ondansetron, a 5-HT<sub>3</sub> antagonist approved for the treatment of nausea and vomiting associated with chemotherapy and post-operative recovery. Ondansetron is available as intravenous injections, intramuscular injections, orally dissolving tablets, oral solution, tablets, and film. Generic and branded products are available, with the branded product



marketed as Zofran by GlaxoSmithKline. According to IQVIA<sup>3</sup>, ondansetron generated 25 million prescriptions and sales of \$127 million in the United States in 2017. We licensed commercial rights for Zuplenz to Midatech Pharma in the United States, Canada, and China. Midatech launched Zuplenz in the United States in 2015. We are the sole and exclusive manufacturer of Zuplenz for Midatech.

## APL-130277 (Apomorphine)

APL-130277 is a sublingual film using apomorphine, a dopamine agonist indicated as an intermittent therapy to overcome episodic off periods in Parkinson's disease. Parkinson's disease affects approximately 500,000 patients in the United States. APL-130277 is designed to address an unmet need in patients who suffer from dysphagia. We licensed intellectual property for PharmFilm technology associated with APL-130277 to Cynapsus Therapeutics, which was acquired by Sunovion. Sunovion, our partner and sponsor of APL-130277, submitted an NDA to the FDA on March 29, 2018. If approved, we will earn a royalty and other milestone payments based on worldwide sales of APL-130277. See "Material Agreements – License Agreement with Sunovion Pharmaceuticals, Inc."

## AQST-119 (Tadalafil)

AQST-119 is an oral soluble film formulation of tadalafil, a vasodilator that is used to treat erectile dysfunction, or ED. ED affects men primarily between the ages of 40 and 70, with approximately 10% having severe or complete ED, and 25% having moderate or intermittent erectile difficulties. AQST-119 is designed to provide patients a discreet product with increased ease of use. We submitted an NDA with the FDA in November 2016 and expect approval in 2018. We are currently seeking a commercialization partner for AQST-119.

# AQST-306 (Edaravone)

Additionally, we are developing AQST-306, a film formulation of edaravone in partnership with Mitsubishi Tanabe Pharma America, Inc. Edaravone is a treatment for ALS currently marketed in injectable form as Radicava.

## **Commercialization Strategy**

We plan to focus our commercial strategy for our proprietary CNS product portfolio on building awareness through healthcare provider education, with a particular focus on neurologists and their treatment teams, as well as patient caregivers.

We have built a commercial team with significant experience earned from multiple product launches prior to joining our company, including several in the CNS space such as Diastat and Onfi. We intend to continue adding relevant experience in sales leadership, regulatory and medical affairs, marketing, and payor and market access management to supplement our capabilities in these areas. Based on the number of treatment specialists, target patients and overlap of our initial CNS product candidates, we believe that we will be able to leverage a focused sales force effectively across these areas. We plan to hire up to 50 dedicated sales representatives in anticipation of multiple product launches through 2019. With a prescribing physician overlap between Libervant and Sympazan of greater than 80%, we estimate that with a dedicated sales team of this size can cover approximately 85% of the target patient population. The launch and marketing of our products will be focused in the United States, with any ex-U.S. commercialization efforts likely outlicensed to other companies.

Assuming FDA approval, we expect to launch Sympazan in late 2018, followed by Libervant in early 2019. In anticipation of our upcoming product launches, we will publish key data, engage a broader array of key opinion leaders, or KOLs, and large practices and continue to develop our body of clinical evidence. Additionally, we intend to utilize KOLs' knowledge through advisory boards to develop best practices and appropriate areas for use, as well as educational materials for peer physicians.

We intend to similarly develop commercialization strategies for AQST-305 and AQST-108 in advance of their respective NDA submissions, including a combination of company and partnered resources.

<sup>3 (</sup>IQVIA FIA Audit, NPA Audit, ChannelDynamics 02/2012 - 01/2018, Extracted 03/2018)

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# Manufacturing and Product Supply

We operate two redundant manufacturing and primary packaging facilities located in Portage, Indiana, where we currently manufacture our partnered products, Suboxone and Zuplenz, on a sole and exclusive basis. These facilities have a combined capacity to accommodate the production of our two marketed products and both our near-term and long-term pipeline of proprietary and partnered products, without any need for additional infrastructure. We have produced over 1.2 billion doses in the last four years. As a company, our research and development laboratories are registered with the DEA, for Schedule II-V drugs.

We do not produce API for any of our products and obtain such API from a number of different sources. The API used in Suboxone is obtained directly from Indivior. We intend to outsource secondary packaging and third-party logistics for our proprietary products.

We are subject to various regulatory requirements, such as the regulations of the FDA, the DEA, and the Therapeutics Goods Administration, or TGA. We are required to adhere to cGMP. This standard requires manufacturers to follow elaborate design, testing, control, documentation and other quality assurance procedures throughout the entire manufacturing process. Our facilities have undergone inspections by the FDA, DEA, TGA, and several quality assurance inspections by pharmaceutical companies for cGMP compliance. In each case, the facilities have passed inspection and are subject to periodic re-inspection.

We purchase our raw materials from qualified, approved vendors both domestically and internationally. While we typically source raw materials from the lowest cost provider whenever possible and continue to pursue a multi-supplier strategy for all of our critical raw materials, our thin film foil is supplied by a single manufacturer. Such manufacturer utilizes multiple manufacturing facilities for production of our thin film foil. We expect that we will enter into more formal supply agreements in the future as production volumes increase and are more predictive.

Subject to the supervision of our internal clinical development staff, we use third party CROs to administer and conduct many aspects of our planned clinical trials including monitoring and managing data, and we will rely upon such CROs, as well as medical institutions, clinical investigators and consultants, to conduct our trials in accordance with our clinical protocols. We intend for such CROs to play a significant role in the subsequent collection and analysis of data from such trials.

# Competition

We compete with pharmaceutical and biotechnology companies that develop and commercialize therapeutics for the treatment of a broad range of disease areas and indications. Additionally, we compete with companies that utilize advanced drug administration platforms, such as oral, injectable, intranasal, transdermal patch and pulmonary delivery, to create improved therapeutics over current standards of care. This industry is highly competitive and new products and technologies evolve and come to market at a rapid pace. The companies operating in this market include multinational organizations, established biotechnology companies, single product pharmaceutical and biotechnology companies, specialty pharmaceutical companies, and generic drug companies. Many of the larger, established organizations currently have commercialization capabilities in-house, and may have partnered agreements in place with smaller companies for commercialization rights. These companies may develop new drugs to treat the indications that we target, or seek to have existing drugs approved for the treatment of the indications that we target.

We will compete with commercialized products in all markets for which we are seeking approval. For outpatient treatment of emergency breakthrough seizures, Diastat (diazepam rectal gel, Valeant Pharmaceuticals International, Inc.) remains the only currently commercialized product. Several marketed products are approved for the treatment of LGS, including two products solely indicated for LGS: Onfi (clobazam, Lundbeck A/S) and Banzel (rufinamide, Eisai Co.). For ALS, generic riluzole tablets are considered the standard of care. Radicava (edaravone, Mitsubishi Tanabe Pharma Corporation), which launched in the United States in 2017, is also expected to be used as part of a comprehensive treatment plan that may also include riluzole. Commercialized products for anaphylaxis include epinephrine

autoinjectors such as EpiPen (Mylan Inc.), among others. In acromegaly, marketed products include short- and longacting somatostatin analogues, such as Sandostatin (octreotide acetate, Novartis AG), as well as the growth hormone receptor antagonist Somavert (pegvisomant, Pfizer Inc.).

There are also several product candidates undergoing clinical trials that, if approved, would compete in the markets for which we are seeking approval for our product candidates. For breakthrough seizure management, in addition to the oral delivery of benzodiazepines, intranasal and inhalable benzodiazepine formulations are also being developed. The leading benzodiazepines in development with alternative delivery forms are: Neurelis, Inc.'s intranasal diazepam currently in Phase 3 development; Xeris Pharmaceuticals, Inc.'s diazepam, an injectable form with the potential to be delivered with a pen or pump, currently in Phase 1 development; Proximagen Ltd.'s intranasal midazolam currently in Phase 3 development; and Engage Therapeutics, Inc.'s inhaled alprazolam currently in Phase 2 development. Two products are anticipated to launch in LGS in the near-term, which may be used in conjunction with the standard of care: GW Pharmaceuticals plc's Epidiolex and Eisai Co, Ltd.'s Fycompa. Two additional product candidates, Zogenix Inc.'s ZX008, currently in Phase 3 development, and Ovid Therapeutics Inc.'s TAK-935, currently in Phase 1/2 development, are oral products that may become part of the treatment paradigm for LGS patients. For anaphylaxis, INSYS Therapeutics, Inc. is developing an epinephrine intranasal spray, and announced the initiation of a Phase 1 proof-of-concept study in December 2017.

## **Material Agreements**

### Commercial Exploitation Agreement with Indivior

In August 2008, we entered into a Commercial Exploitation Agreement with Reckitt Benckiser Pharmaceuticals, Inc., or the Indivior License Agreement. Reckitt Benckiser Pharmaceuticals, Inc. later succeeded to in interest by Indivior, Inc., or Indivior. Pursuant to the Indivior License Agreement, we have agreed to manufacture and supply Indivior's requirements of Suboxone both inside and outside the United States on an exclusive basis.

Under the terms of the Indivior License Agreement, we are required to manufacture Suboxone in accordance with cGMP standards and according to the specifications and processes set forth in the related quality agreements we entered into with Indivior. Additionally, we are required to obtain API for the manufacture of Suboxone directly from Indivior. The Indivior License Agreement specifies a minimum annual threshold quantity of Suboxone that we are obligated to fill and requires Indivior to provide us with a forecast of its requirements at various specified times throughout the year.

The Indivior License Agreement provides for payment by Indivior of a purchase price per unit that is subject to adjustment based on our ability to satisfy minimum product thresholds. Additionally, in the event Indivior purchases certain large quantities of Suboxone during a specified period, Indivior will be entitled to rebates on its purchases.

In addition to the purchase price for the Suboxone supplied, Indivior may be required to make up to low single digit percentage royalty payments tied to net sales value (as provided for in the Indivior License Agreement) subject to annual maximum amounts. In the event that Indivior has paid us a specified aggregate royalty amount in royalties on Suboxone sold in the United States, then it will be required to prepay to us, an additional agreed payment amount, after which all obligations of Indivior's royalty obligations to us continue in the United States and the rest of the world until the expiration of all of the patents (either in the United States or other territories) or upon written notice by Indivior subject to Indivior being required to pay us a final royalty payout. Indivior exercised its right to buy out its future royalty obligations in the United States in 2012. Indivior remains obligated to pay royalties for all sales outside the United States.

The Indivior License Agreement contains customary contractual termination provisions for breach or in the event of bankruptcy or corporate dissolution, the intellectual property surrounding Suboxone is found to be invalid, or either party commits a material breach of the Indivior License Agreement. Additionally, Indivior may terminate if the FDA or other applicable regulatory authority declares our manufacturing site to no longer be suitable for the manufacture of Suboxone or Suboxone is no longer suitable to be manufactured due to health or safety reasons. The initial term of the Indivior License

Agreement was seven years from the commencement date. Thereafter, the Indivior License Agreement automatically renews for successive one year periods, unless Indivior provides us with written notice of its intent not to renew at least one year prior to the expiration of the initial or renewal term.

## Supplemental Agreement with Indivior

On September 24, 2017, we entered into an agreement with Indivior, or the Indivior Supplemental Agreement. Pursuant to this agreement, we conveyed to Indivior all of our existing and future rights in the settlement of various ongoing patent enforcement legal actions and disputes related to the Suboxone product. We also conveyed to Indivior the right to sublicense manufacturing and marketing capabilities to enable an Indivior licensed generic buprenorphrine product to be produced and sold by parties unrelated to Indivior or us. Under the Indivior Supplemental Agreement, we are entitled to receive certain payments from Indivior commencing on the date of the agreement through January 1, 2023. Once paid, all payments made under this Agreement are non-refundable. To date we have received an aggregate of \$30.5 million from Indivior under the Indivior Supplemental Agreement. In addition to amounts received, we may receive up to an additional \$44.5 million, consisting of a royalty equal to a low single digit percentage of net revenue earned by Indivior on Suboxone sales and performance-based milestone payments under the Indivior Supplemental Agreement amounts under the Indivior Supplemental Agreement agreement agreement through the issuance of additional process patent rights to us, with the aggregate payment amounts under the Indivior Supplemental Agreement capped at \$75 million. Accordingly, the Agreement includes certain provisions that may allow Indivior to cease remitting certain payments to us, upon the occurrence of certain events related to unlicensed generic versions of Suboxone. In the event that Indivior's defense of its rights is ultimately successful, then, all payment obligations owed to us are retroactively reinstated.

All payments made by Indivior to us pursuant to the Indivior Supplemental Agreement are in addition to, and not in place of, any amounts owed by Indivior to us pursuant to the Indivior License Agreement. Indivior's payment obligations under the Indivior Supplemental Agreement are subject to certain factors affecting the market for Suboxone and may terminate prior to January 1, 2023 in the event certain contingencies relating to such market occur.

# License Agreement with Sunovion Pharmaceuticals, Inc.

In April 2016, we entered into a license agreement with Cynapsus Therapeutics Inc. (which was later succeeded to in interest by Sunovion), or the Sunovion License Agreement, pursuant to which we granted Sunovion an exclusive, worldwide license (with the right to sub-license) to certain intellectual property, including existing and future patents and patent applications, covering all oral films containing APL-130277 (apomorphine) for the treatment of off episodes in Parkinson's disease patients, as well as two other fields. Sunovion, our partner and sponsor of APL-130277, submitted an NDA to the FDA on March 29, 2018.

In consideration for the rights granted to Sunovion under the Sunovion License Agreement, we received an upfront payment of \$5 million. We are also entitled to receive pursuant to the Sunovion License Agreement (i) an aggregate of \$14 million in connection with specified regulatory and development milestones in the United States and Europe, which are due and payable on or before December 1, 2018 (the "Initial Milestone Payments") \$9 million of which has been received to date, (ii) certain one-time milestone payments related to product availability and regulatory approval in the United States and Europe, (iii) certain one-time milestone payments based on the achievement of specific annual net sales thresholds of APL-130277, and (iv) ongoing mid-single digit percentage royalty payments related to the net sales of APL-130277 (subject to reduction to low-single digit percentage royalty payments in certain circumstances), subject to certain minimum payments. The maximum aggregate milestone payments that may be paid to us pursuant to the Sunovion License Agreement is equal to \$45 million. With the exception of the Initial Milestone Payments, there can be no guarantee that any such milestones will in fact be met or payable.

The Sunovion License Agreement will continue until terminated by us or Sunovion in accordance with the termination provisions of the Sunovion License Agreement.

As more fully described in the Sunovion License Agreement, we may terminate the Sunovion License Agreement if (i) Sunovion fails to make any payments required under the Sunovion License Agreement



when due and after receiving certain notices from us; (ii) Sunovion fails to commercialize APL-130277 in at least one Major Market (as defined in the Sunovion License Agreement) by January 1, 2020; (iii) Sunovion pays us not more than the minimum royalty payment due for any 30 consecutive months from the date of first commercial sale; (iv) Sunovion fails a primary endpoint of its Phase 3 studies (CTH-300 and CTH-301) and either fails to start another Phase 3 study within six months after such failed primary endpoint, or fails a primary endpoint of any subsequent Phase 3 study; (v) Sunovion publicly challenges the validity or enforceability of the Licensed Patents (as defined in the Agreement); or (vi) no further royalty payments are due and payable to us.

As more fully described in the Sunovion License Agreement, Sunovion generally may terminate the Sunovion License Agreement if (i) we fail to use commercially reasonable efforts to defend the Licensed Patents in response to a Patent Infringement Claim (as defined in the Sunovion License Agreement); (ii) we are in material breach of the Sunovion License Agreement, which breach is not remedied after receiving notice thereof; (iii) prior to commercialization of APL-130277, upon certain notice to us, if Sunovion has abandoned further development of APL-130277; or (iv) at any time after December 31, 2024, for any reason upon certain notice to us. Sunovion may also terminate the Sunovion License Agreement if it can establish that a Material Decline (as defined in the Agreement) has occurred in a jurisdiction as a result of us licensing to a third party any Licensed Patents to develop or commercialize apomorphine either alone or in combination with another active agent, for any human use, solely with respect to such jurisdiction(s) that have suffered a Material Decline, upon certain notice to us.

Additionally, either party may terminate the Sunovion License Agreement (i) in connection with certain bankruptcy events; or (ii) in connection with certain material misrepresentations; breach of representations, warranties or covenants; or breach of exclusivity or confidentiality provisions, as set forth in the Sunovion License Agreement. The Sunovion License Agreement also contains, without limitation, customary representations, warranties and covenants of the parties, as well as provisions relating to confidentiality, indemnification and other matters.

# Agreement to Terminate CLA with KemPharm

In March 2012, we entered into an agreement with KemPharm, Inc. or KemPharm, to terminate a Collaboration and License Agreement entered into in April 2011, or the KemPharm Termination Agreement. Pursuant to the KemPharm Termination Agreement, KemPharm made a one-time payment to us of \$11 million upon the closing of a transaction with Shire LLC related to KemPharm's product candidate KP106. We also have the right to receive payments in the mid-single to low double-digit percentages of any "value" (as such term is defined in the KemPharm Termination Agreement) generated by KP415, and any product candidates arising therefrom, including, but not limited to royalty payments on any license of KP415, the sale of KP415 to a third party, the commercialization of KP415 and the portion of any consideration that is attributable to the value of KP415 and paid to KemPharm or its stockholders in a change of control transaction. KP415 is a new molecular entity prodrug of methylphenidate, which is being developed by KemPharm for the treatment of ADHD. KP415 is designed to be a controlled release, abuse-deterrent methylphenidate product.

KemPharm has no obligation pursuant to the KemPharm Termination Agreement to develop or commercialize KP415. The KemPharm Termination Agreement has customary cross-indemnification provisions and KemPharm's payment obligations to us with respect to KP415 continue indefinitely until all payments due under the KemPharm Termination Agreement in respect of "value" received on KP415 are made to us. KP415 recently completed Phase 2 studies.

# **Intellectual Property**

We currently seek, and intend to continue seeking, patent protection whenever commercially reasonable for any patentable aspects of our product candidates and related technology or any new products or product candidates we acquire in the future. Where our intellectual property is not protected by patents, we may seek to protect it through other means, including maintenance of trade secrets and careful protection of our proprietary information.

In addition, we intend to seek orphan drug exclusivity in jurisdictions in which it is available. A prerequisite to orphan drug exclusivity in the United States and in the European Union is orphan drug



designation. An orphan drug designation may be granted where a drug is developed specifically to treat a rare or uncommon medical condition. If a product which has an orphan drug designation subsequently receives the first regulatory approval for the indication for which it has such designation, the product is entitled to orphan exclusivity, meaning that the applicable regulatory authority may not approve any other applications to market the same drug for the same indication, except in certain very limited circumstances, for a period of seven years in the United States and 10 years in the European Union. Orphan drug exclusivity does not prevent competitors from developing or marketing different drugs for the indication protected by exclusivity, or the same drug for a different indication.

### Patents

Our patent portfolio currently comprises at least 200 issued patents worldwide, of which at least 40 are U.S. patents, and more than 75 pending patent applications worldwide. These issued patents and pending patent applications provide both process of making and composition of matter protection for our PharmFilm technology and products and product candidates, including Suboxone and our PharmFilm dosage formulations of, tadalafil, diazepam, clobazam, riluzole, epinephrine and octreotide. These patents and, if issued as patents, pending patent applications will expire between 2022 and 2037. The pending patent applications filed in 2017 will provide composition of matter and process of making protection for our PharmFilm dosage formulations of diazepam, epinephrine and octreotide, and if issued as patents, will expire by 2037. The projected expiration dates exclude any patent term adjustment or patent term extension.

# PharmFilm – Our Oral Film Technology

Our PharmFilm platform technology is covered by at least 8 patent families. These patent families provide process, composition of matter protection for our PharmFilm platform technology, and comprise at least 47 issued patents worldwide, of which at least 18 are U.S. patents, and related pending patent applications worldwide. The patents and pending patent applications, if issued as patents, will expire between 2022 and 2037, excluding any patent term adjustment or patent term extension.

The PharmFilm platform technology patents also generically and specifically protect the technology utilized in the products and product candidates in our CNS programs, our Complex Molecule Programs, as well as our Partner Programs. For example, encompassed within our platform technology patents is specific coverage directed to PharmFilm dosage formulations of CNS molecules such as diazepam. Also encompassed within our platform technology patents for our complex molecule program which includes molecules such as epinephrine. Our platform technology patents further cover the products Suboxone and Zuplenz, as well as our PharmFilm dosage formulations of the molecules apomorphine and tadalafil, which are part of our partnered programs. The expiration dates for patents covering these products and product candidates, and for pending applications if issued as patents, are between 2022 and 2037, excluding any patent term adjustment or patent term extension.

We note that several of our issued patents are or have been involved in administrative proceedings, such as reexamination and inter partes review at the U.S. Patent and Trademark Office, or USPTO and opposition at the European Patent Organization, or EPO. Four of our European patents are under opposition proceedings at the appeal stage. These patents include one European patent which relates to our early process technology, and two European patents which relate to our taste-masking technology, all three of which are included in our PharmFilm platform technology. We also note that several of our issued patents are involved in litigations. For more information, please see the section titled "Business — Legal Proceedings."

Certain of our patents and patent applications if granted, will be published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential generic competitors in support of approval of an abbreviated new drug application, or ANDA, or a 505(b)(2) NDA. If any of these potential generic competitors claim that their product will not infringe our listed patents, or that such patents are invalid, then they must send notice to us once the ANDA or 505(b)(2) NDA has been accepted for filing by the FDA. We may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV



certification, which would automatically prevent the FDA from approving the ANDA or 505(b)(2) NDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit, or a decision in the infringement case that is favorable to the ANDA or 505(b)(2) NDA applicant.

The rest of our patent portfolio largely relates to patents and applications owned by us and directed to our product development portfolio and other product candidates and related compositions and/or manufacturing processes.

## Trade Secrets and Other Proprietary Information

We seek to protect our proprietary information, including our trade secrets and proprietary know-how, by requiring our employees, consultants and other advisors to execute confidentiality agreements upon the commencement of their employment or engagement. These agreements generally provide that all confidential information developed or made known during the course of the relationship with us be kept confidential and not be disclosed to third parties except in specific circumstances. In the case of our employees, the agreements also typically provide that all inventions resulting from work performed for us, utilizing our property or relating to our business and conceived or completed during employment shall be our exclusive property to the extent permitted by law. Where appropriate, agreements we obtain with our consultants also typically contain similar assignment of invention provisions. Further, we generally require confidentiality agreements from business partners and other third parties that receive our confidential information. There can be no assurance, however, that these agreements will provide meaningful protection or adequate remedies for our trade secrets in the event of unauthorized use or disclosure of such information.

## Trademarks

We also rely on trademarks and trade designs to develop and maintain our competitive position. Our trademarks or registered trademarks are filed of ours in the United States and other select geographical areas.

# Regulatory

### **FDA Approval Process**

In the United States, pharmaceutical products are subject to extensive regulation by the FDA. The Federal Food, Drug, and Cosmetic Act, or FDCA and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of pharmaceutical products. Failure to comply with applicable FDA or other requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending applications, clinical holds, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, withdrawal of product from the market, injunctions, fines, civil penalties and criminal prosecution.

FDA approval is required before any new unapproved drug or dosage form, including a new use of a previously approved drug, can be marketed in the United States. The process required by the FDA before a new drug may be marketed in the United States generally involves:

- completion of preclinical laboratory and animal testing and formulation studies in compliance with the FDA's current good laboratory practice, or GLP, regulations;
- submission to the FDA of an Investigational New Drug, or IND, application for human clinical testing which must become effective before human clinical trials may begin in the United States;
- approval by an independent institutional review board, or IRB, at each clinical trial site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with current good clinical practices, or GCP, to establish the safety and efficacy of the proposed drug product for each intended use;

- submission to the FDA of an NDA;
- satisfactory completion of an FDA pre-approval inspection of the facility or facilities at which the product is
  manufactured to assess compliance with the FDA's cGMP regulations to assure that the facilities, methods and
  controls are adequate to preserve the drug's identity, strength, quality and purity;
- · satisfactory completion of a potential review by an FDA advisory committee, if applicable; and
- FDA review and approval of the NDA.

The preclinical and clinical testing and approval process takes many years and the actual time required to obtain approval, if any, may vary substantially based upon the type, complexity and novelty of the product or disease.

Preclinical tests include laboratory evaluation of product chemistry, formulation and toxicity, as well as animal studies to assess the characteristics and potential safety and efficacy of the product. The conduct of the preclinical tests must comply with federal regulations and requirements, including GLPs. The results of preclinical testing are submitted to the FDA as part of an IND application along with other information, including information about product chemistry, manufacturing and controls and a proposed clinical trial protocol. Long-term preclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND application is submitted.

The IND application automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions relating to one or more proposed clinical trials and places the clinical trial on a clinical hold, including concerns that human research subjects will be exposed to unreasonable health risks. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. A separate submission to an existing IND application must also be made for each successive clinical trial conducted during product development. Further, an independent IRB, covering each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and informed consent information for subjects before the trial commences at that site and it must monitor the study until completed. The FDA, the IRB, or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk or for failure to comply with the IRB's requirements, or may impose other conditions. Clinical trials involve the administration of the investigational new drug to healthy volunteers or patients under the supervision of a qualified investigator in accordance with GCP requirements, which include the requirement that all research subjects provide their informed consent in writing for their participation in any clinical trial. Sponsors of clinical trials generally must register and report, at the NIH-maintained website ClinicalTrials.gov, key parameters of certain clinical trials. For purposes of an NDA submission and approval, human clinical trials are typically conducted in the following sequential phases, which may overlap or be combined:

- *Phase 1*: In Phase 1, through the initial introduction of the drug into healthy human subjects or patients, the drug is tested to assess metabolism, pharmacokinetics, pharmacological actions, side effects associated with increasing doses, and, if possible, early evidence on effectiveness.
- *Phase 2*: Phase 2 usually involves trials in a limited patient population to determine the effectiveness of the drug for a particular indication, dosage tolerance and optimum dosage, and to identify common adverse effects and safety risks.
- *Phase 3*: Phase 3 trials are undertaken to obtain the additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit the FDA to evaluate the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the drug. In most cases, the FDA requires two adequate and well controlled Phase 3 clinical trials to demonstrate the efficacy of the drug. A single Phase 3 trial with other confirmatory evidence may be sufficient in rare instances where the study is a large multicenter trial demonstrating internal consistency

and a statistically persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity or prevention of a disease with a potentially serious outcome and confirmation of the result in a second trial would be practically or ethically impossible.

After completion of the required clinical testing, an NDA is prepared and submitted to the FDA. FDA approval of the NDA is required before marketing of the product may begin in the United States. The NDA must include the results of all preclinical, clinical and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture and controls. Under federal law, the submission of most NDAs is subject to a substantial application user fee, and applicant under an approved NDA is also subject to an annual program fee for each prescription drug product, which beginning in Fiscal Year 2018 replaced the product and establishment fees.

The FDA has 60 days from its receipt of an NDA to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the NDA must be resubmitted with the additional information and is subject to payment of additional user fees. The resubmitted application is also 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. Under PDUFA the FDA has agreed to certain performance goals in the review of NDAs through a two-tiered classification system, Standard Review and Priority Review. Priority Review designation is given to drugs that offer major advances in treatment, or provide a treatment where no adequate therapy exists. The FDA endeavors to review applications subject to Standard Review within ten to twelve months, whereas the FDA's goal is to review Priority Review applications within six to eight months.

The FDA may refer applications for proprietary drug products or drug products which present difficult questions of safety or efficacy to an advisory committee for review, evaluation and recommendation as to whether the application should be approved and under what conditions.

Before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP requirements. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. The FDA will not approve the product unless it determines that the manufacturing process and facilities are in compliance with cGMP requirements and are adequate to assure consistent production of the product within required specifications and the NDA contains data that provide substantial evidence that the drug is safe and effective in the indication studied.

After the FDA evaluates the NDA and the manufacturing facilities, it issues either an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the NDA and may require substantial additional testing, or information, in order for the FDA to reconsider the application. Even with submission of this additional information, the FDA may ultimately decide that an application does not satisfy the regulatory criteria for approval. If, or when, the deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

As a condition of NDA approval, the FDA may require a REMS to help ensure that the benefits of the drug outweigh the potential risks. If the FDA determines a REMS is necessary during review of the application, the drug sponsor must agree to the REMS plan at the time of approval. A REMS may be required to include various elements, such as a medication guide or patient package insert, a communication plan to educate healthcare providers of the drug's risks, limitations on who may prescribe or dispense the drug, or other elements to assure safe use, such as special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring and the use of patient registries. In addition, the REMS must include a timetable to periodically assess whether the REMS plan is effective. The requirement for a REMS can materially affect the potential market and profitability of a drug.

Moreover, product approval may require substantial post-approval testing and surveillance to monitor the drug's safety or efficacy, and the FDA has the authority to prevent or limit further marketing of a product based on the results of these post-marketing programs. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following

initial marketing. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved label, and, even if the FDA approves a product, it may limit the approved indications for use for the product or impose other conditions, including labeling or distribution restrictions or other risk-management mechanisms.

Further changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or NDA supplement before the change can be implemented, which may require us to develop additional data or conduct additional preclinical studies and clinical trials. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the similar procedures in reviewing NDA supplements as it does in reviewing NDAs.

# Post-Approval Requirements

Once an NDA is approved, a product will be subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to drug listing and registration, recordkeeping, periodic reporting, product sampling and distribution, adverse event reporting and advertising, marketing and promotion, including standards and regulations for direct to consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the internet. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved labeling. While physicians may prescribe for off-label uses, manufacturers may only promote for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

In addition, quality-control, drug manufacturing, packaging and labeling procedures must continue to conform to cGMPs after approval. Drug manufacturers and certain of their subcontractors are required to register their establishments with FDA and certain state agencies. Registration with the FDA subjects entities to periodic unannounced and announced inspections by the FDA and these state agencies, during which the agency inspects manufacturing facilities to assess compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money, and effort in the areas of production and quality-control to maintain compliance with cGMPs. Regulatory authorities may withdraw product approvals or request product recalls if a company fails to comply with regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered. The FDA may also impose a REMS requirement on a drug already on the market if the FDA determines, based on new safety information, that a REMS is necessary to ensure that the drug's benefits outweigh its risks. In addition, regulatory authorities may take other enforcement action, including, among other things, warning letters, the seizure of products, injunctions, consent decrees placing significant restrictions on or suspending manufacturing operations, refusal to approve pending applications or supplements to approved applications, civil penalties and criminal prosecution.

The FDA may require post-approval studies and clinical trials if the FDA finds that scientific data, including information regarding related drugs, deem it appropriate. The purpose of such studies would be to assess a known serious risk or signals of serious risk related to the drug or to identify an unexpected serious risk when available data indicate the potential for a serious risk. The FDA may also require a labeling change if it becomes aware of new safety information that it believes should be included in the labeling of a drug.

In addition, any distribution of prescription drug products and pharmaceutical samples must comply with the U.S. Prescription Drug Marketing Act, or PDMA, a part of the FDCA. In addition, Title II of the Federal Drug Quality and Security Act of 2013, known as the Drug Supply Chain Security Act or the DSCSA, has imposed new "track and trace" requirements on the distribution of prescription drug products by manufacturers, distributors, and other entities in the drug supply chain. These requirements are being phased in over a ten-year period. The DSCSA ultimately will require product identifiers (*i.e.*, serialization) on prescription drug products in order to establish an electronic interoperable prescription product system to identify and trace certain prescription drugs distributed in the United States. The DSCSA replaced the prior drug "pedigree" requirements under the PDMA, and preempts existing state drug pedigree laws and

regulations. The DSCSA also establishes new requirements for the licensing of wholesale distributors and third-party logistic providers. These licensing requirements preempt states from imposing licensing requirements that are inconsistent with, less stringent than, directly related to, or otherwise encompassed by standards established by FDA pursuant to the DSCSA. Until FDA promulgates regulations to address the DSCSA's new national licensing standard, current state licensing requirements typically remain in effect.

# The Hatch-Waxman Amendments

# ANDA Approval Process

The Hatch-Waxman Amendments established abbreviated FDA approval procedures for drugs that are shown to be equivalent to drugs previously approved by the FDA through its NDA process. Approval to market and distribute these drugs is obtained by submitting an ANDA to the FDA. An ANDA is a comprehensive submission that contains, among other things, data and information pertaining to the active pharmaceutical ingredient, drug product formulation, specifications and stability of the generic drug, as well as analytical methods, manufacturing process validation data and quality control procedures. Premarket applications for generic drugs are termed abbreviated because they generally do not include preclinical and clinical data to demonstrate safety and effectiveness. Instead, a generic applicant must demonstrate that its product is bioequivalent to the innovator drug. In certain situations, an applicant may obtain ANDA approval of a generic product with a strength or dosage form that differs from a referenced innovator drug pursuant to the filing and approval of an ANDA Suitability Petition. The FDA will approve the generic product as suitable for an ANDA application if it finds that the generic product does not raise new questions of safety and effectiveness as compared to the innovator product. A product is not eligible for ANDA approval if the FDA determines that it is not equivalent to the referenced innovator drug, if it is intended for a different use, or if it is not subject to an approved Suitability Petition. However, such a product might be approved under an NDA, with supportive data from clinical trials.

# 505(b)(2) NDAs

As an alternative path to FDA approval for modifications to formulations or uses of products previously approved by the FDA, an applicant may submit an NDA under Section 505(b)(2) of the FDCA. Section 505(b)(2) was enacted as part of the Hatch-Waxman Amendments and 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. If the 505(b)(2) applicant can establish that reliance on FDA's previous findings of safety and effectiveness is scientifically appropriate, it may eliminate the need to conduct certain preclinical or clinical studies of the new product. The FDA may also require companies to perform additional studies or measurements, including clinical trials, to support the change from the approved branded reference drug. The FDA may then approve the new product candidate for all, or some, of the label indications for which the branded reference drug has been approved, as well as for any new indication sought by the 505(b)(2) applicant.

# Orange Book Listing

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 with claims that 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 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 certify to the FDA that (i) no patent information on the drug product that is the subject of the application has been submitted to the FDA; (ii) such patent has expired; (iii) the date on which such patent expires; or (iv) 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 drug NDA holder and 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.

#### Non-Patent Exclusivity

In addition to patent exclusivity, the holder of the NDA for the listed drug may be entitled to a period of non-patent related exclusivity, during which the FDA cannot review, or in some cases, approve an ANDA or 505(b)(2) application that relies on the listed drug. For example, a company may obtain five years of non-patent exclusivity upon NDA approval of a NCE which is a drug that contains an active moiety that has not been approved by FDA in any other NDA. An "active moiety" is defined as the molecule or ion responsible for the drug substance's physiological or pharmacologic action. During the five year exclusivity period, the FDA cannot accept for filing any ANDA seeking approval of a generic version of that drug or any 505(b)(2) NDA for the same active moiety and that relies on the FDA's findings regarding that drug, except that FDA may accept an application for filing after four years if the follow-on applicant makes a paragraph IV certification.

A drug, including one approved under Section 505(b)(2), may obtain a three-year period of exclusivity for a particular condition of approval, or change to a marketed product, such as a new formulation of a previously approved product, if one or more new clinical studies (other than bioavailability or bioequivalence studies) was essential to the approval of the application and was conducted/sponsored by the applicant. Should this occur, the FDA would be precluded from approving any ANDA or 505(b)(2) application for the protected modification until after that three-year exclusivity period has run. However, unlike NCE exclusivity, the FDA can accept an application and begin the review process during the exclusivity period.

# Orphan Drug Designation and Exclusivity

The Orphan Drug Act provides incentives for the development of products intended to treat rare diseases or conditions. Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biological product intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making a drug or biological product available in the United States for this type of disease or condition will be recovered from sales of the product. If a sponsor demonstrates that a drug is intended to treat rare diseases or conditions, the FDA will grant orphan designation for that product for the orphan disease indication. Orphan designation must be requested before submitting an NDA. After the FDA grants orphan product designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation, however, does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

Orphan drug designation provides manufacturers with research grants, tax credits and eligibility for orphan drug exclusivity. If a product that has orphan drug designation subsequently receives the first FDA approval of the active moiety for that disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which for seven years prohibits the FDA from approving another product with the same active ingredient for the same indication, except in limited circumstances. If a drug designated as an orphan product receives marketing approval for an indication broader than the orphan indication for which it received the designation, it will not be entitled to orphan drug exclusivity will not bar approval of another product under certain circumstances, including if a subsequent product with the same active ingredient for the same indication is shown to be clinically superior to the approved product on the basis of greater efficacy or safety, or providing a major contribution to patient care, or if the company with orphan drug exclusivity is not able to meet market demand. Further, the FDA may approve more than one product for the same orphan indication or disease as long as the products contain different active ingredients. Moreover, competitors may receive approval of different products for



the indication for which the orphan product has exclusivity or obtain approval for the same product but for a different indication for which the orphan product has exclusivity. As a result, even if one of our product candidates receives orphan exclusivity, we may still be subject to competition. Orphan exclusivity also could block the approval of one of our products for seven years if a competitor obtains approval of the same drug or if our product candidate is determined to be contained within the competitor's product for the same indication or disease.

# Anti-Kickback and False Claims Laws and Other Regulatory Matters

In the United States, we are subject to complex laws and regulations pertaining to healthcare "fraud and abuse," including, but not limited to, the Federal Anti-Kickback Statute, the Federal False Claims Act, and other state and federal laws and regulations. The Federal Anti-Kickback Statute makes it illegal for any person, including a prescription drug manufacturer (or a party acting on its behalf) to knowingly and willfully solicit, receive, offer, or pay any remuneration that is intended to induce the referral of business, including the purchase, order, or prescription of a particular drug, for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. Violations of this law are punishable by up to five years in prison, criminal fines, administrative civil money penalties, and exclusion from participation in federal healthcare programs. In addition, many states have adopted laws similar to the Federal Anti-Kickback Statute. Some of these state prohibitions apply to the referral of patients for healthcare services reimbursed by any insurer, not just federal healthcare programs such as Medicare and Medicaid.

The Federal False Claims Act prohibits anyone from knowingly presenting, or causing to be presented, for payment to federal programs (including Medicare and Medicaid) claims for items or services, including drugs, that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. Although we would 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 or promoting a product off-label. In addition, our future 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, pharmaceutical companies have been found liable under the Federal False Claims Act in connection with their off-label promotion of drugs. Penalties for a False Claims Act violation include three times the actual damages sustained by the government, plus mandatory civil penalties of between \$10,000 and \$25,000 for each separate false claim, the potential for exclusion from participation in federal healthcare programs, and, although the Federal False Claims Act is a civil statute, conduct that results in a False Claims Act violation may also implicate various federal criminal statutes. In addition, private individuals have the ability to bring actions under the Federal False Claims Act and certain states have enacted laws modeled after the Federal False Claims Act.

The Health Insurance Portability and Accountability Act of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, which we refer to collectively as HIPAA, also created several additional federal crimes, including healthcare fraud and false statements relating to healthcare matters. The healthcare fraud statute prohibits, among other things, knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payors. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false, fictitious or fraudulent statement or services.

There are also an increasing number of state laws with requirements for manufacturers and/or marketers of pharmaceutical products. Some states require the reporting of expenses relating to the marketing and promotion of drug products and the reporting of gifts and payments to individual healthcare practitioners in these states. Other states prohibit various marketing-related activities, such as the provision of certain kinds of gifts or meals. Still other states require the reporting of certain pricing information, including information pertaining to and justification of price increases, or prohibit prescription drug price gouging. In addition, states such as California, Connecticut, Nevada, and Massachusetts require pharmaceutical companies to implement compliance programs and/or marketing codes. Many of

these laws contain ambiguities as to what is required to comply with the laws. In addition, as discussed below, a similar federal requirement requires manufacturers to track and report to the federal government certain payments made to physicians and teaching hospitals made in the previous calendar year. These laws may affect our sales, marketing and other promotional activities by imposing administrative and compliance burdens on us. In addition, given the lack of clarity with respect to these laws and their implementation, our reporting actions could be subject to the penalty provisions of the pertinent state, and soon federal, authorities.

The Physician Payments Sunshine Act, implemented as the Open Payments program, and its implementing regulations, requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to CMS information related to certain payments made in the previous calendar year and other transfers of value to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members.

In addition, HIPAA, and its implementing regulations impose certain obligations on entities subject to the law, such as health plans and most healthcare providers, and their business associates who provide certain services involving the use or disclosure of HIPAA protected health information on their behalf, with respect to the privacy and security of such protected health information. Further, most states have enacted laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts in certain circumstances, such as specific disease states.

Compliance with such laws and regulations will require substantial resources. Because of the breadth of these various fraud and abuse laws, it is possible that some of our business activities could be subject to challenge under one or more of such laws. Such a challenge could have material adverse effects on our business, financial condition and results of operations. In the event governmental authorities conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations, they may impose sanctions under these laws, which are potentially significant and may include civil monetary penalties, damages, exclusion of an entity or individual from participation in government health care programs, criminal fines and individual imprisonment, additional reporting requirements if we become subject to a corporate integrity agreement or other settlement to resolve allegations of violations of these laws, as well as the potential curtailment or restructuring of our operations. Further, we may be subject to contractual damages and reputational harm as result of such non-compliance. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity.

## International Regulation

In addition to regulations in the United States, we are and will be subject to a variety of foreign regulations regarding development, approval, commercial sales and distribution of our products. 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 from country to country and can involve additional product testing and additional review periods, and the time may be longer or shorter than that required to obtain FDA approval. The requirements governing, among other things, the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from country to country. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others. If we fail to comply with applicable foreign regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

In the European Union, or EU, we may seek marketing authorization under either the centralized authorization procedure or national authorization procedures.

*Centralized procedure.* The European Medicines Agency, or EMA, implemented the centralized procedure for the approval of human medicines to facilitate marketing authorizations that are valid

throughout the EU. This procedure results in a single marketing authorization issued by the European Commission following a favorable opinion by the EMA that is valid across the European Union, as well as Iceland, Liechtenstein and Norway. The centralized procedure is compulsory for human medicines that are: derived from biotechnology processes, such as genetic engineering, contain a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative disorders or autoimmune diseases and other immune dysfunctions, and officially designated orphan medicines. For medicines that do not fall within these categories, an applicant has the option of submitting an application for a centralized marketing authorization to the EMA, as long as the medicine concerned is a significant therapeutic, scientific or technical innovation, or if its authorization would be in the interest of public health.

National authorization procedures. There are also two other possible routes to authorize medicinal products in several European Union countries, which are available for investigational medicinal products that fall outside the scope of the centralized procedure: the decentralized procedure and the mutual recognition procedure. Under the decentralized procedure, an applicant may apply for simultaneous authorization in more than one EU country for medicinal products that have not yet been authorized in any EU country and that do not fall within the mandatory scope of the centralized procedure. Under the mutual recognition procedure, a medicine is first authorized in one EU Member State, in accordance with the national procedures of that country. Following a national authorization, the applicant may seek further marketing authorizations from other EU countries under a procedure whereby the countries concerned agree to recognize the validity of the original, national marketing authorization.

In the EU, medicinal products designated as orphan products benefit from financial incentives such as reductions in marketing authorization application fees or fee waivers and 10 years of marketing exclusivity following medicinal product approval. For a medicinal product to qualify as orphan: (i) it must be intended for the treatment, prevention or diagnosis of a disease that is life-threatening or chronically debilitating; (ii) the prevalence of the condition in the EU must not be more than five in 10,000 or it must be unlikely that marketing of the medicine would generate sufficient returns to justify the investment needed for its development; and (iii) no satisfactory method of diagnosis, prevention or treatment of the condition concerned can be authorized, or, if such a method exists, the medicine must be of significant benefit to those affected by the condition.

# United States Healthcare Reform

Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or, collectively, the PPACA, substantially changes the way healthcare is financed by both governmental and private insurers and significantly impacts the pharmaceutical industry. Changes that may affect our business include those governing enrollment in federal healthcare programs, reimbursement changes, benefits for patients within a coverage gap in the Medicare Part D prescription drug program, or commonly known as the donut hole, rules regarding prescription drug benefits under the health insurance exchanges, changes to the Medicaid Drug Rebate program, expansion of the Public Health Service's 340B drug pricing discount program, or 340B program, fraud and abuse, and enforcement. These changes impact existing government healthcare programs and are resulting in the development of new programs, including Medicare payment for performance initiatives and improvements to the physician quality reporting system and feedback program.

Some states have elected not to expand their Medicaid programs to individuals with an income of up to 133% of the federal poverty level, as is permitted under the PPACA. For each state that does not choose to expand its Medicaid program, there may be fewer insured patients overall, which could impact our sales of products for which we receive regulatory approval, business and financial condition. Where new patients receive insurance coverage under any of the new Medicaid options made available through the PPACA, the possibility exists that manufacturers may be required to pay Medicaid rebates on drugs used under these circumstances, a decision that could impact manufacturer revenues.

Some of the provisions of the PPACA have yet to be implemented, and there have been judicial and Congressional challenges to certain aspects of the PPACA, as well as recent efforts by the Trump



administration to repeal or replace certain aspects of the PPACA. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the PPACA or otherwise circumvent some of the requirements for health insurance mandated by the PPACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the PPACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the PPACA have been signed into law. The Tax Cuts and Jobs Act of 2017 includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the PPACA 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". Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain PPACA-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. Further, the Bipartisan Budget Act of 2018, or the BBA, among other things, amends the PPACA, effective January 1, 2019, to increase from 50% to 70% the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the Medicare Part D donut hole. Congress will likely consider other legislation to replace elements of the PPACA.

Moreover, other legislative changes have been proposed and adopted since the PPACA was enacted. In August 2011, then President Obama signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals for spending reductions. The Joint Select Committee did not achieve a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reduction to several government programs. This includes reductions to Medicare payments to providers of 2% per fiscal year, which went into effect in April 2013 and, due to subsequent legislative amendments, including the BBA, will remain in effect through 2027 unless additional Congressional action is taken. Further, in January 2013, then President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

In addition, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. 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. While any proposed measures will require authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures are increasingly passing legislation and implementing 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.

We expect that the PPACA, as currently enacted or as it may be amended or replaced in the future, and other healthcare reform measures that may be adopted in the future could have a material adverse effect on our industry generally and on our ability to maintain or increase sales of products for which we receive regulatory approval or to successfully commercialize our product candidates, if approved.

### **Coverage and Reimbursement**

Payor coverage uncertainty exists for all pharmaceutical products that are launched. This uncertainty exists as to the coverage of any products for which we may obtain regulatory approval. Sales of any of our products and product candidates, if approved, will depend, in part, on the extent to which the costs of the products will be covered by third-party payors, including government healthcare programs such as Medicare and Medicaid, and private payors, such as commercial health insurers and managed care organizations. Third-party payors determine which drugs they will cover. In the United States, there is no uniform system among payors for making coverage decisions. Decisions regarding the extent of coverage for any product candidates that we develop will be made on a payor-by-payor basis. Each payor determines whether or not it will provide coverage for a therapy, what amount it will pay the manufacturer for the therapy, and on what tier of its formulary it will be placed. The position on a payor's list of covered drugs, or formulary, generally determines the co-payment that a patient will need to make to obtain the therapy and can strongly influence the adoption of such therapy by patients and physicians. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results. A decision by a payor to not cover our product candidates could reduce physician adoption of our product candidates, once approved, and have a material adverse effect on our sales, results of operations and financial condition.

In order to secure coverage for our products, if approved for sale, we may need to conduct pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, in addition to the studies required to obtain FDA or other comparable regulatory approvals. Even if we conduct such pharmacoeconomic studies, our products and product candidates may not be considered medically necessary or cost-effective by payors.

We intend to pursue a reasonable and credible approach to the pricing of our products, in order to avoid such products being categorized as specialty products. Determination of responsible pricing will be based on the value proposition of our products, a full therapeutic category review, competitive pricing analysis and a strategic review of the payor landscape and payor dynamics. The payor type (business mix), will determine net pricing. Payor type by product (*e.g.*, Medicaid, Medicare, Commercial) will vary and therefore require varying discount levels. The Centers for Medicare and Medicaid Services, or CMS, surveys and publishes retail pharmacy acquisition cost information in the form of National Average Drug Acquisition Cost, or NADAC, files to provide state Medicaid agencies with a basis of comparison for their own reimbursement and pricing methodologies and rates.

Participation in the Medicaid Drug Rebate program would require us to pay a rebate for each unit of drug reimbursed by Medicaid. The amount of the "basic" portion of the rebate for each product is set by law as the larger of: (i) 23.1% of quarterly Average Manufacturer Price, or AMP, or (ii) the difference between quarterly AMP and the quarterly best price available from us to any commercial or non-governmental customer, or Best Price. AMP must be reported on a monthly and quarterly basis and Best Price is reported on a quarterly basis only. In addition, the rebate also includes the "additional" portion, which adjusts the overall rebate amount upward as an "inflation penalty" when the drug's latest quarter's AMP exceeds the drug's AMP from the first full quarter of sales after launch, adjusted for increases in the Consumer Price Index-Urban. The upward adjustment in the rebate amount per unit is equal to the excess amount of the current AMP over the inflation-adjusted AMP from the first full quarter of sales. The rebate amount is recomputed each quarter based on our report to CMS of current quarterly AMP and Best Price for our drug. The terms of our participation in the program would impose a requirement for us to report revisions to AMP or Best Price within a period not to exceed 12 quarters from the quarter in which the data was originally due. Any such revisions could have the impact of increasing or decreasing our rebate liability for prior quarters, depending on the direction of the revision. This "inflation penalty", also known as the Medicaid CPI Penalty, results from price increases in excess of the Consumer Price Index.

Federal law requires that any manufacturer that participates in the Medicaid Drug Rebate program also participate in the 340B program in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B program requires participating manufacturers to agree to charge statutorily defined covered entities no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs. These 340B covered entities include a variety of community health clinics and

other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low-income patients. The 340B ceiling price is calculated using a statutory formula, which is based on the AMP and rebate amount for the covered outpatient drug as calculated under the Medicaid Drug Rebate program. Any changes to the definition of AMP and the Medicaid rebate amount under the PPACA or other legislation could affect our 340B ceiling price calculations and negatively impact our results of operations.

In the United States Medicare program, outpatient prescription drugs may be covered under Medicare Part D. Medicare Part D is a voluntary prescription drug benefit, through which Medicare beneficiaries may enroll in prescription drug plans offered by private entities for coverage of outpatient prescription drugs. Part D plans include both standalone prescription drug benefit plans and prescription drug coverage as a supplement to Medicare Advantage plans provided for under Medicare Part C.

Coverage for covered outpatient drugs under Part D is not standardized. Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Although Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, they have some flexibility to establish those categories and classes and are not required to cover all of the drugs in each category or class. Medicare Part D prescription drug plans may use formularies to limit the number of drugs that will be covered in any therapeutic class and/or impose differential cost sharing or other utilization management techniques.

The availability of coverage under Medicare Part D may increase demand for products for which we receive marketing approval. However, in order for the products that we market to be included on the formularies of Part D prescription drug plans, we likely will have to offer net pricing that is lower than the prices we might otherwise obtain. Changes to Medicare Part D that give plans more freedom to limit coverage or manage utilization, and other cost reduction initiatives in the program could decrease the coverage and price that we receive for any approved products and could harm our business.

Pricing and rebate calculations, which vary across products and programs, are complex, and are often subject to interpretation by manufacturers, governmental or regulatory agencies, and the courts. Civil monetary penalties can be applied if a manufacturer is found to have knowingly submitted any false price information to the government or fails to submit the required price data on a timely basis. Such conduct also could be grounds for CMS to terminate the manufacturer's Medicaid drug rebate agreement, in which case federal payments may not be available under Medicaid. In addition, claims submitted to federally-funded healthcare programs, such as Medicare and Medicaid, for drugs priced based on incorrect pricing data provided by a manufacturer can implicate the federal Civil False Claims Act.

The containment of healthcare costs has become a priority of federal, state and foreign governments, and the prices of drugs have been a focus in this effort. The United States government, state legislatures, and foreign governments 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 requirements for substitution of generic products for branded prescription drugs. For example, the PPACA expanded manufacturers' rebate liability under the Medicaid program from fee-for-service Medicaid utilization to include the utilization of Medicaid managed care organizations as well, increased the minimum Medicaid rebate due for most innovator drugs, and capped the total rebate amount for innovator drugs at 100% of AMP. The PPACA and subsequent legislation also changed the definition of AMP. In addition, the PPACA requires pharmaceutical manufacturers of branded prescription drugs (excluding orphan drugs) to pay a branded prescription drug fee to the federal government. Each such manufacturer pays a prorated share of the branded prescription drug fee of \$4.0 billion in 2017, based on the dollar value of its branded prescription drug sales to certain federal programs identified in the law. The PPACA also expanded the Public Health Service's 340B program to include additional types of covered entities. Substantial new provisions affecting compliance have also been enacted, which may affect our business practices with healthcare practitioners, and a significant number of provisions are not yet, or have only recently become, effective. It appears likely that the PPACA will continue the pressure on pharmaceutical pricing, especially under the Medicare and Medicaid programs, and may also increase our regulatory burdens and operating costs.

Legislative changes to and regulatory changes under the PPACA and other healthcare statutes remain possible in the 115th United States Congress and under the Trump administration, as discussed above under the heading "United States Healthcare Reform." In addition, there likely will continue to be proposals by legislators at both the federal and state levels, regulators, and third-party payors to contain healthcare costs. Thus, even if we obtain favorable coverage for any products for which we receive regulatory approval, less favorable coverage policies may be implemented in the future.

Additional information regarding these programs is discussed under the heading "If we are unable to achieve and maintain adequate levels of coverage and reimbursement for our products or product candidates, if approved, their commercial success may be severely hindered" in the "Risk Factors" section of this prospectus.

### **Other Regulation**

We are also subject to various laws and regulations regarding laboratory practices, the experimental use of animals, and the use and disposal of hazardous or potentially hazardous substances in connection with our research. In each of these areas, as above, the FDA and other government agencies have broad regulatory and enforcement powers, including, among other things, the ability to levy fines and civil penalties, suspend or delay issuance of approvals, seize or recall products, and withdraw approvals, any one or more of which could have a material adverse effect on us.

## Employees

As of March 31, 2018, we had 195 employees (including temporary workers). Of these employees, six hold Ph.D. degrees, 21 are directly involved in research and development, and 132 are involved in manufacturing operations.

We are subject to local labor laws and regulations with respect to our employees in those jurisdictions. These laws principally concern matters such as paid annual vacation, paid sick days, length of the workday and work week, minimum wages, pay for overtime, and insurance for workers' compensation.

Our employees are not represented by a labor union. We do not have written employment contracts with most of our employees, and it is our understanding that our relations with our employees are satisfactory.

### **Properties/Facilities**

We lease our 8,400-square-foot current production facility (Melton) in Portage, Indiana, which houses certain research and development offices and current good manufacturing practices, or cGMP, manufacturing operations. The lease contains an option to purchase the facility at any time during the lease term along with a right of first refusal to purchase the facility. In October 2017, we extended our Melton facility lease which will expire during March 2023 under the same terms and conditions as its former lease. Our current monthly rent for this facility is \$18,664.

We also lease a 73,000-square-foot facility (Ameriplex) in Portage, Indiana, to house additional packaging, R&D and other operations. As amended, this lease has a term that extends through September 30, 2022 and contains a renewal option that could extend the lease through September 30, 2026. Our monthly rent for this facility is currently \$45,570.

We lease our headquarters and principal laboratory facility in Warren, New Jersey. Pursuant to various amendments in February 2011, June 2012 and May 2013, we have secured additional space to provide for the growth of its laboratory facilities and corporate and administrative requirements. The lease included five two-year renewal options, one of which was exercised in July 2016 to extend this lease through February 28, 2020. Our monthly rent for this facility is currently \$23,020.

# Legal Proceedings

We are involved in various claims, legal proceedings and investigations both in the United States and internationally, most of which are either immaterial or incidental to the ordinary course of our business,



other than those proceedings described below. While it is not feasible to predict the outcome of such pending claims, proceedings and investigations with certainty, management is of the opinion that their ultimate resolution should not have a material adverse effect on Aquestive's financial position, cash flows, or results of operations, except where noted below.

## Patent-Related Litigation

Beginning in August 2013, we were informed of ANDA filings in the United States by Watson Laboratories, Inc. (now Actavis Laboratories, Inc., or Actavis), Par Pharmaceutical, Inc., or Par, Alvogen Pine Brook, Inc., or Alvogen, Teva Pharmaceuticals USA, Inc., or Teva, Sandoz Inc., or Sandoz, and Mylan Technologies Inc. or Mylan, for the approval by the FDA of generic versions of Suboxone Sublingual Film in the United States. We filed patent infringement lawsuits against all six generic companies in the U.S. District Court for the District of Delaware. Of these, cases against two of the six generic companies have been resolved.

- Sandoz. By court order in August 2016, our ANDA patent litigation case against Sandoz has been dismissed without prejudice for lack of subject matter jurisdiction because Sandoz is no longer pursuing a Paragraph IV certification for its proposed generic version of Suboxone Sublingual Film, and therefore is no longer challenging the validity or infringement of our Orange Book-listed patents.
- *Mylan*. The case against Mylan was settled and the Court signed a Consent Judgment in September 2017 disposing of the entire case.

After the commencement of litigation the above-mentioned ANDA patent litigation case against Teva, Dr. Reddy's Laboratories acquired the ANDA filings for Teva's buprenorphine and naloxone sublingual film that are at issue in these trials.

Trials against Dr. Reddy's, Actavis and Par in the lawsuits involving the Orange Book and process patents occurred in November-December of 2015 and November of 2016. On June 3, 2016, the Court issued its Trial Opinion finding that the asserted claims of U.S. Patent No. 8,603,514, or the '514 patent, are valid and infringed by Actavis's and Par's ANDA Products. On August 31, 2017, the Court upheld U.S. Patent No. 8,900,497, or the '497 patent, as valid but not infringed by Par's, Actavis's or Dr. Reddy's proposed processes for making their ANDA Products. The Court also again upheld the validity of the '514 patent but held it was not infringed by Dr. Reddy's ANDA Products, and upheld the validity of U.S. Patent No. 8,017,150, or the '150 patent, but held that it was not infringed by Dr. Reddy's ANDA Products. All of these cases are consolidated on appeal to the Federal Circuit, except the cases between Indivior and us on the one hand and Par and certain affiliates.

Trial against Alvogen was held in September, 2017. The only issue raised at trial was whether Alvogen's ANDA Products and processes infringe the '514 and '497 patents; Alvogen did not challenge the validity of the patents. In March 2018, the Court issued its opinion finding that Alvogen's ANDA products and processes would not infringe the '514 and '497 patents. Indivior has announced its intention to appeal the ruling. If any company is able to obtain FDA approval for its generic version of Suboxone Sublingual Film, it may be able to launch the product prior to the expiration of any or all the applicable patents protecting our Suboxone Film, which could have a material adverse effect on our business, prospects, results of operations and financial condition.

We are also seeking to enforce our patent rights in multiple cases against BioDelivery Sciences International, Inc., or BDSI. Two cases are currently pending but stayed in the U.S. District Court for the Eastern District of North Carolina:

- The first, a declaratory judgment action brought by BDSI against Indivior and Aquestive, seeks declarations of
  invalidity and non-infringement of U.S. Patents Nos. 7,897,080, or the '080 patent, 8,652,378, or the '378
  patent, and 8,475,832, or the '832 patent. This case stayed pending *inter partes* review of the '832 patent and
  reexamination of the '080 patent.
- The second was filed by us and Indivior related to BDSI's infringing Bunavail product, and alleges infringement
  of our patent, U.S. Patent No. 8,765,167, or the '167 patent. This case was initially filed in September 2014 in
  the U.S. District Court for the District of New Jersey but was transferred to North Carolina. Shortly after the
  case was filed, BDSI filed an IPR challenging the



asserted '167 patent. On March 24, 2016, the Patent Trial and Appeal Board, or the PTAB, issued a final written decision finding the '167 patent was not unpatentable. This case is stayed pending the outcome and final determination of the proceedings concerning the '167 patent, which is currently on appeal to the Federal Circuit (discussed below).

On January 13, 2017, we also sued BDSI asserting infringement of the '167 patent by BDSI's Belbuca product. The case was originally filed in the U.S. District Court for the District of New Jersey, and was later transferred to the U.S. District Court for the District of Delaware by agreement of the parties.

On November 28, 2016, after the PTAB issued its final written decisions finding that the '167 patent was not unpatentable in IPR2015-00165, IPR2015-00168 and IPR2015-00169, BDSI filed a notice of appeal of those decisions to the U.S. Court of Appeals for the Federal Circuit. The case has been fully briefed and the Court heard oral arguments on February 9, 2018. As of the date of this prospectus, there have been no further updates on this matter.

In September 2017, Indivior brought suit against Alvogen for infringement of U.S. Patent No. 9,687,454, or the '454 patent, based on the filing of an ANDA seeking approval for a generic version of Suboxone Sublingual Film, in the U.S. District Court for the District of New Jersey. In February 2018, we and Indivior amended the complaint, which added us as a plaintiff and a claim for infringement of U.S. Patent No. 9,855,221, or the '221 patent.

Indivior brought suits against Dr. Reddy's and Teva in September 2017, and against Par and certain affiliates in October 2017, for infringement of the '454 patent, in the U.S. District Court for the District of New Jersey. Indivior also brought suit in September 2017 against Actavis Laboratories UT, Inc. for infringement of the '454 patent, in the U.S. District Court for the District of Utah. On March 13, 2018, the Court granted transfer of this case to the U.S. District Court for the District of Delaware.

In February 2018, we and Indivior brought suit against Actavis, Dr. Reddy's, Teva, and Par and certain affiliates for infringement of the '221 patent. The suit against Actavis was filed in the U.S. District Court for the District of Utah, and the other three cases were filed in the U.S. District Court for the District of New Jersey.

In April 2018, we brought suit with Indivior against Actavis, Alvogen, Dr. Reddy's, Teva, and Par and certain affiliates for infringement of U.S. Patent No. 9,931,305, or the '305 patent. The cases against Alvogen, Dr. Reddy's, Teva, and Par are pending in the U.S. District Court for the District of New Jersey. Following transfer of the case asserting the '454 patent from Utah to Delaware, and by agreement of the parties, the cases against Actavis asserting infringement of the '454, '221, and '305 patents are consolidated in a single action pending in the U.S. District Court for the District of Delaware.

The matters involving Par were resolved on May 11, 2018, when we, Indivior, and Par and certain of its affiliates entered into a settlement agreement resolving patent litigation related to SUBOXONE (buprenorphine and Naloxone) Sublingual Film. Under the settlement agreement, Par and IntelGenX are permitted to launch their proposed generic version of the buprenorphine and Naloxone sublingual film on January 1, 2023, or earlier under certain circumstances. The patent-infringement litigation has been pending in the U.S. District Court for the District of Delaware. As required by law, the parties will submit the settlement agreement of the U.S. Federal Trade Commission and the U.S. Department of Justice for review.

# Antitrust Litigation

On September 22, 2016, forty-one states and the District of Columbia, or the States, brought suit against Indivior and us in the U.S. District Court for the Eastern District of Pennsylvania, alleging violations of federal and state antitrust statutes and state unfair trade and consumer protection laws relating to Indivior's launch of Suboxone Sublingual Film in 2010. After filing, the case was consolidated for pre-trial purposes with the *In re Suboxone (Buprenorphine Hydrochloride and Naloxone) Antitrust Litigation*, MDL No. 2445, or the Suboxone MDL, a multidistrict litigation relating to putative class actions on behalf of various private plaintiffs against Indivior relating to its launch of Suboxone Sublingual Film. While we were not named as a defendant in the original Suboxone MDL cases, the action brought by the States alleges that we participated in an antitrust conspiracy with Indivior in connection with Indivior's launch of Suboxone Sublingual Film and engaged in related conduct in violation of federal and state

antitrust law. We moved to dismiss the States' claims conspiracy claims, and by order dated October 30, 2017, the Court denied our motion to dismiss. We filed an answer denying the States' claims on November 20, 2017. The parties are now proceeding with fact discovery, which is currently scheduled to be completed by July 27, 2018.

# **Products Liability Litigation**

On December 27, 2016, we were named as a co-defendant in a product liability suit brought by Laurence and Michelle Allen, as Co-Administrators of the Estate of John Bradley Allen, in the U.S. District Court for the Northern District of New York. The suit, which also named Indivior Inc. and Indivior PLC as defendants, asserts causes of action for negligence, strict liability, and failure to warn against the defendants in connection with the manufacture and sale of Suboxone Sublingual Film. Plaintiffs allege that John Bradley Allen's use of Suboxone Sublingual Film was a substantial contributing cause of his mental anguish and death, and seek \$100 million in damages. All defendants moved to dismiss the complaint on April 10, 2017, and those motions were fully briefed on May 18, 2017. The motions to dismiss remain pending.

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# MANAGEMENT

# **Executive Officers, Directors and Key Employees**

The following table sets forth certain information regarding our executive officers, directors and key employees as of March 31, 2018:

Name	Age	Position(s)
Executive Officers and Key Employees		
Keith J. Kendall	60	President, Chief Executive Officer and Director
Daniel Barber	42	Corporate, Business & Product Development Executive
Peter Boyd	52	Operations and Management
Ken Marshall	58	Commercial
John T. Maxwell	53	Chief Financial Officer
A. Mark Schobel	62	Chief Innovation and Technology Officer
Theresa Wood	55	Human Resources
Non-Employee Directors		
Douglas Bratton <sup>(2)(3)</sup>	59	Chairman of the Board of Directors
Gregory Brown, M.D. <sup>(1)(3)</sup>	64	Director
John Cochran <sup>(2)(3)</sup>	52	Director
Santo Costa <sup>(2)</sup>	72	Director
Nancy Lurker <sup>(1)(2)</sup>	60	Director
James S. Scibetta <sup>(1)</sup>	53	Director

(1) Member of the audit committee.

(2) Member of the compensation committee.

(3) Member of the nominating and corporate governance committee.

# **Executive Officers and Key Employees**

*Keith J. Kendall* has served as our President and Chief Executive Officer since November 2014, after having served as our President and Chief Operating Officer since November 2011, and has served on our board of directors since November 2014. Mr. Kendall also served as our Executive Vice President and Chief Financial Officer beginning in 2006. Mr. Kendall served on the board of directors of Midatech, Pharma Plc (Nasdaq: MTP), from January 2010 to December 2014. From 1999 to 2006, Mr. Kendall served as the Vice President and Managing Director of the Americas for Hewlett Packard Financial Services. Mr. Kendall held a number of positions with AT&T Capital Corporation, including President of AT&T Credit Corporation and NCR Credit Corporation, from 1985 to 1998. Mr. Kendall is a certified management accountant, and holds a BS from St. John's University and an MBA from Pace University. Our board of directors believes that Mr. Kendall's perspective and experience as our President and Chief Executive Officer, as well as his depth of operating and senior management experience in our industry, qualifies him to serve on our board of directors.

Daniel Barber joined our team in July 2007 and has led our Corporate, Business and Product Development functions since April 2014. Prior to joining our team, Mr. Barber held various positions with Quest Diagnostics in its corporate planning and international divisions. In 2010, Mr. Barber had executive oversight of our launch activities for our first two FDA approved products. Beginning in 2013, Mr. Barber helped lead our effort to develop an internal pipeline of proprietary assets. Since that time, he has had executive responsibility for our pipeline and partnership activities. Mr. Barber received his BA degree from State University of New York at Geneseo and an MBA from Seton Hall University.

*Peter Boyd* joined our company in August 2013 and has led our Operations and Management function since April 2014. Prior to his current position, Mr. Boyd was our Vice President of Business Process at Aquestive. Prior to joining us, Mr. Boyd served as Senior Director of Operations for the Americas and APJ Regions, at Hewlett-Packard Company. Throughout his 15-year career at the

Hewlett-Packard Company, Mr. Boyd held a variety of positons in business process improvement and in operations. Mr. Boyd received a BA in History from Wittenberg University and an MBA in Finance from Seton Hall University. Mr. Boyd also received an MS in Management and Urban Policy Analysis from the New School University.

*Ken Marshall* joined our company in January 2018 as the head of our commercial function. Prior to that, Mr. Marshall served as U.S. President and Global Chief Marketing Officer for Aerocrine Inc. In that role, he developed the global marketing strategy and led all aspects of the U.S. business. Between 2008 and 2011, Mr. Marshall served as Vice President of Sales and Marketing for Ikaria, Inc., a drug and device company focused on critical care. Mr. Marshall also spent 17 years with GlaxoSmithKline and held several senior positions including Vice President of Marketing for the Neurology, Urology, Lifecycle and HIV business units. Mr. Marshall received his BSBA in Marketing and Economics from Western Carolina University and MBA from Houston Baptist University.

*John T. Maxwell* has served as our Chief Financial Officer since January 2017. Prior to joining our team, Mr. Maxwell held senior financial roles at WIL Research, InfoNXX, PanAmSat, ADP and General Signal, including as Chief Financial Officer of WIL Research from September 2008 to April 2016. In addition, Mr. Maxwell served as a freelance consultant from April 2016 until January 2017. Mr. Maxwell started his career at Ernst & Young, serving in the Dallas, New York and Stamford offices. Mr. Maxwell helped lead the successful strategic sale transactions by the private equity sponsors of WIL Research in April 2016 to Charles River Labs and of PanAmSat in 2006 to Intelsat. Mr. Maxwell also helped lead the initial public offering of PanAmSat in 2005 and multiple public and private debt transactions for WIL Research, InfoNXX and PanAmSat. Mr. Maxwell is a licensed certified public accountant and holds a BBA in Accounting from Texas Tech University and an MBA in Finance and International Business from New York University Stern School of Business.

A. Mark Schobel joined our team in December 2005 and has served as our Chief Innovation and Technology Officer since November 2015. Mr. Schobel served as our Chief Executive Officer and Co-President through November 2014 and served as a member of our board of directors from November 2005 through 2018. From 2001 to 2005, he was the Global Head of New Technology and Product Innovation for the Consumer Health Business Unit at Novartis where he pioneered thin film delivery of systemic drugs. Prior to Novartis, Mr. Schobel held various general management positions with Reed & Carnrick Pharmaceuticals, Warner-Lambert and Pharmaceutical Formulations Inc. Mr. Schobel received his BS in Chemistry from Fairleigh Dickinson University and has been awarded 21 patents along with having multiple patents pending in fields ranging from film drug delivery to nanoparticle delivery systems. Our board of directors believes that Mr. Schobel's extensive knowledge of our company, as well as his experience in the biotechnology industry qualifies him to serve on our board of directors.

*Theresa Wood* has served as the head of our Human Resources function since September 2006. Prior to joining our team, Ms. Wood was the Director, Human Resources, for the Hewlett Packard Financial Services Americas division from 1999 to 2006. From 1995 to 1998, Ms. Wood provided consulting services to several companies in the Financial Services, Healthcare and Consumer Goods market. Prior to that, Ms. Wood spent seven years with Sea-Land Service Corp. Ms. Wood received her BS in Management Science and Marketing from Kean University.

# **Non-Employee Directors**

*Douglas Bratton* has served as Chairman of our board of directors since January 2004. Mr. Bratton is the Founder, President and Chief Investment Officer of Crestline Investors, an institutional alternative investment management firm. Mr. Bratton has been an investment professional specializing in alternative asset strategies since 1983 and has managed assets on behalf of the Bass family of Fort Worth, Texas, since 1988. Mr. Bratton received a BS from North Carolina State University in 1981 and an MBA with Honors from Duke University in 1984. Mr. Bratton serves on the board of directors of Bounty Minerals Corporation, a private company, and the Board of Visitors of Duke University's Fuqua School of Business. Our board of directors believes that Mr. Bratton's business experience, as well as his strong finance and management background, qualifies him to serve on our board of directors.

*Gregory Brown, M.D.* has served as a member of our board of directors since March 2007. Dr. Brown is a co-founder and Vice Chairman at HealthCare Royalty Partners, or HCR Partners, and chairs that

firm's Senior Advisor Board. Educated as a transplantation immunologist and trained as a thoracic and vascular surgeon, Dr. Brown practiced thoracic and vascular surgery in a community setting where he also founded and led a health maintenance organization. Before co-founding HCR Partners, Dr. Brown was a partner at Paul Capital Partners, where he co-managed that firm's royalty investments as a member of the royalty management committee. Prior to beginning his principal investment career in 2003, Dr. Brown was co-head of investment banking and head of healthcare at Adams, Harkness & Hill (now Canaccord Genuity) and a ranked biotechnology research analyst at Vector Securities International. Dr. Brown holds a BA from Yale University, an M.D. from SUNY Upstate Medical Center and an MBA from Harvard University. He currently serves on the boards of the following public pharmaceutical companies: Caladrius Biosciences, Inc. (Nasdaq: CLBS), Cambrex Corporation (NYSE: CBM) and Faron Pharmaceuticals Oy (LSN: FARN), and the board of Vanderbilt Clinical S.a.r.l., a private company. Our board of directors believes that Dr. Brown's extensive experience in the pharmaceutical industry and investing in life sciences companies, as well as his medical and scientific background, qualifies him to serve on our board of directors.

John Cochran has served as a member of our board of directors since January 2004. Mr. Cochran has been a partner at Bratton Capital Management L.P. since October 1998, and is responsible for its private equity investments. Mr. Cochran is also a partner and Chief Operating Officer of Crestline Management, a credit-oriented alternative asset management platform. Prior to joining Bratton Capital Management L.P., Mr. Cochran spent 10 years with KPMG focused primarily on audit and merger and acquisition due diligence. Mr. Cochran received his BA in Accounting from Texas Christian University and is also a licensed certified public accountant. Our board of directors believes that Mr. Cochran's private equity investment and company oversight experience along with his strong finance and management background, qualifies him to serve on our board of directors.

Santo Costa has served as a member of our board of directors since December 2015. Since 2007, Mr. Costa has served as Of Counsel to the law firm of Smith, Anderson, Blount, Dorsett, Mitchell and Jernigan, L.L.P. of Raleigh, North Carolina, specializing in corporate law for healthcare companies. Mr. Costa has served on the board of directors of Cytokinetics Inc. (Nasdag: CYTK) since October 2010, and on the board of directors of Metabolon, Inc., a private company, since April 2013. From 1994 to 2001, he held various positions at Quintiles Transnational Corporation, including as Vice Chairman, President and Chief Operating Officer. Prior to joining Ouintiles, Mr. Costa spent 23 years in the pharmaceutical industry, most recently as General Counsel and Senior Vice President, Administration with Glaxo Inc. Prior to joining Glaxo, he served as U.S. Area Counsel with Merrell Dow Pharmaceuticals and as Food & Drug Counsel with Norwich Eaton Pharmaceuticals, Inc. Mr. Costa served as Chairman of the board of directors of Alchemia Limited, a private biopharmaceutical company, from March 2014 to June 2015. He also served on the board of directors of Magor Corporation, formerly Biovest Corp. I, from March 2010 until March 2013. He also served as Chairman of the board of directors of LaboPharm, Inc. from March 2006 to November 2011 and a director of OSI Pharmaceuticals from June 2006 to June 2010, as well as serving as a director at other private companies. Mr. Costa earned both a BS in Pharmacy and a JD from St. John's University. Our board of directors believes that Mr. Costa's experience in the biotechnology industry, his broad experience advising financial institutions, global corporations and boards of directors of publicly held companies, and his experience serving as a director of public and private companies, qualifies him to serve on our board of directors.

*Nancy Lurker* has served as a member of our board of directors since April 2018. Ms. Lurker has been serving as President and Chief Executive Officer of Eyepoint Pharmaceuticals, Inc. (Nasdaq: EYPT) ("Eyepoint Pharmaceuticals") since September 2016. Prior to assuming her position with Eyepoint Pharmaceuticals, Ms. Lurker was a freelance consultant from December 2015 to September 2016. From 2008 to December 2015, Ms. Lurker served as President and Chief Executive Officer and a director of PDI, Inc., a NASDAQ-listed healthcare commercialization company now named Interpace Diagnostics Group, Inc., (Nasdaq: IDXG). From 2006 to 2007, Ms. Lurker was Senior Vice President and Chief Marketing Officer of Novartis Pharmaceuticals Corporation, the U.S. subsidiary of Novartis AG (NYSE: NVS). In addition, she also served as President and Chief Executive Officer of ImpactRx, Inc., a privately held healthcare information company. Ms. Lurker currently serves on the board of directors of the Cancer Treatment Centers of America, a privately held company. Ms. Lurker previously served as a member of the boards of directors of publicly held Auxilium Pharmaceuticals, Inc. from 2011 to 2015. Mallinckrodt

Pharmaceuticals, plc from 2013 to 2016 Elan Corporation, plc from 2005-2006 and ConjuChem Biotechnologies from 2004-2006 Ms. Lurker received a B.S. in Biology from Seattle Pacific University and an M.B.A. from the University of Evansville. Our board of directors believes Ms. Lurker's broad ranging experience in the pharmaceutical industry and her track record of maximizing the potential of new therapies and successfully implementing innovative U.S. and global drug launches qualifies her to serve on our board of directors.

*James S. Scibetta* has served as a member of our board of directors since April 2017. Mr. Scibetta has been serving as Chief Executive Officer of Maverick Therapeutics, a development stage immuno-oncology company since July 2017. Prior to Maverick, Mr. Scibetta was appointed President of Pacira Pharmaceuticals, or Pacira (Nasdaq: PCRX), in October 2015, where he oversaw commercial and medical support activities, and directed commercial manufacturing, tech transfer and research and development. Mr. Scibetta served as Pacira's Chief Financial Officer from August 2008 through May 2016 where he led its 2011 initial public offering and subsequent debt and equity financings. Prior to that, Mr. Scibetta served as Chief Financial Officer of Bioenvision Inc., a commercial-stage public oncology company acquired by Genzyme, and Merrimack Pharmaceuticals, an oncology-focused systems biology company. Earlier in his career, Mr. Scibetta spent over a decade in investment banking where he was responsible for sourcing and executing transactions for a broad base of public and private healthcare and life sciences companies. Mr. Scibetta also serves as a director and chairman of the audit committee of Matinas BioPharma Holdings, Inc. (NYSE: MTNB), a biopharmaceutical company. Mr. Scibetta received his BS in Physics from Wake Forest University and his MBA from the University of Michigan. Our board of directors believes that Mr. Scibetta's extensive senior management experience in the biotechnology industry, as well as his experience on the boards of both public and private companies, qualifies him to serve on our board of directors.

## **Board Composition**

Our business and affairs are organized under the direction of our board of directors, which currently consists of six non-executive members, and one executive members. Our directors may be removed for cause by the affirmative vote of the holders of at least 66<sup>2/3</sup>% of our voting stock. The primary responsibilities of our board of directors are to provide oversight, strategic guidance, counseling and direction to our management. Our board of directors meets on a regular basis and additionally as required.

Our board of directors has determined that all of our directors are independent directors, other than Keith J. Kendall, as defined by Rule 5605(a)(2) of the Nasdaq Listing Rules.

Effective upon the consummation of this offering, we will divide our board of directors into three classes, as follows:

- Class I, which will consist of
- Class II, which will consist of ; and
- Class III, which will consist of

At each annual meeting of stockholders to be held after the initial classification, the successors to directors whose terms then expire will serve until the third annual meeting following their election and until their successors are duly elected and qualified. The authorized size of our board of directors is currently nine members. The authorized number of directors may be changed only by resolution of the board of directors. Any additional directorships resulting from an increase in the number of directors will be distributed between the three classes so that, as nearly as possible, each class will consist of one-third of the directors. This classification of the board of directors may have the effect of delaying or preventing changes in our control or management.

# **Board Leadership Structure**

Our board of directors is currently chaired by Douglas Bratton. As a general policy, our board of directors believes that separation of the positions of Chairman and Chief Executive Officer reinforces the independence of the board of directors from management, creates an environment that encourages

objective oversight of management's performance and enhances the effectiveness of the board of directors as a whole. As such, Mr. Kendall serves as our President and Chief Executive Officer, while Douglas Bratton serves as our Chairman of the board of directors, but is not an officer. We expect and intend the positions of Chairman of the board of directors and Chief Executive Officer to continue to be held by two individuals in the future.

### Role of the Board in Risk Oversight

One of the key functions of our board of directors is informed oversight of our risk management process. The board of directors does not have a standing risk management committee, but rather administers this oversight function directly through the board of directors as a whole, as well as through various standing committees of our board of directors that address risks inherent in their respective areas of oversight. In particular, our board of directors is responsible for monitoring and assessing strategic risk exposure and our audit committee has the responsibility to consider and discuss our major financial risk exposures and the steps our management has taken to monitor and control these exposures, including guidelines and policies to govern the process by which risk assessment and management is undertaken. The audit committee also monitors compliance with legal and regulatory requirements. Our nominating and corporate governance committee monitors the effectiveness of our corporate governance practices, including whether they are successful in preventing illegal or improper liability-creating conduct. Our compensation committee assesses and monitors whether any of our compensation policies and programs has the potential to encourage excessive risk-taking.

### **Board Committees**

Our board of directors has established an audit committee, a compensation committee and a nominating and corporate governance committee, each of which has the composition and responsibilities described below. From time to time, the board may establish other committees to facilitate the management of our business.

# Audit Committee

Our audit committee currently consists of Gregory Brown, M.D., Santo Costa, Nancy Lurker and James S. Scibetta. Immediately following the closing of this offering, our audit committee will consist of Gregory Brown, M.D., Nancy Lurker and James S. Scibetta, each of whom our board of directors has determined satisfies the Nasdaq Global Market and SEC independence requirements. The chairperson of our audit committee is currently James S. Scibetta, and following the closing of this offering, Mr. Scibetta will continue to serve as the chair of our audit committee. The functions of this committee include, among other things:

- evaluating the performance, independence and qualifications of our independent auditors and determining whether to retain our existing independent auditors or engage new independent auditors;
- reviewing and approving the engagement of our independent auditors to perform audit services and any permissible non-audit services;
- monitoring the rotation of partners of our independent auditors on our engagement team as required by law
  and considering whether, in order to assure continuing auditor independence, it is appropriate to adopt a policy
  of rotating the independent auditing firm on a regular basis;
- reviewing relationships that may reasonably be thought to bear on our auditors' independence, and assessing
  and otherwise taking the appropriate action to oversee the independence of our independent auditors;
- reviewing our annual and quarterly financial statements and reports, including the disclosures contained under the caption "Management's Discussion and Analysis of Financial Condition and Results of Operations," and discussing the statements and reports with our independent auditors and management;
- reviewing with our independent auditors and management significant issues that arise regarding accounting
  principles and financial statement presentation and matters concerning the scope, adequacy and effectiveness
  of our financial controls;

- reviewing with management and our auditors any earnings announcements and other public announcements regarding material developments;
- establishing procedures for the receipt, retention and treatment of complaints received by us regarding financial controls, accounting or auditing matters and other matters;
- · preparing the report that the SEC requires in our annual proxy statement;
- reviewing and providing oversight of any related-person transactions and reviewing and monitoring compliance with legal and regulatory responsibilities, including our code of business conduct and ethics;
- reviewing our major financial risk exposures, including the guidelines and policies to govern the process by which risk assessment and risk management is implemented; and
- reviewing and evaluating on an annual basis the performance of the audit committee, including compliance of the audit committee with its charter.

Our board of directors has determined that James Scibetta qualifies as an audit committee financial expert within the meaning of SEC regulations and meets the financial sophistication requirements of the Nasdaq Listing Rules. In making this determination, our board has considered Mr. Scibetta's extensive financial experience and business background. Both our independent registered public accounting firm and management periodically meet privately with our audit committee.

Our audit committee will operate under a written charter, to be effective immediately prior to the consummation of this offering, that satisfies the applicable rules of the SEC and the listing standards of the Nasdaq Global Market.

# **Compensation Committee**

Our compensation committee currently consists of John Cochran, Santo Costa, Nancy Lurker and Douglas Bratton, and following the closing of this offering, the committee shall continue to consist of these same individuals. The chairperson of our compensation committee is currently Douglas Bratton, and following the closing of this offering, Santo Costa will serve as the chair of our compensation committee. Our board of directors has determined that each of the members of our compensation committee is a non-employee director, as defined in Rule 16b-3 promulgated under the Securities Exchange Act of 1934, as amended, or Exchange Act, is an outside director, as defined pursuant to Section 162(m) of the Code and satisfies the Nasdaq Global Market independence requirements. The functions of this committee includes, among other things:

- reviewing, modifying and approving our overall compensation strategy and policies;
- · reviewing and approving the compensation and other terms of employment of our executive officers;
- · reviewing the succession plans for our executive officers;
- reviewing and approving the equity incentive plans, compensation plans and similar programs advisable for us, as well as modifying, amending or terminating existing plans and programs;
- establishing policies with respect to votes by our stockholders to approve executive compensation as required by Section 14A of the Exchange Act and determining our recommendations regarding the frequency of advisory votes on executive compensation;
- retaining or terminating a compensation consultant or firm to be used to assist the Committee in benchmarking and setting appropriate compensation levels and policies and approving such consultant's or firm's fees and other retention terms;
- approving, modifying and administering our equity incentive plans;
- establishing policies with respect to equity compensation arrangements;
- reviewing and approving the terms of any employment agreements, severance arrangements, change in control protections and any other compensatory arrangements for our executive officers;

- reviewing the adequacy of its charter on a periodic basis;
- preparing the report that the SEC requires in our annual proxy statement; and
- reviewing and assessing on an annual basis the performance of the compensation committee.

Our compensation committee will operate under a written charter, to be effective immediately prior to the consummation of this offering, that satisfies the applicable rules of the SEC and the listing standards of the Nasdaq Global Market.

# Nominating and Corporate Governance Committee

Our nominating and corporate governance currently committee consists of Douglas Bratton, Gregory Brown and John Cochran, and following the closing of this offering, the committee shall continue to consist of these same individuals. Our board of directors has determined that each of the members of our nominating and corporate governance satisfies the Nasdaq Global Market independence requirements. The chairperson of our nominating and corporate governance committee is currently Douglas Bratton and following the closing of this offering, Mr. Bratton will continue to serve as the chair of our nominating and corporate governance committee. The functions of this committee includes, among other things:

- identifying, reviewing and evaluating candidates to serve on our board of directors consistent with criteria approved by our board of directors;
- determining the minimum qualifications for service on our board of directors;
- evaluating, nominating and recommending individuals for membership on our board of directors;
- evaluating nominations by stockholders of candidates for election to our board of directors;
- considering and assessing the independence of members of our board of directors;
- developing a set of corporate governance policies and principles, including a code of business conduct and ethics, periodically reviewing and assessing these policies and principles and their application and recommending to our board of directors any changes to such policies and principles;
- considering questions of possible conflicts of interest of directors as such questions arise;
- reviewing the adequacy of its charter on an annual basis; and
- annually evaluating the performance of the nominating and corporate governance committee.

Our nominating and governance committee will operate under a written charter, to be effective immediately prior to the consummation of this offering that satisfies the applicable rules of the SEC and the listing standards of the Nasdaq Global Market.

# Compensation Committee Interlocks and Insider Participation

None of the members of our compensation committee has ever been an executive officer or employee of ours. None of our executive officers currently serves, or has served during the last completed fiscal year, on the compensation committee or board of directors of any other entity that has one or more executive officers serving as a member of our board of directors or compensation committee.

# Code of Business Conduct and Ethics

In connection with this offering, we intend to adopt a Code of Business Conduct and Ethics, or the Code of Conduct, applicable to all of our employees, executive officers and directors. Following the consummation of this offering, the Code of Conduct will be available on our website at www.aquestive.com. The nominating and corporate governance committee of our board of directors will be responsible for overseeing the Code of Conduct and must approve any waivers of the Code of Conduct for employees, executive officers and directors. We expect that any amendments to the Code of Conduct, or any waivers of its requirements, will be disclosed on our website.



# EXECUTIVE AND DIRECTOR COMPENSATION

Our named executive officers for the fiscal year ended December 31, 2017, which consist of our principal executive officer and the next three most highly compensated executive officers who were serving as executive officers as of December 31, 2017, are:

Keith J. Kendall, our President and Chief Executive Officer;

Daniel Barber, our Corporate, Business and Product Development Executive;

John T. Maxwell, our Chief Financial Officer; and

A. Mark Schobel, our Chief Innovation and Technology Officer.

### **Summary Compensation Table**

The following table provides information regarding the compensation provided to our named executive officers during the fiscal year ended December 31, 2017:

Name and Principal Position	Year	Salary (\$) <sup>(1)</sup>	Bonus (\$)	Stock Awards (\$) <sup>(2)</sup>	Non-Equity Incentive Plan Compensation (\$) <sup>(3)</sup>	All Other Compensation (\$)	Total Compensation (\$)
Keith J. Kendall President and Chief Executive Officer	2017	400,000		1,178,666	525,000	24,769(4)	2,128,435
Daniel Barber Corporate, Business and Product Development Executive	2017	300,000	_	378,652	201,390	18,858(5)	898,901
John T. Maxwell <sup>(8)</sup> Chief Financial Officer	2017	350,000	70,000(8)	874,335	306,250	19,615(5)	1,620,200
A. Mark Schobel Chief Innovation & Technology Officer	2017	350,000	_	56,115	367,500	21,590(6)	795,205

(1) See "Narrative to the Summary Compensation Table" below.

(2) This column reflects the aggregate grant date fair value of the awards granted under the PUP Plans during 2017 assuming that, at the time of grant, the contingency of events to occur in order to settle awards granted under the PUP Plans were deemed to be probable to occur. However, because of the general uncertainty surrounding the contingency of the events that must occur in order for PUP Plan awards to be settled at the time of their grant, no compensation expense was recorded in our audited financial statements in 2017 as it was not probable at the time of grant that the performance requirements would be met. The assumptions used in calculating the grant date fair value of these awards are set forth in Note 17 to our audited consolidated financial statements included in this prospectus.

(3) The amounts in this column represent performance bonuses earned by the named executive officers in the calendar year 2016 based upon the achievement of pre-established performance objectives. See "- Annual Bonus Compensation" below.

(4) Includes Company contributions to the named executive officer's 401(k) plan account (\$16,200) and disability insurance benefits (\$8,569).

(5) Includes Company contributions to the named executive officer's 401(k) plan account (\$16,200) and disability insurance benefits (\$2,658).

(6) Includes Company contributions to the named executive officer's 401(k) plan account (\$16,200) and disability insurance benefits (\$3,415).

(7) Includes Company contributions to the named executive officer's 401(k) plan account (\$16,200) and disability insurance benefits (\$5,390).

(8) Mr. Maxwell commenced his employment on January 9, 2017.

(9) Includes a sign-on bonus of \$70,000 paid to Mr. Maxwell upon commencement of his employment on January 9, 2017 pursuant to his employment agreement.

### Narrative to the Summary Compensation Table

Our Compensation Committee reviews compensation annually for our named executive officers and uses base salaries to recognize the experience, skills, knowledge and responsibilities required of our named executive officers. In setting executive base salaries and bonuses, we consider compensation for

comparable positions in the market, the historical compensation levels of our executives, individual performance as compared to our expectations and objectives, our desire to motivate our executives to achieve short-and long-term results that are in the best interests of our stockholders, and a long-term commitment to our company. None of our named executive officers currently has an employment agreement or other agreement or arrangement that specifically provides for automatic or scheduled increases in base salary.

The Compensation Committee has historically determined our named executive officers' compensation and has typically reviewed and discussed, on an annual basis, management's proposed compensation with our president and chief executive officer for all our named executive officers (other than for our president and chief executive officer). Based on those discussions and its discretion, the Compensation Committee and our full board of directors then approved the compensation of each named executive officer. Upon the completion of this offering, the Compensation Committee will continue to determine our named executive officers' compensation following this process and will approve the compensation of each of our named executive officers.

# **Annual Base Salary**

Base salaries for our named executive officers are initially established through arm's-length negotiations at the time of the named executive officer's hiring, taking into account such named executive officer's qualifications, experience, prior salary, the scope of the named executive officer's responsibilities and competitive market compensation paid by other companies for similar positions within the industry. The chart below reflects the base salaries approved by our board of directors and Compensation Committee for our named executive officers during fiscal year ended December 31, 2017.

Name	2017 Base Salary (\$)
Keith J. Kendall	400,000
Daniel Barber	300,000
John T. Maxwell	350,000
A. Mark Schobel	350,000

### **Annual Bonus Compensation**

We have an annual objective-setting and review process for our named executive officers that is the basis for the determination of potential annual bonuses for our named executive officers. Our employment agreements with our named executive officers provide that they will be eligible for annual performance-based bonuses up to a specific target percentage of their salary based on the Compensation Committee's assessment of their and the Company's performance against goals established by the Compensation Committee. Our Compensation Committee sets our annual objectives which are based in part on our revenue and EBITDA for the year as well as the individual objectives of each employee which are focused on each employee's specific performance relative to the Company's achievements as a whole.

The target bonus opportunities for our named executive officers for fiscal year 2017, expressed as a percentage of their annual base salary, were 75% for Mr. Kendall, 35 % for Mr. Barber, 50% for Mr. Maxwell and 75% for Mr. Schobel.

As previously discussed, our Compensation Committee sets our annual objectives which are based in part on our revenue and EBITDA for the year as well as the individual objectives of each employee which are focused on each employee's specific performance relative to the Company's achievements as a whole. The Compensation Committee determined that the Company achieved the annual objectives for the fiscal year 2017.

#### **Executive Bonus Plan**

Prior to the consummation of this offering, we intend to adopt the Aquestive Therapeutics Executive Bonus Plan, or the "Bonus Plan". The Bonus Plan provides additional cash compensation, referred to as "Bonuses," to selected employees of the Company and its subsidiaries based on the achievement of

performance goals. The Bonus Plan will be administered by our Compensation Committee. The following is a summary of the material terms of the Bonus Plan. In the event of a conflict between this summary and the Bonus Plan, the terms of the Bonus Plan will control.

### Performance Goals

Bonuses will be subject to the achievement of one or more performance goals within a specified performance period. The Compensation Committee will establish performance goals for each participant for each performance period as well as the method for computing Bonuses. Performance goals are established by the Compensation Committee in its sole discretion at a time when the attainment of performance goals is substantially uncertain. Performance goals may be described in terms of Company-wide objectives or objectives related to the performance goals may be based on any criteria determined by the Compensation Committee, including, without limitation, financial measures, regulatory body approvals for commercialization of products, implementation or completion of critical projects or related milestones, or partnering or similar transactions. The Compensation Committee is authorized to make adjustments in the terms and conditions of, and the criteria included in performance goals, in recognition of unusual or nonrecurring events affecting the Company or any of our subsidiaries, or in response to changes in applicable laws, regulations, or accounting principles.

#### Payment of Bonuses

Payment of any Bonus will be contingent upon certification by the Compensation Committee that the applicable performance goals were achieved. Bonuses will be paid in cash no later than 74 days after the end of the performance period with respect to which the Bonus is earned. Except as the Compensation Committee may determine otherwise in connection with special circumstances, no participant will have any right to receive any Bonus unless the participant remains employed by the Company or a subsidiary through the date of payment of such Bonus.

#### Amendment and Termination

Our board of directors may at any time and without the consent of any participant, amend or terminate the Bonus Plan, whether prospectively or retroactively, including in any manner that adversely affects the rights of participants.

#### **Employment Agreements with Our Named Executive Officers**

We entered into an employment agreement with each of Keith J. Kendall, our President and Chief Executive Officer, and A. Mark Schobel, our Chief Innovation and Technology Officer, on November 17, 2008. We entered into an employment agreement with John T. Maxwell, our Chief Financial Officer, on January 9, 2017. These agreements set forth the initial terms and conditions of each executive's employment with us, including base salary, target annual bonus opportunity and standard employee benefit plan participation. These employment agreements provide for "at will" employment. The material terms of these employment agreements with our named executive officers are described below. The terms "cause," "good reason" and "change in control" referred to below are defined in each named executive officer's employment agreement. We have yet not entered into an employment agreement with Daniel Barber. Prior to the consummation of this offering, we intend to enter into an employment agreement with Daniel Barber in the same form as our employment agreement with John T. Maxwell, with any differences in such terms to be fully described in an amendment to this Registration Statement.

# Keith J. Kendall

The term of employment for Mr. Kendall under his employment agreement renews annually, unless we give him prior written notice of non-renewal or until his employment with us terminates for any reason. Mr. Kendall's base salary for 2017 was equal to \$400,000, his annual target incentive compensation is equal to 75% of his base salary, and he is eligible to participate in our benefit plans as in effect from time to time. His base salary and target bonus opportunity is subject to annual review and adjustment. His



bonus award will be made at the discretion of the Compensation Committee. His employment agreement provides that he agrees to grant us certain intellectual property rights. His employment agreement includes additional provisions that require him to refrain from competing with our business, soliciting or interfering with our suppliers, customers, prospective customers and other business relationships, and from soliciting, hiring or otherwise interfering with our relationship with any person employed or previously employed by us, with the duration of such restrictions to last during his employment and for 18 months thereafter. Pursuant to his employment agreement, upon the effectiveness of this offering, Mr. Kendall is entitled to receive (i) stock appreciation rights equal to 5% of our common stock outstanding following the consummation of this offering on a fully diluted basis or of common stock he received upon the termination of our PUP Plans in April 2018 and (ii) restricted stock equal to 0.24% of our common stock outstanding following the consummation of this offering on a fully diluted basis or shares of restricted stock, each of which will be granted under the 2018 Plan. The stock appreciation rights will vest in 36 equal monthly installments beginning on the last day of the month next following the month in which this offering is completed and the restricted stock will vest in eight equal quarterly installments beginning on the last day of the month next following the month in which this offering is completed.

In the event Mr. Kendall's employment is terminated by the Company for "cause", he will be entitled to receive his salary and benefits that had accrued but had remained unpaid through the date of termination, or the Accrued Payments.

In the event that Mr. Kendall's employment is terminated by reason of death or disability, in addition to the Accrued Payments, he will be entitled to a cash payment consisting of an amount equal to (i) his unpaid annual bonus earned for the year preceding the year in which his employment terminated, (ii) any accrued and unused vacation pay for the year in which his employment terminated, (iii) a portion of his target annual bonus for the year in which his employment terminated, pro-rated for the number of days he was employed during the year in which his employment terminated, and (iv) accelerated vesting of his outstanding unvested equity-based compensation awards as if he had continued being employed through the end of the year in which his employment terminated, or, in the case of awards subject to "cliff vesting," pro-rata accelerated vesting based on the percentage of the vesting period that had elapsed as of the date of his termination. Additionally, Mr. Kendall will be able to exercise any equity awards that vest upon the termination of his employment for one year following such termination.

In the event that Mr. Kendall's employment is terminated by us without "cause" or he terminates his employment for "good reason", and subject to the delivery of a fully effective release of claims and continued compliance with his restrictive covenant obligations, in addition to the Accrued Payments, he will be entitled to receive (i) a cash payment of an amount equal to his unpaid annual bonus earned for the year preceding the year in which his employment terminated, (ii) a cash payment of an amount equal to any accrued and unused vacation pay for the year in which his employment terminated, (iii) a cash payment consisting of an amount equal to a portion of his target annual bonus for the year in which his employment terminated, pro-rated for the number of days he was employed during the year in which his employment terminated, (iv) monthly payments for a period of 18 months following the termination of his employment, with each monthly payment equal to 1/12 of the sum of his base salary and target annual bonus, (v) for 18 months following the termination of his employment, continuing coverage under our group health and life insurance plans in which he was a participant immediately prior to the termination of his employment, at the same levels and on the same terms and conditions as are provided to similarly situated executives, and (vi) full and immediate vesting of all outstanding unvested equity-based compensation awards, and any equity compensation awards that are or become vested upon termination of his employment remain exercisable for at least one year after the date of termination or, if earlier, until the expiration of the stated term of the award.

If Mr. Kendall's employment is terminated by us without "cause" or he terminates his employment for good reason, in each case during the period beginning 180 days before and ending 24 months following the effective date of a change in control, then subject to the delivery of a fully effective release of claims and continued compliance with his respective restrictive covenant obligations, he will be entitled to all the severance that he would have received had his employment been terminated by the Company not for cause or by him for good reason, provided that, in lieu of the payments described in section (iv) of the

paragraph immediately above, Mr. Kendall will be entitled to receive an immediate lump sum cash payment of an amount equal to 2.75 times the sum of his base salary and target annual bonus, and, with respect to the benefit continuation described in section (v) of the paragraph immediately above, such benefits shall continue for a period of 33 months following termination.

Additionally, pursuant to his employment agreement, in the event that payments to or for the benefit of Mr. Kendall relating to a change in control would be subject to an excise tax imposed by Section 4999 of the Internal Revenue Code, the aggregate amount of such payments will be increased so that, after the payment of taxes, he will be in the same position as he would have been had he not been required to pay such excise taxes. Additionally, in the event that the continuation of coverage under our group health plan triggers taxable income to Mr. Kendall, the Company will pay him additional cash payments as are necessary for him to receive the same net after-tax benefits that he would have received under such plans if he had continued to receive such plan benefits while employed with the Company.

Under the terms of the PUP Plans prior to its termination, all awards granted thereunder become fully vested and payable upon a change in control.

### John T. Maxwell

The term of employment for Mr. Maxwell under his employment agreement ends on January 9, 2019, and will thereafter renew annually unless we give prior written notice of non-renewal or until Mr. Maxwell's employment with us terminates for any reason. Mr. Maxwell's base salary for 2017 was \$350,000, his annual target incentive compensation is equal to 50% of his base salary, and he is eligible to participate in our benefit plans as in effect from time to time. His base salary and target bonus opportunity is subject to annual review and adjustment. His bonus award will be made at the discretion of the Compensation Committee. Mr. Maxwell was entitled to a one-time lump sum signing bonus of \$70,000, which was paid with the first regular payroll following the effective date of his employment agreement. His employment agreement provides that he agrees to grant us certain intellectual property rights. His employment agreement includes additional provisions that require him to refrain from competing with our business, soliciting or interfering with our suppliers, customers, prospective customers and other business relationships, and from soliciting, hiring or otherwise interfering with our relationship with any person employed or previously employed by us, with the duration of such restrictions to last during his employment and for 12 months thereafter.

In the event Mr. Maxwell's employment is terminated by the Company for "cause, he will be entitled to receive Accrued Payments through the date of termination.

In the event that Mr. Maxwell's employment is terminated by reason of death or disability, in addition to the Accrued Payments, he will be entitled to a cash payment consisting of an amount equal to a portion of the bonus he received for the year prior to the year of his termination, pro-rated for the number of days he was actively working during the year of termination through the effective date of termination.

In the event that Mr. Maxwell's employment is terminated by us without "cause" or he terminates his employment for "good reason, and subject to the delivery of a fully effective release of claims and continued compliance with his restrictive covenant obligations, in addition to the Accrued Payments, he will be entitled to (i) continued base salary for a period of 12 months, in equal installments in accordance with our normal payroll practices and (ii) for a period of 12 months following the termination of his employment continuing coverage under our group health and life insurance plans in which he was a participant immediately prior to the termination of his employment.

Under the terms of our Performance Unit Plans, or PUP Plans, prior to its termination, all awards granted thereunder become fully vested and payable upon a change in control.

### A. Mark Schobel

The term of employment for Mr. Schobel under his employment agreement renews annually, unless we give him prior written notice of non-renewal or until his employment with us terminates for any reason. Mr. Schobel's base salary for 2017 was equal to \$350,000, his annual target incentive compensation is equal to 75% of his base salary, and he is be eligible to participate in our benefit plans as in effect from time to time. His base salary and target bonus opportunity is subject to annual review and adjustment. His

bonus award will be made at the discretion of the Compensation Committee. His employment agreement provides that he agrees to grant us certain intellectual property rights. His employment agreement includes additional provisions that require him to refrain from competing with our business, soliciting or interfering with our suppliers, customers, prospective customers and other business relationships, and from soliciting, hiring or otherwise interfering with our relationship with any person employed or previously employed by us, with the duration of such restrictions to last during his employment and for 18 months thereafter. Pursuant to his employment agreement, upon the effectiveness of this offering, Mr. Schobel is entitled to receive (i) stock appreciation rights equal to 5% of our common stock outstanding following the consummation of this offering on a fully diluted basis, or stock appreciation rights, minus any shares of common stock he received upon the termination of our PUP Plans in April 2018 and (ii) restricted stock equal to 0.47% of our common stock outstanding following the consummation of this offering on a fully diluted under the 2018 Plan. The stock appreciation rights will vest in 36 equal monthly installments beginning on the last day of the month next following the month in which this offering is completed.

In the event Mr. Schobel's employment is terminated by the Company for "cause," he will be entitled to receive Accrued Payments through the date of termination.

In the event that Mr. Schobel's employment is terminated by reason of death or disability, in addition to the Accrued Payments, he will be entitled to a cash payment consisting of an amount equal to (i) his unpaid annual bonus earned for the year preceding the year in which his employment terminated, (ii) any accrued and unused vacation pay for the year in which his employment terminated, (ii) any accrued and unused vacation pay for the year in which his employment terminated, (ii) any accrued and unused vacation pay for the year in which his employment terminated, pro-rated for the number of days he was employed during the year in which his employment terminated, and (iv) accelerated vesting of his outstanding unvested equity-based compensation awards as if he had continued being employed through the end of the year in which his employment terminated, or, in the case of awards subject to "cliff vesting," pro-rata accelerated vesting based on the percentage of the vesting period that had elapsed as of the date of his termination. Additionally, Mr. Schobel will be able to exercise any equity awards that vest upon the termination of his employment for one year following such termination.

In the event that Mr. Schobel's employment is terminated by us without "cause" or he terminates his employment for "good reason," and subject to the delivery of a fully effective release of claims and continued compliance with his restrictive covenant obligations, he will be entitled to receive (i) a cash payment of an amount equal to his unpaid annual bonus earned for the year preceding the year in which his employment terminated, (ii) a cash payment of an amount equal to any accrued and unused vacation pay for the year in which his employment terminated, (iii) a cash payment consisting of an amount equal to a portion of his target annual bonus for the year in which his employment was terminated, pro-rated for the number of days he was employed during the year in which his employment terminated, (iv) monthly payments for a period of 18 months following the termination of his employment, with each monthly payment equal to 1/12 of the sum of his base salary and target annual bonus, (v) for 18 months following the termination of his employment, continuing coverage under our group health and life insurance plans in which he was a participant immediately prior to the termination of his employment, at the same levels and on the same terms and conditions as are provided to similarly situated executives, and (vi) full and immediate vesting of all outstanding unvested equity-based compensation awards, and any equity compensation awards that are or become vested upon termination of his employment remain exercisable for at least one year after the date of termination or, if earlier, until the expiration of the stated term of the award.

If Mr. Schobel's employment is terminated by us without cause or he terminates his employment for good reason, in each case during the period beginning 180 days before and 24 months following the effective date of a change in control, then subject to the delivery of a fully effective release of claims and continued compliance with his respective restrictive covenant obligations, in addition to the Accrued Payments he will be entitled to all the severance that he would have received had his employment been terminated by the Company not for cause or by him for good reason, provided that, in lieu of the payments described in section (iv) of the paragraph immediately above, Mr. Schobel will be entitled to

receive an immediate cash payment of an amount consisting of three times the sum of his base salary and target annual bonus, and, with respect to the benefit continuation described in section (v) of the paragraph immediately above, such benefits shall continue until the third anniversary of such date of termination.

Additionally, pursuant to his employment agreement, in the event that payments to or for the benefit of Mr. Schobel relating to a change in control would be subject to an excise tax imposed by Section 4999 of the Internal Revenue Code, the aggregate amount of such payments will be increased so that, after the payment of taxes, he will be in the same position as he would have been had he not been required to pay such excise taxes. Additionally, in the event that the continuation of coverage under our group health plan triggers taxable income to Mr. Schobel, the Company will pay him additional cash payments as are necessary for him to receive the same net after-tax benefits that he would have received under such plans if he had continued to receive such plan benefits while employed with the Company.

Under the terms of the PUP Plan prior to its termination, all awards granted thereunder become fully vested and payable upon a change in control.

# Outstanding Equity Awards at December 31, 2017

The following table provides information about the number of outstanding equity awards held by our named executive officers at December 31, 2017.

		Stock Awards	
Name	Grant Date	Equity Incentive Plan Awards: Number of Unearned Shares, Units or Other Rights That Have Not Vested (#) <sup>(1)</sup>	Equity Incentive Plan Awards: Market Value of Unearned Shares, Units or Other Rights That Have Not Vested (\$) <sup>(2)</sup>
Keith J. Kendall	January 13, 2017	122,162	35,857
	January 1, 2017	2,443,249	717,377
	December 18, 2015	202,201	66,453
	August 1, 2010	2,392,698	1,000,217
	October 21, 2008	2,462,136	1,275,257
	June 16, 2006	4,715,961	1,934,023
Daniel Barber	January 2, 2017	824,143	241,981
	December 1, 2011	125,000	49,188
	October 1, 2010	100,000	41,803
	October 1, 2008	171,857	97,458
John T. Maxwell	January 9, 2017	1,710,274	589,837
A. Mark Schobel	January 13, 2017	122,162	35,857
	December 18, 2015	252,750	83,066
	August 1, 2010	2,392,698	1,000,217
	October 21, 2008	3,282,848	1,700,342
	September 21, 2006	2,453,872	882,036
	June 16, 2006	114,755	47,061
	March 22, 2006	91,175	55,135
	February 13, 2006	1,468,235	887,877
	November 17, 2005	2,159,910	1,476,596

(1) PUP awards vest at varying rates from immediate to time-based over three years, depending on the specific grant and the agreement with the employee. Upon termination of the PUP Plans, vesting of all outstanding awards was accelerated. None of these grants are payable until certain performance conditions have been met, and none of these conditions were met as of this date. The PUP Plans were terminated in April 2018, effective January 1, 2010, and all amounts were paid out to the participants.

(2) Market value is based on a third party valuation of the Company as of December 31, 2017 and is net of the base value of each grant.

# Equity-Based Incentive Awards

Historically, the equity-based awards we granted to our named executive officers were units in our PUP Plans. The purpose of the PUP Plans, which was originally instituted by us in 2004 when we were organized as a limited liability company, was to reward executives and employees for appreciation in the enterprise value of Aquestive.

Under the PUP Plans, a grantee would receive a grant of units that would entitle him or her to a percentage of the appreciation in value of the Company above a base value. Units granted under the PUP Plans are not actual equity securities in the Company and did not convey any ownership interest on the grantee unless and until they were settled in securities. These grants would vest over time and on a distribution event (*e.g.* change of control, initial public offering or dissolution or liquidation of the Company), could be settled in cash or equity securities.

With respect to the 2017 fiscal year, the Company granted the number of units under the PUP Plans to the named executive officers as set forth in the table below. These units vest over three years, generally subject to the named executive officer's continued employment with us on the applicable vesting date (except as provided above in the section titled "Employment Agreements with Our Named Executive Officers").

		Base Value
Named Executive Officer	Number of Units Granted	Per Unit (\$)
Mr. Kendall	2,565,412	116,261,261
Mr. Barber	824,143	116,244,973
Mr. Maxwell	1,710,274	103,594,973
Mr. Schobel	122,162	116,269,405

Our board of directors authorized the termination of the PUP Plans in April 2018. In termination thereof, each award granted under the PUP Plans became fully vested and each award holder received the number of shares of our non-voting common stock equal to the number of units held without regard to the base value, plus an additional payment designed to compensate the grantee for any taxes owed with respect to the shares of non-voting common stock received upon such termination. These non-voting shares will become regular voting common stock at the time of the initial public offering. For our named executive officers, this resulted in the following distributions:

Named Executive Officer	Number of Shares of Non-Voting Common Stock Granted (#)	Other Payment Amounts (\$)
Mr. Kendall	12,338,408	1,642,241
Mr. Barber	1,221,000	94,660
Mr. Maxwell	1,710,274	135,823
Mr. Schobel	12,338,405	1,642,241

Following this offering, we expect to grant equity incentive compensation to our employees, including the named executive officers, pursuant to the 2018 Plan, which is described in detail below in the section titled "2018 Plan." Although we do not have a formal policy with respect to the grant of equity incentive awards to our named executive officers, or any formal equity ownership guidelines applicable to them, we believe that equity grants will provide our named executive officers with a strong link to our long-term performance, create an ownership culture and help to align the interests of our named executive officers and our stockholders. In addition, we believe that equity grants with a time-based vesting feature will promote executive retention because this feature incentivizes our named executive officers to remain in our employment during the vesting period. Accordingly, our Compensation Committee plans to periodically review the equity incentive compensation of our named executive officers and from time to time expects to grant equity incentive awards.

# 2018 Equity Incentive Plan

Prior to the consummation of this offering, we intend to adopt the 2018 Plan. The purpose of the 2018 Plan is to assist the Company and its subsidiaries in attracting and retaining valued employees,



consultants and non-employee directors by offering them a greater stake in our success and a closer identity with us, and to encourage ownership of the Company's common stock by such employees, consultants and non-employee directors. Under the 2018 Plan, we may grant awards in respect of shares of common stock, or Awards, to employees, directors and consultants of the Company and its subsidiaries. Awards may consist of options, stock appreciation rights, or SARs, restricted stock, restricted stock units, or RSUs, performance stock, performance stock units, or PSUs, and other stock-based awards. Each Award will be governed by the provisions of the 2018 Plan and the applicable award agreement. The following is a summary of the material terms of the 2018 Plan. In the event of a conflict between this summary and the 2018 Plan, the terms set forth in the 2018 Plan shall control.

## Eligibility

Any employee, director or consultant of the Company or any of its subsidiaries is eligible to receive Awards under the 2018 Plan.

### Administration

The 2018 Plan will be administered by the Compensation Committee. Awards granted to non-employee members of the board of directors shall be administered by the board of directors. The Compensation Committee will have full and final authority in its discretion to: (i) select the employees, non-employee directors and consultants who will receive Awards, provided that Awards to non-employee directors will be subject to ratification by the board of directors; (ii) determine the type or types of Awards to be granted to each participant; (iii) determine the number of shares to which an Award will relate, the terms and conditions of any Award (including, but not limited to, restrictions as to vesting, performance goals relating to an Award, transferability or forfeiture, exercisability or settlement of an Award, waivers or accelerations thereof and waivers of or modifications to performance goals relating to an Award) and all other matters to be determined in connection with an Award; (iv) determine the strike price, grant price or purchase price (if any) of an Award: (v) determine whether, to what extent, and under what circumstances an Award may be cancelled, forfeited, or surrendered: (vi) determine whether, and to certify that, performance goals to which an Award is subject are satisfied; (vii) determine whether participants will be permitted to defer the settlement of certain Awards; (viii) correct any defect or supply any omission or reconcile any inconsistency in the 2018 Plan and Award agreements thereunder, and to adopt, amend and rescind such rules, regulations, guidelines, forms of agreements and instruments as, in its opinion, may be advisable; (ix) construe and interpret the 2018 Plan and Award agreements thereunder, and (x) make all other determinations as it may deem necessary or advisable for the administration of the 2018 Plan and Award agreements. The Compensation Committee may delegate some or all of its powers to any of our executive officers or any other person, other than its authority to grant awards to certain individuals (such as board members and executive officers).

# Shares Available Under the 2018 Plan

Subject to adjustment as provided in the 2018 Plan, the total number of shares available for Awards under the 2018 Plan as of the effective date of the 2018 Plan shall be , or the Plan Limit; provided, however, that on January 1, 2019 and each January 1<sup>st</sup> thereafter prior to the termination of the 2018 Plan, the Plan Limit shall be increased by the lesser of (x) 4.0% of the number of shares of common stock outstanding as of the immediately preceding December 31<sup>st</sup> and (y) such lesser number as the board of directors may determine in its discretion. Up to shares available for Awards under the 2018 Plan may be issued pursuant to incentive stock options, or the ISO Limit, provided that on January 1, 2019 and each January 1<sup>st</sup> thereafter prior to the termination of the 2018 Plan, the ISO Limit shall be increased by the lesser of (x) % of the number of shares of common stock outstanding as of the immediately preceding December 31<sup>st</sup>, (y) shares and (z) such lesser number as the board of directors may determine in its discretion. The maximum value (determined as of the grant date) of shares underlying Awards granted to any nonemployee director on the board of directors during any calendar year is \$500,000, except that such limit shall be increased by 50% for the first calendar year in which a non-employee director is elected to the board of directors. For purposes of determining the number of shares available for Awards under the 2018 Plan, each stock-settled SAR shall count against the Plan Limit based on the number of shares underlying the exercised portion of such SAR rather than the

number of shares issued in settlement of such SAR. Any shares tendered, with the Committee's approval, by a participant in payment of an exercise price for an Award or the tax liability with respect to an Award, including shares withheld from any such Award, shall not be available for future Awards hereunder. Shares awarded under the Plan may be reserved or made available from the Company's authorized and unissued common stock or from common stock reacquired and held in the Company's treasury. Any shares issued by the Company through the assumption or substitution of outstanding grants from an acquired company shall not reduce the shares available for Awards under the 2018 Plan. If any shares subject to an Award under the 2018 Plan are forfeited or such Award otherwise terminates for any reason whatsoever without an actual distribution of shares to the participant, any shares counted against the number of shares available for issuance pursuant to the 2018 Plan with respect to such Award shall, to the extent of any such forfeiture or termination, be added back to the Plan Limit and shall again be available for Awards under the 2018 Plan; provided, however, that the Committee may adopt procedures for the counting of shares relating to any Award to ensure appropriate counting, avoid double counting, provide for adjustments in any case in which the number of shares actually distributed differs from the number of shares previously counted in connection with such Award, and if necessary, to comply with applicable law or regulations.

# Awards

Awards that can be granted under the 2018 Plan include restricted stock, RSUs, stock options, SARs, and other stock-based awards.

### **Performance Goals**

In the discretion of the Compensation Committee, the vesting, earning or settlement of any Award may be conditioned upon the achievement of specified performance goals that are substantially uncertain to be met during the applicable performance period at the time such goals are established.

# Types of Awards

*Options.* Options give a participant the right to purchase a specified number of shares from the Company for a specified time period at a fixed price. Options may be either ISOs or non-qualified options, however, ISOs may only be granted to employees of the Company and its subsidiaries. The price at which shares may be purchased upon exercise may not be less than the fair market value of one share on the grant date, or, in the case of an ISO granted to a more than ten percent stockholder, less than 110% of the fair market value of a share on the grant date. The Compensation Committee may grant options that have a term of up to ten years, or, in the case of an ISO granted to a more than ten percent stockholder, five years. The Award agreement will specify the exercise price, term, vesting requirements, including any performance goals, and any other terms and conditions applicable to the option.

Stock Appreciation Rights. A grant of a SAR entitles a participant to receive, upon exercise of the SAR, the excess of (i) the fair market value of one share on the date of exercise, over (ii) the grant price of the SAR as determined by the Compensation Committee. No payment from the participant is required upon the exercise of a SAR. The Compensation Committee will determine and specify in each Award agreement the number of SARs granted, the grant price of the SAR (which may not be less than 100% of the fair market value of a share on the grant date), the time or times at which a SAR may be exercised in whole or in part, the method by which shares will be delivered or deemed to be delivered to a participant, the term of the SAR (which may not be greater than 10 years) and any other terms and conditions of the SAR.

Restricted Stock. An Award of restricted stock is a grant of a specified number of shares, which shares are subject to forfeiture upon the occurrence of certain events during a specified restriction period. Each Award of restricted stock will specify the duration of the restriction period, the conditions under which the shares may be forfeited, and the amount, if any, the participant must pay to receive the shares. Generally, during the restriction period, the participant will have all of the rights of a stockholder with respect to the restricted stock, including the right to vote the shares of restricted stock and to receive dividends. However, dividends may, at the discretion of the Compensation Committee, be paid currently or subject to the same restrictions as the underlying stock (and the Compensation Committee may



withhold cash dividends paid on restricted stock until the applicable restrictions have lapsed), provided that, dividends paid on unvested restricted stock that is subject to performance goals will not be paid or released until the applicable performance goals have been achieved.

Restricted Stock Units. An Award of RSUs is a grant of the right to receive a payment in shares or cash, or a combination thereof, equal to the fair market value of a share on the applicable settlement date. RSUs are solely a device for determining amounts to be paid to a participant, do not constitute shares, and will not be treated as a trust fund of any kind. Prior to the settlement of an award and the receipt of shares, the participant will have no rights as a stockholder with respect to any such shares. Notwithstanding the previous sentence, the Compensation Committee may provide in an Award agreement that amounts equal to dividends declared during the restriction period on the shares covered by the Award will be credited to the participant's account and settled in shares at the same time as the RSUs to which such dividend equivalents relate. Awards of RSUs will be settled in shares, unless otherwise provided in an Award agreement. Unless otherwise provided in an Award Agreement, subject to the Participant's continued employment or other service with us from the grant date through the expiration of the restriction period, the vested portion of an Award of RSUs will be settled within 60 days after the expiration of the restriction period.

*Performance Stock.* An Award of performance stock generally is the same as an Award of restricted stock, as described above, but vesting is conditional on the achievement of one or more performance goals during a performance period.

*Performance Stock Units.* An Award of PSUs generally is the same as an Award of restricted stock units, as described above, but vesting and settlement are conditional on the achievement of one or more performance goals during a performance period.

Other Stock-Based Awards. The Compensation Committee may grant, subject to applicable law, any other type of Award under the 2018 Plan that is payable in, or valued in whole or in part by reference to, shares, and that is deemed by the Compensation Committee to be consistent with the purposes of the 2018 Plan, including, without limitation, fully vested shares and dividend equivalents.

# Termination of Employment of Service

Unless otherwise provided in an Award agreement or an effective employment, consulting, severance or similar agreement with the Company or a subsidiary, or as otherwise provided below in the section titled "Change in Control and Other Corporate Transactions," upon a participant's termination of employment or service, the unvested portion of such participant's Awards will cease to vest and will be forfeited (with no compensation due to the participant) and the vested portion of such participant's options and SARs will remain exercisable for a period of (i) 90 days in the event of a termination for cause, (ii) one year in the event of a termination (a) due to death or disability, (b) by the Company or a subsidiary without Cause, (c) by the participant for good reason, or (d) as the result of the participant's retirement, and (iii) six months in the event of a participant's resignation without good reason and not due to retirement; provided, however, no option or SAR will be exercisable after its stated term has expired.

#### Change in Control and Other Corporate Transactions

Unless otherwise provided in an Award agreement or an effective employment, consulting, severance or other similar agreement with the Company or one of its subsidiaries, a change in control will not, in and of itself, accelerate the vesting, settlement, or exercisability of outstanding Awards. Notwithstanding the foregoing and unless otherwise provided in an Award agreement or an effective employment, consulting, severance or similar agreement with the Company or a subsidiary, if (i) the successor corporation (or its direct or indirect parent) does not agree to assume an outstanding Award or does not agree to substitute or replace such Award, in either case, with an award involving the registered and publicly traded ordinary equity securities of such successor corporation (or its direct or indirect parent) on terms and conditions necessary to preserve the rights of the applicable participant with respect to such Award or (ii) the change in control is not approved by a majority of the board of directors immediately prior to such change in control, then the Compensation Committee, in its sole discretion, may take one or more of the following actions with respect to all, some or any such Awards: (a) accelerate the vesting and, if applicable, exercisability of such Awards such that the Awards are fully vested and, if applicable, exercisable

(effective immediately prior to such change in control); (b) with respect to any Awards that do not constitute "nongualified deferred compensation" within the meaning of Section 409A of the Code, accelerate the settlement of such Awards upon such change in control; (c) with respect to Awards that constitute "non-qualified deferred compensation" within the meaning of Section 409A of the Code, terminate all such Awards and settle all such Awards for a cash payment equal to the fair market value of the shares underlying such Awards less the amount the participant is required to pay for such shares, if any, provided that (I) such change in control satisfies the requirements of Treasury Regulation Section 1.409A-3(i)(5)(v), (vi) or (vii) and (II) all other arrangements that would be aggregated with such Awards under Section 409A of the Code are terminated and liquidated within 30 days before or 12 months after such change in control; (d) cancel outstanding options or SARs in exchange for a cash payment in an amount equal to the excess, if any, of the fair market value of the shares underlying the unexercised portion of the option or SAR as of the date of the change in control over the exercise price or grant price, as the case may be, of such portion, provided that any option or SAR with a per share exercise price or grant price, as the case may be, that equals or exceeds the fair market value of one share on the date of the change in control will be cancelled with no payment due the participant; and (e) take such other actions as the Compensation Committee deems appropriate. If any action is taken with respect to any Award under items (a) through (e) and such Award is subject to performance goals, such performance goals shall be deemed satisfied based on the actual level of achievement of the applicable performance goals through the date of the change in control or, if determined by the Compensation Committee in its sole discretion prior to such change in control, using the applicable target level of achievement rather than such actual level of achievement.

Unless provided otherwise in an Award agreement, or an effective employment, consulting, severance or other similar agreement, or as otherwise may be determined by the Compensation Committee prior to a change in control, in the event that Awards are assumed in connection with a change in control or substituted with new awards, and a participant's employment or other service with the Company and its subsidiaries is terminated by the Company without cause or due to disability, as the result of the participant's death or by the participant for good reason, in any case, within 24 months following a change in control, then generally (i) the unvested portion of such participant's Awards will vest in full (with any applicable performance goals being deemed to have been achieved at target or, if greater, actual levels of performance), (ii) Awards of options and SARs will remain exercisable by the participant or the participant's beneficiary or legal representative, as the case may be, for a period of one-year (but not beyond the stated term of the option or SAR), (iii) all RSUs and PSUs will be settled within 30 days after such termination and (iv) all other stock-based awards will be settled within 30 days after such termination.

In the event of a share dividend, recapitalization, forward share split, reverse share split, reorganization, spin-off, extraordinary or unusual cash distribution, or other similar non-reciprocal corporate transaction or event between the Company and its shareholders, the Compensation Committee will make equitable adjustments in (i) the number and kind of shares which may thereafter be issued in connection with Awards, (ii) the number and kind of shares issuable in respect of outstanding Awards, (iii) the aggregate number and kind of shares available under the 2018 Plan, and (iv) the exercise or grant price relating to any Award, or if deemed appropriate, the Compensation Committee may also make provision for a cash payment with respect to any outstanding Award.

# **Clawback and Recoupment**

Any Award granted under the 2018 Plan (and all shares acquired thereunder) will be subject to mandatory repayment and clawback pursuant to the terms of the Company's clawback policy, if any, and as may otherwise be required by any federal or state laws or the rules of any applicable securities exchange. Additional recoupment and clawback policies may be provided in the participant's Award agreement.

# **Restrictions on Transfer**

Generally, the 2018 Plan prohibits participants from pledging, encumbering, assigning or transferring any Award, right or interest under the 2018 Plan, except for assignments or transfers that occur by way of the laws of descent and distribution. Awards and rights under the 2018 Plan will be exercisable during the

life of a participant only by the participant or his legal guardian. However, to the extent permitted by the law and the rules of any applicable stock exchange, non-qualified options, SARs, performance stock and/or restricted stock and any other Award that is not "deferred compensation" within the meaning of Section 409A of the Code may be transferred without consideration to certain immediate family members of the participant, to trusts for the benefit of the participant and/or such family members are the only partners.

### Non-U.S. Participants

Without amending the 2018 Plan, Awards may be granted to participants who are foreign nationals or are employed or providing services outside the United States or both, on such terms and conditions different from those specified in the 2018 Plan as may, in the judgment of the Compensation Committee, be necessary or desirable to further the purpose of the 2018 Plan. Moreover, the Compensation Committee may approve such supplements to, or amendments, restatements or alternative versions of, the 2018 Plan as it may consider necessary or appropriate for such purposes without thereby affecting the terms of the 2018 Plan as in effect for any other purpose.

# Amendment and Termination

The board of directors may amend, alter, suspend, discontinue or terminate the 2018 Plan without the consent of our stockholders, except that the board of directors must obtain stockholder approval for actions that would: (i) increase the number of shares subject to the 2018 Plan; (ii) decrease the price at which Awards may be granted; or (iii) require stockholder approval under any applicable federal, state or foreign law or regulation or the rules of any stock exchange or automated quotation system on which shares are then listed or quoted. However, without prior written consent of an affected participant, no amendment, alteration, suspension, discontinuation or termination of the 2018 Plan may materially and adversely affect the rights of a participant under any outstanding Award unless such action is required by law or regulation, or the rules of any applicable securities exchange or automated quotation system. No underwater Option or underwater SAR may be repriced, replaced or regranted through cancellation or purchased for cash without the approval of our stockholders.

Unless earlier terminated, the 2018 Plan will terminate with respect to the grant of new Awards on the earlier of the 10-year anniversary of the effective date of the 2018 Plan or the 10-year anniversary of the date the 2018 Plan was approved by the board of directors.

### Employee Stock Purchase Plan

Prior to the consummation of this offering, we intend to adopt the Aquestive Therapeutics, Inc. Employee Stock Purchase Plan, referred to as the "ESPP." The ESPP allows eligible employees to purchase shares of our common stock at a discount with accumulated elective payroll deductions. The following is a summary of the material terms of the ESPP. In the event of a conflict between this summary and the plan document for the ESPP, the plan document will control.

A committee appointed by our board of directors will have the exclusive power and authority to administer the ESPP, including, without limitation, the power to interpret the provisions of the ESPP, determine whether the Company or any parent or subsidiary will be designated as a participating company for any offering under the ESPP, and to make all other determinations for administering the ESPP. The ESPP includes a component that is intended to qualify as an employee stock purchase plan under Section 423 of the Code, and therefore provide participants with favorable tax treatment under the Code. In addition, the ESPP includes a component that is not intended to qualify as an employee stock purchase plan under Section 423 of the Code. The qualified component and non-qualified component are intended to operate together where possible. The committee administering the ESPP may adopt procedures and subplans as deemed necessary or appropriate to facilitate participation by eligible employees who are employed or located in a jurisdiction other than the United States.

# Eligible Employees

The ESPP will be offered to our employees and employees of any parent or subsidiary, in each case, that is designated as a "participating company." Generally, each employee of a participating company may participate in the ESPP except for: (i) employees who own (or are deemed to own) 5% or more of the

combined voting power or value of all our classes of shares or of all the classes of shares of any parent or subsidiary company; or (ii) employees who are citizens or residents of a jurisdiction (other than the United States) in which participation is prohibited by applicable law our would violate Section 423 of the Code.

#### Shares Available

We intend to initially reserve shares for sale under the ESPP. On each January 1 that the ESPP is in effect, the number of shares authorized for sale under the ESPP shall be increased by . These amounts are subject to adjustment to reflect stock splits, stock dividends, recapitalizations and similar corporate events.

# Offering Periods

Participants will be offered the option to purchase shares at a discount during an offering period, which is anticipated to be the semi-annual periods commencing on January 1 and ending on June 30 and commencing on July 1 and ending on December 31. However, the committee administering the ESPP may change the offering periods under the ESPP and may establish other offering periods as it deems appropriate (and different offering periods are not required to have identical terms).

# Purchase Price

The option purchase price per share will be the lower of 85% of the fair market value of one share on the first day of the offering period or 85% of the fair market value of one share on the last day of the offering period, and in all events, not less than the par value of one share.

#### Participation

Eligible employees may elect to contribute, on an after-tax basis, an amount that is at least [1]% but not more than 10% of the participant's eligible compensation. Unless a participant has previously withdrawn participation in the ESPP, as of the last day of each offering period, each participant will be deemed to have elected to purchase the number of whole shares that can be purchased at the purchase price with the participant's account balance. Notwithstanding the foregoing, a participant may not purchase shares at a rate that exceeds \$25,000 in fair market value of our shares (determined at the beginning of the offering period) for each calendar year in which any option granted to the participant is outstanding at any time. In addition, subject to adjustment by the committee administering the ESPP, a participant may not purchase more than shares in any offering period.

# Amendment and Termination

Generally, our board of directors may amend, suspend or terminate the ESPP at any time. Notwithstanding the foregoing, any increase in shares to be authorized for sale under the ESPP (other than increases or adjustments specified by the terms of the ESPP), shall be subject to approval by a vote of our shareholders. In addition, any other amendment to the ESPP shall be subject to approval by our shareholders to the extent required by applicable law, rule or regulation, or by the rules of any securities exchange on which our shares are traded or quoted. Unless assumed in a change in control, the ESPP will terminate on the day immediately prior to a change in control and all contributions then credited to participants' accounts will be used to purchase whole shares at the purchase price specified in the ESPP.

## Perquisites, Health, Welfare and Retirement Benefits

All of our current named executive officers are eligible to participate in our employee benefit plans, including our medical, dental and vision insurance plans, in each case on the same basis as all of our other employees.

# 401(k) Plan

We maintain a 401(k) retirement savings plan that provides eligible U.S. employees with an opportunity to save for retirement on a tax advantaged basis. Eligible employees may defer eligible compensation on a pre-tax basis, up to the statutorily prescribed annual limits on contributions under the

Code. The 401(k) plan provides us with the discretion to match employee contributions. During 2017, we made 100% matching contributions on up to 6% of an employee's eligible compensation deferred. These contributions vest in full after an employee has attained six years of service.

### **Non-Employee Director Compensation**

We provide cash and equity-based compensation to our non-employee directors for the time and effort necessary to serve as a member of our board of directors.

Upon the completion of this offering we expect to adopt a non-employee director compensation policy. Under this policy, we will pay each of our non-employee directors a cash retainer for service on the board of directors and for service on each committee on which the director is a member. The chairperson of each committee will receive a higher retainer for such service. These retainers will be payable in arrears in four equal quarterly installments on the last day of each quarter, provided that the amount of such payment will be prorated for any portion of such quarter that the director is not serving on our board of directors. The retainers to be paid to non-employee directors for service on the board of directors and for service on each committee of the board of directors on which the director is a member are expected to be as follows:

Name	An	nual Service Retainer	A	Chairperson dditional Retainer
Board of Directors	\$	40,000	\$	30,000
Audit Committee		10,000		20,000
Compensation Committee		7,000		15,000
Nominating and Corporate Governance Committee		5,000		10,000

In addition, under our non-employee director compensation policy to be effective upon the completion of this offering, each non-employee director elected to our board of directors after the completion of this offering are expected to receive an option to purchase shares of our common stock. The shares subject to each such stock option will vest monthly over a three-year period, subject to the director's continued service as a director. Further, on the date of each annual meeting of stockholders held after the completion of this offering, each non-employee director that continues to serve as a non-employee member on our board of directors are expected to receive an option to purchase

shares of our common stock. The shares subject to each such stock option will vest in full on the date that is 12 months after the grant date, subject to the director's continued service as a director. The exercise price of these options will equal the fair market value of our common stock on the date of grant.

This policy is intended to provide a total compensation package that enables us to attract and retain qualified and experienced individuals to serve as directors and to align our directors' interests with those of our stockholders.

# 2017 Director Compensation Table

The following table sets forth in summary form information concerning the compensation that we paid or awarded to our non-executive directors during the fiscal year ended December 31, 2017. Each of Mr. Kendall and Mr. Schobel served on our board of directors during 2017, but did not receive any additional compensation for their service as a director and therefore are not included in the table below. The compensation for Mr. Kendall and Mr. Schobel as an executive officer is set forth above under "—Summary Compensation Table."

Name	Fees Earned or Paid in Cash (\$) <sup>(1)</sup>	Stock Awards <sup>(2)</sup> (\$)	Total (\$)
Douglas Bratton	—	—	—
Gregory Brown, M.D.	41,000		41,000
John Cochran	_		
Santo Costa	41,000		41,000
James S. Scibetta	49,500	—	49,500

(1) These amounts represent fees paid to directors for board meetings and committee meetings. Neither Mr. Bratton nor Mr. Cochran received a fee for their service on our board of directors for the 2017 fiscal year because they represent the Bratton Capital Management Group.

(2) This column reflects the aggregate grant date fair value of the awards granted under the PUP Plans during 2017, calculated in accordance with FASB Accounting Standards Codification Topic 718 Compensation — Stock Compensation ("ASC Topic 718"), and assumes no forfeiture rate derived in the calculation of the grant date fair value of these awards. The assumptions used in calculating the grant date fair value of these awards are set forth in Note 17 to our audited consolidated financial statements included in this prospectus. Because of the contingency of the events that must occur in order for PUP Plan awards to be settled, no compensation expense was recorded because it was not probable at the time of grant that the performance requirements would be met. If, at the time of grant, such performance was probable, the grant date value of the PUP Plan awards granted in 2017 would have been \$31,376 for each of Messrs. Bratton, Cochran, Costa and Scibetta and Dr. Brown.

As of December 31, 2017, our non-employee directors held the following number of awards under our PUP Plans:

Non-Employee Director	Number of PUP Plan Awards (#)
Douglas Bratton	926,421
Gregory Brown, M.D.	926,421
John Cochran	926,426
Santo Costa	213,789
James S. Scibetta	71,263

As indicated above, our PUP Plans were terminated and liquidated in April 2018, effective January 1, 2018. As the result, our non-employee directors received the following number of shares of our non-voting common stock and bonus payments (or rights to future bonus payments):

Non-Employee Director	Number of Shares of Non-Voting Common Stock Granted (#)	Additional Payment Amount (\$)
Douglas Bratton	926,421	103,377
Gregory Brown, M.D.	926,426	103,377
John Cochran	926,421	103,377
Nancy Lurker <sup>(1)</sup>	—	—
Santo Costa	213,789	23,856
James S. Scibetta	71,263	7,952

<sup>(1)</sup> Ms. Lurker joined our board of directors in April 2018. Accordingly, she will not receive any shares of our non-voting common stock or bonus payments in connection with the termination of the PUP Plans.

# CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The following includes a summary of transactions since January 1, 2015 to which we have been a party, in which the amount involved in the transaction exceeded \$120,000, and in which any of our directors, executive officers or, to our knowledge, beneficial owners of more than 5% of our capital stock or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest, other than equity and other compensation, termination, change in control and other arrangements, which are described under "Compensation Discussion and Analysis."

# Share Issuances to Employers and Directors

### Series A-3 Preferred Interests Issuance

In December 2015, Aquestive, LLC, our parent and predecessor, issued 5,055,000 Series A-3 Preferred Interests to certain investors, including Monoline RXIII, L.P., who purchased 4,950,000 Series A-3 Preferred Interests for \$4,950,000. The Series A-3 Preferred Interests contain a conversion option exercisable upon the offering, giving the holder the right to convert the interests into shares of our common stock.

# PUP Plans

The PUP Plans of Aquestive, LLC were terminated in April 2018, with such termination deemed to be effective as of January 1, 2018. In connection with the termination of the PUP Plans and in lieu of cash, we plan to pay the equivalent value in shares of our common stock. Shares of common stock will be issued to directors, officers and key employees in the following amounts:

•	
Keith J. Kendall	12,338,408
Daniel Barber	1,221,000
Peter Boyd	610,000
John T. Maxwell	1,710,274
A. Mark Schobel	12,338,405
Theresa Wood	978,000
Douglas Bratton	926,421
Gregory Brown, M.D.	926,421
John Cochran	926,426
Santo Costa	213,789
James S. Scibetta	71,263

See "Executive and Director Compensation — Narrative to the Summary Compensation Table — Equity Incentive Plans — PUP Plans" for more information about the PUP Plans.

### **Employment Arrangements**

We have entered into or intend to enter into employment arrangements with our executive officers, as more fully described in "Executive and Director Compensation — Agreements with our Named Executive Officers," "— Incentive Compensation" and "— Potential Payments upon Termination or Change in Control."

# Indemnification Agreements

We intend to enter into indemnification agreements with each of our directors and executive officers, in addition to the indemnification provided for in our bylaws and our certificate of incorporation. These agreements, among other things, provide our directors and executive officers with contractual rights to indemnification and, in some cases, expense advancement in any action or proceeding arising out of their services as one of our directors or executive officers of any other company or enterprise to which the person provides services at our request. For more information regarding these agreements, see the section of this prospectus entitled "Executive and Director Compensation — Limitations on liability and indemnification matters."

# Policies and Procedures for Transactions with Related Persons

Prior to this offering, we have not had a formal policy regarding approval of transactions with related parties. We have adopted a related person transaction policy that sets forth our procedures for the identification, review, consideration and approval or ratification of related person transactions, which will become effective immediately upon the consummation of this offering. For purposes of our policy only, a "related-person transaction" will be defined as a transaction, arrangement or relationship (or any series of similar transactions, arrangements or relationships) in which we and any "related person" are participants involving an amount that exceeds \$120,000.

Transactions involving compensation for services provided to us as an employee, consultant or director will not be considered related-person transactions under this policy. A related person will be defined as any executive officer, director or a holder of more than 5% of our common stock, including any of their immediate family members and any entity owned or controlled by such persons.

Under the policy, where a transaction has been identified as a related-person transaction, management must present information regarding the proposed related-person transaction to our audit committee (or, where review by our audit committee would be inappropriate, to another independent body of our board of directors) for review. The presentation must include a description of, among other things, the material facts, the direct and indirect interests of the related persons, the benefits of the transaction to us and whether any alternative transactions are available. To identify related-person transactions in advance, we rely on information supplied by our executive officers, directors and certain significant stockholders. In considering related-person transactions, our audit committee or other independent body of our board of directors will take into account the relevant available facts and circumstances including, but not limited to:

- the risks, costs and benefits to us;
- the impact on a director's independence in the event the related person is a director, immediate family member of a director or an entity with which a director is affiliated;
- the terms of the transaction;
- the availability of other sources for comparable services or products; and
- the terms available to or from, as the case may be, unrelated third parties or to or from our employees generally.

The policy requires that, in determining whether to approve, ratify or reject a related person transaction, our audit committee, or other independent body of our board of directors, must consider, in light of known circumstances, whether the transaction is in, or is not inconsistent with, our best interests and those of our stockholders, as our audit committee, or other independent body of our board of directors, determines in the good faith exercise of its discretion. In the event a director has an interest in the proposed transaction, the director must recuse himself or herself from the deliberations and approval.

All of the transactions described above were entered into prior to the adoption of the written policy.

# PRINCIPAL STOCKHOLDERS

The following table sets forth information regarding beneficial ownership of our capital stock by:

- each person, or group of affiliated persons, known by us to beneficially own more than 5% of our common stock;
- each of our directors;
- · each of our named executive officers and key employees; and
- all of our current executive officers and directors as a group.

The number of shares beneficially owned by each entity, person, director or executive officer is determined in accordance with the rules of the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Under such rules, beneficial ownership includes any shares over which the individual has sole or shared voting power or investment power as well as any shares that the individual has the right to acquire within 60 days of

\_\_\_\_\_, 2018 through the exercise of any stock options or other rights. Except as otherwise indicated, and subject to applicable community property laws, the persons named in the table have sole voting and investment power with respect to all shares of common stock held by that person.

The table below does not give effect to the potential purchases by such stockholders in this offering.

The percentage of shares beneficially owned before the offering is computed on the basis of shares of our common stock outstanding as of , 2018. The percentage of shares beneficially owned after the offering is computed on the basis of shares of our common stock outstanding as of , 2018 which reflects shares of our common stock sold in the offering.

Except as otherwise noted below, the address for each person or entity listed in the table is c/o Aquestive Therapeutics, Inc., 30 Technology Drive, Warren, NJ 07059.

The percentages depicted in the table below account for:

- shares of common stock issuable immediately prior to the effective date of this offering pursuant to the automatic exercise of the Perceptive Warrants; and
- the distribution of our shares held by Aquestive Partners, LLC to the holders of interests in Aquestive Partners, LLC.

	Shares Beneficially Owned			
	Prior to the Offering		After the Offering	
	Number	%	Number	%
Five percent stockholders:				
		%		%
		%		%
		%		%
		%		%
		%		%
Directors, executive officers and key employees:				
Keith J. Kendall		%		%
Daniel Barber		%		%
Peter Boyd		%		%
John T. Maxwell		%		%
A. Mark Schobel		%		%
Theresa Wood		%		%
Douglas Bratton		%		%
Gregory Brown, M.D.		%		%
John Cochran		%		%
Santo Costa		%		%
Nancy Lurker		%		%
James S. Scibetta		%		%
All directors executive officers and key employees as a				
group (11 persons)		%		%

\* Represents beneficial ownership of less than 1%.

### DESCRIPTION OF CAPITAL STOCK

The following descriptions are summaries of the material terms of our restated certificate of incorporation and amended and restated bylaws, which will be effective upon consummation of this offering. The descriptions of the common stock and preferred stock give effect to changes to our capital structure that will occur immediately prior to the closing of this offering. We refer in this section to our restated certificate of incorporation as our certificate of incorporation, and we refer to our amended and restated bylaws as our bylaws.

### General

Upon the closing of this offering and the filing of our certificate of incorporation, our authorized capital stock will consist of 250,000,000 shares of common stock, par value \$0.001 per share, and 10,000,000 shares of preferred stock, par value \$0.001 per share. All of our authorized preferred stock upon the closing of this offering will be undesignated. The following is a summary of the rights of our common and preferred stock and some of the provisions of our certificate of incorporation and bylaws, which will become effective upon the closing of this offering and of the Delaware General Corporation Law. This summary is not complete. For more detailed information, please see our certificate of incorporation and bylaws, which are filed as exhibits to the registration statement of which this prospectus is a part, as well as the relevant provisions of the Delaware General Corporation Law.

# **Common Stock**

# **Outstanding Shares**

The holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of the stockholders. The holders of our common stock do not have any cumulative voting rights. Holders of our common stock are entitled to receive ratably any dividends declared by the board of directors out of funds legally available for that purpose, subject to any preferential dividend rights of any outstanding preferred stock. Our common stock has no preemptive rights, conversion rights or other subscription rights or redemption or sinking fund provisions.

### Voting Rights

Each holder of common stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders. The affirmative vote of holders of at least 66<sup>2/3</sup>% of the voting power of all of the then-outstanding shares of capital stock, voting as a single class, will be required to amend certain provisions of our certificate of incorporation, including provisions relating to amending our bylaws, the classified board, the size of our board, removal of directors, director liability, vacancies on our board, special meetings, stockholder notices, actions by written consent and exclusive jurisdiction, provided, however, that this restriction shall not apply to, and such 66<sup>2/3</sup>% vote shall not be required for, any such amendment, change or repeal approved by the affirmative vote of at least a majority of the then current duly elected board of directors, in which case such action shall require only the vote of shareholders as required under Delaware law.

#### Dividends

Subject to preferences that may apply to any outstanding preferred stock, holders of our common stock are entitled to receive ratably any dividends that our board of directors may declare out of funds legally available for that purpose on a non-cumulative basis.

### Liquidation

In the event of our liquidation, dissolution or winding up, holders of our common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities, subject to the satisfaction of any liquidation preference granted to the holders of any outstanding shares of preferred stock.

# **Rights and Preferences**

Holders of our common stock have no preemptive, conversion or subscription rights, and there are no redemption or sinking fund provisions applicable to our common stock. The rights, preferences and

privileges of the holders of our common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of our preferred stock that we may designate and issue in the future.

#### **Preferred Stock**

As of , we had shares of preferred stock outstanding, held of record by stockholders. Immediately after the consummation of this offering, our certificate of incorporation will be amended and restated to remove all references to such shares of preferred stock. Under our amended and restated certificate of incorporation, our board of directors will have the authority, without further action by the stockholders, to issue up to 10,000,000 shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each such series, to fix the rights, preferences and privileges of the shares of each wholly unissued series and any qualifications, limitations or restrictions thereon and to increase or decrease the number of shares of any such series, but not below the number of shares of such series then outstanding.

Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of the common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in our control that may otherwise benefit holders of our common stock and may adversely affect the market price of the common stock and the voting and other rights of the holders of common stock. We have no current plans to issue any shares of preferred stock.

#### **Options and Warrants**

As of March 31, 2018, we had granted no options to any of our directors or officers. For additional information regarding terms of our equity incentive plan and future grants to be made thereunder, see the section titled "Executive and Director Compensation — 2018 Equity Incentive Plan."

In connection with the Loan Agreement, on August 16, 2016 we issued to Perceptive 11,625,437 warrants to purchase shares of our common stock representing 4.5% of our fully diluted common stock on an as converted basis at an exercise price of \$0.01 per interest. The Perceptive Warrants expire on August 16, 2023 and have certain rights and preferences including anti-dilution adjustments so that, upon exercise, they will represent 4.5% of our fully diluted common stock on an as converted basis, subject to dilution for certain financing transactions including the issuance of shares upon termination of our PUP Plans.

### **Registration Rights**

### Series A-2 Registration Rights

We granted registration rights to holders of our Series A-2 Preferred Interests with respect to the shares of common equity issuable upon conversion of the Series A-2 Preferred Interests we issued in July 2008. Upon consummation of this offering, the holders of Series A-2 Preferred Interests will receive shares of our common stock in exchange for their Series A-2 Preferred Interests, or the A-2 Exchange. Pursuant to the terms of the Limited Liability Company Agreement of Aquestive Partners, LLC, or the LLC Agreement, following the A-2 Exchange, the holders of 82,071,200 shares of our common stock, or the Series A-2 Registrable Securities, will continue to be entitled to rights with respect to the registration of the Series A-2 Registrable Securities under the Securities Act, as described below. However, the holders of a majority of the Series A-2 Preferred Interests have waived all registration rights with respect to the Series A-2 Preferred Interests in connection with this offering.

### Demand Registration Rights

Holders of at least 40% of the Series A-2 Registrable Securities then outstanding can request that we register all or part of their securities on Form S-1 and holders of at least 50% of the Series A-2 Registrable Securities then outstanding can request that we register all or part of their securities on Form S-3 if we are eligible to file a registration statement on Form S-3 and if the aggregate price to the



public of the Series A-2 Registrable Securities offered, net of underwriting discounts and commissions, is at least \$20,000,000. We and the underwriters of any underwritten offering will have the right to limit the number of shares registered by these holders if they determine that marketing factors require limitation, in which case the number of shares to be registered will be apportioned pro rata among these holders, according to the total amount of Series A-2 Registrable Securities entitled to be included by each holder.

# "Piggyback" Registration Rights

If we register any of our securities for public sale in another offering, holders of Series A-2 Registrable Securities will have the right to include their shares in the registration statement. However, this right does not apply to the registration relating to employee benefit plans or a registration relating solely to a transaction under Rule 144 of the Securities Act. We shall not be required to complete a Form S-3 if the holders of the Series A-2 Registrable Securities have had the opportunity to participate in two or more piggyback registrations in the preceding 12-month period. We and the underwriters of any underwritten offering will have the right to limit the number of shares registered by these holders if they determine that marketing factors require limitation, in which case the number of shares to be registered will be apportioned pro rata among these holders, according to the total amount of Series A-2 Registrable Securities entitled to be included by each holder.

# Expenses of Registration

We generally will pay all expenses related to the registrations, other than sales commissions, stock transfer taxes, underwriting discounts and the fees and disbursements of counsel for the selling security holders.

## Expiration of Registration Rights

The registration rights for the Series A-2 Registrable Securities granted under the LLC Agreement will terminate on July 31, 2018.

## Series A-3 Registration Rights

We granted registration rights to holders of our Series A-3 Preferred Interests with respect to the shares of common equity issuable upon conversion of the Series A-3 Preferred Interests we issued in December 2015. Upon consummation of this offering, the holders of Series A-3 Preferred Interests will receive shares of our common stock in exchange for their Series A-3 Preferred Interests, or the A-3 Exchange. Pursuant to the terms of the LLC Agreement, following the A-3 Exchange, the holders of 5,055,000 shares of our common stock, or the Series A-3 Registrable Securities, will be entitled to rights with respect to the registration of the Series A-3 Registrable Securities under the Securities Act, as described below. However, the holders of a majority of the Series A-3 Preferred Interests have waived all registration rights with respect to the Series A-3 Preferred Interests in connection with this offering.

# Demand Registration Rights

Beginning 180 days after the consummation of this offering, holders of at least 40% of the Series A-3 Registrable Securities then outstanding can request that we register all or part of their securities on Form S-1 and holders of at least 50% of the Series A-3 Registrable Securities then outstanding can request that we register all or part of their securities on Form S-3 if we are eligible to file a registration statement on Form S-3 and if the aggregate price to the public of the registrable securities offered, net of underwriting discounts and commissions, is at least \$5,000,000. We and the underwriters of any underwritten offering will have the right to limit the number of shares registered by these holders if they determine that marketing factors require limitation, in which case the number of shares to be registered will be apportioned pro rata among these holders, according to the total amount of Series A-3 Registrable Securities entitled to be included by each holder.

# "Piggyback" Registration Rights

If we register any of our securities for public sale in another offering, holders of Series A-3 Registrable Securities will have the right to include their shares in the registration statement. However, this right does not apply to a registration relating to employee benefit plans or a registration relating solely

to a transaction under Rule 144 of the Securities Act. We shall not be required to complete a Form S-3 if the holders of the Series A-3 Registrable Securities have had the opportunity to participate in two or more piggyback registrations in the preceding 12-month period. We and the underwriters of any underwritten offering will have the right to limit the number of shares registered by these holders if they determine that marketing factors require limitation, in which case the number of shares to be registered will be apportioned pro rata among these holders, according to the total amount of Series A-3 Registrable Securities entitled to be included by each holder.

## Expenses of Registration

We generally will pay all expenses related to the registrations, other than sales commissions, stock transfer taxes, underwriting discounts and the fees and disbursements of counsel for the selling security holders.

## Anti-Takeover Effects of Provisions of Our Certificate of Incorporation and Our Bylaws

Our certificate of incorporation and bylaws will contain certain provisions that are intended to enhance the likelihood of continuity and stability in the composition of the board of directors and which may have the effect of delaying, deferring or preventing a future takeover or change in control of the company unless such takeover or change in control is approved by the board of directors.

## These provisions include:

**Classified Board**. Our certificate of incorporation will provide that our board of directors will be divided into three classes of directors, with the classes as nearly equal in number as possible. As a result, approximately one-third of our board of directors will be elected each year. The classification of directors will have the effect of making it more difficult for stockholders to change the composition of our board. Our certificate of incorporation will also provide that, subject to any rights of holders of preferred stock to elect additional directors under specified circumstances, the number of directors will be fixed exclusively pursuant to a resolution adopted by our board of directors. Upon consummation of this offering, we expect that our board of directors will continue to have seven members.

Action by Written Consent; Special Meetings of Stockholders. Our certificate of incorporation will provide that stockholder action can be taken only at an annual or special meeting of stockholders and cannot be taken by written consent in lieu of a meeting. Our certificate of incorporation and the bylaws will also provide that, except as otherwise required by law, special meetings of the stockholders can be called only by or at the direction of the board of directors pursuant to a resolution adopted by a majority of the total number of directors. Stockholders will not be permitted to call a special meeting or to require the board of directors to call a special meeting.

**Removal of Directors.** Our certificate of incorporation will provide that our directors may be removed only for cause by the affirmative vote of at least 66<sup>2/3</sup>% of the votes that all our stockholders would be entitled to cast in an annual election of directors, voting together as a single class, at a meeting of the stockholders called for that purpose. This requirement of a supermajority vote to remove directors could enable a minority of our stockholders to prevent a change in the composition of our board.

Advance Notice Procedures. Our bylaws will establish an advance notice procedure for stockholder proposals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to the board of directors. Stockholders at an annual meeting will only be able to consider proposals or nominations specified in the notice of meeting or brought before the meeting by or at the direction of the board of directors or by a stockholder who was a stockholder of record on the record date for the meeting, who is entitled to vote at the meeting and who has given our secretary timely written notice, in proper form, of the stockholder's intention to bring that business before the meeting. Although the bylaws will not give the board of directors the power to approve or disapprove stockholder nominations of candidates or proposals regarding other business to be conducted at a special or annual meeting, the bylaws may have the effect of precluding the conduct of certain business at a meeting if the proper procedures are not followed or may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect its own slate of directors or otherwise attempting to obtain control of the company.

*Super Majority Approval Requirements*. The Delaware General Corporation Law generally provides that the affirmative vote of a majority of the shares entitled to vote on any matter is required to amend a corporation's certificate of incorporation or bylaws, unless either a corporation's certificate of incorporation or bylaws requires a greater percentage. A majority vote of our board of directors or the affirmative vote of holders of at least 66<sup>2/3</sup>% of the total votes of the outstanding shares of our capital stock entitled to vote with respect thereto, voting together as a single class, will be required to amend, alter, change or repeal the bylaws. In addition, the affirmative vote of the holders of at least 66<sup>2/3</sup>% of the total votes of the outstanding shares of our capital stock entitled to vote with respect thereto, voting together as a single class, will be required to amend, alter, change or repeal, or to adopt any provisions inconsistent with, any of the provisions in our certificate of incorporation relating to amendments to our certificate of incorporation and bylaws and as described under "Action by Written Consent; Special Meetings of Stockholders", "Classified Board" and "Removal of Directors" above. This requirement of a supermajority vote to approve amendments to our bylaws and certificate of incorporation could enable a minority of our stockholders to exercise veto power over any such amendments.

Authorized but Unissued Shares. Our authorized but unissued shares of common stock and preferred stock will be available for future issuance without stockholder approval. These additional shares may be utilized for a variety of corporate purposes, including future public offerings to raise additional capital and corporate acquisitions. The existence of authorized but unissued shares of common stock and preferred stock could render more difficult or discourage an attempt to obtain control of a majority of our common stock by means of a proxy contest, tender offer, merger or otherwise. For example, if in the due exercise of its fiduciary obligations, our board of directors were to determine that a takeover proposal is not in the best interests of us or our stockholders, our board of directors could cause shares of preferred stock to be issued without stockholder approval in one or more private offerings or other transactions that might dilute the voting or other rights of the proposed acquirer or insurgent stockholder or stockholder group. In this regard, our certificate of incorporation grants our board of directors broad power to establish the rights and preferences of authorized and unissued shares of preferred stock. The issuance of shares of preferred stock could decrease the amount of earnings and assets available for distribution to holders of shares of common stock. The issuance may also adversely affect the rights and powers, including voting rights, of these holders and may have the effect of delaying, deterring or preventing a change in control of us.

**Exclusive Forum**. Our certificate of incorporation will provide that, subject to limited exceptions, the state or federal courts located in 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, officers or other employees to us or our stockholders, (iii) any action asserting a claim against us arising pursuant to any provision of the Delaware General Corporation Law, our certificate of incorporation or our bylaws, or (iv) any other action asserting a claim against us that is governed by the internal affairs doctrine. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of our certificate of incorporation described above. Although we believe these provisions benefit us by providing increased consistency in the application of Delaware law for the specified types of actions and proceedings, the provisions may have the effect of discouraging lawsuits against our directors and officers. The enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that, in connection with one or more actions or proceedings described above, a court could find the choice of forum provisions contained in our certificate of incorporation to be inapplicable or unenforceable.

# Section 203 of the Delaware General Corporation Law

Upon consummation of this offering, we will be subject to the provisions of Section 203 of the Delaware General Corporation Law, or Section 203. In general, Section 203 prohibits a publicly-held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a three-year period following the time that this stockholder becomes an interested stockholder, unless the business combination is approved in a prescribed manner. A "business combination" includes, among

other things, a merger, asset or stock sale or other transaction resulting in a financial benefit to the interested stockholder. An "interested stockholder" is a person who, together with affiliates and associates, owns, or did own within three years prior to the determination of interested stockholder status, 15% or more of the corporation's voting stock.

Under Section 203, a business combination between a corporation and an interested stockholder is prohibited unless it satisfies one of the following conditions: before the stockholder became interested, the board of directors approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder; upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder owned at least 75% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, shares owned by persons who are directors and also officers, and employee stock plans, in some instances; or at or after the time the stockholder became interested, the business combination was approved by the board of directors of the corporation and authorized at an annual or special meeting of the stockholders by the affirmative vote of at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

A Delaware corporation may "opt out" of these provisions with an express provision in its original certificate of incorporation or an express provision in its certificate of incorporation or bylaws resulting from a stockholders' amendment approved by at least a majority of the outstanding voting shares. We have not opted out of these provisions. As a result, mergers or other takeover or change in control attempts of us may be discouraged or prevented.

## **Nasdaq Listing**

We have applied to list our common stock on the Nasdaq Global Market under the symbol "AQST."

## **Transfer Agent and Registrar**

The transfer agent and registrar for our common stock is Computershare Trust Company, N.A.

## SHARES ELIGIBLE FOR FUTURE SALE

Immediately prior to this offering, there has been no public market for our common stock. Future sales of substantial amounts of common stock in the public market could adversely affect prevailing market prices. Furthermore, since only a limited number of shares will be available for sale shortly after this offering because of contractual and legal restrictions on resale described below, sales of substantial amounts of common stock in the public market price for our common stock as well as our ability to raise equity capital in the future.

Based on the number of shares of common stock outstanding as of March 31, 2018, upon the closing of this offering, shares of common stock will be outstanding, assuming no exercise of the underwriters' option to purchase additional shares. All of the shares sold in this offering will be freely tradable unless purchased by our "affiliates" as that term is defined in Rule 144 under the Securities Act or purchased by existing stockholders and their affiliated entities that are subject to lock-up agreements. Except as set forth below, the remaining shares of common stock outstanding after this offering will be restricted as a result of securities laws and lock-up agreements with us and/or the underwriters. These remaining shares will generally become available for sale in the public market as follows:

Approximate Number of Shares	First Date Available for Sale into Public Market
shares	181 days after the date of this prospectus, upon expiration of the lock-up
	agreements referred to below, subject in some cases to applicable volume,
	manner of sale and other limitations under Rule 144 and Rule 701.

We may issue shares of common stock from time to time as consideration for future acquisitions, investments or other corporate purposes. In the event that any such acquisition, investment or other transaction is significant, the number of shares of common stock that we may issue may in turn be significant. We may also grant registration rights covering those shares of common stock issued in connection with any such acquisition and investment.

## Rule 144

In general, under Rule 144 as currently in effect, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, any person who is not an affiliate of ours and has held their shares for at least six months, including the holding period of any prior owner other than one of our affiliates, may sell shares without restriction, provided current public information about us is available. In addition, under Rule 144, any person who is not an affiliate of ours and has held their shares for at least one year, including the holding period of any prior owner other than one of our affiliates, would be entitled to sell an unlimited number of shares immediately upon the closing of this offering without regard to whether current public information about us is available. Beginning 90 days after the effective date of the registration statement of which this prospectus is a part, a person who is an affiliate of ours and who has beneficially owned restricted securities for at least six months, including the holding period of any prior owner other than one of our affiliates, is entitled to sell a number of restricted shares within any three-month period that does not exceed the greater of:

- 1% of the number of shares of our common stock then outstanding, which will equal approximately shares immediately after this offering; or
- the average weekly trading volume of our common stock on the Nasdaq Global Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale.

Sales of restricted shares under Rule 144 held by our affiliates are also subject to requirements regarding the manner of sale, notice and the availability of current public information about us. Rule 144 also provides that affiliates relying on Rule 144 to sell shares of our common stock that are not restricted shares must nonetheless comply with the same restrictions applicable to restricted shares, other than the holding period requirement.

Notwithstanding the availability of Rule 144, the holders of substantially all of our restricted shares have entered into lock-up agreements as described below and their restricted shares will become eligible for sale at the expiration of the restrictions set forth in those agreements.

# Rule 701

Under Rule 701, shares of our common stock acquired upon the exercise of currently outstanding options or pursuant to other rights granted under our stock plans may be resold by:

- persons other than affiliates, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, subject only to the manner-of-sale provisions of Rule 144; and
- our affiliates, beginning 90 days after the effective date of the registration statement of which this prospectus is a part, subject to the manner-of-sale and volume limitations, current public information and filing requirements of Rule 144, in each case, without compliance with the six-month holding period requirement of Rule 144.

#### **Lock-Up Agreements**

We, along with our directors, executive officers and substantially all of our other stockholders and option holders, have agreed that for a period of 180 days after the date of this prospectus, subject to specified exceptions, we or they will not offer, sell, contract to sell, pledge or otherwise dispose of, directly or indirectly, any shares of our common stock or securities convertible into or exchangeable or exercisable for any shares of our common stock without the consent of BMO Capital Markets Corp. and RBC Capital Markets, LLC. Upon expiration of the "lock-up" period, certain of our stockholders will have the right to require us to register their shares under the Securities Act. See "Registration Rights" below.

After this offering, certain of our employees, including our executive officers and/or directors, may enter into written trading plans that are intended to comply with Rule 10b5-1 under the Exchange Act. Sales under these trading plans would not be permitted until the expiration of the lock-up agreements described above.

## **Registration Rights**

Upon consummation of this offering, the holders of shares of our common stock will be entitled to rights with respect to the registration of their shares under the Securities Act, subject to the lock-up arrangement described above. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares purchased by affiliates, immediately upon the effectiveness of such registration statement. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock. See "Description of Capital Stock — Registration Rights."

# **Equity Incentive Plans**

We intend to file with the SEC a registration statement on Form S-8 under the Securities Act covering the shares of common stock subject to stock awards outstanding or reserved for issuance under the 2018 Plan. The registration statement is expected to be filed and become effective as soon as practicable after the closing of this offering. Accordingly, shares registered under the registration statement will be available for sale in the open market following its effective date, subject to Rule 144 volume limitations and the lock-up agreements described above, if applicable.

## MATERIAL U.S. FEDERAL INCOME TAX CONSEQUENCES TO NON-U.S. HOLDERS OF OUR COMMON STOCK

The following discussion is a general summary of the material U.S. federal income tax considerations related to the acquisition, ownership and disposition of our common stock to Non-U.S. Holders as of the date hereof.

For the purposes of this discussion, a "Non-U.S. Holder" of our common stock means a holder that is not a U.S. person or an entity treated as a partnership for U.S. federal income tax purposes. The term U.S. person means:

- an individual who is a citizen or resident of the United States;
- a corporation (or other entity taxable as a corporation) created or organized in or under the laws of the United States, any state thereof or the District of Columbia;
- an estate the income of which is subject to U.S. federal income taxation regardless of its source; or
- a trust, if it (1) is subject to the primary supervision of a court within the United States and one or more U.S. persons have the authority to control all substantial decisions of the trust or (2) has a valid election in effect under applicable U.S. Treasury regulations to be treated as a U.S. person.

This summary is not intended to be a complete analysis of all the U.S. federal income tax considerations that may be relevant to Non-U.S. Holders. This summary does not consider specific facts and circumstances that may be relevant to a particular Non-U.S. Holder's tax particular circumstances and does not consider the state, local or non-U.S. tax consequences of an investment in our common stock. It also does not consider Non-U.S. Holders subject to special tax treatment under U.S. federal income tax laws (including partnerships or other pass-through entities, banks and insurance companies, regulated investment companies, real estate investment trusts, dealers in securities, controlled entities of foreign sovereigns, holders of our common stock held as part of a "straddle," "hedge," "conversion transaction" or other risk-reduction transaction, controlled foreign corporations, passive foreign investment companies, companies that accumulate earnings to avoid U.S. federal income tax, foreign tax-exempt organizations, "expatriated entities," companies subject to the "stapled stock" rules, persons that own or are deemed to own more than 5% of our capital stock, former U.S. citizens or residents and persons who hold or receive the shares of common stock as compensation). This summary is based on provisions of the Internal Revenue Code of 1986, as amended, or the Code, applicable Treasury regulations, administrative pronouncements of the U.S. Internal Revenue Service, or the IRS, and judicial decisions, all as in effect on the date hereof, and all of which are subject to change, possibly on a retroactive basis, and different interpretations.

This summary is general information only. It is not tax advice. We urge each prospective Non-U.S. Holder to consult their own tax advisor concerning the particular U.S. federal, state, local and non-U.S. income, estate and other tax consequences of the purchase, ownership and disposition of our common stock.

## **U.S. Trade or Business Income**

For purposes of this discussion, dividend income and gain on the sale or other taxable disposition of shares of our common stock will be considered to be "U.S. trade or business income" if such dividend income or gain is (1) effectively connected with the conduct by a Non-U.S. Holder of a trade or business within the United States; and (2) in the case of a Non-U.S. Holder that is eligible for the benefits of an income tax treaty with the United States, attributable to a "permanent establishment" or "fixed base" maintained by the Non-U.S. Holder in the United States. Generally, U.S. trade or business income is not subject to U.S. federal withholding tax (provided the Non-U.S. Holder complies with applicable certification and disclosure requirements); instead, U.S. trade or business income is subject to U.S. federal income tax rates in the same manner as if the recipient were a U.S. person. Any U.S. trade or business income received by a Non-U.S. Holder that is treated as a corporation also may be subject to a "branch profits tax" at a 30% rate, or such lower rate as provided under an applicable income tax treaty.

## Distributions

Distributions of cash or property (other than certain stock distributions) that we pay with respect to our common stock (or certain redemptions that are treated as distributions with respect to our shares of common stock) will be taxable as dividends for U.S. federal income tax purposes to the extent paid out of our current or accumulated earnings and profits as determined for U.S. federal income tax purposes. Subject to the discussion in "-Foreign Account Tax Compliance Act (FATCA)" below, a Non-U.S. Holder generally will be subject to withholding of U.S. federal income tax at a rate of 30% of the gross amount of our distributions taxable as dividends or such lower rate as may be specified by an applicable income tax treaty. In order to obtain a reduced rate of U.S. federal withholding tax under an applicable income tax treaty, a Non-U.S. Holder will be required to provide a properly executed IRS Form W-8BEN or W-8BEN-E (or appropriate substitute or successor form) certifying its entitlement to benefits under the treaty. A Non-U.S. Holder of our common stock that is eligible for a reduced rate of U.S. federal withholding tax under an income tax treaty may obtain a refund or credit of any excess amounts withheld by filing an appropriate claim for refund with the IRS. A Non-U.S. Holder is encouraged to consult its own tax advisor regarding its possible entitlement to benefits under an income tax treaty. If the amount of a distribution exceeds our current and accumulated earnings and profits, such excess first will be treated as a tax-free return of capital to the extent of the Non-U.S. Holder's adjusted tax basis in our shares, and thereafter will be treated as capital gain. A Non-U.S. Holder's adjusted tax basis in our shares will generally be egual to the amount the Non-U.S. Holder paid for its shares, reduced by the amount of any distributions treated as a return of capital. See, "-Sale, Exchange or Other Disposition of Our Common Stock" below.

The U.S. federal withholding tax does not apply to dividends that are U.S. trade or business income, as described above, of a Non-U.S. Holder who provides a properly executed IRS Form W-8ECI (or appropriate substitute or successor form), certifying that the dividends are subject to tax as income effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States.

#### Sale, Exchange or Other Disposition of Our Common Stock

Subject to the discussion in "—Foreign Account Tax Compliance Act (FATCA)" below, a Non-U.S. Holder generally will not be subject to U.S. federal income tax or withholding tax in respect of any gain recognized on a sale, exchange or other disposition of shares of our common stock unless:

- the gain is U.S. trade or business income, as described above;
- if a Non-U.S. Holder is an individual and holds shares of our common stock as a capital asset, the Non-U.S. Holder is present in the United States for 183 or more days in the taxable year of the sale or other disposition but is not treated as a resident of the United States for that year, and certain other conditions are met; or
- we are or have been during a specified testing period a "United States real property holding corporation" for U.S. federal income tax purposes.

Gain described in the first bullet above will be subject to U.S. federal income tax in the manner described under "— U.S. Trade or Business Income." Gain described in the second bullet above will be subject to a flat 30% tax (or such lower rate specified by an applicable income tax treaty), but may be offset by certain U.S. source capital losses (even though the Non-U.S. Holder is not considered a resident of the United States), provided that the Non-U.S. Holder has timely filed U.S. federal income tax returns with respect to such losses.

In general, a corporation is a "United States real property holding corporation" if the fair market value of its "U.S. real property interests" equals or exceeds 50% of the sum of the fair market value of its worldwide (domestic and foreign) real property interests and its other assets used or held for use in a trade or business. Although there can be no assurance, we believe that we have not been, and we are not and do not anticipate becoming, a "United States real property holding corporation" for U.S. federal income tax purposes. If we are or become a "United States real property holding corporation," a Non-U.S. Holder, nevertheless, will not be subject to U.S. federal income or withholding tax in respect of any gain on a sale or other disposition of our common stock so long as shares of our common stock are "regularly traded on an established securities market" as defined under applicable Treasury regulations and a

Non-U.S. Holder owns, actually or constructively, 5% or less of our shares at all times during the shorter of the five-year period ending on the date of disposition and such Non-U.S. Holder's holding period for our shares. If we are a United States real property holding corporation and either our common stock is not regularly traded on an established securities market or a Non-U.S. Holder holds, or is treated as holding, more than 5% of our outstanding common stock, directly or indirectly, during the applicable testing period, any gain recognized by such Non-U.S. Holder will generally be subject to U.S. federal income tax rates in the same manner as if the Non-U.S. Holder were a resident of the United States. If we are a U.S. real property holding corporation and our common stock is not regularly traded on an established securities market, such Non-U.S. Holder's proceeds received on the disposition of shares will also generally be subject to withholding at a rate of 15%. Prospective investors should be aware that no assurance can be given that our shares will be so regularly traded when a Non-U.S. Holder sells its shares of our common stock.

## Information Reporting Requirements and Backup Withholding

We must annually report to the IRS and to each Non-U.S. Holder any dividend income that is subject to U.S. federal withholding tax, or that is exempt from such withholding tax pursuant to an income tax treaty with the United States. Copies of these information returns also may be made available under the provisions of a specific treaty or agreement to the tax authorities of the country in which the Non-U.S. Holder resides. Under certain circumstances, the Code imposes a backup withholding obligation on certain reportable payments. Dividends paid to a Non-U.S. Holder of our common stock generally will be exempt from backup withholding if the Non-U.S. Holder provides a properly executed IRS Form W-8BEN or W-8BEN-E (or other applicable form) or otherwise establishes an exemption.

The payment of the proceeds from the disposition of our common stock to or though the U.S. office of any broker, U.S. or foreign, will be subject to information reporting and possible backup withholding unless the owner certifies (usually on IRS Form W-8BEN or W-8BEN-E) as to its non-U.S. status under penalties of perjury or otherwise establishes an exemption, provided that the broker does not have actual knowledge or reason to know that the holder is a U.S. person or that the conditions of any other exemption are not, in fact, satisfied. The payment of the proceeds from the disposition of our common stock to or through a non-U.S. office of a non-U.S. broker will not be subject to information reporting or backup withholding unless the non-U.S. broker has certain types of relationships with the United States (which we refer to as a United States related person). In the case of the payment of the proceeds from the disposition of our common stock to or through a non-U.S. office of a broker that is either a U.S. person or a United States related person, the Treasury Regulations require information reporting (but not the backup withholding) on the payment unless the broker has documentary evidence in its files that the owner is a non-U.S. Holder and the broker has no knowledge to the contrary. Non-U.S. Holders should consult their own tax advisors on the application of information reporting and backup withholding to them in their particular circumstances (including upon their disposition of our common stock).

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules from a payment to a Non-U.S. Holder will be credited against the Non-U.S. Holder's U.S. federal income tax liability, if any, with any excess withholding refunded to the Non-US. Holder, provided that the required information is furnished on a timely basis to the IRS.

## Foreign Account Tax Compliance Act (FATCA)

Pursuant to sections 1471 through 1474 of the Code, commonly known as the Foreign Account Tax Compliance Act, or FATCA, withholding taxes may apply to certain types of payments made to "foreign financial institutions" (as specifically defined in the Code) and certain other non-United States entities. Specifically, a 30% withholding tax may be imposed on dividends and gross proceeds from the sale, exchange or other disposition of our common stock paid to a foreign financial institution or to a non-financial foreign entity unless (i) the foreign financial institution undertakes certain diligence and reporting, (ii) the non-financial foreign entity either certifies it does not have any substantial United States owners or furnishes identifying information regarding each substantial United States owner or (iii) the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from these rules. If the payee is a foreign financial institution and is subject to the diligence and reporting requirements in clause (i) above, it may be required to enter into an agreement with the IRS requiring,



among other things, that it undertake to identify accounts held by certain United States persons or United States-owned foreign entities, annually report certain information about such accounts, and withhold 30% on payments to noncompliant foreign financial institutions and certain other account holders or may be required to comply with reporting and other compliance obligations under an intergovernmental agreement between their country of organization and the U.S. Treasury. The withholding provisions above currently applies to payments of dividends and will generally apply to payments of gross proceeds from the sale or disposition of stock on or after January 1, 2019. A Non-U.S. Holder that is not subject to FATCA withholding generally may certify its exempt status by furnishing a properly executed IRS Form W-8BEN or Form W-8BEN-E (or other appropriate form), as applicable. Under certain circumstances, a non-U.S. Holder may be eligible for refunds or credits of the tax. Non-U.S. Holders are urged to consult their own tax advisors regarding the possible implications of FATCA on their investment in our common stock.

THE PRECEDING DISCUSSION OF U.S. FEDERAL INCOME TAX CONSIDERATIONS IS FOR GENERAL INFORMATION ONLY. IT IS NOT TAX ADVICE. EACH PROSPECTIVE INVESTOR SHOULD CONSULT ITS OWN TAX ADVISOR REGARDING THE TAX CONSEQUENCES OF PURCHASING, HOLDING AND DISPOSING OF OUR COMMON STOCK, INCLUDING THE CONSEQUENCES OF ANY PROPOSED CHANGE IN APPLICABLE LAW.

## UNDERWRITING

We and the underwriters named below have entered into an underwriting agreement, dated the date of this prospectus, with respect to the shares being offered. Subject to certain conditions, each underwriter has severally agreed to purchase the respective number of shares of common stock shown opposite its name in the following table. BMO Capital Markets Corp. and RBC Capital Markets, LLC are the representatives of the underwriters.

Underwriters	Number of Shares
BMO Capital Markets Corp.	
RBC Capital Markets, LLC	
Wedbush Securities Inc.	
JMP Securities LLC	
Total	

The underwriters are committed to take and pay for all of the shares being offered, if any are taken, other than the shares covered by the option described below unless and until that option is exercised. If an underwriter fails or refuses to purchase any of its committed shares, the purchase commitments of the non-defaulting underwriters may be increased or the offering may be terminated.

The underwriters have an option to buy up to an additional shares from us to cover sales by the underwriters of a greater number of shares than the total number set forth in the table above. They may exercise this option for 30 days. If any shares are purchased pursuant to this option, the underwriters will severally purchase shares in approximately the same proportion as set forth in the table above, and the underwriters will offer the additional shares on the same terms as those on which the shares are being offered.

The underwriters propose to offer the shares of our common stock directly to the public at the initial public offering price set forth on the cover of this prospectus and to certain dealers at such offering price less a concession not in excess of \$ per share. After the initial public offering of the shares, the offering price and the selling concession may be changed by the underwriters.

The following table shows the per share and total underwriting discounts and commissions to be paid by us to the underwriters assuming both no exercise and full exercise of the underwriters' option to purchase additional shares.

	No Exercise	Full Exercise
Per Share	\$	\$
Total	\$	\$

We estimate that the total expenses of the offering, including registration, filing and listing fees, printing fees and legal and accounting expenses, but excluding underwriting discounts and commissions, will be approximately \$, all of which will be paid by us. We have agreed to reimburse the underwriters for certain of their expenses incurred in connection with the clearance of this offering with the Financial Industry Regulatory Authority, Inc.

We and our officers and directors and the holders of substantially all of our capital stock and options have agreed with the underwriters that, for a period of 180 days after the date of this prospectus, subject to certain exceptions, we and they will not (i) offer, sell, pledge, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of (or enter into any transaction which is designed to, or might reasonably be expected to, result in the disposition), directly or indirectly, including the filing (or participation in the filing) with the SEC of a registration statement under the Securities Act to register, any shares of our common stock or any securities convertible into or exercisable or exchangeable for our common stock or warrants or other rights to acquire shares of our common stock of which such officer, director or holder is now, or may in the future become, the beneficial owner (within the meaning of Rule 13d-3 under the Exchange Act), or (ii) enter into any swap or other derivatives transaction that transfers to another, in whole or in part, directly or indirectly or indirectly, any of the economic benefits or risks of ownership of such common

stock, securities, warrants or other rights to acquire common stock, whether any such transaction described in clause (i) or (ii) above is to be settled by delivery of common stock or other securities, in cash or otherwise, or (3) publicly disclose the intention to enter into any transaction described in clause (i) or (ii) above, except with the prior written consent of BMO Capital Markets Corp. and RBC Capital Markets, LLC; provided that BMO Capital Markets Corp. and RBC Capital Markets, LLC, on behalf of the underwriters, have agreed to notify us at least three business days before the effective date of any release or waiver granted to one of our officers or directors, and we have agreed to announce the impending release or waiver by issuing a press release through a major news service at least two business days before the effective date of the release or waiver.

The restrictions above do not apply to transfers of securities as a bona fide gift, subject to certain limitations set forth in the lock-up agreements.

See "Shares Eligible for Future Sale" for a discussion of certain transfer restrictions.

Prior to the offering, there has been no public market for our common stock. The initial public offering price will be negotiated among us and the representatives. Among the factors to be considered in determining the initial public offering price of the shares, in addition to prevailing market conditions, will be our historical performance, estimates of our business potential and earnings prospects, an assessment of our management and the consideration of the above factors in relation to market valuation of companies in related businesses.

We have applied to have our common stock listed on the Nasdag Global Market under the symbol "AQST." In connection with the offering, the underwriters may purchase and sell shares of our common stock in the open market. These transactions may include short sales, stabilizing transactions and purchases to cover positions created by short sales. Short sales involve the sale by the underwriters of a greater number of shares than they are required to purchase in the offering, and a short position represents the amount of such sales that have not been covered by subsequent purchases. A "covered short position" is a short position that is not greater than the amount of additional shares for which the underwriters' option described above may be exercised. The underwriters may cover any covered short position by either exercising their option to purchase additional shares or purchasing shares in the open market. In determining the source of shares to cover the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase additional shares pursuant to the option described above. "Naked" short sales are any short sales that create a short position greater than the amount of additional shares for which the option described above may be exercised. The underwriters must cover any such naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common stock in the open market after pricing that could adversely affect investors who purchase in the offering. Stabilizing transactions consist of various bids for or purchases of common stock made by the underwriters in the open market prior to the consummation of the offering.

The underwriters may also impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the representatives have repurchased shares sold by or for the account of such underwriter in stabilizing or short covering transactions.

Purchases to cover a short position and stabilizing transactions, as well as other purchases by the underwriters for their own accounts, may have the effect of preventing or retarding a decline in the market price of our stock, and together with the imposition of the penalty bid, may stabilize, maintain or otherwise affect the market price of the common stock. As a result, the price of our common stock may be higher than the price that otherwise might exist in the open market. The underwriters are not required to engage in these activities and may end any of these activities at any time. These transactions may be effected on the Nasdaq Global Market, in the over-the-counter market or otherwise.

In connection with this offering, the underwriters may engage in passive market making transactions in the common stock on the Nasdaq Global Market in accordance with Rule 103 of Regulation M under the Exchange Act during a period before the commencement of offers or sales of common stock and extending through the completion of distribution. A passive market maker must display its bid at a price

not in excess of the highest independent bid of that security. However, if all independent bids are lowered below the passive market maker's bid, that bid must then be lowered when specified purchase limits are exceeded. Passive market making may cause the price of our common stock to be higher than the price that otherwise would exist in the open market in the absence of those transactions. The underwriters are not required to engage in passive market making and may end passive market making activities at any time.

The underwriters do not expect sales to discretionary accounts to exceed five percent of the total number of shares offered.

We have agreed to indemnify the several underwriters against certain liabilities, including liabilities under the Securities Act and to contribute to payments that the underwriters may be required to make for these liabilities.

A prospectus in electronic format may be made available on websites maintained by one or more underwriters, or selling group members, if any, participating in this offering. The representatives may agree to allocate a number of shares of our common stock to underwriters for sale to their online brokerage account holders. Internet distributions will be allocated by the representatives to underwriters that may make Internet distributions on the same basis as other allocations.

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include sales and trading, commercial and investment banking, advisory, investment management, investment research, principal investment, hedging, market making, brokerage and other financial and non-financial activities and services. Certain of the underwriters and their respective affiliates have provided, and may in the future provide, a variety of these services to us and to persons and entities with relationships with us, for which they received or will receive customary fees and expenses.

In the ordinary course of their various business activities, the underwriters and their respective affiliates, officers, directors and employees may purchase, sell or hold a broad array of investments and actively trade securities, derivatives, loans, commodities, currencies, credit default swaps and other financial instruments for their own account and for the accounts of their customers, and such investment and trading activities may involve or relate to our assets, securities and/or instruments (directly, as collateral securing other obligations or otherwise) and/or persons and entities with relationships with us. The underwriters and their respective affiliates may also communicate independent investment recommendations, market color or trading ideas and/or publish or express independent research views in respect of such assets, securities or instruments and may at any time hold, or recommend to clients that they should acquire, long and/or short positions in such assets, securities and instruments.

#### Offer Restrictions Outside the United States

Other than in the United States, no action has been taken by us or the underwriters that would permit a public offering of the securities offered by this prospectus in any jurisdiction where action for that purpose is required. The securities offered by this prospectus may not be offered or sold, directly or indirectly, nor may this prospectus or any other offering material or advertisements in connection with the offer and sale of any such securities be distributed or published in any jurisdiction. Persons into whose possession this prospectus comes are advised to inform themselves about and to observe any restrictions relating to the offering and the distribution of this prospectus. This prospectus does not constitute an offer to sell or a solicitation of an offer to buy any securities offered by this prospectus in any jurisdiction is unlawful.

## Australia

No prospectus or other disclosure document, as defined in the Corporations Act 2001 (Cth) of Australia, or Corporations Act, in relation to our securities has been or will be lodged with the Australian Securities & Investments Commission, or ASIC. This document has not been lodged with ASIC and is only directed to certain categories of exempt persons. Accordingly, if you receive this document in Australia:

- (a) you confirm and warrant that you are either:
  - (i) a "sophisticated investor" under section 708(8)(a) or (b) of the Corporations Act;
  - (ii) a "sophisticated investor" under section 708(8)(c) or (d) of the Corporations Act and that you have provided an accountant's certificate to us which complies with the requirements of section 708(8)(c)(i) or (ii) of the Corporations Act and related regulations before the offer has been made;
  - (iii) a person associated with the company under section 708(12) of the Corporations Act; or
  - (iv) a "professional investor" within the meaning of section 708(11)(a) or (b) of the Corporations Act, and to the extent that you are unable to confirm or warrant that you are an exempt sophisticated investor, associated person or professional investor under the Corporations Act, any offer made to you under this document is void and incapable of acceptance; and
- (b) you warrant and agree that you will not offer any of our securities for resale in Australia within 12 months of that security being issued unless any such resale offer is exempt from the requirement to issue a disclosure document under section 708 of the Corporations Act.

## Canada

The common stock may be sold in Canada only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 *Prospectus Exemptions* or subsection 73.3(1) of the *Securities Act* (Ontario), and are permitted clients, as defined in National Instrument 31-103 *Registration Requirements, Exemptions and Ongoing Registrant Obligations*. Any resale of the common stock must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 (or, in the case of securities issued or guaranteed by the government of a non-Canadian jurisdiction, section 3A.4) of National Instrument 33-105 *Underwriting Conflicts*, or NI 33-105, the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

## China

The information in this document does not constitute a public offer of the securities, whether by way of sale or subscription, in the People's Republic of China (excluding, for purposes of this paragraph, Hong Kong Special Administrative Region, Macau Special Administrative Region and Taiwan). The securities may not be offered or sold directly or indirectly in the PRC to legal or natural persons other than directly to "qualified domestic institutional investors."

#### **European Economic Area**

Any distributor subject to MiFID II that is offering, selling or recommending the securities is responsible for undertaking its own target market assessment in respect of the securities and determining its own distribution channels for the purposes of the MiFID product governance rules under Commission

Delegated Directive (EU) 2017/593, or Delegated Directive. Neither the issuer nor the underwriters make any representations or warranties as to a distributor's compliance with the Delegated Directive.

In relation to each member state of the European Economic Area that has implemented the Prospectus Directive, or, each, a relevant member state, with effect from and including the date on which the Prospectus Directive is implemented in that relevant member state (the relevant implementation date), an offer of securities described in this prospectus may not be made to the public in that relevant member state other than:

- to any legal entity which is a qualified investor as defined in the Prospectus Directive;
- to fewer than 100 or, if the relevant member state has implemented the relevant provision of the 2010 PD Amending Directive, 150 natural or legal persons (other than qualified investors as defined in the Prospectus Directive), as permitted under the Prospectus Directive, subject to obtaining the prior consent of the relevant Dealer or Dealers nominated by us for any such offer; or
- in any other circumstances falling within Article 3(2) of the Prospectus Directive;

provided that no such offer of securities shall require us or any underwriter to publish a prospectus pursuant to Article 3 of the Prospectus Directive.

For purposes of this provision, the expression an "offer of securities to the public" in any relevant member state means the communication in any form and by any means of sufficient information on the terms of the offer and the securities to be offered so as to enable an investor to decide to purchase or subscribe for the securities, as the expression may be varied in that member state by any measure implementing the Prospectus Directive in that member state, and the expression "Prospectus Directive" means Directive 2003/71/EC (and amendments thereto, including the 2010 PD Amending Directive, to the extent implemented in the relevant member state) and includes any relevant implementing measure in the relevant member state. The expression 2010 PD Amending Directive means Directive 2010/73/EU.

The sellers of the securities have not authorized and do not authorize the making of any offer of securities through any financial intermediary on their behalf, other than offers made by the underwriters with a view to the final placement of the securities as contemplated in this prospectus. Accordingly, no purchaser of the securities, other than the underwriters, is authorized to make any further offer of the securities on behalf of the sellers or the underwriters.

## France

Neither this prospectus nor any other offering material relating to the securities described in this prospectus has been submitted to the clearance procedures of the *Autorité des Marchés Financiers* or of the competent authority of another member state of the European Economic Area and notified to the *Autorité des Marchés Financiers*. The securities have not been offered or sold and will not be offered or sold, directly or indirectly, to the public in France. Neither this prospectus nor any other offering material relating to the securities has been or will be:

- released, issued, distributed or caused to be released, issued or distributed to the public in France; or
- used in connection with any offer for subscription or sale of the securities to the public in France.

Such offers, sales and distributions will be made in France only:

- to qualified investors (*investisseurs qualifiés*) and/or to a restricted circle of investors (*cercle restreint d'investisseurs*), in each case investing for their own account, all as defined in, and in accordance with articles L.411-2, D.411-1, D.411-2, D.734-1, D.744-1, D.754-1 and D.764-1 of the French Code monétaire et financier;
- to investment services providers authorized to engage in portfolio management on behalf of third parties; or

 in a transaction that, in accordance with article L.411-2-II-1° -or-2° -or 3° of the French Code monétaire et financier and article 211-2 of the General Regulations (Règlement Général) of the Autorité des Marchés Financiers, does not constitute a public offer (appel public à l'épargne).

The securities may be resold directly or indirectly, only in compliance with articles L.411-1, L.411-2, L.412-1 and L.621-8 through L.621-8-3 of the French *Code monétaire et financier*.

## Hong Kong

The securities may not be offered or sold in Hong Kong by means of any document other than (i) in circumstances which do not constitute an offer to the public within the meaning of the Companies Ordinance (Cap. 32, Laws of Hong Kong), or (ii) to "professional investors" within the meaning of the Securities and Futures Ordinance (Cap. 571, Laws of Hong Kong) and any rules made thereunder, or (iii) in other circumstances which do not result in the document being a "prospectus" within the meaning of the Companies Ordinance (Cap. 32, Laws of Hong Kong) and no advertisement, invitation or document relating to the securities may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public in Hong Kong (except if permitted to do so under the laws of Hong Kong) other than with respect to the securities which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" within the meaning of the Securities and Futures Ordinance (Cap. 571, Laws of Hong Kong) and any rules made thereunder.

#### Ireland

The information in this document does not constitute a prospectus under any Irish laws or regulations, and this document has not been filed with or approved by any Irish regulatory authority as the information has not been prepared in the context of a public offering of securities in Ireland within the meaning of the Irish Prospectus (Directive 2003/71/EC) Regulations 2005, or the Prospectus Regulations. The common stock has not been offered or sold, and will not be offered, sold or delivered directly or indirectly in Ireland by way of a public offering, except to (i) qualified investors as defined in Regulation 2(I) of the Prospectus Regulations and (ii) fewer than 100 natural or legal persons who are not qualified investors.

#### Israel

The common stock offered by this prospectus have not been approved or disapproved by the Israeli Securities Authority, or the ISA, nor have such common stock been registered for sale in Israel. The shares and warrants may not be offered or sold, directly or indirectly, to the public in Israel, absent the publication of a prospectus. The ISA has not issued permits, approvals or licenses in connection with the offering or publishing the prospectus; nor has it authenticated the details included herein, confirmed their reliability or completeness, or rendered an opinion as to the quality of the common stock being offered. Any resale in Israel, directly or indirectly, to the public of the common stock offered by this prospectus is subject to restrictions on transferability and must be effected only in compliance with the Israeli securities laws and regulations.

#### Italy

The offering of the common stock in the Republic of Italy has not been authorized by the Italian Securities and Exchange Commission (Commissione Nazionale per le Società e la Borsa), the "CONSOB," pursuant to the Italian securities legislation and, accordingly, no offering material relating to the common stock may be distributed in Italy and such securities may not be offered or sold in Italy in a public offer within the meaning of Article 1.1(t) of Legislative Decree No. 58 of 24 February 1998, or Decree No. 58, other than:

- to Italian qualified investors, as defined in Article 100 of Decree No. 58 by reference to Article 34-ter of CONSOB Regulation no. 11971 of 14 May 1999, or Regulation No. 1197I, as amended, or the Qualified Investors; and
- in other circumstances that are exempt from the rules on public offer pursuant to Article 100 of Decree No. 58 and Article 34-ter of Regulation No. 11971 as amended.

Any offer, sale or delivery of the common stock or distribution of any offer document relating to the common stock in Italy (excluding placements where a Qualified Investor solicits an offer from the issuer) under the paragraphs above must be:

- made by investment firms, banks or financial intermediaries permitted to conduct such activities in Italy in accordance with Legislative Decree No. 385 of 1 September 1993 (as amended), Decree No. 58, CONSOB Regulation No. 16190 of 29 October 2007 and any other applicable laws; and
- in compliance with all relevant Italian securities, tax and exchange controls and any other applicable laws.

Any subsequent distribution of the common stock in Italy must be made in compliance with the public offer and prospectus requirement rules provided under Decree No. 58 and the Regulation No. 11971 as amended, unless an exception from those rules applies. Failure to comply with such rules may result in the sale of such common stock being declared null and void and in the liability of the entity transferring the common stock for any damages suffered by the investors.

## Japan

The securities offered in this prospectus have not been and will not be registered under the Financial Instruments and Exchange Law of Japan. The securities have not been offered or sold and will not be offered or sold, directly or indirectly, in Japan or to or for the account of any resident of Japan (including any corporation or other entity organized under the laws of Japan), except (i) pursuant to an exemption from the registration requirements of the Financial Instruments and Exchange Law and (ii) in compliance with any other applicable requirements of Japanese law.

## Portugal

This document is not being distributed in the context of a public offer of financial securities (oferta púbica de valores mobiliários) in Portugal, within the meaning of Article 109 of the Portuguese Securities Code (Código dos Valores Mobiliários). The common stock has not been offered or sold and will not be offered or sold, directly or indirectly, to the public in Portugal. This document and any other offering material relating to the common stock has not been, and will not be, submitted to the Portuguese Securities Market Commission (Comissão do Mercado de Valores Mobiliários) for approval in Portugal and, accordingly, may not be distributed or caused to distributed, directly or indirectly, to the public in Portugal, other than under circumstances that are deemed not to qualify as a public offer under the Portuguese Securities Code. Such offers, sales and distributions of common stock in Portugal are limited to persons who are "qualified investors" (as defined in the Portuguese Securities Code). Only such investors may receive this document and they may not distribute it or the information contained in it to any other person.

## Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the securities may not be circulated or distributed, nor may the securities be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore, or the SFA, (ii) to a relevant person pursuant to Section 275(1), or any person pursuant to Section 275(1A), and in accordance with the conditions specified in Section 275 of the SFA or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA, in each case subject to compliance with conditions set forth in the SFA.

Where the securities are subscribed or purchased under Section 275 of the SFA by a relevant party which is:

 a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or

• a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor,

securities of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the securities pursuant to an offer made under Section 275 of the SFA except:

- to an institutional investor (for corporations, under Section 274 of the SFA) or to a relevant person defined in Section 275(2) of the SFA, or to any person pursuant to an offer that is made on terms that such securities of that corporation or such rights and interest in that trust are acquired at a consideration of not less than \$200,000 (or its equivalent in a foreign currency) for each transaction, whether such amount is to be paid for in cash or by exchange of securities or other assets, and further for corporations, in accordance with the conditions specified in Section 275 of the SFA;
- where no consideration is or will be given for the transfer; or
- where the transfer is by operation of law.

# Sweden

This document has not been, and will not be, registered with or approved by Finansinspektionen, or the Swedish Financial Supervisory Authority. Accordingly, this document may not be made available, nor may the common stock be offered for sale in Sweden, other than under circumstances that are deemed not to require a prospectus under the Swedish Financial Instruments Trading Act (1991:980) (Sw. lag (1991:980) om handel med finansiella instrument). Any offering of common stock in Sweden is limited to persons who are "qualified investors" (as defined in the Financial Instruments Trading Act). Only such investors may receive this document and they may not distribute it or the information contained in it to any other person.

## Switzerland

The common stock may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange, or SIX, or on any other stock exchange or regulated trading facility in Switzerland. This document has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering material relating to the common stock may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering material relating to the common stock has been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of common stock will not be supervised by, the Swiss Financial Market Supervisory Authority (FINMA).

This document is personal to the recipient only and not for general circulation in Switzerland.

## **United Arab Emirates**

Neither this document nor the common stock have been approved, disapproved or passed on in any way by the Central Bank of the United Arab Emirates or any other governmental authority in the United Arab Emirates, nor have we received authorization or licensing from the Central Bank of the United Arab Emirates or any other governmental authority in the United Arab Emirates to market or sell the common stock within the United Arab Emirates. This document does not constitute and may not be used for the purpose of an offer or invitation. No services relating to the common stock, including the receipt of applications and/or the allotment or redemption of such shares, may be rendered within the United Arab Emirates by us.

No offer or invitation to subscribe for common stock is valid or permitted in the Dubai International Financial Centre.



# **United Kingdom**

Neither the information in this document nor any other document relating to the offer has been delivered for approval to the Financial Services Authority in the United Kingdom and no prospectus (within the meaning of Section 85 of the Financial Services and Markets Act 2000, as amended, or the FSMA) has been published or is intended to be published in respect of the common stock. This document is issued on a confidential basis to "qualified investors" (within the meaning of Section 86(7) of FSMA) in the United Kingdom, and the common stock may not be offered or sold in the United Kingdom by means of this document, any accompanying letter or any other document, except in circumstances that do not require the publication of a prospectus pursuant to Section 86(1) FSMA. This document should not be distributed, published or reproduced, in whole or in part, nor may its contents be disclosed by recipients to any other person in the United Kingdom.

Any invitation or inducement to engage in investment activity (within the meaning of Section 21 of FSMA) received in connection with the issue or sale of the common stock has only been communicated or caused to be communicated and will only be communicated or caused to be communicated in the United Kingdom in circumstances in which Section 21(1) of FSMA does not apply to us.

In the United Kingdom, this document is being distributed only to, and is directed at, persons (i) who have professional experience in matters relating to investments falling within Article 19(5) (investment professionals) of the Financial Services and Markets Act 2000 (Financial Promotions) Order 2005, or the FPO, (ii) who fall within the categories of persons referred to in Article 49(2)(a) to (d) (high net worth companies, unincorporated associations, etc.) of the FPO or (iii) to whom it may otherwise be lawfully communicated, or, together, relevant persons. The investments to which this document relates are available only to, and any invitation, offer or agreement to purchase will be engaged in only with, relevant persons. Any person who is not a United Kingdom relevant person should not act or rely on this document or any of its contents.

#### LEGAL MATTERS

The validity of the shares of common stock being offered by this prospectus will be passed upon for us by Dechert LLP, New York, New York. Certain legal matters relating to this offering will be passed upon for the underwriters by Cooley LLP, New York, New York.

# EXPERTS

The consolidated financial statements of MonoSol Rx, LLC, as of December 31, 2017 and 2016, and for each of the years in the two-year period ended December 31, 2017, have been included herein and in the registrants statement appearing elsewhere herein, and in reliance upon the report of KPMG LLP, an independent registered public accounting firm, upon the authority of said firm as experts in accounting and auditing.

## WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act, with respect to the shares of common stock being offered by this prospectus. This prospectus does not contain all of the information in the registration statement and its exhibits. For further information with respect to us and the common stock offered by this prospectus, we refer you to the registration statement and its exhibits. Statements contained in this prospectus as to the contents of any contract or any other document referred to are not necessarily complete, and in each instance, we refer you to the copy of the contract or other document filed as an exhibit to the registration statement. Each of these statements is qualified in all respects by this reference.

You can read our SEC filings, including the registration statement, over the Internet at the SEC's website at www.sec.gov. You may also read and copy any document we file with the SEC at its public reference facilities at 100 F Street, N.E., Washington, D.C. 20549. You may also obtain copies of these documents at prescribed rates by writing to the Public Reference Section of the SEC at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the public reference facilities. You may also request a copy of these filings, at no cost, by writing us at 30 Technology Drive, Warren, New Jersey 07059 or telephoning us (908) 941-1900.

Upon the closing of this offering, we will be subject to the information reporting requirements of the Exchange Act, and we will file reports, proxy statements and other information with the SEC. These reports, proxy statements and other information will be available for inspection and copying at the public reference room and web site of the SEC referred to above. We also maintain a website at www.aquestive.com, at which, following the closing of this offering, you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. The information contained in, or that can be accessed through, our website is incorporated by reference in, and is not part of, this prospectus.

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#### **Report of Independent Registered Public Accounting Firm**

To the Members and Board of Directors MonoSol Rx, LLC:

# Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of MonoSol Rx, LLC and its subsidiary (the "Company") as of December 31, 2017 and 2016, the related consolidated statements of operations and comprehensive loss, changes in members' deficit, and cash flows for each of the years in the two-year period ended December 31, 2017, and the related notes (collectively, the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2017 and 2016, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2017 and 2016, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2017, in conformity with U.S. generally accepted accounting principles.

#### Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated 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 in accordance with the standards of the PCAOB and in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated 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 consolidated 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 consolidated 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 consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

## /s/ KPMG LLP

We have served as the Company's auditor since 2006.

New York, New York April 2, 2018



# MonoSol Rx, LLC Consolidated Balance Sheets (In thousands, except unit amounts)

	December 31, 2017		December 31, 2016	
Assets				
Current assets:				
Cash and cash equivalents	\$	17,379	\$	9,209
Trade and other receivables, net		6,179		10,817
Inventories		4,014		2,886
Prepaid expenses and other current assets		591		420
Total current assets		28,163		23,332
Property and equipment, net		13,460		15,122
Intangible assets, net		254		305
Other assets		1,239		630
Total assets	\$	43,116	\$	39,389
Liabilities and Members' Deficit				
Current liabilities:				
Accounts payable	\$	9.601	\$	6.638
Accrued expenses	Ŧ	4,402	Ŧ	3,366
Deferred revenue		1,347		802
Total current liabilities		15,350		10,806
Noncurrent liabilities:		10,000		10,000
Loans payable, net		45,507		38,650
Warrant liability		7,673		6,550
Asset retirement obligations		1,081		959
Total noncurrent liabilities		54.261		46.159
Redeemable Preferred A-3 interests and accrued dividends		5,896		5,458
Redeemable Preferred A-2 interests and accrued dividends		36,205		34,163
Members' equity (deficit):		30,205		34,103
Preferred A interests, no par value. Authorized 100,000,000 units; 16,886,750 units				
issued and outstanding at December 31, 2017 and 2016		16,887		16,887
Preferred A-1 interests, no par value. Authorized 100,000,000 units; 21,526,850		10,001		10,001
units issued and outstanding at December 31, 2017 and 2016		21,883		21,883
Common interests, no par value. Authorized 500,000,000 units; 121,228,353 and 118,785,104 units issued and outstanding at December 31, 2017 and 2016,		,		,
respectively		12,727		11,243
Additional paid-in capital		_		1,460
Accumulated deficit		(120,093)		(108,670)
Total members' deficit		(68,596)		(57,197)
Total liabilities and members' equity	\$	43,116	\$	39,389

See accompanying notes to the consolidated financial statements

MonoSol Rx, LLC Consolidated Statements of Operations and Comprehensive Loss (In thousands, except per membership interest and per share data amounts)

		Year Ended December 31, 2017		Year Ended December 31, 2016
Revenues	\$	66,918	\$	51,785
Costs and expenses:				
Manufacture and supply		19,820		16,378
Research and development		22,133		15,450
Selling, general and administrative		25,078		20,804
Total costs and expenses		67,031		52,632
Operating loss		(113)		(847)
Other expenses:				
Interest expense		(7,707)		(6,143)
Loss on extinguishment of debt		—		(757)
Loss on impairment of investment		—		(1,006)
Change in fair value of warrant		(1,123)		(750)
Other income (expense)				(99)
Net loss before income taxes		(8,943)		(9,602)
Income taxes				
Net loss		(8,943)		(9,602)
Dividends on redeemable preferred interests		(2,480)		(2,342)
Net loss attributable to members' interests		(11,423)		(11,944)
Comprehensive loss	\$	(11,423)	\$	(11,944)
Net loss per membership interest basic and diluted	\$	(0.09)	\$	(0.10)
	Ψ	(0.03)	Ψ	(0.10)
Weighted-average number of membership interests outstanding basic and diluted		121,228,353	_	118,785,104

See accompanying notes to the consolidated financial statements

# MonoSol Rx, LLC Consolidated Statements of Changes in Members' Deficit (In thousands, except unit amounts)

	Preferred A	interests	Preferred A-1 interests		Common interests		Additional paid-in	Accumulated	Total members'
	Units	Amount	Units	Amount	Units	Amount	capital	deficit	deficit
Balance at December 31, 2015	16,886,750	\$16,887	21,526,850	\$21,883	118,785,104	\$11,243	\$ 1,460	\$ (96,726)	\$ (45,253)
Dividends on preferred interests	_	_	_	_	_	_	_	(2,342)	(2,342)
Net loss								(9,602)	(9,602)
Balance at December 31, 2016	16,886,750	16,887	21,526,850	21,883	118,785,104	11,243	1,460	(108,670)	(57,197)
Dividends on preferred interests	_	_	_	_	_	_	_	(2,480)	(2,480)
Net loss		_		_		_	_	(8,943)	(8,943)
Issuance of common interests upon exercise of warrants	_	_	_	_	2,443,249	1,484	(1,460)	_	24
Balance at December 31, 2017	16,886,750	\$16,887	21,526,850	\$21,883	121,228,353	\$12,727	<u>\$                                    </u>	\$ (120,093)	\$ (68,596)

See accompanying notes to the consolidated financial statements

# MonoSol Rx, LLC Consolidated Statements of Cash Flows (In thousands)

	For the Year Ended December 31,			
		2017		2016
ash flows from operating activities:				
Net loss	\$	(8,943)	\$	(9,60
Adjustments to reconcile net loss to net cash provided by (used for) operating activities:				
Depreciation and amortization		3,750		3,8
Loss on impairment of investment		—		1,0
Change in fair value of warrant		1,123		7
Asset retirement obligation accretion		122		1
Amortization of intangible		51		
Amortization of debt issuance costs and discounts		1,860		8
Loss on extinguishment of debt		—		7
Equity in milestone revenue of affiliate		—		2
Loss on sale of investment		—		
Non-cash interest expense		33		(
Bad debt (recovery) provision		(53)		
Changes in operating assets and liabilities:				
Trade receivables and other receivables		4,691		(6,5
Inventories		(1,128)		(1,5
Prepaid expenses		(171)		(
Accounts payable		2,943		1,6
Accrued expenses		1,001		4
Deferred revenue		545		(2
Net cash provided by (used for) operating activities		5,824		(8,1
Cash flows from investing activities:				
Capital expenditures		(2,068)		(9
Proceeds from sale of investment		_		1,1
Net cash (used for) provided by investing activities		(2,068)		1
Cash flows from financing activities:				
Proceeds from warrant exercise		24		
Proceeds from issuance of debt		5,000		45,0
Debt repayment				(37,5
Payments for debt issuance costs		(610)		(1,2
Payment of premium on early extinguishment of debt		_		(5
Net cash provided by financing activities		4,414		5,6
Net increase (decrease) in cash and cash equivalents		8,170		(2,2
Cash and cash equivalents:		-1		(-,-
Beginning of period		9,209		11,5
End of period	\$	17,379	\$	9,2
	<u> </u>		<u> </u>	0,2
Supplemental disclosures of cash flow information:				
Cash payments for interest	\$	5,814	\$	5,0
Capital expenditures included in accounts payable		20		1
Accrued Series A-2 and A-3 preferred dividends		2,480		2,3

See accompanying notes to the consolidated financial statements

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(In thousands, except unit and per unit information)

# 1. Nature of Business

MonoSol Rx, LLC ("MonoSol" or "the Company") is a specialty pharmaceutical company focused on identifying, developing and commercializing differentiated products to address unmet medical needs. The Company has a latestage proprietary product pipeline focused on the treatment of diseases of the central nervous system, or CNS. The Company's major customer has global operations headquartered in the United Kingdom with principal operations in the United States; other customers are principally located in the United States.

The Company conducts its production activities at facilities located in Portage, Indiana, and maintains its headquarters and its primary research laboratory in Warren, New Jersey.

The Company has incurred operating losses since inception and had an accumulated deficit of \$120,093 and \$108,670 as of December 31, 2017 and 2016, respectively. The Company expects to continue to incur net losses for at least the next several years and is highly dependent on its ability to find additional sources of funding in the form of debt or equity financings to fund its operations. Management believes that its cash and cash equivalents of \$17,379 at December 31, 2017 combined with expected revenue from partnered product activities are sufficient to fund operations through at least May 2019. Management expects that future sources of funding may include new or expanded partnering arrangements and sales of equity or debt securities. Adequate additional funding may not be available to the Company on acceptable terms or at all. The failure to raise capital as and when needed could have a negative impact on the Company's financial condition and ability to pursue business strategies. The Company may be required to delay, reduce the scope of or eliminate research and development programs, or obtain funds through arrangements with collaborators or others that may require the Company to relinquish rights to certain product candidates that the Company might otherwise seek to develop or commercialize independently.

The Company changed its name to Aquestive Therapeutics, Inc. on January 1, 2018, and at the same time became a Delaware corporation.

# 2. Significant Accounting Policies

## (A) Basis of Presentation

These consolidated financial statements are prepared in conformity with accounting principles generally accepted in the United States ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative United States generally accepted principles as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board ("FASB").

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. This basis of accounting contemplates the recovery of the Company's assets and the satisfaction of liabilities in the normal course of business. The consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

## (B) Principles of Consolidation

These consolidated financial statements include the accounts of the Company and its wholly owned subsidiary, MonoSol Rx, Inc. Other than corporate formation activities, MonoSol Rx, Inc. has conducted no commercial, developmental or operational activities and has no customers or vendors.

# NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

(In thousands, except unit and per unit information)

#### (C) Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results may differ from those estimates.

## (D) Net Loss Attributable to Members' Interest

Basic net loss per membership interest is calculated by dividing net loss attributable to members' interest less cumulative preferred stock dividends. During periods of income, the Company allocates participating securities a proportional share of income determined by dividing total weighted-average participating securities by the sum of the total weighted-average common interests and participating securities (the "two class method"). The Company's convertible preferred stock participating securities have the effect of diluting both basic and diluted earnings per share during periods of income. During periods of loss, the Company allocates no loss to participating securities because they have no contractual obligation to share in the losses of the Company. Diluted net loss per membership interest is calculated by adjusting weighted-average shares outstanding for the dilutive effect of common stock equivalents outstanding for the period, determined using the treasury-stock method and if-converted methods. For purposes of the diluted net loss per membership interest calculation, convertible preferred stock and stock options are considered to be common stock equivalents, but have been excluded from the calculation of diluted net loss per membership interest, as their effect would be anti-dilutive for all periods presented. Therefore, basic and diluted net loss per share were the same for all periods presented.

	For the Year Ended December 31,			
	 2017	_	2016	
Numerator:				
Net income (loss)	\$ (8,943)	\$	(9,602)	
Accrued dividends on redeemable preferred interests	 (2,480)		(2,342)	
Loss attributable to common shares - basic and diluted	 (11,423)		(11,944)	
Denominator:				
Weighted-average number of common shares - basic and diluted	 121,228,353		118,785,104	
Loss per common share - basic and diluted	\$ (0.09)	\$	(0.10)	

#### (E) Deferred Transaction Costs

Deferred Transaction costs, primarily costs of direct incremental legal, accounting and other fees relating to the Company's contemplated initial public offering ("IPO"), are capitalized as incurred. The deferred transaction costs will be offset against IPO proceeds upon the consummation of the offering. In the event the IPO is terminated, which would include a postponement of 90 days or greater, any deferred transaction costs will be expensed. The Company has capitalized costs totaling approximately \$1,050 that have been incurred in connection with ongoing equity raising initiatives. These amounts are recorded in Other assets.

# (F) Off-Balance Sheet Risk and Concentration of Credit Risk

Cash and cash equivalents are maintained at one federally insured financial institution. The Company has not experienced any losses in such accounts and management believes that the Company



# NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

#### (In thousands, except unit and per unit information)

is not exposed to any credit risk due to the financial position of the banking institution. The Company has no off-balance sheet risk, such as foreign exchange contracts, option contracts, or other foreign hedging arrangements.

## (G) Segment Information

Operating segments are defined as components of an entity about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. The Company manages its operations as a single segment for purposes of assessing performance and making operating decisions.

## (H) Fair Value of Financial Instruments

FASB guidance specifies a hierarchy of valuation techniques based on whether the inputs to those valuation techniques are observable or unobservable. Observable inputs reflect market data obtained from independent sources, while unobservable inputs reflect market assumptions. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurement) and the lowest priority to unobservable inputs (Level 3 measurement).

The three levels of the fair value hierarchy are as follows:

- Level 1 Unadjusted quoted prices in active markets for identical assets or liabilities that the reporting entity
  has the ability to access at the measurement date. Level 1 primarily consists of financial instruments whose
  value is based on quoted market prices such as exchange-traded instruments and listed equities.
- Level 2 Inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly (*e.g.*, quoted prices of similar assets or liabilities in active markets, or quoted prices for identical or similar assets or liabilities in markets that are not active). Level 2 includes financial instruments that are valued using models or other valuation methodologies. The Company had no Level 2 assets or liabilities as of December 31, 2017 and 2016.
- Level 3 Unobservable inputs for the asset or liability. Financial instruments are considered Level 3 when the fair values are determined using pricing models, discounted cash flows or similar techniques and at least one significant model assumption or input is unobservable. The Company's Level 3 liabilities consisted of warrants totaling \$7,673 and \$6,550 at December 31, 2017 and 2016, respectively. The Company's warrant liability is stated at fair value.

The carrying amounts reported in the balance sheets for trade and other receivables, prepaid and other current assets, accounts payable, accrued expenses and deferred revenue approximate fair value based on the short-term maturity of these instruments.

## (I) Cash and Cash Equivalents

The Company considers investments with an original maturity of three months or less to be cash equivalents. At December 31, 2017 and 2016, the Company had no cash equivalents.

# (J) Foreign Currency

The functional currency of the Company's wholly-owned subsidiary is the U.S. dollar.

## (K) Trade Receivables

The Company's credit terms generally range from 30 to 60 days, depending on the customer and type of invoice. Trade receivables are carried at original invoice amount less an estimate of doubtful receivables based on a review of all outstanding amounts on a periodic basis. Management determines

# NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

#### (In thousands, except unit and per unit information)

the allowance for doubtful accounts by identifying troubled accounts and, in the absence of historical experience, applies an estimate that is believed to be a reasonable indicator of future potential losses. Trade receivables are written off when deemed uncollectible. Recoveries of trade receivables previously written off are recorded when received.

# (L) Inventories

Inventories are stated at the lower of cost or net realizable value. Cost is determined on a first-in, first-out basis. Inventory includes the cost of materials, production labor and overhead. The Company regularly reviews its inventories for impairment and reserves are established when necessary.

#### (M) Property and Equipment

Property and equipment are stated at cost. Leasehold improvements are amortized over the shorter of the term of the lease or their estimated useful lives. Depreciation of equipment, furniture and fixtures is calculated using the straight-line method over the estimated useful lives of the assets. Repairs and maintenance costs are expensed. The Company reviews the recoverability of all long-lived assets, including the related useful life, whenever events or changes in circumstances indicate that the carrying value amount of a long-lived asset may not be recoverable.

## (N) Impairment of Long-Lived Assets

In accordance with the Subsections of FASB ASC Subtopic 360-10, *Property, Plant and Equipment – Overall*, longlived assets, such as property and equipment and intangible assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. That carrying value is considered unrecoverable if it exceeds the sum of the undiscounted cash flows expected from the use and eventual disposition of the asset.

As a result of management's evaluation of the recoverability of the carrying value of long-lived assets subject to ASC 360-10, no impairment charges were recorded for the years ended December 31, 2017 and 2016.

## (O) Investments

For entities or ventures that are under shared control, owned and managed equally by the Company and a third party and in which the Company is a direct and active participant in the entity's operating activities and through which it is directly exposed to the risks and rewards of operating activities, the Company's investments are carried at cost. Acting as principal in carrying out its operational responsibilities, the Company records its share of related revenue and its expense transactions reflecting all of that revenue and its third-party expenses in its consolidated financial statements in accordance with the nature of the revenue or in a manner to proportional consolidation.

# (P) Intangible Assets

Intangible assets include the costs of acquired composition and process technologies and the costs of purchased patents used in the manufacture of orally soluble film. The Company amortizes these assets using the straight-line method over the shorter of their legal lives or estimated useful lives.

#### (Q) Patent Costs

Patent procurement, prosecution and defense litigation costs are expensed as incurred, including costs for patent continuation applications. The Company's primary domestic and international patents expire between 2022 and 2031.

# NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

## (In thousands, except unit and per unit information)

#### (R) Retirement Plan

The Company maintains a 401(k)-retirement plan for its employees that is intended to qualify under Sections 401(a) and 501(a) of the U.S. Internal Revenue Code of 1986, as amended ("Code"), in 2016. The Company provides all active employees with 100% matching contribution equal to 6% of an employee's eligible compensation. These safe harbor employer match contributions vest as follows: less than one year: 0%; one year: 20%; two years: 40%; three years: 60%; four years: 80%; and five years: 100%.

## (S) Research and Development

Costs incurred in connection with research and development activities are expensed as incurred. Research and development expenses include (i) employee-related expenses, including salaries, benefits, travel and share-based compensation expense, (ii) external research and development expenses incurred under arrangements with third parties, such as contract research and contract manufacturing organizations, investigational sites and consultants, (iii) the cost of acquiring, developing and manufacturing clinical study materials, and (iv) costs associated with preclinical and clinical activities and regulatory operations. Nonrefundable advance payments for goods and services that will be used in future research and development activities are expensed when the activity is performed or when the goods have been received, rather than when payment is made, in accordance with ASC 730, *Research and Development*.

## (T) Income Taxes

From its founding through October 31, 2017, the Company was a limited liability company ("LLC") treated as a partnership for income tax purposes. From November 1, 2017 through December 31, 2017, the LLC elected to be taxed as a C corporation.

From November 1, 2017, the Company accounts for income taxes under the asset and liability method, which requires deferred tax assets and liabilities to be recognized for the estimated future tax consequences attributable to differences between financial statement carrying amounts and respective tax bases of existing assets and liabilities, as well as net operating loss carryforwards and research and development credit. Valuation allowances are provided if it is more likely than not that some portion or all of the deferred tax asset will not be realized.

## (U) Revenue Recognition

Pursuant to FASB ASC Topic 605, *Revenue Recognition*, revenue is recognized when there is persuasive evidence of an agreement, title has passed or delivery has occurred, the price is fixed and determinable, and collection is reasonably assured.

*Manufacture and Supply Revenue* – The Company records revenues when products are shipped and title passes to the customers.

*Co-development and Research Fees* – Co-development and research fees are earned through performance of specific tasks, activities or completion of stages of development defined within a contractual arrangement with a customer. The nature of these performance obligations, broadly referred to as milestones or deliverables, are usually dependent on the scope and structure of the project as contracted, as well as the complexity of the product and the specific regulatory approval path necessary for that product. Accordingly, the duration of the Company's research and development projects may range from several months to approximately three years. Although each contractual arrangement is unique, common milestones included in these arrangements include those for the performance of efficacy and other tests, reports of findings, formulation of initial prototypes, production of stability clinical and/or scale-up batches, and stability testing of those batches. Additional milestones may be established and



# NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

#### (In thousands, except unit and per unit information)

linked to clinical results of the product submission and/or approval of the product by the FDA and the commercial launch of the product. Co-development and research fees are recognized when related milestones are completed and delivered and, in some cases, accepted by the customer.

*License and Royalty Revenue* – License revenue is recognized in accordance with the terms of the license agreement. The revenue will be recognized ratably over the initial term of the license agreement. If the term of the license is perpetual, the Company will recognize the revenue upon the execution of the license as long as there are no contingencies in the license agreement. If a contingency exists, the revenue will need to be deferred until such time that the contingencies are lifted. Royalty revenue is recognized in accordance with contractual rates when they can be reasonably estimated based on reported sales data and when collection is reasonably assured. In the event that reasonable sales data is unavailable, revenue is recognized when royalty reports are received.

*Collaborative Arrangements* – A contractual arrangement falls within the scope of FASB ASC Subtopic 808-10, Collaborative Arrangements, if the arrangement requires the parties to be active participants and the arrangement exposes the parties to significant risks that are tied to the commercial success of the endeavor. Costs incurred and revenues generated on sales to third parties are reported in the consolidated statement of operations based on the guidance in FASB ASC Subtopic 605-45, *Revenue Recognition – Principal Agent Considerations*. Revenue earned from collaboration partners as of December 31, 2017 and 2016 was not material.

#### (V) Share-Based Payments

The Company issues share-based payments under the terms of its Performance Unit Plans (the "PUP Plans"). The cost of employee services received in exchange for equity-based awards are determined based on FASB ASC Topic 718, *Compensation – Stock Compensation* using the grant-date fair value of the awards. Under the Company's PUP Plans, all outstanding equity-based payments are to be recognized as an expense based on their fair value at the measurement date, which is delayed until achievement of specified performance conditions can be considered probable. At the time that all contingencies are satisfied, the performance units granted to both employees and consultants will be reflected as liability-classified instruments based on the application of FASB ASC Topic 718.

## (W) Asset Retirement Obligations

FASB ASC Subtopic 410-20, Asset Retirement and Environmental Obligations – Asset Retirement Obligations, addresses financial accounting and reporting for obligations associated with the retirement of tangible long-lived assets and the associated asset retirement costs. The Company's asset retirement obligation ("ARO") consists of estimated future spending to remove certain leasehold improvements and return each leased facility to its original condition. The Company records an ARO asset (a component of property and equipment) and associated liability equal to the present value of the estimated future spending at the date the asset is placed in service. Spending estimates are discounted at the credit-adjusted risk-free rate. The ARO asset is amortized on the straight-line method over the lesser of its expected life or the lease term and the ARO liability is accreted over the lesser of expected life or the lease term.

## (X) Comprehensive Loss

Comprehensive loss is the change in members' equity (deficit) from transactions and other events and circumstances other than those resulting from investments by members and distributions to members.

# NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

(In thousands, except unit and per unit information)

#### (Y) Recent Accounting Pronouncements

As a public emerging growth company, the Company has elected to take advantage of the extended transition period afforded by Jumpstart Our Business Startups Act for the implementation of new or revised accounting standards and, as a result, the Company will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for public emerging growth companies.

From time to time, new accounting pronouncements are issued by the FASB and adopted by the Company as of the specified effective date. Unless otherwise discussed, the Company believes that the impact of recently issued standards that are not yet effective will not have a material impact on its financial position or results of operations upon adoption.

In May 2014, the FASB issued ASU 2014-09, Revenue from Contracts with Customers (Topic 606). The standard will apply one comprehensive revenue recognition model across all contracts, entities, and sectors. The core principle of the new standard is that revenue should be recognized to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. Once effective, ASU 2014-09 will replace most of the existing revenue recognition requirements in U.S. GAAP. The FASB also issued ASU 2015-14, Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date, which deferred the effective date of the standard one year. As a result, the new standard is effective for annual reporting periods beginning after December 15, 2019, including interim periods within the reporting period. The Company is currently assessing the effect that adoption of the new standard will have on its consolidated financial statements. As of part of the Company's assessment, an entity can elect to apply the guidance under one of the following two methods: (i) retrospectively to each prior reporting period presented, referred to as the full retrospective method, or (ii) retrospectively with the cumulative effect of initially applying the standard recognized at the date of initial application in retained earnings, referred to as the modified retrospective method. The Company is in the process of its initial assessment of the potential changes from adopting ASU No. 2014-09. The initial assessment consists of a review of a representative sample of contracts, discussions with key stakeholders, and a cataloging of potential impacts on its consolidated financial statements, accounting policies, financial control, and operations. The Company has not yet completed its final review of the impact; however, the Company anticipates applying the modified retrospective method when implementing this guidance. As a result, this standard is effective for the Company for annual reporting periods beginning after December 15, 2019. The Company continues to monitor additional changes, modifications, clarifications or interpretations being undertaken by the FASB, which may impact its initial conclusions.

In January 2016, the FASB issued revised guidance governing accounting and reporting of financial instruments. This guidance requires that equity investments with readily determinable fair values that are classified as available-forsale be measured at fair value with changes in value reflected in current earnings. This guidance also simplifies the impairment testing of equity investments without readily determinable fair values and alters certain disclosure requirements. ASU No. 2016-01, *Financial Instruments-Overall: Recognition and Measurement of Financial Assets and Financial Liabilities*, also provides guidance as to classification of the change in fair value of financial liabilities. These revised standards are effective for the Company for annual periods in fiscal years beginning after December 15, 2018. The Company is currently evaluating the impact of these revised standards.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)* which establishes a comprehensive new lease accounting model. The new standard: (i) clarifies the definition of a lease; (ii) requires a dual approach to lease classification similar to current lease classifications; and (iii) causes lessees to recognize leases on the balance sheet as a lease liability with a corresponding right-of-use asset for leases with a lease-term of more than twelve months. The new standard is effective for the

# NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

#### (In thousands, except unit and per unit information)

Company for fiscal years and interim periods beginning after December 15, 2019 and requires modified retrospective application. Early adoption is permitted. The Company is currently evaluating the impact that the adoption of ASU 2016-02 will have on its consolidated financial statements.

In March 2016, the FASB issued ASU 2016-09, *Compensation – Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting.* This guidance simplifies aspects of accounting for employee share-based payments, including income tax consequences, classification of awards as either equity or liabilities, and classifications within the statement of cash flows. This guidance is effective for annual periods beginning after December 15, 2017, with early adoption permitted. Under the Company's PUP Plans (note 18), vested grants may not be exercised prior to either a change in control of the Company or completion of an IPO, rendering the grants contingent and requiring deferred expense recognition until either of the conditions is satisfied. Accordingly, the adoption of ASU 2016-09 will have no impact on the Company's consolidated financial statements until these contingencies are met.

In June 2016, the FASB issued, ASU No. 2016-13, *Financial Instruments – Credit Losses (Topic 326)*, amending existing guidance on the accounting for credit losses on financial instruments within its scope. The guidance introduces an expected loss model for estimating credit losses, replacing the incurred loss model. The new guidance also changes the impairment model for available-for-sale debt securities, requiring the use of an allowance to record estimated credit losses (and subsequent recoveries). The new guidance is effective for the Company beginning after December 15, 2020. The Company is currently evaluating the impact of adoption on its consolidated financial statements.

In August 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments, providing* guidance on the classification of certain cash receipts and payments in the statement of cash flows intended to reduce diversity in practice. The guidance is effective for the Company for fiscal years beginning after December 15, 2018. Early adoption is permitted. The Company is currently evaluating the effect of the standard on its Consolidated Statement of Cash Flows.

## 3. Revenues and Trade Receivables, Net

The Company's revenue was comprised of the following:

		For the Year Ended December 31,			
	2017		2016		
Manufacture and supply revenue	\$ 40,0	)92 \$	37,324		
License and royalty revenue	23,2	_33	11,320		
Co-development and research fees	3,6	693	3,141		
Revenues	\$ 66,9	)18 \$	51,785		
Trade receivables, net consist of the following:					

Trade receivables, net consist of the following:

		December 31,			
	2017			2016	
Trade receivables	\$	6,156	\$	10,764	
Less: allowance for bad debts		(55)		(108)	
Trade receivables, net	\$	6,101	\$	10,656	

Other nontrade receivables totaled \$78 and \$161 as of December 31, 2017 and 2016, respectively, consisting primarily of reimbursable costs incurred on behalf of a major customer.

# NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

#### (In thousands, except unit and per unit information)

The following table presents the changes in the allowance for bad debts account for the years ended December 31,

	 2017	 2016
Allowance for doubtful accounts at beginning of year	\$ 108	\$ 92
Additions charged to bad debt expense	0	16
Recoveries of amounts previously reserved	(53)	0
Allowance for doubtful accounts at end of year	\$ 55	\$ 108

## 4. Customer Concentrations

Customers are considered major customers when sales exceed 10% of total net sales for the period or outstanding receivable balances exceed 10% of total receivables. During 2017, one customer represented 88% of the total revenue for the period. During 2016, the Company had two customers meeting this criteria with approximately 76% and 17% of the total revenue for the period.

As of December 31, 2017 and 2016, the Company's outstanding receivable balance from the Company's major customer represented approximately 93% and 97%, respectively, of total receivables. As of December 31, 2016, our second largest customer had no outstanding receivable balance.

# 5. Material Agreements

## Commercial Exploitation Agreement with Indivior

In August 2008, the Company entered into a Commercial Exploitation Agreement with Reckitt Benckiser Pharmaceuticals, Inc. (the "Indivior License Agreement"). Reckitt Benckiser Pharmaceuticals, Inc. was later succeeded to in interest by Indivior, Inc. ("Indivior"). Pursuant to the Indivior License Agreement, the Company agreed to manufacture and supply Indivior's requirements of Suboxone, a sublingual film formulation, both inside and outside the United States on an exclusive basis.

Under the terms of the Indivior License Agreement, the Company is required to manufacture Suboxone in accordance with current Good Manufacturing Practice standards and according to the specifications and processes set forth in the related quality agreements the Company entered into with Indivior. Additionally, the Company is required to obtain Active Pharmaceutical Ingredients ("API") for the manufacture of Suboxone directly from Indivior. The Indivior License Agreement specifies a minimum annual threshold quantity of Suboxone that the Company is obligated to fill and requires Indivior to provide the Company with a forecast of its requirements at various specified times throughout the year.

In addition to the purchase price for the Suboxone supplied, Indivior is required to make certain single digit percentage royalty payments tied to net sales value (as provided for in the Indivior License Agreement) in each of the United States and in the rest of the world subject to annual maximum amounts. In the event that Indivior has paid the Company a specified aggregate royalty amount in royalties on Suboxone sold in the United States, then it will be required to prepay to the Company, an additional agreed payment amount, after which all obligations of Indivior's royalty obligations to the Company continue in the United States and the rest of the world until the expiration of all of the patents (either in the United States or other territories) or upon written notice by Indivior subject to Indivior being required to pay the Company a final royalty payout. Indivior exercised its right to buy out its future royalty obligations in the United States.

The Indivior License Agreement contains customary contractual termination provisions for breach or in the event of bankruptcy or corporate dissolution, the intellectual property surrounding Suboxone is



## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

#### (In thousands, except unit and per unit information)

found to be invalid, or either party commits a material breach of the Indivior License Agreement. Additionally, Indivior may terminate if the U.S. Food and Drug Administration ("FDA") or other applicable regulatory authority declares the Company's manufacturing site to no longer be suitable for the manufacture of Suboxone or Suboxone is no longer suitable to be manufactured due to health or safety reasons. The initial term of the Indivior License Agreement was seven years from the commencement date. Thereafter, the Indivior License Agreement automatically renews for successive one year periods, unless Indivior provides the Company with written notice of its intent not to renew at least one year prior to the expiration of the initial or renewal term.

## Supplemental Agreement with Indivior

On September 24, 2017, the Company entered into an agreement with Indivior (the "Indivior Supplemental Agreement") to clarify the scope of the relationship between the parties. Under the Indivior Supplemental Agreement, the Company is entitled to receive certain payments from Indivior commencing on the date of the agreement through January 1, 2023. In consideration for the rights granted to Indivior under the Indivior Supplemental Agreement, the Company received a non-refundable payment of \$17,000, which was recognized as revenue in 2017 and is presented in License and royalty revenue above. The Company may receive up to an additional \$49,000, consisting of a royalty equal to a low single digit percentage of net revenue earned by Indivior on Suboxone sales and performance-based milestone payments, with the aggregate payment amounts under the Indivior Supplemental Agreement capped at \$75,000.

All payments made by Indivior to the Company pursuant to the Indivior Supplemental Agreement are in addition to, and not in place of, any amounts owed by Indivior to the Company pursuant to the Indivior License Agreement. Indivior's payment obligations under the Indivior Supplemental Agreement are subject to certain factors affecting the market for Suboxone and may terminate prior to January 1, 2023 in the event certain contingencies relating to such market occur.

# License Agreement with Sunovion Pharmaceuticals, Inc.

In April 2016, the Company entered into a license agreement with Cynapsus Therapeutics Inc. (which was later succeeded to in interest by Sunovion Pharmaceuticals, Inc. ("Sunovion")) (the "Sunovion License Agreement"), pursuant to which the Company granted Sunovion an exclusive, worldwide license (with the right to sub-license) to certain intellectual property, including existing and future patents and patent applications, covering all oral films containing APL-130277 (apomorphine) for the treatment of off episodes in Parkinson's disease patients, as well as two other fields.

Under the Sunovion License Agreement, the Company received milestone payments of \$14,000, of which \$5,000 and \$9,000 for years ended December 31, 2017 and 2016, respectively, are presented in License and royalty revenue above. The Company is eligible to receive remaining milestone payments of up to \$11,000 for certain regulatory events and up to \$20,000 for commercial milestone events that are contingent on the achievement of certain sales levels. In addition to the milestone payments, the Company is entitled to receive low single digit percentage royalty payments on global net sales of products commercialized by Sunovion that include apormorphine as their API.

Absent early termination, the Sunovion License Agreement continues (on a country-by-country basis) until the expiration of all applicable licensed patents. Upon termination, all rights to intellectual property granted to Sunovion to develop and commercialize products will revert to the Company and Sunovion must continue to pay royalties to the Company on each sale of their remaining inventory of products commercialized by Sunovion which include apormorphine as their API.

# NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

## (In thousands, except unit and per unit information)

#### Collaboration and License Agreement with Mitsubishi Tanabe

In August 2017, the Company entered into an agreement with Mitsubishi Tanabe ("MT") to perform feasability studies related to Radicava, MT's Amyotrophic Lateral Sclerosis treatment using the compound edaravone. The activities for this arrangement were not material in 2017.

#### Agreement to Terminate CLA with KemPharm

In March 2012, the Company entered into an agreement with KemPharm, Inc. ("KemPharm"), to terminate a Collaboration and License Agreement entered into in April 2011, under this arrangement, we have the right to receive payments, including, but not limited to, royalty payments on any license of KP415, the sale of KP415 to a third party, the commercialization of KP415 and the portion of any consideration that is attributable to the value of KP415 and paid to KemPharm or its stockholders in a change of control transaction. The Company has not received payments under this arrangement in 2017 and 2016.

# 6. Inventory

Inventory consists of the following:

	 December 31,			
	2017		2016	
Raw material	\$ 725	\$	611	
Packaging material	2,225		1,433	
Finished goods	 1,064		842	
Total inventory	\$ 4,014	\$	2,886	

# 7. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist primarily of costs incurred in advance of services being received, including insurance, software licenses and service agreements.

	 December 31,		
	 2017		2016
Insurance	\$ 148	\$	125
Software licenses	125		54
Service agreements	75		29
Medical premiums	70		60
Subscriptions	44		8
Lab equipment	39		58
Memberships	30		27
Other	60		59
Total prepaid expenses and other current assets	\$ 591	\$	420



# NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

(In thousands, except unit and per unit information)

# 8. Property and Equipment, Net

	Useful	 December 31,			
	Lives	201	17		2016
Machinery	3-15 yrs	\$ 20,056	\$	19,130	
Furniture and fixtures	3-15 yrs	1,109		1,066	
Leasehold improvements	(a)	21,271		21,110	
Computer, network equipment and software	3-7 yrs	2,108		1,387	
Construction in progress		921		684	
		45,465		43,377	
Less: accumulated depreciation and amortization		(32,005)		(28,255)	
Total property and equipment, net		\$ 13,460	\$	15,122	

(a) Leasehold improvements are amortized over the shorter of the lease term or their estimated useful lives.

Total depreciation and amortization related to property and equipment were \$3,750 and \$3,840 for the years ended December 31, 2017 and 2016, respectively.

## 9. Intangible Assets

The following table provides the components of identifiable intangible assets, all of which are finite lived:

	 December 31,		
	 2017		2016
Purchase technology-based intangible	\$ 2,358	\$	2,358
Purchased patent	 509		509
	2,867		2,867
Less: accumulated amortization	 (2,613)		(2,562)
Intangible assets, net	\$ 254	\$	305

Amortization expense was \$51 for each of the years ended December 31, 2017 and 2016. During the remaining life of the purchased patent, estimated annual amortization expense is \$51 for each of the years from 2018 to 2022.

# **10. Investments**

During the fourth quarter of 2016, the Company sold all holdings of equity interests in Midatech Pharma, PLC, realizing proceeds of \$1,166. Through a series of investments in Midatech shares, warrants and convertible loan notes, the Company's investment grew to a total of \$5,802 between 2008 and 2013. As a result of a series of dilutive equity transactions executed by Midatech between 2013 and 2015, the Company's ownership position declined from 12.4% to 2.6% as of December 31, 2015, and the Company then determined to monetize this asset. As a result of this dilution, declining market valuations and the decision to liquidate this investment, impairment charges aggregating to \$1,006 were reflected in earnings in 2016. The Company's investment in this joint venture, carried at cost, totaled \$6 as of December 31, 2017 and is recorded in Other assets on the consolidated balance sheets.

Concurrent with the sales of these interests in 2016, losses on disposals totaling \$95 were recognized.

# NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

#### (In thousands, except unit and per unit information)

In addition to its investments in Midatech shares, pursuant to the agreement between the parties, the Company also funded certain project development costs. These costs are expensed to research and development as paid and totaled \$4,842 through December 31, 2017.

In 2011, Midatech Ltd. and the Company entered into a Joint Venture Agreement for the development and commercialization of diabetes-related products and formed MidaSol Therapeutics (the "JV") to conduct planned activities. The agreement provides each of the two venture partners with 50% ownership interests, identical voting and management rights and responsibilities, equal representation on the governing four-member board of managers, the requirement to contribute relevant intellectual property by each party and equal sharing of profits and losses to each party for JV products or services. Each of the parties actively participates in the conduct and performance of the venture's undertakings, each acts as principal in the completion of its obligations and each is subject to the risks and rewards inherent in related joint operations. All of MidaSol's research, development, production and sales activities have been conducted through the facilities of each party and carried out by the parties' employees or contractors. For all products and services provided to its customers, except those related to research studies, costs are reimbursed to the parties from earned revenues prior to the sharing of profits.

#### **11. Accrued Expenses**

Accrued expenses consisted of the following:

	Decen	nber 31,
	2017	2016
Bonus	\$ 3,257	\$ 2,360
Payroll and benefits	548	585
Other	597	421
Total accrued expenses	\$ 4,402	\$ 3,366

# 12. Loans Payable

On August 16, 2016, the Company entered into a Loan Agreement and Guaranty with Perceptive Credit Opportunities Fund, LP ("Perceptive"). At closing, the Company borrowed \$45,000 from Perceptive and was permitted to borrow up to an additional \$5,000 within one year of the closing date based upon achievement of a defined milestone. In March 2017, the Company met its performance obligations under the terms of the credit agreement with Perceptive and submitted a formal request to draw down the remaining \$5,000 of its \$50,000 credit facility. The loan proceeds have been used to pay the existing debt obligation of \$37,500 due to White Oak Global Advisors, LLC, with the balance available for general business purposes. This debt retirement resulted in a loss on extinguishment of debt in the amount of \$757, consisting primarily of early retirement fees, the write-off of unamortized debt discounts and acquisition fees and related legal expenses.

The loan from Perceptive will mature on August 16, 2020 and bears interest, payable monthly, at one-month LIBOR or 2% plus 9.75%, subject to a minimum rate of 11.75%. Commencing on January 31, 2019, seven monthly loan principal payments are due in the amount of \$550. Thereafter, monthly principal payments in the amount of \$750 are due through the maturity date, at which time the full amount of the remaining outstanding loan balance is due. The Company's tangible and intangible assets are subject to first priority liens to the extent of the outstanding debt. Other significant terms include financial covenants, change of control triggers and limitations on additional indebtedness, asset sales, acquisitions and dividend payments. As of December 31, 2017, the Company was in compliance with all financial covenants. As of December 31, 2017, the Company's carrying value of this loan payable approximates its fair market value. At closing, Perceptive received a warrant to purchase senior common equity interests representing 4.5% of the fully diluted common units of the Company on an as converted basis (see Note 13).

# NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

#### (In thousands, except unit and per unit information)

The Company capitalizes legal and other third-party costs incurred in connection with obtaining debt as deferred debt issuance costs, and applies the unamortized portion as a reduction of the outstanding face amount of the related loan in accordance with ASU 2015-03, *Interest – Imputation of Interest: Simplifying the Presentation of Debt Issuance Costs.* Similarly, the Company amortizes debt discounts, such as those represented by warrants issued to its lenders, and offsets those as a direct reduction of its outstanding debt. Amortization expense arising from deferred debt issuance costs and debt discounts for the years ended December 31, 2017 and 2016 were \$1,860 and \$857, respectively.

Unamortized deferred debt issuance costs and deferred debt discounts totaled \$4,493 as of December 31, 2017 and \$6,350 as of December 31, 2016.

#### 13. Warrant Liability

The warrant issued to Perceptive in connection with the August 16, 2016 Loan Agreement expires on August 16, 2023 and has certain rights and preferences including anti-dilution adjustments so that, upon exercise, they will represent 4.5% of the Company's fully diluted common stock on an as converted basis subject to dilution for certain financing including the issuance of shares upon termination of our PUP Plans.

The warrant also provides Perceptive with a put right which, if exercised under certain circumstances, would require the Company to purchase the warrant for \$3,000 within the first year of the loan or \$5,000 thereafter. These re-purchase terms may require net-cash settlement, and as a result, the appraised value of this warrant at the time of issuance of \$5,800 is classified as a liability, rather than as a component of equity, and is treated as a debt discount, with the unamortized portion applied to reduce the face amount of the loan in the accompanying Consolidated Balance Sheet. The \$1,123 change in value of this warrant liability from December 31, 2016 to December 31, 2017 and the \$750 change in value of this warrant liability from the date of issuance to December 31, 2016 are reported in the accompanying Consolidated Statement of Operations as a "Change in fair value of warrant".

The Company uses a third–party valuation to assist in determining the fair value of these warrants due to the absence of available Level 1 and Level 2 inputs. The appraisals at both the date of the issuance and the balance sheet date were based on unobservable Level 3 inputs. The first step in determining the fair value of the warrant liability is to determine the value of the aggregate equity of the Company which was estimated utilizing the income and market valuation approaches. A probability weighted return model was then utilized to allocate the aggregate equity value of the Company to the underlying securities. Estimates and assumptions impacting the fair value measurement include the following factors: the progress of the Company's pipeline products since the prior valuations, including status of clinical trials; the Company's progress towards an IPO, including selecting lead investment bankers to underwrite the planned IPO; discount rates of 26.5% and 34.5% for 2017 and 2016, respectively, and volatility rates of 90% and 80% for December 31, 2017 and 2016, respectively.

# 14. Commitments and Contingencies

# (A). Leases

The Company has entered into various lease agreements for production and research facilities and offices. Most leases contain renewal options. Certain leases contain purchase options and require the Company to pay for taxes, maintenance and operating expenses. All of the Company's leases are classified as operating leases.

#### Production and Research Facilities, Portage, Indiana

The Company leases a 73,000-square-foot facility (Ameriplex) in Portage, Indiana, to house additional packaging, R&D and other operations. As amended, this lease has a term that extends through September 30, 2022 and contains a renewal option that could extend the lease through September 30, 2026.

# NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

## (In thousands, except unit and per unit information)

The Company also leases its current 8,400-square-foot production facility (Melton) in Portage, Indiana, which houses certain research and development offices and current good manufacturing practices, or cGMP, manufacturing operations. The lease contains an option to purchase the facility at any time during the lease term along with a right of first refusal to purchase the facility. In October 2012, the Company entered into an additional five-year extension of the lease of this facility, through March 31, 2018, under the same terms and conditions. In October 2017, the Company extended its lease located in Portage, Indiana, which will expire during March 2023 under the same terms and conditions as its former lease.

# Office and Laboratory Facilities, Warren, New Jersey

The Company leases its headquarters and principal laboratory facility in Warren, New Jersey. Pursuant to various amendments in February 2011, June 2012 and May 2013, the Company has secured additional space to provide for the growth of its laboratory facilities and corporate and administrative requirements. The lease included five two-year renewal options, one of which was exercised in July 2016 to extend this lease through August 31, 2018. During February 2018, the Company extended this lease by eighteen months through February 28, 2020.

## Rent Expense and Commitments

Rent expense for all leased manufacturing facilities and sales, laboratory and office space were \$1,344 and \$1,301 for the years ended December 31, 2017 and 2016, respectively.

The following schedule presents future minimum lease payments under operating leases as of December 31, 2017, including those derived from renewal options that are deemed noncancelable under FASB ASC Section 840-10-35, *Leases - Subsequent Measurement*:

	Am	ount
2018	\$	967
2019		801
2020		808
2021		815
2022		682
Thereafter		65
Total	\$	4,138

# (B). Facility Construction Obligation

In December 2011, the Company entered into an agreement with a major customer to construct a packaging suite at its Ameriplex facility for a fee of \$2,500, which the Company has amortized ratably over the five-year preferred-use period provided under that agreement, culminating in recognition of \$769 during 2016.

## (C). Litigation and Contingencies

The Company is involved in various claims, legal proceedings and investigations, including (as of December 2017, except where noted below) those described below. While it is not feasible to predict the outcome of such pending claims, proceedings and investigations with certainty, management is of the opinion that their ultimate resolution should not have a material adverse effect on the Company's financial position, cash flows, or results of operations, except where noted below.

Beginning in August 2013, the Company was informed of abbreviated new drug application ("ANDA") filings in the United States by Watson Laboratories, Inc. (now Actavis Laboratories, Inc. ("Actavis")), Par

# NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

#### (In thousands, except unit and per unit information)

Pharmaceutical, Inc. ("Par"), Alvogen Pine Brook, Inc. ("Alvogen"), Teva Pharmaceuticals USA, Inc. ("Teva"), Sandoz Inc. ("Sandoz") and Mylan Technologies Inc. ("Mylan") for the approval by the FDA of generic versions of Suboxone Sublingual Film in the United States. The Company filed patent infringement lawsuits against all six generic companies in the U.S. District Court for the District of Delaware. By a court order dated August 22, 2016, the Company's ANDA patent litigation case against Sandoz has been dismissed without prejudice for lack of subject matter jurisdiction because Sandoz is no longer pursuing a Paragraph IV certification for its proposed generic version of Suboxone Sublingual Film, and therefore is no longer challenging the validity or noninfringement of our Orange Book-listed patents. The case against Mylan was settled and a Consent Judgment was entered in September 2017 disposing of the entire case as to Mylan. Dr. Reddy's Laboratories ("Dr. Reddy's) acquired from Teva the ANDA filings for Teva's buprenorphine HCl and naloxone sublingual film that are at issue in these trials.

Trials against Dr. Reddy's, Actavis and Par in the lawsuits involving the Orange Book and process patents occurred in November-December of 2015 and November of 2016. On June 3, 2016, the Court issued its Trial Opinion finding that the asserted claims of U.S. Patent No. 8,603,514 ("the '514 patent") are valid and infringed by Watson's and Par's ANDA Products. On August 31, 2017, the Court upheld the asserted U.S. Patent No. 8,900,497 ("the '497 patent") as valid but not infringed by Par's, Watson's or Dr. Reddy's proposed processes for making their ANDA Products. The Court also again upheld the validity of the '514 patent but held it was not infringed by Dr. Reddy's ANDA Products. All of these cases are consolidated on appeal to the Federal Circuit. The trial against Alvogen was held in September 2017. The only issue raised at trial was whether Alvogen's ANDA Products and processes infringe the '514 patent and '497 patent; Alvogen did not challenge the validity of the patents. The Court has not yet issued an opinion in that case. If any company is able to obtain FDA approval for its generic version of Suboxone Sublingual Film, it may be able to launch the product prior to the expiration of any or all the applicable patents protecting our Suboxone Sublingual Film, which could have a material adverse effect on our business, prospects, results of operations and financial condition.

In 2016, the Company prevailed in ongoing litigated cases against certain competitors. On April 7, 2016, the USPTO upheld the validity of all challenged patent claims initiated by a competitor against certain key patents held by the Company. On June 3, 2016, the U.S. District Court of Delaware ruled that certain generic competitors have infringed on key patents held by the Company. This Court's ruling represents a barrier preventing generic formulations of Suboxone from entering the market prior to patent expiration in 2024. The ruling is subject to appeal. The Company continues to explore potential patent right enforcement actions against other competitors, particularly in the United States.

The Company is also seeking to enforce its patent rights in multiple cases against BioDelivery Sciences International, Inc. ("BDSI"). Two cases are currently pending but stayed in the Eastern District of North Carolina. The first was filed by the Company and Indivior related to BDSI's infringing Bunavail product, and alleges infringement of the Company's patent, U.S. Patent No. 8,765,167 ("the '167 patent"). This case was initially filed in September 2014 in the District of New Jersey but was transferred to North Carolina. Shortly after the case was filed, BDSI filed an IPR challenging the asserted '167 patent. On March 24, 2016, the Patent Trial and Appeal Board ("PTAB") issued a final written decision finding the '167 patent was not unpatentable. The North Carolina case is stayed pending the outcome and final determination of the proceedings concerning the '167 patent, which is currently on appeal to the Federal Circuit (discussed below). There is also a declaratory judgment action in North Carolina brought by BDSI for invalidity and non-infringement of the Company's U.S. Patents Nos. 7,897,080 ("the '080 patent"), 8,652,378 ("the '378 patent") and 8,475,832 ("the '832 patent"). The parties jointly moved the court for a stay of the proceeding pending *inter partes* review of the '832 patent and reexamination of the '080 patent. The case is currently stayed.

On January 13, 2017, the Company filed an additional claim against BDSI asserting infringement of the '167 patent by BDSI's Belbuca product. The case was transferred from New Jersey to the District of

# NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

#### (In thousands, except unit and per unit information)

Delaware by agreement of the parties. BDSI has filed motions to dismiss and motions to transfer to the Eastern District of North Carolina. The Judge has not yet ruled on these motions. On November 28, 2016, BDSI filed a notice of appeal to the Federal Circuit of the PTAB's final written decisions finding that the '167 patent was not unpatentable in IPR2015-00165, IPR2015-00168 and IPR2015-00169. The case has been fully briefed and the Court heard oral arguments on February 9, 2018. Nothing further has occurred on this matter.

In September 2017, Indivior brought suit against Alvogen for infringement of U.S. Patent No. 9,687,454 ("the '454 patent") based on the filing of an ANDA seeking approval for a generic version of Suboxone Sublingual Film, in the U.S. District Court for the District of New Jersey. In February 2018, the Company and Indivior amended the complaint, which added it as a plaintiff and added a claim for infringement of U.S. Patent No. 9,855,221 ("the '221 patent").

Indivior brought suits against Dr. Reddy's and Teva in September 2017, and against Par and certain affiliates in October 2017, for infringement of the '454 patent, in the U.S. District Court for the District of New Jersey.

Indivior also brought suit in September 2017 against Actavis Laboratories UT, Inc. for infringement of the '454 patent, in the U.S. District Court for the District of Utah. On March 13, 2018, the Court granted transfer of this case to the U.S. District Court for the District of Delaware.

In February 2018, the Company and Indivior brought suit against Actavis, Dr. Reddy's, Teva, and Par and certain affiliates for infringement of the '221 patent. The suit against Actavis was filed in the U.S. District Court for the District of Utah, and the other three cases were filed in the U.S. District Court for the District of New Jersey.

The Company has also been named as a Defendant in a Complaint filed by 41 U.S. states and the District of Columbia, alleging violations of federal and state antitrust and consumer protection laws related to Suboxone Sublingual Film. The Court denied the Company's motion to dismiss on October 30, 2017. The case is in early stages of discovery.

From time to time, the Company may become involved in other various lawsuits and legal proceedings, the results of which are inherently unpredictable due to the uncertainties that must be resolved as these matters are adjudicated or settled. These legal actions arise in the ordinary course of business. Provisions for liabilities arising from these matters are made when it is both probable that a liability has been incurred and the amount of that liability can be reasonably estimated. Management is currently not aware of any such legal proceedings or claims against the Company that may have, individually or in the aggregate, a material adverse effect on the Company's business, financial condition, operating results, or liquidity.

The Company has defended, and is committed to prudently defending, its patent portfolio and rights. The patent defense expense were \$4,759 and \$4,791 for the years ended December 31, 2017 and 2016, respectively. These costs consist of fees incurred for the services of patent attorneys, litigation attorneys and certain other experts that may be required to protect the Company's patent rights against infringement from unlicensed users, including actions involving defense of patents during review and reexamination proceedings before the U.S. Patent and Trademark Office ("USPTO"), as well as those involving matters brought before U.S. Federal District or other courts.

# NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

(In thousands, except unit and per unit information)

## 15. Geographic Information

The Company manages its operations geographically as United States, Australia and Malaysia. The United States is the only country to contribute more than 10% of total revenue in 2017 and 2016.

The following table provides revenue by geographic area:

		For the Year Ended December 31,		
	2017	2016		
United States	\$ 63,840	\$ 50,356		
Australia	3,046	1,355		
Malaysia	32	74		
Revenues	\$ 66,918	\$ 51,785		

The Company's long-lived assets are entirely located in the United States.

## **16. Redeemable Preferred Membership Interests**

## A. Redeemable Preferred Series A-3 Interests

A Private Placement Offering of Redeemable Preferred Series A-3 Interests (the "Series A-3 interests") was completed in December 2015 in the net amount of \$5,038. The Series A-3 interests are senior to all membership interests with respect to dividends. In the event of additional issuances of certain equity interests at a price lower than specified minimum levels, the Series A-3 interests are to be adjusted to diminish the effects of resulting dilution. The Series A-3 interests are also provided with specified preemptive purchase rights, and further, in the event of a private placement or public offering, the Series A-3 interests may elect to convert their interests into the new offering. In the event of liquidation, holders of the Series A-3 interests will receive the greater of three times their original investment or 10% of any remaining distributable assets plus any accrued and unpaid dividends prior to any distributions to the Series A, Series A-1, Series A-2 or common holders, or senior common holders if any. On or after December 31, 2015, subject to the limitations of the current Loan Agreement that restrict dividend or other cash payments to specified preferred interests (Note 12), the holders of more than 50% of the outstanding A-3 interests, voting separately as a class, may require the Company to redeem all, or any part, of the Series A-3 interests at their original issue price plus accrued and unpaid dividends upon 60 days' notice out of funds legally available for distribution. As the redemption option is not within the control of the Company, the Series A-3 interests are classified outside of permanent equity on the consolidated balance sheets. These interests accrue a cumulative and compounding dividend of 8% per annum. At December 31, 2017 and 2016, accrued dividends totaled \$858 and \$420, respectively.

#### **B. Redeemable Preferred Series A-2 Interests**

A Private Placement Offering for \$20,887 Redeemable Preferred Series A-2 Interests (the "Series A-2 interests") was completed in July 2008. The Series A-2 interests are senior to all membership interests other than those of the Series A-3 interests with respect to dividends. In the event of additional issuances of certain equity interests at a price lower than specified minimum levels, the Series A-2 interests are to be adjusted to diminish the effects of resulting dilution. Series A-2 interests are also provided with specified preemptive purchase rights. Upon liquidation, holders of the Series A-2 interests will receive two times their original investment plus any accrued and unpaid dividends prior to any distributions to the Series A. Series A-1, or common holders. Beginning after the fifth anniversary of the closing of the offering of the Series A-2 interests, subject to the limitations of the current Loan Agreement that restrict dividend or other cash payments to A-2 interests (Note 12), the holders of more than 50% of the outstanding Series A-2 interests, voting separately as a class, may require the Company to redeem

# NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

#### (In thousands, except unit and per unit information)

all, or any part, of the Series A-2 interests at their original issue price plus accrued and unpaid dividends upon 60 days' notice out of funds legally available for distribution. As the redemption option is not within the control of the Company, the Series A-2 interests are classified outside of permanent equity on the consolidated balance sheets. These interests accrue a cumulative and compounding dividend of 6% per annum. At December 31, 2017 and 2016, accrued dividends totaled \$15,283 and \$13,241, respectively.

# 17. Members' Equity

The preferred interests included in permanent equity are presented in the accompanying consolidated financial statements in order of liquidation preference.

The Series A interests rank senior to the Series A-1 interests and common interests with respect to payment of dividends and amounts due upon liquidation, dissolution, or winding up of the Company. The Series A-1 interests are senior to the common interests with respect to dividends and liquidation proceeds.

The Series A and A-1 interests hold the same voting rights and equivalent shares in the Company's earnings and losses as the common interests and any senior common interests that may be issued. In the event of an initial public offering or under certain other specified events, outstanding preferred, senior common and common interests in the Company may be converted into equity interests of the newly established public entity or merger partner relative to their then-existing equity account balances.

The Company is required to receive the written consent of more than 50% of the preferred interests prior to:

- liquidating, dissolving, or winding up the Company,
- amending or repealing the Limited Liability Company Agreement, or
- creating or authorizing a security senior to the preferred interests or increasing the authorized number of preferred interests.

During January 2017, White Oak Global Advisors, LLC, exercised its right to convert warrants, obtained as part of the 2013 financing transaction, into common membership interests. This warrant exercise resulted in an increase of membership interests of 2,443,249 and proceeds of approximately \$24 to the Company.

## 18. Performance Unit Plans

The Company has two PUP Plans, both of which are considered to be within the scope of FASB ASC Subtopic 718-30, *Compensation – Stock Compensation – Awards Classified as Liabilities*. Pursuant to the Plans, vested grants may not be exercised prior to either a change in control of the Company or completion of an IPO. These performance conditions render the grants contingent and defer expense recognition until either of the conditions is satisfied.

Each performance unit granted represents the right to receive an amount equal to the increase in the fair value of a unit of membership interest in the Company from the date of grant to the date of settlement, all as determined by the Company's advisory board. For purposes of establishing the initial fair value of awards granted, the advisory board has in certain instances relied on third-party investments at or near the award date as the basis for estimating the underlying value of the Company. In instances where recent third-party investments, at or near the award date, are not available, the advisory board has measured the underlying value of the Company by utilizing an enterprise value approach, which takes into account the cash invested in the Company and outstanding debt at the time of grant. In general, performance units awarded by the Company vest over time and have an indefinite contractual term, subject to continuing employment or other service with the Company. Vesting accelerates upon a change

# NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

## (In thousands, except unit and per unit information)

in control or IPO of the Company. The Company has the right to redeem vested performance units within 12 months following a termination of the unit holder's employment or other service. Vested units can be settled for cash or equity interests of the Company or an acquiring or successor company, as the case may be, at the Company's discretion. However, the holder is not entitled to settlement of his or her vested performance units unless and until there is a change in control of the Company or the completion of an IPO. As of December 31, 2017 and 2016, respectively, there were 60,707 and 54,214 performance units outstanding that would be redeemable in the event either of the performance conditions were met. If these awards were to be cash settled based on the estimated enterprise value as of December 31, 2017, the Company's operating loss and net loss would have included an additional \$12,870 in compensation expense.

Certain participants in the Plans, principally senior management, have been granted protection against dilution of their interests by future equity events (dilution protection). This protection survives the termination of the Plans and entitles the participant to receive additional shares of common stock to maintain the relative equity percentage held by the participant upon the occurrence of a dilutive event. As of December 31, 2017 and 2016, respectively, 24,677 and 21,989 of the outstanding units were covered by dilution protection.

Performance unit plan activity for the years ended December 31, 2017 and 2016 were as follows:

	Units	Weighted-average grant-date fair value	Weighted-average per unit base value	Aggregate settlement value <sup>(2)</sup>
Outstanding at December 31, 2015	55,773	\$ 64,562	\$ 0.26	\$ 9,823
Granted <sup>(1)</sup>	431	114,941	0.47	_
Exercised		—	—	_
Forfeited/cancelled/expired	(1,989)	(103,276)	0.42	_
Outstanding at December 31, 2016	54,215	63,542	0.26	11,694
Granted <sup>(1)</sup>	6,561	113,298	0.46	_
Exercised				_
Forfeited/cancelled/expired	(69)	(106,718)	0.43	—
Outstanding at December 31, 2017	60,707	68,832	0.28	12,870
Vested at December 31, 2017	55,986	\$ 65,023	\$ 0.26	\$ 12,688
Exercisable at December 31, 2017				

(1) Based on the estimated fair value of the Company on the grant dates of the performance units.

(2) Represents the estimated cash settlement value of these awards based on an independent third-party valuation in 2015 of \$108,000 and enterprise values, which approximate fair value of \$121,300 and \$116,200 in 2017 and 2016, respectively, and the base values inherent in the underlying awards. Broadly viewed, settlement value is determined on the basis of a portion of the increase from the Company's fair value on grant dates to its fair value on the settlement date. The portion allocable to the PUP Plans is relative to vested performance units outstanding and actual equity interests outstanding.

During 2017 and 2016, no performance units were exercised, no share-based liabilities were recorded and 2,880 and 874 units vested, respectively.

# NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

# (In thousands, except unit and per unit information)

Activity in non-vested performance units for the years ended December 31, 2017 and 2016 were as follows:

	Units	Weighted-average grant-date fair value <sup>(1)</sup>	Weighted-average per unit base value
Nonvested at December 31, 2015	3,541	\$ 103,070	\$ 0.41
Granted	431	114,941	0.47
Vested	(874)	102,575	0.42
Forfeited/cancelled/expired	(1,989)	103,276	0.42
Nonvested at December 31, 2016	1,109	107,737	0.44
Granted	6,561	113,298	0.46
Vested	(2,880)	114,044	0.46
Forfeited/cancelled/expired	(69)	106,718	0.43
Nonvested at December 31, 2017	4,721	\$ 111,131	\$ 0.45

(1) Based on the estimated fair value of the Company on the grant dates of the performance units.

#### **19. Employee Benefit Plans**

The Company sponsors a defined-contribution 401(k) plan covering all full-time employees and makes matching employer contributions as defined by the terms of that plan. The Company may also make discretionary contributions. Total contributions made to the plan by the Company for the years ended December 31, 2017 and 2016 were \$616 and \$524, respectively.

# 20. Asset Retirement Obligations

The Company's ARO consists of estimated future spending related to removing certain leasehold improvements at its Portage, Indiana, laboratory, the Ameriplex production facility and the Warren, New Jersey, laboratory and returning all facilities to their original condition. Below is a schedule of activity in the Company's liability for AROs for the years ended December 31, 2017 and 2016:

Balance at December 31, 2015	\$ 852
Accretion	 107
Balance at December 31, 2016	959
Accretion	 122
Balance at December 31, 2017	\$ 1,081

Depreciation expense related to the ARO assets included in overall depreciation expense for the periods ended December 31, 2017 and 2016 were \$25 and \$26, respectively.

## 21. Income Taxes

From the period January 1, 2017 through October 31, 2017 and for all 2016, the Company was a limited liability company ("LLC") that passed through income and losses to its members for U.S. federal and state income tax purposes. From November 1, 2017 through December 31, 2017, the LLC elected to be taxed as a C corporation.



# NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

## (In thousands, except unit and per unit information)

The tax effect of temporary differences between the tax bases of assets and liabilities and their financial reporting amounts that give rise to the deferred tax assets and deferred tax liabilities at December 31, 2017 are as follows:

	De	ecember 31, 2017
Deferred tax assets:		
Accounts receivable	\$	14
Inventory		49
Accrued expenses		12
NOL carryforwards		1,330
Other		319
Property and equipment		1,145
Credits		113
	\$	2,982
Deferred tax liabilities:		
Intangible assets	\$	(45)
Prepaid expenses		(148)
		(193)
Valuation Allowance	\$	(2,789)
Net deferred tax asset/(liability)	\$	

At December 31, 2017, the Company had federal and state net operating loss carryforwards of approximately \$9,900, which expire during 2038. The Company has determined, based upon available evidence that is more likely than not that the net deferred tax asset will not be realized and accordingly, has provided a full valuation allowance against its net deferred tax assets. Valuation allowances of approximately \$2,800 have been established at December 31, 2017. The Company may also be subject to the net operating loss utilization provisions of Section 382 of the Internal Revenue Code. The effect of an ownership change would be the imposition of an annual limitation on the use of NOL carry forwards attributable to periods before the change. Although we have not completed an analysis under Section 382 of the Code, it is possible that the utilization of the NOLs will be limited.

Entities are also required to evaluate, measure, recognize and disclose any uncertain income tax provisions taken on their income tax returns. The Company has analyzed its tax positions and has concluded that as of December 31, 2017, there were no uncertain positions. The Company did not have any unrecognized tax benefits and has not accrued any interest or penalties through 2017.

A reconciliation of income tax benefit and the amount computed by applying the statutory federal income tax rate of 34% to loss before taxes for December 31, 2017 as follows:

	2017
Income taxes at statutory rate	34.00%
Increase (decrease) resulting from:	
State income tax	4.06
Permanent differences	(8.90)
Research & development credit	1.72
Valuation allowance	(13.54)
Effect of the deferred rate change	(17.34)
Effective tax rate	0.00%

# NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS (continued)

#### (In thousands, except unit and per unit information)

The Tax Cuts and Jobs Act (the "TCJA") was signed into law on December 22, 2017. This tax reform legislation, which included a reduction in the U.S. Federal income tax rate from 34% to 21% resulted in a reduction of approximately \$1,100 for the deferred tax assets related to net operating losses and other assets. This did not have a material impact on the Company's provision for income taxes for the year ended December 31, 2017 due to the valuation allowance against the Company's net deferred tax assets. Additionally, the Company does not expect to incur the deemed repatriation tax established by that legislation due to the aggregate cumulative losses of its foreign operations.

On December 22, 2017, the SEC staff issued Staff Accounting Bulletin No. 118 ("SAB 118") to address the application of U.S. GAAP in situations when a registrant does not have the necessary information available, prepared, or analyzed in reasonable detail to complete the accounting for certain income tax effects of the TCJA. We did not identify items for which the income tax effects of the 2017 TCJA have not been completed and could not be reasonably estimated as of December 31, 2017, and as such, our financial results reflect the income tax effects of the TCJA for which the accounting under ASC Topic 740 is complete.

Should the Company have been treated as a taxable entity in 2016, no provision would have been recorded given the history of operating losses and the full valuation allowance which would have net against the deferred tax assets.

#### 22. Subsequent Event

In preparing the consolidated financial statements as of and for the year ended December 31, 2017, the Company has evaluated subsequent events for recognition and measurement purposes through April 2, 2018, the date that the report of the independent registered public accounting firm was issued and the audited annual consolidated financial statements were available for issuance. The Company has concluded the following event requires disclosure in the accompanying consolidated financial statements:

## **Conversion to Corporation**

On January 1, 2018, the Company converted from a Delaware limited liability company to a Delaware corporation and incorporated as Aquestive Therapeutics, Inc.

# Aquestive Therapeutics, Inc. (formerly known as MonoSol Rx, LLC) Consolidated Balance Sheets (In thousands, except unit amounts)

	March 31, 2018		Pro Forma March 31, 2018 (Note 2(D))
	(Unaudited)	2017	(Unaudited)
Assets			
Current assets:			
Cash and cash equivalents	\$ 16,488	17,379	
Trade and other receivables, net	9,441	6,179	9,441
Inventories	3,850	4,014	3,850
Prepaid expenses and other current assets	642	591	642
Total current assets	30,421	28,163	30,421
Property and equipment, net	12,764	13,460	12,764
Intangible assets, net	241	254	241
Other assets	2,656	1,239	2,656
Total assets	\$ 46,082	43,116	\$ 46,082
Liabilities and Shareholders' / Members' Deficit			
Current liabilities:			
Accounts payable	\$ 10,989	9,601	\$ 10,989
Accrued expenses	2,263	4,402	9,663
Deferred revenue	1,170	1,347	1,170
Loans payable, current	1,650		1,650
Total current liabilities	16,072	15,350	23,472
Noncurrent liabilities:		· · · · ·	
Loans payable, net	44,315	45,507	44,315
Warrant liability	6,976	7,673	·
Asset retirement obligations	1,115	1,081	1,115
Total noncurrent liabilities	52,406	54,261	45,430
Redeemable Preferred A-3 interests and accrued dividends		5,896	
Redeemable Preferred A-2 interests and accrued dividends	_	36,205	_
Shareholders' / Members' deficit:		00,200	
Preferred A interests, no par value. Authorized 100,000,000 units; 16,886,750 units issued and outstanding at December 31, 2017 and 2016		16 997	
Preferred A-1 interests, no par value. Authorized 100,000,000		16,887	
units; 21,526,850 units issued and outstanding at December 31, 2017	_	21,883	_
Common interests, no par value. Authorized 500,000,000 units; 121,228,353 units issued and outstanding at December 31, 2017			
Common stock, \$0.001 par value. Authorized 350,000,000 shares, 186,061,577 issued and outstanding at March 31,		12,727	
2018; 246,768,153 issued and outstanding at March 31, 2018 (pro forma)	186	_	247
Additional paid-in capital	93,412		111,827
Accumulated deficit	(115,994)	(120,093)	(134,894)
Total shareholders' / members' deficit	(22,396)		(22,820)
Total liabilities and shareholders'/members' equity	\$ 46,082	43,116	\$ 46,082
rota nasinitos ana snarcholacis/members equity	+ +0,002		+ +0,002

See accompanying notes to the consolidated financial statements

# Aquestive Therapeutics, Inc. (formerly known as MonoSol Rx, LLC) Consolidated Statements of Operations and Comprehensive Income (Loss) (In thousands, except per membership interest and per share data amounts) (Unaudited)

	Thre	e Months Ended March 31, 2018	Th	ree Months Ended March 31, 2017
Revenues	\$	23,411	\$	16,436
Costs and expenses:				
Manufacture and supply		5,636		4,184
Research and development		4,901		5,343
Selling, general and administrative		7,569		6,128
Total costs and expenses		18,106		15,655
Operating income		5,305		781
Other income (expense):				
Interest expense		(1,927)		(1,818)
Change in fair value of warrant		697		(420)
Other income		24		_
Net income (loss) before income taxes		4,099		(1,457)
Income taxes				_
Net income (loss)		4,099		(1,457)
Dividends on redeemable preferred interests				(613)
Net income (loss) attributable to common shares / members' interests		4,099		(2,070)
Comprehensive income (loss)	\$	4,099	\$	(2,070)
Net income (loss) per share / membership interest basic and diluted	\$	0.02	\$	(0.02)
Weighted-average number of common shares / membership interests outstanding - basic and diluted		186,061,577		121,228,353
Unaudited pro forma net loss (Note 2(D))	\$	(14,801)		
Unaudited pro forma net loss per share (Note 2(D))	\$	(0.06)		
Unaudited pro forma basic and diluted weighted-average shares of common stock outstanding (Note 2(D))		246,768,153		

See accompanying notes to the consolidated financial statements

# Aquestive Therapeutics, Inc. (formerly known as MonoSol Rx, LLC) Consolidated Statements of Changes in Stockholders' Equity (In thousands, except unit amounts)

					•		1 2 (				,	
		Preferred A Units	interests Amount	Preferre intere		Common in Units	iterests Amount	<u>Common</u> Shares	stock Amount	Additional paid-in capital	Accumulated deficit	Total members'/ shareh olders' deficit
		Units	Amount	Units	Amount	Units	Amount	Sildles	Amount	Capital	uencit	uencit
	Balance at December 31, 2017 MonoSol Rx LLC	16,886,750	\$ 16,887	21,526,850	\$ 21,883	121,228,353	\$ 12,727	_	\$ —	\$ —	\$ (120,093)	(68,596)
	Reorganization to C-Corporation (unaudited)	(16,886,750)	\$(16,887)	(21,526,850)	\$(21,883)	(121,228,353)	\$(12,727)	5,000	_	93,598	_	42,101
	Effect of stock split (unaudited)	_	_	_	_	_	_	186,056,577	186	(186)	_	_
	Net income (unaudited)										4,099	4,099
E	Balance at March 31, 2018 (unaudited)	_	\$ —	_	\$ —	_	\$ —	186,061,577	\$ 186	\$ 93,412	\$ (115,994)	\$ (22,396)
	Termination and conversion of performance unit plans (unaudited) (Note 2(D) and Note 16)	_	_	_	_	_	_	60,706,576	61	11,439	(18,900)	(7,400)
	Conversion of warrants (unaudited) (Note 2(D))									6,976		6,976
	Pro Forma Balance at March 31, 2018 (unaudited)		\$		\$		\$	246,768,153	\$ 247	\$ 111,827	\$ (134,899)	<u>\$ (22,820)</u>

See accompanying notes to the consolidated financial statements

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# Aquestive Therapeutics, Inc. (formerly known as MonoSol Rx, LLC) Consolidated Statements of Cash Flows (In thousands) (Unaudited)

	For the Three March 3			
	_	2018	_	2017
Cash flows from operating activities:				
Net income (loss)	\$	4,099	\$	(1,457)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:				
Depreciation and amortization		940		915
Change in fair value of warrant		(697)		420
Asset retirement obligation accretion		34		29
Amortization of intangible		13		13
Amortization of debt issuance costs and discounts		458		457
Non-cash interest expense		(16)		—
Bad debt (recovery) provision		39		(34)
Changes in operating assets and liabilities:				
Trade receivables and other receivables		(3,301)		3,509)
Inventories		165		(613)
Prepaid expenses		(51)		(18)
Accounts payable		1,404		1,594
Accrued expenses		(2,125)		(1,431)
Deferred revenue		(177)		524
Net cash provided by operating activities		785		3,908
Cash flows from investing activities:				
Capital expenditures		(259)		(657)
Net cash (used for) investing activities		(259)		(657)
Cash flows from financing activities:				
Proceeds from warrant exercise		—		24
Proceeds from issuance of debt				5,000
Payments for transaction costs		(1,417)		_
Net cash (used for) provided by financing activities		(1,417)		5,024
Net (decrease) increase in cash and cash equivalents		(891)		8,275
Cash and cash equivalents:				
Beginning of period		17,379		9,209
End of period	\$	16,488	\$	17,484
		<u> </u>	_	<u> </u>
Supplemental disclosures of cash flow information:				
Cash payments for interest	\$	1,485	\$	1,359
Capital expenditures included in accounts payable	Ŧ	15	Ŧ	212
Accrued Series A-2 and A-3 preferred dividends				613

See accompanying notes to the consolidated financial statements

# NOTES TO THE UNAUDITED INTERIM CONSOLIDATED FINANCIAL STATEMENTS

(In thousands, except share and per share information)

# 1. Nature of Business

# (A) Background

Aquestive Therapeutics, Inc. ("Aquestive" or the "Company") was formed effective on January 1, 2018 via the conversion of MonoSol Rx, LLC to, a Delaware corporation and a simultaneous name change. From the Company's inception through that date, the business operated as MonoSol Rx, LLC, a Delaware limited liability company. The financial statement information presented from periods prior to January 1, 2018 are that of MonoSol Rx, LLC.

Aquestive is a specialty pharmaceutical company focused on identifying, developing and commercializing differentiated products to address unmet medical needs and solve critical healthcare challenges. The Company has a late-stage proprietary product pipeline focused on the treatment of diseases of the central nervous system, or CNS. Aquestive is pursuing its business objectives through both in-licensing and out-licensing arrangements. The Company's major customer and primary commercialization partner has global operations headquartered in the United Kingdom with principal operations in the United States; other customers are principally located in the United States.

The Company conducts its production activities at facilities located in Portage, Indiana, and maintains its headquarters and its primary research laboratory in Warren, New Jersey.

The Company has incurred operating losses since inception and had an accumulated deficit of \$115,994 as of March 31, 2018. The Company expects to continue to incur net losses for at least the next several years and is highly dependent on its ability to find additional sources of funding in the form of debt or equity financings to fund its operations. Management believes that its cash and cash equivalents of \$16,488 at March 31, 2018 combined with expected revenue from partnered product activities are sufficient to fund operations through at least July 2019.

Management expects that future sources of funding may include new or expanded partnering arrangements and sales of equity or debt securities. Adequate additional funding may not be available to the Company on acceptable terms or at all. The failure to raise capital as and when needed could have a negative impact on the Company's financial condition and ability to pursue business strategies. The Company may be required to delay, reduce the scope of or eliminate research and development programs, or obtain funds through arrangements with collaborators or others that may require the Company to relinquish rights to certain product candidates that the Company might otherwise seek to develop or commercialize independently.

## (B) Corporate Conversion, Reorganization and Stock split

#### Corporate Conversion

MonoSol Rx, LLC was originally formed in Delaware in January 2004 and until December 31, 2017, the Company conducted its business through MonoSol Rx, LLC, a Delaware limited liability company, or MonoSol. On January 1, 2018, MonoSol converted from a Delaware LLC into a Delaware corporation pursuant to a statutory conversion and changed its name to Aquestive Therapeutics, Inc.

## Reorganization

In a corporate reorganization conducted following the conversion of MonoSol into a Delaware corporation, the holders of units of MonoSol contributed their interests in MonoSol to Aquestive Partners, LLC, or APL, in exchange for identical interests in APL. As a result of the exchange, APL was issued 5,000 shares of voting common stock in the Company and became the parent and sole stockholder of the Company.



# NOTES TO THE UNAUDITED INTERIM CONSOLIDATED FINANCIAL STATEMENTS (continued)

#### (In thousands, except share and per share information)

The table below depicts the number of redeemable and non-redeemable interests outstanding for each series of membership interests at December 31, 2017, which were converted to identical interests in APL on a 1:1 basis effective January 1, 2018;

	December 31, 2017
Redeemable Preferred A-3 Interests	5,055,000
Redeemable Preferred A-2 Interests	82,071,200
Nonredeemable A-1 interests	21,526,850
Nonredeemable A interests	16,886,750
Common Interests	121,228,353
	246,768,153

# Stock Split

In April 2018, the board approved an amendment to the Certificates of Incorporation of the Company to:

- (i) increase the authorized number of capital stock from 25,000 to 350,000,000 shares,
- (ii) authorize the Non-Voting Common Stock, and

(iii) effect a stock split of the Company's common stock, par value \$0.001 per share, such that each share be subdivided and reclassified into 37,212 shares of Voting Common Stock, par value \$0.001 per share.

For purposes of these financial statements, the stock split has been presented as if it had occurred on January 1, 2018.

# 2. Significant Accounting Policies

## (A) Basis of Presentation

The accompanying unaudited interim consolidated financial statements are prepared in conformity with accounting principles generally accepted in the United States ("U.S. GAAP") and with Article 10 of Regulation S-X for interim financial reporting. In compliance with those rules, certain information and footnote disclosures normally included in the annual consolidated financial statements prepared in accordance with U.S. GAAP have been condensed or omitted. These financial statements do not include all disclosures necessary for a complete presentation of financial position, results of operations, and cash flows in conformity with U.S. GAAP. These unaudited interim consolidated financial statements and related notes for the year ended December 31, 2017. In the opinion of management, the accompanying unaudited interim consolidated financial statements contain all material adjustments consisting of normal and adjustments accruals necessary to present fairly the Company's consolidated financial position as of March 31, 2018, and the results of operations and cash flows for the three months ended March 31, 2018 and 2017. The results that may be expected for the entire fiscal year or for any other interim period.

Any reference in these notes to applicable guidance is meant to refer to the authoritative United States generally accepted principles as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board ("FASB").

The accompanying unaudited interim consolidated financial statements have been prepared assuming that the Company will continue as a going concern. This basis of accounting contemplates the



## NOTES TO THE UNAUDITED INTERIM CONSOLIDATED FINANCIAL STATEMENTS (continued)

#### (In thousands, except share and per share information)

recovery of the Company's assets and the satisfaction of liabilities in the normal course of business. The unaudited interim consolidated financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that might be necessary should the Company be unable to continue as a going concern.

#### (B) Principles of Consolidation

On January 1, 2018 MonoSol Rx, LLC (which consolidated MonoSol Rx, Inc. in 2017) was converted from a Delaware LLC into a Delaware corporation pursuant to a statutory conversion under the laws of the State of Delaware. The resulting entity is Aquestive Therapeutics, Inc.

These consolidated financial statements presented for periods earlier than January 1, 2018 include the accounts of the MonoSol Rx, LLC. and its wholly owned subsidiary, MonoSol Rx, Inc. Other than corporate formation activities, MonoSol Rx, Inc. has conducted no commercial, developmental or operational activities and has no customers or vendors.

## (C) Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results may differ from those estimates.

## (D) Unaudited Pro Forma Presentation

The unaudited pro forma balance sheet information as of March 31, 2018 reflects the issuance of 60,706,576 shares of non-voting common stock granted in connection with the termination of the Performance Unit Plans (see Note 16).

The unaudited pro forma net loss, along with the pro forma balance sheet reflects the termination of the Performance Unit Plans (the "PUP Plans") effective January 1, 2018. The Company will recognize a charge of \$18,900 to general and administrative expense in May 2018 (see Note 16).

The unaudited pro forma balance sheet also reflects the conversion of the warrant liability of \$6,976 as an addition to additional paid-in capital and a reduction of the warrant liability as of March 31, 2018 (see Note 13).

Unaudited pro forma net loss per share attributable to common stockholders for the three months ended March 31, 2018 is computed using the weighted-average number of shares of common stock outstanding after giving effect to the common stock granted in connection with the termination of the performance unit plans as if such conversion had occurred at January 1, 2018

		ree Months Ended rch 31, 2018
	(L	inaudited)
Numerator:		
Net income attributable to common shares - basic and diluted	\$	4,099
Add: Charge for termination of PUP Plans		(18,900)
Net loss attributable to common shares - basic and diluted	\$	(14,801)
Denominator:		
Weighted-average number of common shares outstanding		186,061,577
Effect of pro forma adjustments:		
Issuance of common stock for performance units		60,706,576
Pro forma weighted average shares outstanding		246,768,153
Unaudited pro forma net loss per share - basic and diluted	\$	( 0.06)

# NOTES TO THE UNAUDITED INTERIM CONSOLIDATED FINANCIAL STATEMENTS (continued)

(In thousands, except share and per share information)

#### (E) Net Income (Loss) Attributable to Shareholders' / Members' Interest

Basic net loss per membership interest is calculated by dividing net loss attributable to members' interest less cumulative preferred stock dividends. During periods of income, the Company allocates participating securities a proportional share of income determined by dividing total weighted-average participating securities by the sum of the total weighted-average common interests and participating securities (the "two class method"). The Company's convertible preferred stock participates in any dividends declared by the Company and is therefore considered to be a participating security. Participating securities have the effect of diluting both basic and diluted earnings per share during periods of income. During periods of loss, the Company allocates no loss to participating securities because they have no contractual obligation to share in the losses of the Company. For the three month period ended March 31, 2017, diluted net loss per membership interest is calculated by adjusting weighted-average shares outstanding for the dilutive effect of common stock equivalents outstanding for the period, determined using the treasury-stock method and if-converted methods. For purposes of the diluted net loss per membership interest calculation, convertible preferred stock, performance units, and senior common interests are considered to be common stock equivalents, but have been excluded from the calculation of diluted net loss per membership interest, as their effect would be anti-dilutive for all periods presented.

As a result of the corporate conversion and reorganization described in Note 1(B), there were no potentially dilutive instruments outstanding at March 31, 2018. Therefore, basic and diluted net loss per share were the same for all periods presented as reflected below.

	For the Three Months Ended March 31,																					
	(unaudited)																					
	2018		2018		2018		2018		2018		2018		2018		2018		2018		2018		2018	
Numerator:																						
Net income (loss)	\$	4,099	\$	(1,457)																		
Accrued dividends on redeemable preferred interests		_		(613)																		
Income (loss) attributable to common shares / member interest - basic and																						
diluted	\$	4,099	\$	(2,070)																		
Denominator:																						
Weighted-average number of common shares / member interest – basic																						
and diluted		186,061,577		121,228,353																		
Income (loss) per common share / member interest – basic and diluted	\$	0.02	\$	(0.02)																		

# (F) Deferred Transaction Costs

Deferred Transaction costs, primarily costs of direct incremental legal, accounting and other fees relating to the Company's contemplated initial public offering ("IPO"), are capitalized as incurred. The deferred transaction costs will be offset against IPO proceeds upon the consummation of the offering. In the event the IPO is terminated, which would include a postponement of 90 days or greater, any deferred transaction costs will be expensed. The Company has capitalized costs totaling approximately \$2,583 that have been incurred in connection with ongoing equity raising initiatives. These amounts are recorded in Other assets.

## NOTES TO THE UNAUDITED INTERIM CONSOLIDATED FINANCIAL STATEMENTS (continued)

(In thousands, except share and per share information)

## (G) Off-Balance Sheet Risk and Concentration of Credit Risk

Cash and cash equivalents are maintained at one federally insured financial institution. The Company has not experienced any losses in such accounts and management believes that the Company is not exposed to any credit risk due to the financial position of the banking institution. The Company has no off-balance sheet risk, such as foreign exchange contracts, option contracts, or other foreign hedging arrangements.

# (H) Segment Information

The Company manages its operations as a single segment for purposes of assessing performance and making operating decisions.

# (I) Fair Value of Financial Instruments

FASB guidance specifies a hierarchy of valuation techniques based on whether the inputs to those valuation techniques are observable or unobservable. Observable inputs reflect market data obtained from independent sources, while unobservable inputs reflect market assumptions. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurement) and the lowest priority to unobservable inputs (Level 3 measurement).

The three levels of the fair value hierarchy are as follows:

- Level 1 Unadjusted quoted prices in active markets for identical assets or liabilities that the reporting entity
  has the ability to access at the measurement date. Level 1 primarily consists of financial instruments whose
  value is based on quoted market prices such as exchange-traded instruments and listed equities.
- Level 2 Inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly (*e.g.*, quoted prices of similar assets or liabilities in active markets, or quoted prices for identical or similar assets or liabilities in markets that are not active). Level 2 includes financial instruments that are valued using models or other valuation methodologies. The Company had no Level 2 assets or liabilities as of March 31, 2018 and December 31, 2017.
- Level 3 Unobservable inputs for the asset or liability. Financial instruments are considered Level 3 when the fair values are determined using pricing models, discounted cash flows or similar techniques and at least one significant model assumption or input is unobservable. The Company's Level 3 liabilities consisted of warrants totaling \$6,976 and \$7,673 at March 31, 2018 and December 31, 2017, respectively. The Company's warrant liability is stated at fair value.

The carrying amounts reported in the balance sheets for trade and other receivables, prepaid and other current assets, accounts payable, accrued expenses and deferred revenue approximate fair value based on the short-term maturity of these instruments.

# (J) Cash and Cash Equivalents

The Company considers investments with an original maturity of three months or less to be cash equivalents. At March 31, 2018 and December 31, 2017, the Company had no cash equivalents.

# (K) Foreign Currency

The functional currency of the Company is the U.S. dollar.

# (L) Trade Receivables

The Company's credit terms generally range from 30 to 60 days, depending on the customer and type of invoice. Trade receivables are carried at original invoice amount less an estimate of doubtful receivables based on a review of all outstanding amounts on a periodic basis. Management determines



# NOTES TO THE UNAUDITED INTERIM CONSOLIDATED FINANCIAL STATEMENTS (continued)

#### (In thousands, except share and per share information)

the allowance for doubtful accounts by identifying troubled accounts and, in the absence of historical experience, applies an estimate that is believed to be a reasonable indicator of future potential losses. Trade receivables are written off when deemed uncollectible. Recoveries of trade receivables previously written off are recorded when received.

# (M) Inventories

Inventories are stated at the lower of cost or net realizable value. Cost is determined on a first-in, first-out basis. Inventory includes the cost of materials, production labor and overhead. The Company regularly reviews its inventories for impairment and reserves are established when necessary.

# (N) Property and Equipment

Property and equipment are stated at cost. Leasehold improvements are amortized over the shorter of the term of the lease or their estimated useful lives. Depreciation of equipment, furniture and fixtures is calculated using the straight-line method over the estimated useful lives of the assets. Repairs and maintenance costs are expensed. The Company reviews the recoverability of all long-lived assets, including the related useful life, whenever events or changes in circumstances indicate that the carrying value amount of a long-lived asset may not be recoverable.

# (O) Impairment of Long-Lived Assets

In accordance with the Subsections of FASB ASC Subtopic 360-10, *Property, Plant and Equipment – Overall*, longlived assets, such as property and equipment and intangible assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying value of an asset may not be recoverable. That carrying value is considered unrecoverable if it exceeds the sum of the undiscounted cash flows expected from the use and eventual disposition of the asset.

As a result of management's evaluation of the recoverability of the carrying value of long-lived assets subject to ASC 360-10, no impairment charges were recorded for the three months ended March 31, 2018 and 2017.

## (P) Investments

For entities or ventures that are under shared control, owned and managed equally by the Company and a third party and in which the Company is a direct and active participant in the entity's operating activities and through which it is directly exposed to the risks and rewards of operating activities, the Company's investments are carried at cost. Acting as principal in carrying out its operational responsibilities, the Company records its share of related revenue and its expense transactions reflecting all of that revenue and its third-party expenses in its consolidated financial statements in accordance with the nature of the revenue or in a manner to proportional consolidation.

# (Q) Intangible Assets

Intangible assets include the costs of acquired composition and process technologies and the costs of purchased patents used in the manufacture of orally soluble film. The Company amortizes these assets using the straight-line method over the shorter of their legal lives or estimated useful lives.

#### (R) Patent Costs

Patent procurement, prosecution and defense litigation costs are expensed as incurred, including costs for patent continuation applications. The Company's primary domestic and international patents expire between 2022 and 2031.

# NOTES TO THE UNAUDITED INTERIM CONSOLIDATED FINANCIAL STATEMENTS (continued)

(In thousands, except share and per share information)

#### (S) Retirement Plan

The Company maintains a 401(k)-retirement plan for its employees that is intended to qualify under Sections 401(a) and 501(a) of the U.S. Internal Revenue Code of 1986, as amended ("Code"), in 2016. The Company provides all active employees with 100% matching contribution equal to 6% of an employee's eligible compensation. These safe harbor employer match contributions vest as follows: less than one year: 0%; one year: 20%; two years: 40%; three years: 60%; four years: 80%; and five years: 100%.

#### (T) Research and Development

Costs incurred in connection with research and development activities are expensed as incurred. Research and development expenses include (i) employee-related expenses, including salaries, benefits, travel and share-based compensation expense, (ii) external research and development expenses incurred under arrangements with third parties, such as contract research and contract manufacturing organizations, investigational sites and consultants, (iii) the cost of acquiring, developing and manufacturing clinical study materials, and (iv) costs associated with preclinical and clinical activities and regulatory operations. Nonrefundable advance payments for goods and services that will be used in future research and development activities are expensed when the activity is performed or when the goods have been received, rather than when payment is made, in accordance with ASC 730, *Research and Development*.

## (U) Income Taxes

From its founding through October 31, 2017, the Company was a limited liability company ("LLC") treated as a partnership for income tax purposes. From November 1, 2017 through December 31, 2017, the LLC elected to be taxed as a C-corporation. On January 1, 2018, MonoSol converted from a Delaware LLC into a Delaware C-corporation pursuant to a statutory conversion and changed its name to Aquestive Therapeutics, Inc.

From November 1, 2017, the Company accounts for income taxes under the asset and liability method, which requires deferred tax assets and liabilities to be recognized for the estimated future tax consequences attributable to differences between financial statement carrying amounts and respective tax bases of existing assets and liabilities, as well as net operating loss carryforwards and research and development credit. Valuation allowances are provided if it is more likely than not that some portion or all of the deferred tax asset will not be realized.

#### (V) Revenue Recognition

Pursuant to FASB ASC Topic 605, *Revenue Recognition*, revenue is recognized when there is persuasive evidence of an agreement, title has passed or delivery has occurred, the price is fixed and determinable, and collection is reasonably assured.

*Manufacture and Supply Revenue* – The Company records revenues when products are shipped and title passes to the customers.

*Co-development and Research Fees* – Co-development and research fees are earned through performance of specific tasks, activities or completion of stages of development defined within a contractual arrangement with a customer. The nature of these performance obligations, broadly referred to as milestones or deliverables, are usually dependent on the scope and structure of the project as contracted, as well as the complexity of the product and the specific regulatory approval path necessary for that product. Accordingly, the duration of the Company's research and development projects may range from several months to approximately three years. Although each contractual arrangement is unique, common milestones included in these arrangements include those for the performance of efficacy

# NOTES TO THE UNAUDITED INTERIM CONSOLIDATED FINANCIAL STATEMENTS (continued)

#### (In thousands, except share and per share information)

and other tests, reports of findings, formulation of initial prototypes, production of stability clinical and/or scale-up batches, and stability testing of those batches. Additional milestones may be established and linked to clinical results of the product submission and/or approval of the product by the FDA and the commercial launch of the product. Co-development and research fees are recognized when related milestones are completed and delivered and, in some cases, accepted by the customer.

*License and Royalty Revenue* – License revenue is recognized in accordance with the terms of the license agreement. The revenue will be recognized ratably over the initial term of the license agreement. If the term of the license is perpetual, the Company will recognize the revenue upon the execution of the license as long as there are no contingencies in the license agreement. If a contingency exists, the revenue will need to be deferred until such time that the contingencies are lifted. Upfront payments are recorded when incurred and milestone revenue is recognized upon the achievement of specific milestones. Payments received in excess of amounts achieved are classified as deferred revenue until earned. Royalty revenue is recognized in accordance with contractual rates when they can be reasonably estimated based on reported sales data and when collection is reasonably assured. In the event that reasonable sales data is unavailable, revenue is recognized when royalty reports are received.

*Collaborative Arrangements* – A contractual arrangement falls within the scope of FASB ASC Subtopic 808-10, Collaborative Arrangements, if the arrangement requires the parties to be active participants and the arrangement exposes the parties to significant risks that are tied to the commercial success of the endeavor. Costs incurred and revenues generated on sales to third parties are reported in the consolidated statement of operations based on the guidance in FASB ASC Subtopic 605-45, *Revenue Recognition – Principal Agent Considerations*. Revenue earned from collaboration partners as of March 31, 2018 and 2017 was not material.

# (W) Share-Based Payments

The Company issues share-based payments under the terms of its PUP Plans. The cost of employee services received in exchange for equity-based awards are determined based on FASB ASC Topic 718, *Compensation – Stock Compensation* using the grant-date fair value of the awards. Under the Company's PUP Plans, all outstanding equity-based payments are to be recognized as an expense based on their fair value at the measurement date, which is delayed until achievement of specified performance conditions can be considered probable. At the time that all contingencies are satisfied, the performance units granted to both employees and consultants will be reflected as liability-classified instruments based on the application of FASB ASC Topic 718.

#### (X) Asset Retirement Obligations

FASB ASC Subtopic 410-20, Asset Retirement and Environmental Obligations – Asset Retirement Obligations, addresses financial accounting and reporting for obligations associated with the retirement of tangible long-lived assets and the associated asset retirement costs. The Company's asset retirement obligation ("ARO") consists of estimated future spending to remove certain leasehold improvements and return each leased facility to its original condition. The Company records an ARO asset (a component of property and equipment) and associated liability equal to the present value of the estimated future spending at the date the asset is placed in service. Spending estimates are discounted at the credit-adjusted risk-free rate. The ARO asset is amortized on the straight-line method over the lesser of its expected life or the lease term and the ARO liability is accreted over the lesser of expected life or the lease term.

# (Y) Comprehensive Income/(Loss)

Comprehensive income/(loss) is the change in shareholders'/members' equity (deficit) from transactions and other events and circumstances other than those resulting from investments by members and distributions to shareholders'/members.

# NOTES TO THE UNAUDITED INTERIM CONSOLIDATED FINANCIAL STATEMENTS (continued)

(In thousands, except share and per share information)

#### (Z) Recent Accounting Pronouncements

As a public emerging growth company, the Company has elected to take advantage of the extended transition period afforded by Jumpstart Our Business Startups Act for the implementation of new or revised accounting standards and, as a result, the Company will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for public emerging growth companies.

From time to time, new accounting pronouncements are issued by the FASB and adopted by the Company as of the specified effective date. Unless otherwise discussed, the Company believes that the impact of recently issued standards that are not yet effective will not have a material impact on its financial position or results of operations upon adoption.

In May 2014, the FASB issued ASU 2014-09, Revenue from Contracts with Customers (Topic 606). The standard will apply one comprehensive revenue recognition model across all contracts, entities, and sectors. The core principle of the new standard is that revenue should be recognized to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. Once effective, ASU 2014-09 will replace most of the existing revenue recognition requirements in U.S. GAAP. The FASB also issued ASU 2015-14, Revenue from Contracts with Customers (Topic 606): Deferral of the Effective Date, which deferred the effective date of the standard one year. As a result, the new standard is effective for annual reporting periods beginning after December 15, 2019, including interim periods within the reporting period. The Company is currently assessing the effect that adoption of the new standard will have on its consolidated financial statements. As of part of the Company's assessment, an entity can elect to apply the guidance under one of the following two methods: (i) retrospectively to each prior reporting period presented, referred to as the full retrospective method, or (ii) retrospectively with the cumulative effect of initially applying the standard recognized at the date of initial application in retained earnings, referred to as the modified retrospective method. The Company is in the process of its initial assessment of the potential changes from adopting ASU No. 2014-09. The initial assessment consists of a review of a representative sample of contracts, discussions with key stakeholders, and a cataloging of potential impacts on its consolidated financial statements, accounting policies, financial control, and operations. The Company has not yet completed its final review of the impact; however, the Company anticipates applying the modified retrospective method when implementing this guidance. As a result, this standard is effective for the Company for annual reporting periods beginning after December 15, 2019. The Company continues to monitor additional changes, modifications, clarifications or interpretations being undertaken by the FASB, which may impact its initial conclusions.

In January 2016, the FASB issued revised guidance governing accounting and reporting of financial instruments. This guidance requires that equity investments with readily determinable fair values that are classified as available-forsale be measured at fair value with changes in value reflected in current earnings. This guidance also simplifies the impairment testing of equity investments without readily determinable fair values and alters certain disclosure requirements. ASU No. 2016-01, *Financial Instruments – Overall: Recognition and Measurement of Financial Assets and Financial Liabilities*, also provides guidance as to classification of the change in fair value of financial liabilities. These revised standards are effective for the Company for annual periods in fiscal years beginning after December 15, 2018. The Company is currently evaluating the impact of these revised standards.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)* which establishes a comprehensive new lease accounting model. The new standard: (i) clarifies the definition of a lease; (ii) requires a dual approach to lease classification similar to current lease classifications; and (iii) causes lessees to recognize leases on the balance sheet as a lease liability with a corresponding right-of-use asset for leases with a lease-term of more than twelve months. The new standard is effective for the

# NOTES TO THE UNAUDITED INTERIM CONSOLIDATED FINANCIAL STATEMENTS (continued)

#### (In thousands, except share and per share information)

Company for fiscal years and interim periods beginning after December 15, 2019 and requires modified retrospective application. Early adoption is permitted. The Company is currently evaluating the impact that the adoption of ASU 2016-02 will have on its consolidated financial statements.

In March 2016, the FASB issued ASU 2016-09, *Compensation – Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting.* This guidance simplifies aspects of accounting for employee share-based payments, including income tax consequences, classification of awards as either equity or liabilities, and classifications within the statement of cash flows. This guidance is effective for annual periods beginning after December 15, 2017, with early adoption permitted. Under the Company's PUP Plans (Note 16), vested grants may not be exercised prior to either a change in control of the Company or completion of an IPO, rendering the grants contingent and requiring deferred expense recognition until either of the conditions is satisfied. Accordingly, the adoption of ASU 2016-09 had no impact on the Company's consolidated financial statements.

In June 2016, the FASB issued, ASU No. 2016-13, *Financial Instruments – Credit Losses (Topic 326)*, amending existing guidance on the accounting for credit losses on financial instruments within its scope. The guidance introduces an expected loss model for estimating credit losses, replacing the incurred loss model. The new guidance also changes the impairment model for available-for-sale debt securities, requiring the use of an allowance to record estimated credit losses (and subsequent recoveries). The new guidance is effective for the Company beginning after December 15, 2020. The Company is currently evaluating the impact of adoption on its consolidated financial statements

In August 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments, providing* guidance on the classification of certain cash receipts and payments in the statement of cash flows intended to reduce diversity in practice. The guidance is effective for the Company for fiscal years beginning after December 15, 2018. Early adoption is permitted. The Company is currently evaluating the effect of the standard on its Consolidated Statement of Cash Flows.

# 3. Revenues and Trade Receivables, Net

The Company's revenue was comprised of the following:

 2018 (unai	udited	2017
 (unai	udited	)
\$ 11,560	\$	10,155
9,500		5,223
2,351		1,058
\$ 23,411	\$	16,436
\$	9,500 2,351	9,500 2,351

Trade receivables, net consist of the following:

	Ma	<u> </u>		ecember 31,
				2017
	(Un	audited)		
Trade receivables	\$	9,386	\$	6,156
Less: allowance for bad debts		(94)		(55)
Trade receivables, net	\$	9,292	\$	6,101

Other nontrade receivables totaled \$149 and \$78 as of March 31, 2018 and December 31, 2017 respectively, consisting primarily of reimbursable costs incurred on behalf of a major customer.

# NOTES TO THE UNAUDITED INTERIM CONSOLIDATED FINANCIAL STATEMENTS (continued)

(In thousands, except share and per share information)

The following table presents the changes in the allowance for bad debts account:

	March 31,		Decer	mber 31,			
	2018			2018		2	2017
	(Unaudite	d)					
Allowance for doubtful accounts at beginning of year	\$	55	\$	108			
Additions charged to bad debt expense		39		0			
Recoveries of amounts previously reserved		0		(53)			
Allowance for doubtful accounts at end of the period	\$	94	\$	55			

#### 4. Customer Concentrations

Customers are considered major customers when sales exceed 10% of total net sales for the period or outstanding receivable balances exceed 10% of total receivables. During the three month period ending March 31, 2018, Indivior, Inc. ("Indivior") represented 97% of the total revenue for the period. During 2017, Indivior represented 88% of the total revenue for the period.

As of March 31, 2018 and December 31, 2017, the Company's outstanding receivable balance from Indivior represented approximately 95% and 93%, respectively, of total receivables.

## 5. Material Agreements

## Commercial Exploitation Agreement with Indivior

In August 2008, the Company entered into a Commercial Exploitation Agreement with Reckitt Benckiser Pharmaceuticals, Inc. (the "Indivior License Agreement"). Reckitt Benckiser Pharmaceuticals, Inc. was later succeeded to in interest by Indivior, Inc. ("Indivior"). Pursuant to the Indivior License Agreement, the Company agreed to manufacture and supply Indivior's requirements of Suboxone, a sublingual film formulation, both inside and outside the United States on an exclusive basis.

Under the terms of the Indivior License Agreement, the Company is required to manufacture Suboxone in accordance with current Good Manufacturing Practice standards and according to the specifications and processes set forth in the related quality agreements the Company entered into with Indivior. Additionally, the Company is required to obtain Active Pharmaceutical Ingredients ("API") for the manufacture of Suboxone directly from Indivior. The Indivior License Agreement specifies a minimum annual threshold quantity of Suboxone that the Company is obligated to fill and requires Indivior to provide the Company with a forecast of its requirements at various specified times throughout the year.

In addition to the purchase price for the Suboxone supplied, Indivior is required to make certain single digit percentage royalty payments tied to net sales value (as provided for in the Indivior License Agreement) in each of the United States and in the rest of the world subject to annual maximum amounts. In the event that Indivior has paid the Company a specified aggregate royalty amount in royalties on Suboxone sold in the United States, then it will be required to prepay to the Company, an additional agreed payment amount, after which all obligations of Indivior's royalty obligations to the Company continue in the United States and the rest of the world until the expiration of all of the patents (either in the United States or other territories) or upon written notice by Indivior subject to Indivior being required to pay the Company a final royalty payout. Indivior exercised its right to buy out its future royalty obligations in the United States.

The Indivior License Agreement contains customary contractual termination provisions for breach or in the event of bankruptcy or corporate dissolution, the intellectual property surrounding Suboxone is

# NOTES TO THE UNAUDITED INTERIM CONSOLIDATED FINANCIAL STATEMENTS (continued)

#### (In thousands, except share and per share information)

found to be invalid, or either party commits a material breach of the Indivior License Agreement. Additionally, Indivior may terminate if the U.S. Food and Drug Administration ("FDA") or other applicable regulatory authority declares the Company's manufacturing site to no longer be suitable for the manufacture of Suboxone or Suboxone is no longer suitable to be manufactured due to health or safety reasons. The initial term of the Indivior License Agreement was seven years from the commencement date. Thereafter, the Indivior License Agreement automatically renews for successive one year periods, unless Indivior provides the Company with written notice of its intent not to renew at least one year prior to the expiration of the initial or renewal term.

# Supplemental Agreement with Indivior

On September 24, 2017, the Company entered into an agreement with Indivior (the "Indivior Supplemental Agreement"). Pursuant to this agreement, the Company conveyed to Indivior all of its existing and future rights in the settlement of various ongoing patent enforcement legal actions and disputes related to Suboxone product. The Company also conveyed to Indivior the right to sublicense manufacturing and marketing capabilities to enable an Indivior licensed generic buprenorphrine product to be produced and sold by parties unrelated to Indivior or the Company. Under the Indivior Supplemental Agreement, the Company is entitled to receive certain payments from Indivior commencing on the date of the agreement through January 1, 2023. Once paid, all payments made under this Agreement are non-refundable. In consideration for the rights granted to Indivior under the Indivior Supplemental Agreement, the Company received in September 2017, a non-refundable payment of \$17,000, which was recognized as revenue in 2017 in License and royalty revenue. The Company received \$9,250 during the three months ended March 31, 2018 and is presented in License and royalty revenue above. The Company also received \$3,000 and \$1,250 in April 2018 and May 2018, respectively, as part of this agreement. In addition to amounts received, the Company may receive up to an additional \$44,500, consisting of a royalty equal to a low single digit percentage of net revenue earned by Indivior on Suboxone sales and performance-based milestone payments that may be earned through the issuance of additional process patent rights to the Company, with the aggregate payment amounts under the Indivior Supplemental Agreement capped at \$75,000. Accordingly, the Agreement includes certain provisions that may allow Indivior to cease remitting certain payments to the Company upon the occurrence of certain events related to unlicensed generic versions of Suboxone. In the event that Indivior's defense of its rights is ultimately successful, then, all payment obligations owed to the Company are retroactively reinstated.

All payments made by Indivior to the Company pursuant to the Indivior Supplemental Agreement are in addition to, and not in place of, any amounts owed by Indivior to the Company pursuant to the Indivior License Agreement. Indivior's payment obligations under the Indivior Supplemental Agreement are subject to certain factors affecting the market for Suboxone and may terminate prior to January 1, 2023 in the event certain contingencies relating to such market occur.

# License Agreement with Sunovion Pharmaceuticals, Inc.

In April 2016, the Company entered into a license agreement with Cynapsus Therapeutics Inc. (which was later succeeded to an interest by Sunovion Pharmaceuticals, Inc. ("Sunovion")) (the "Sunovion License Agreement"), pursuant to which the Company granted Sunovion an exclusive, worldwide license (with the right to sub-license) to certain intellectual property, including existing and future patents and patent applications, covering all oral films containing APL-130277 (apomorphine) for the treatment of off episodes in Parkinson's disease patients, as well as two other fields.

Under the Sunovion License Agreement, the Company received \$0 and \$5,000 milestone payments during the three months ended March 31, 2018 and 2017, respectively, which was recognized as revenue and is presented in License and royalty revenue above. The Company is eligible to receive remaining milestone payments of up to \$11,000 for certain regulatory events and up to \$20,000 for commercial

# NOTES TO THE UNAUDITED INTERIM CONSOLIDATED FINANCIAL STATEMENTS (continued)

#### (In thousands, except share and per share information)

milestone events that are contingent on the achievement of certain sales levels. In addition to the milestone payments, the Company is entitled to receive low single digit percentage royalty payments on global net sales of products commercialized by Sunovion that include apormorphine as their API.

Absent early termination, the Sunovion License Agreement continues (on a country-by-country basis) until the expiration of all applicable licensed patents. Upon termination, all rights to intellectual property granted to Sunovion to develop and commercialize products will revert to the Company and Sunovion must continue to pay royalties to the Company on each sale of their remaining inventory of products commercialized by Sunovion which include apormorphine as their API.

#### Collaboration and License Agreement with Mitsubishi Tanabe

In August 2017, the Company entered into an agreement with Mitsubishi Tanabe ("MT") to perform feasibility studies related to Radicava, MT's Amyotrophic Lateral Sclerosis treatment using the compound edaravone. The activities for this arrangement were not material during the three months ended March 31, 2018 and 2017.

## Agreement to Terminate CLA with KemPharm

In March 2012, the Company entered into an agreement with KemPharm, Inc. ("KemPharm"), to terminate a Collaboration and License Agreement entered into in April 2011, under this arrangement, we have the right to receive payments, including, but not limited to, royalty payments on any license of KP415, the sale of KP415 to a third party, the commercialization of KP415 and the portion of any consideration that is attributable to the value of KP415 and paid to KemPharm or its stockholders in a change of control transaction. The Company has not received payments under this arrangement during the three months ended March 31, 2018 and 2017.

#### 6. Inventory

Inventory consists of the following:

	March 31,		December 31,			
		2018		2018		2017
	(Un	audited)				
Raw material	\$	754	\$	725		
Packaging material		2,147		2,225		
Finished goods		949		1,064		
Total inventory	\$	3,850	\$	4,014		

# NOTES TO THE UNAUDITED INTERIM CONSOLIDATED FINANCIAL STATEMENTS (continued)

(In thousands, except share and per share information)

# 7. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist primarily of costs incurred in advance of services being received, including insurance, software licenses and service agreements.

	Mar	March 31, 2018		cember 31,
	2			2018
	(Una	udited)		
Insurance	\$	69	\$	148
Software licenses		193		125
Service agreements		168		75
Medical premiums		75		70
Subscriptions		57		44
Lab equipment		34		39
Memberships		28		30
Other	_	18		60
Total prepaid expenses and other current assets	\$	642	\$	591

# 8. Property and Equipment, Net

	Useful Lives	м	March 31,		March 31,		March 31,		ecember 31,
		2018			2017				
		(Uı	naudited)						
Machinery	3-15 yrs	\$	20,124	\$	20,056				
Furniture and fixtures	3-15 yrs		1,109		1,109				
Leasehold improvements	(a)		21,271		21,271				
Computer, network equipment and software	3-7 yrs		2,108		2,108				
Construction in progress			1,097		921				
			45,709		45,465				
Less: accumulated depreciation and amortization			(32,945)		(32,005)				
Total property and equipment, net		\$	12,764	\$	13,460				

(a) Leasehold improvements are amortized over the shorter of the lease term or their estimated useful lives.

Total depreciation and amortization related to property and equipment was \$940 and \$915 for the three months ended March 31, 2018 and 2017, respectively (unaudited).

# 9. Intangible Assets

The following table provides the components of identifiable intangible assets, all of which are finite lived:

	Mar	ch 31,	December 31,		
	2	2018		2017	
	(Una	udited)			
Purchase technology-based intangible	\$	2,358	\$	2,358	
Purchased patent		509		509	
		2,867		2,867	
Less: accumulated amortization		(2,626)		(2,613)	
Intangible assets, net	\$	241	\$	254	

# NOTES TO THE UNAUDITED INTERIM CONSOLIDATED FINANCIAL STATEMENTS (continued)

#### (In thousands, except share and per share information)

Amortization expense was \$13 and \$13 for the three months ended March 31, 2018 and 2017, respectively. During the remaining life of the purchased patent, estimated annual amortization expense is \$51 for each of the years from 2018 to 2022.

# **10. Investments**

During the fourth quarter of 2016, the Company sold all holdings of equity interests in Midatech Pharma, PLC, realizing proceeds of \$1,166. The Company's investment in this joint venture, carried at cost, totaled \$6 as of March 31, 2018 and December 31, 2017, respectively, and is recorded in Other assets on the consolidated balance sheets.

In addition to its investments in Midatech shares, pursuant to the agreement between the parties, the Company also funded certain project development costs. These costs from inception are expensed to research and development as paid and totaled \$4,842. through December 31, 2016. There were no costs incurred during the three months ended March 31, 2018 and 2017, respectively.

In 2011, Midatech Ltd. and the Company entered into a Joint Venture Agreement for the development and commercialization of diabetes-related products and formed MidaSol Therapeutics (the "JV") to conduct planned activities. The agreement provides each of the two venture partners with 50% ownership interests, identical voting and management rights and responsibilities, equal representation on the governing four-member board of managers, the requirement to contribute relevant intellectual property by each party and equal sharing of profits and losses to each party for JV products or services. Each of the parties actively participates in the conduct and performance of the venture's undertakings, each acts as principal in the completion of its obligations and each is subject to the risks and rewards inherent in related joint operations. All of MidaSol's research, development, production and sales activities have been conducted through the facilities of each party and carried out by the parties' employees or contractors. For all products and services provided to its customers, except those related to research studies, costs are reimbursed to the parties from earned revenues prior to the sharing of profits.

#### 11. Accrued Expenses

Accrued expenses consisted of the following:

	<u>March 31,</u> 2018		December 31, 2017	
	(Una	udited)		
Bonus	\$	677	\$	3,257
Payroll and benefits		892		504
Real estate and personal property taxes		427		340
Other		267		301
Total accrued expenses	\$	2,263	\$	4,402

# 12. Loans Payable

On August 16, 2016, the Company entered into a Loan Agreement and Guaranty with Perceptive Credit Opportunities Fund, LP ("Perceptive"). At closing, the Company borrowed \$45,000 from Perceptive and was permitted to borrow up to an additional \$5,000 within one year of the closing date based upon achievement of a defined milestone. In March 2017, the Company met its performance obligations under the terms of the credit agreement with Perceptive and submitted a formal request to draw down the remaining \$5,000 of its \$50,000 credit facility. The loan proceeds have been used to pay the existing debt obligation of \$37,500 due to White Oak Global Advisors, LLC, with the balance available for general business purposes.



# NOTES TO THE UNAUDITED INTERIM CONSOLIDATED FINANCIAL STATEMENTS (continued)

#### (In thousands, except share and per share information)

The loan from Perceptive will mature on August 16, 2020 and bears interest, payable monthly, at one-month LIBOR or 2% plus 9.75%, subject to a minimum rate of 11.75%. Commencing on January 31, 2019, seven monthly loan principal payments are due in the amount of \$550. Thereafter, monthly principal payments in the amount of \$750 are due through the maturity date, at which time the full amount of the remaining outstanding loan balance is due. At March 31, 2018, \$1,650 was classified as current debt. The Company's tangible and intangible assets are subject to first priority liens to the extent of the outstanding debt. Other significant terms include financial covenants, change of control triggers and limitations on additional indebtedness, asset sales, acquisitions and dividend payments. Financial covenant requirements include (1) Minimum liquidity we must maintain a monthly cash balance of \$4,000 at all times and (2) Minimum revenue requirement whereby on a quarterly basis (calculation date) we must maintain minimum revenues for the twelve consecutive months ended prior to the calculation date. As of March 31, 2018, the Company was in compliance with all financial covenants. As of March 31, 2018, the Company's carrying value of this loan payable approximates its fair market value. At closing, Perceptive received a warrant to purchase senior common equity interests representing 4.5% of the fully diluted common units of the Company on an as converted basis (see Note 13).

The Company capitalizes legal and other third-party costs incurred in connection with obtaining debt as deferred debt issuance costs, and applies the unamortized portion as a reduction of the outstanding face amount of the related loan in accordance with ASU 2015-03, *Interest – Imputation of Interest: Simplifying the Presentation of Debt Issuance Costs.* Similarly, the Company amortizes debt discounts, such as those represented by warrants issued to its lenders, and offsets those as a direct reduction of its outstanding debt. Amortization expense arising from deferred debt issuance costs and debt discounts for the three months ended March 31, 2018 and 2017 were \$458 and \$457, respectively.

Unamortized deferred debt issuance costs and deferred debt discounts totaled \$4,035 as of March 31, 2018 and \$4,493 as of December 31, 2017.

## 13. Warrant Liability

The warrant issued to Perceptive in connection with the August 16, 2016 Loan Agreement expires on August 16, 2023 and has certain rights and preferences including anti-dilution adjustments so that, upon exercise, they will represent 4.5% of the Company's fully diluted common stock on an as converted basis, subject to dilution for certain financing transactions including the issuance of shares upon termination of our PUP Plans. The warrant also provides Perceptive with a put right which, if exercised under certain circumstances, would require the Company to purchase the warrant for \$3,000 within the first year of the loan or \$5,000 thereafter. These re-purchase terms may require net-cash settlement, and as a result, the appraised value of this warrant at the time of issuance of \$5,800 was classified as a liability, rather than as a component of equity, and is treated as a debt discount, with the unamortized portion applied to reduce the face amount of the loan in the accompanying Consolidated Balance Sheet. The (\$697) change in value of this warrant liability from December 31, 2017 to March 31, 2018 and the \$420 change in value of this warrant liability from December 31, 2017 are reported in the accompanying Consolidated Statement of Operations as a "Change in fair value of warrant".

The Company uses a third-party valuation to assist in determining the fair value of the warrant due to the absence of available Level 1 and Level 2 inputs. The appraisals at both the date of the issuance and the balance sheet date were based on unobservable Level 3 inputs. The first step in determining the fair value of the warrant liability is to determine the value of the aggregate equity of the Company which was estimated utilizing the income and market valuation approaches. A probability weighted return model was then utilized to allocate the aggregate equity value of the Company to the underlying securities. Estimates and assumptions impacting the fair value measurement include the following factors: the progress of the

# NOTES TO THE UNAUDITED INTERIM CONSOLIDATED FINANCIAL STATEMENTS (continued)

#### (In thousands, except share and per share information)

Company's pipeline products since the prior valuations, including status of clinical trials; the Company's progress towards an IPO,; discount rates of 27.5% and 35.0% for the three months ended March 31, 2018 and 2017, respectively and volatility rates of 90% and 80% for the three months ended March 31, 2018 and 2017, respectively.

## 14. Commitments and Contingencies

## (A). Leases

The Company has entered into various lease agreements for production and research facilities and offices. Most leases contain renewal options. Certain leases contain purchase options and require the Company to pay for taxes, maintenance and operating expenses. All of the Company's leases are classified as operating leases.

#### Production and Research Facilities, Portage, Indiana

The Company leases a 73,000-square-foot facility (Ameriplex) in Portage, Indiana, to house additional packaging, R&D and other operations. As amended, this lease has a term that extends through September 30, 2022 and contains a renewal option that could extend the lease through September 30, 2026.

The Company also leases its current 8,400-square-foot production facility (Melton) in Portage, Indiana, which houses certain research and development offices and current good manufacturing practices, or cGMP, manufacturing operations. The lease contains an option to purchase the facility at any time during the lease term along with a right of first refusal to purchase the facility. In October 2012, the Company entered into an additional five-year extension of the lease of this facility, through March 31, 2018, under the same terms and conditions. In October 2017, the Company extended its lease located in Portage, Indiana, which will expire during March 2023 under the same terms and conditions as its former lease.

# Office and Laboratory Facilities, Warren, New Jersey

The Company leases its headquarters and principal laboratory facility in Warren, New Jersey. Pursuant to various amendments in February 2011, June 2012 and May 2013, the Company has secured additional space to provide for the growth of its laboratory facilities and corporate and administrative requirements. The lease included five two-year renewal options, one of which was exercised in July 2016 to extend this lease through August 31, 2018. During February 2018, the Company extended this lease by eighteen months through February 28, 2020.

## Rent Expense and Commitments

Rent expense for all leased manufacturing facilities and sales, laboratory and office space was approximately \$331 and \$322 for the three months ended March 31, 2018 and 2017, respectively.

# (B). Litigation and Contingencies

The Company is involved in various claims, legal proceedings and investigations, including (as of March 31, 2018, except where noted below) those described below. While it is not feasible to predict the outcome of such pending claims, proceedings and investigations with certainty, management is of the opinion that their ultimate resolution should not have a material adverse effect on the Company's financial position, cash flows, or results of operations, except where noted below.

Beginning in August 2013, the Company was informed of abbreviated new drug application ("ANDA") filings in the United States by Watson Laboratories, Inc. (now Actavis Laboratories, Inc. ("Actavis")), Par Pharmaceutical, Inc. ("Par"), Alvogen Pine Brook, Inc. ("Alvogen"), Teva Pharmaceuticals USA, Inc.



# NOTES TO THE UNAUDITED INTERIM CONSOLIDATED FINANCIAL STATEMENTS (continued)

#### (In thousands, except share and per share information)

("Teva"), Sandoz Inc. ("Sandoz") and Mylan Technologies Inc. ("Mylan") for the approval by the FDA of generic versions of Suboxone Sublingual Film in the United States. The Company filed patent infringement lawsuits against all six generic companies in the U.S. District Court for the District of Delaware. By a court order dated August 22, 2016, the Company's ANDA patent litigation case against Sandoz has been dismissed without prejudice for lack of subject matter jurisdiction because Sandoz is no longer pursuing a Paragraph IV certification for its proposed generic version of Suboxone Sublingual Film, and therefore is no longer challenging the validity or noninfringement of our Orange Book-listed patents. The case against Mylan was settled and a Consent Judgment was entered in September 2017 disposing of the entire case as to Mylan. Dr. Reddy's Laboratories ("Dr. Reddy's) acquired from Teva the ANDA filings for Teva's buprenorphine HCl and naloxone sublingual film that are at issue in these trials.

Trials against Dr. Reddy's, Actavis and Par in the lawsuits involving the Orange Book and process patents occurred in November-December of 2015 and November of 2016. On June 3, 2016, the Court issued its Trial Opinion finding that the asserted claims of U.S. Patent No. 8,603,514 ("the '514 patent") are valid and infringed by Actavis's and Par's ANDA Products. On August 31, 2017, the Court upheld the asserted U.S. Patent No. 8,900,497 ("the '497 patent") as valid but not infringed by Par's, Actavis's or Dr. Reddy's proposed processes for making their ANDA Products. The Court also again upheld the validity of the '514 patent but held it was not infringed by Dr. Reddy's ANDA Products. All of these cases are consolidated on appeal to the Federal Circuit, except the cases between the Company and Indivior on the one hand and Par and certain affiliates.

In 2016, the Company prevailed in ongoing litigated cases against certain competitors. On April 7, 2016, the USPTO upheld the validity of all challenged patent claims initiated by a competitor against certain key patents held by the Company. On June 3, 2016, the U.S. District Court of Delaware ruled that certain generic competitors have infringed on key patents held by the Company. This Court's ruling upholds the Company's right to exclusive use of patents and the delivery of Suboxone film until patent expiration in 2024. The ruling is subject to appeal. The Company continues to explore potential patent right enforcement actions against other competitors, particularly in the United States.

The Company is also seeking to enforce its patent rights in multiple cases against BioDelivery Sciences International, Inc. ("BDSI"). Two cases are currently pending but stayed in the Eastern District of North Carolina. The first was filed by the Company and Indivior related to BDSI's infringing Bunavail product, and alleges infringement of the Company's patent, U.S. Patent No. 8,765,167 ("the '167 patent"). This case was initially filed in September 2014 in the District of New Jersey but was transferred to North Carolina. Shortly after the case was filed, BDSI filed an IPR challenging the asserted '167 patent. On March 24, 2016, the Patent Trial and Appeal Board ("PTAB") issued a final written decision finding the '167 patent was not unpatentable. The North Carolina case is stayed pending the outcome and final determination of the proceedings concerning the '167 patent, which is currently on appeal to the Federal Circuit (discussed below). There is also a declaratory judgment action in North Carolina brought by BDSI for invalidity and non-infringement of the Company's U.S. Patents Nos. 7,897,080 ("the '080 patent"), 8,652,378 ("the '378 patent") and 8,475,832 ("the '832 patent"). The parties jointly moved the court for a stay of the proceeding pending *inter partes* review of the '832 patent and reexamination of the '080 patent. The case is currently stayed.

On January 13, 2017, the Company filed an additional case against BDSI asserting infringement of the '167 patent by BDSI's Belbuca product. The case was transferred from New Jersey to the District of Delaware by agreement of the parties. BDSI has filed motions to dismiss and motions to transfer to the Eastern District of North Carolina. The Judge has not yet ruled on these motions. On November 28, 2016, BDSI filed a notice of appeal to the Federal Circuit of the PTAB's final written decisions finding that the '167 patent was not unpatentable in IPR2015-00165, IPR2015-00168 and IPR2015- 00169. The case has been fully briefed and the Court heard oral arguments on February 9, 2018. Nothing further has occurred on this matter.

# NOTES TO THE UNAUDITED INTERIM CONSOLIDATED FINANCIAL STATEMENTS (continued)

#### (In thousands, except share and per share information)

In September 2017, Indivior brought suit against Alvogen for infringement of U.S. Patent No. 9,687,454 ("the '454 patent") based on the filing of an ANDA seeking approval for a generic version of Suboxone Sublingual Film, in the U.S. District Court for the District of New Jersey. In February 2018, the Company and Indivior amended the complaint, which added it as a plaintiff and added a claim for infringement of U.S. Patent No. 9,855,221 ("the '221 patent").

Indivior brought suits against Dr. Reddy's and Teva in September 2017, and against Par and certain affiliates in October 2017, for infringement of the '454 patent, in the U.S. District Court for the District of New Jersey.

Indivior also brought suit in September 2017 against Actavis Laboratories UT, Inc. for infringement of the '454 patent, in the U.S. District Court for the District of Utah. On March 13, 2018, the Court granted transfer of this case to the U.S. District Court for the District of Delaware.

In February 2018, the Company and Indivior brought suit against Actavis, Dr. Reddy's, Teva, and Par and certain affiliates for infringement of the '221 patent. The suit against Actavis was filed in the U.S. District Court for the District of Utah, and the other three cases were filed in the U.S. District Court for the District of New Jersey.

In April 2018, the Company and Indivior brought suit against Actavis, Alvogen, Dr. Reddy's, Teva, and Par and certain affiliates for infringement of U.S. Patent No. 9,931,305 ("the '305 patent"). The cases against Alvogen, Dr. Reddy's, Teva, and Par are pending in the U.S. District Court for the District of New Jersey. Following transfer of the case asserting the '454 patent from Utah to Delaware, and by agreement of the parties, the cases against Actavis asserting infringement of the '454, '221, and '305 patents are consolidated in a single action pending in the U.S. District Court for the District of Delaware.

The matters involving Par were resolved on May 11, 2018, when the Company, Indivior and Par and certain of its affiliates entered into a settlement agreement resolving patent litigation related to SUBOXONE<sup>®</sup> (buprenorphine and naloxone) Sublingual Film. Under the settlement agreement, Par and IntelGenX are permitted to launch their proposed generic version of the buprenorphine and Naloxone sublingual film on January 1, 2023, or earlier under certain circumstances. The patent-infringement litigation has been pending in the U.S. District Court for the District of Delaware. As required by law, the parties will submit the settlement agreement of the U.S. Federal Trade Commission and the U.S. Department of Justice for review.

The Company has also been named as a Defendant in a Complaint filed by 41 U.S. states and the District of Columbia, alleging violations of federal and state antitrust and consumer protection laws related to Suboxone Sublingual Film. The Court denied the Company's motion to dismiss on October 30, 2017. The case is in early stages of discovery.

From time to time, the Company may become involved in other various lawsuits and legal proceedings, the results of which are inherently unpredictable due to the uncertainties that must be resolved as these matters are adjudicated or settled. These legal actions arise in the ordinary course of business. Provisions for liabilities arising from these matters are made when it is both probable that a liability has been incurred and the amount of that liability can be reasonably estimated. Management is currently not aware of any such legal proceedings or claims against the Company that may have, individually or in the aggregate, a material adverse effect on the Company's business, financial condition, operating results, or liquidity.

The Company has defended, and is committed to prudently defending, its patent portfolio and rights. The patent defense expense was \$1,583 and \$938 for the three months ended March 31, 2018 and 2017, respectively. These costs consist of fees incurred for the services of patent attorneys, litigation attorneys

# NOTES TO THE UNAUDITED INTERIM CONSOLIDATED FINANCIAL STATEMENTS (continued)

#### (In thousands, except share and per share information)

and certain other experts that may be required to protect the Company's patent rights against infringement from unlicensed users, including actions involving defense of patents during review and as well as those involving matters brought before U.S. Federal District or other courts.

# 15. Geographic Information

The Company manages its operations geographically as United States, Australia and Malaysia. The United States is the only country to contribute more than 10% of total revenue for the three months ended March 31, 2018 and 2017, respectively.

The following table provides revenue by geographic area:

	Fo	For the Three Months Ended March 31,			
	2	2018		2017	
		(unaudited)			
United States	\$	23,197	\$	15,889	
Australia		181		520	
Malaysia		33		27	
Revenues	\$	23,411	\$	16,436	

The Company's long-lived assets are entirely located in the United States.

## 16. Performance Unit Plans

The Company has two PUP Plans, both of which are considered to be within the scope of FASB ASC Subtopic 718-30, *Compensation – Stock Compensation – Awards Classified as Liabilities*. Pursuant to the Plans, vested grants may not be exercised prior to either a change in control of the Company or completion of an IPO. These performance conditions render the grants contingent and defer expense recognition until either of the conditions is satisfied. Neither of these conditions were satisfied as of December 31, 2017 or March 31, 2018. As of December 31, 2017 and March 31, 2018 there were 60,707 units outstanding.

Subsequent to the March 31, 2018 balance sheet date, the Company terminated the Performance Unit Plans. The termination was executed on April 16, 2018 in accordance with the provisions of the Plans' termination, which required both Board of Directors and the Plan A participant approval. As a result, the Company accelerated the vesting of any unvested performance units and issued non-voting common shares to compensate the performance unit holders. In accordance with ASC 718, *Compensation – Stock Compensation*, the Company will record a charge to earnings of \$11,500 in the second quarter of 2018 to reflect the compensation cost associated with the issuance of the non-voting common shares. The compensation expense was estimated using an independent third-party valuation prepared in accordance with the American Institute of Certified Public Accountants Practice Aide, Valuation of Privately-Held Company Equity Securities Issued as Compensation.

The Company, pursuant to the provisions of the termination of the Plans, has elected to pay the withholding tax on behalf of the performance unit holders and will record an additional liability and compensation expense in the second quarter 2018, of approximately \$7,400.

## 17. Employee Benefit Plans

The Company sponsors a defined-contribution 401(k) plan covering all full-time employees and makes matching employer contributions as defined by the terms of that plan. The Company may also make discretionary contributions. Total contributions made to the plan by the Company for the three months ended March 31, 2018 and 2017 were \$194 and \$160, respectively.

## Aquestive Therapeutics, Inc. (formerly known as MonoSol Rx, LLC)

# NOTES TO THE UNAUDITED INTERIM CONSOLIDATED FINANCIAL STATEMENTS (continued)

(In thousands, except share and per share information)

### **18. Asset Retirement Obligations**

The Company's ARO consists of estimated future spending related to removing certain leasehold improvements at its Portage, Indiana, laboratory, the Ameriplex production facility and the Warren, New Jersey, laboratory and returning all facilities to their original condition. The Company's liability for AROs at March 31, 2018 and December 31, 2017 was \$1,115 and \$1,081, respectively. Accretion expense recognized during the three month periods ended March 31, 2018 and 2017 was \$34 and \$29, respectively.

Depreciation expense related to the ARO assets included in overall depreciation expense for the three months ended March 31, 2018 and 2017 were \$6 and \$6, respectively.

## 19. Income Taxes

The Company's tax provision for interim periods is determined using an estimate of its annual effective tax rate, adjusted for discrete items.

For the three months ended March 31, 2018, the Company recorded income tax expense of \$0 million on a pretax income of \$4,100.

The Company's U.S. statutory rate is 21%. The primary factor impacting the effective tax rate for the three months ended March 31, 2018 is the anticipated full year losses which will be incurred by the Company's operations that have valuation allowances against their net deferred tax assets.

The Company may also be subject to the net operating loss utilization provisions of Section 382 of the Internal Revenue Code. The effect of an ownership change would be the imposition of an annual limitation on the use of NOL carry forwards attributable to periods before the change. Although we have not completed an analysis under Section 382 of the Code, it is possible that the utilization of the NOLs will be limited.

## 20. Subsequent Event

In preparing the unaudited interim consolidated financial statements as of and for the three months ended March 31, 2018, the Company has evaluated subsequent events for recognition and measurement purposes through May 22, 2018. The Company has concluded the following event requires disclosure in the accompanying unaudited interim consolidated financial statements:

# (A) Amendment to Perceptive Loan Agreement and Guaranty

On May 21, 2018, the Company and Perceptive agreed to make certain amendments to the loan agreement then in effect. In the event that a qualified IPO is consummated on or before December 31, 2018, the parties have agreed to postpone the initial loan principal payments and to delay the loan maturity date, as follows:

- the seven monthly loan principal payments of \$550 each will begin in May 2019 rather than January 2019,
- the twelve monthly loan principal payments of \$750 each will begin in December 2019 rather than August 2019, and
- the final principal payment in the amount of \$37,150 will be due on December 16, 2020 rather than on August 16, 2020 as originally scheduled.



# Aquestive Therapeutics, Inc. (formerly known as MonoSol Rx, LLC)

# NOTES TO THE UNAUDITED INTERIM CONSOLIDATED FINANCIAL STATEMENTS (continued)

(In thousands, except share and per share information)

In addition, a minimum revenue covenant was added for the period ended September 30, 2020 in the amount of \$40,000, and the parties have also agreed that a mandatory prepayment and any applicable prepayment premiums that would become due upon consummation of an initial public offering would not apply in the event that listing on the NYSE or the Nasdaq exchange would occur.

Finally, the Company and Perceptive have also agreed that certain royalty income rights may be monetized through securitization, financing or other appropriate financial arrangement and to the release of this secured lender's lien on this asset.

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**Shares** 



# **Aquestive Therapeutics, Inc.**

# **Common Stock**

PRELIMINARY PROSPECTUS

# **BMO Capital Markets**

# **RBC Capital Markets**

Wedbush PacGrow

**JMP Securities** 

, 2018

Through and including , 2018 (25 days after the commencement of this offering), all dealers that buy, sell or trade shares of our common stock, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

## PART II Information not required in prospectus

# Item 13. Other Expenses of Issuance and Distribution.

The following table sets forth all costs and expenses, other than underwriting discounts and commissions, payable by Aquestive Therapeutics, Inc., or the Registrant, in connection with the sale of the common stock being registered. All amounts shown are estimates except for the SEC registration fee, the Financial Industry Regulatory Authority, Inc., or FINRA, filing fee and the Nasdaq listing fee.

SEC registration fee	\$ *
FINRA filing fee	*
Nasdag listing fee	*
Blue sky qualification fees and expenses	*
Printing and engraving expenses	*
Legal fees and expenses	*
Accounting fees and expenses	*
Transfer agent and registrar fees and expenses	*
Miscellaneous expenses	*
Total	\$ *

\* To be completed by amendment.

## Item 14. Indemnification of Directors and Officers.

The Registrant is incorporated under the laws of the State of Delaware. Section 145 of the Delaware General Corporation Law provides that a Delaware corporation may indemnify any persons who are, or are threatened to be made, parties to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of such corporation), by reason of the fact that such person is or was an officer, director, employee or agent of such corporation, or is or was serving at the request of such person as an officer, director, employee or agent of another corporation or enterprise. The indemnity may include expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with such action, suit or proceeding, provided that such person acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the corporation's best interests and, with respect to any criminal action or proceeding, had no reasonable cause to believe that his or her conduct was illegal. A Delaware corporation may indemnify any persons who are, or are threatened to be made, a party to any threatened, pending or completed action or suit by or in the right of the corporation by reason of the fact that such person is or was a director, officer. employee or agent of such corporation, or is or was serving at the request of such corporation as a director, officer, employee or agent of another corporation or enterprise. The indemnity may include expenses (including attorneys' fees) actually and reasonably incurred by such person in connection with the defense or settlement of such action or suit provided that such person acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the corporation's best interests except that no indemnification is permitted without judicial approval if the officer or director is adjudged to be liable to the corporation. Where an officer or director is successful on the merits or otherwise in the defense of any action referred to above, the corporation must indemnify him or her against the expenses which such officer or director has actually and reasonably incurred. The Registrant's certificate of incorporation and bylaws provide for the indemnification of our directors and officers to the fullest extent permitted under the Delaware General Corporation Law.

Section 102(b)(7) of the Delaware General Corporation Law permits a corporation to provide in its certificate of incorporation that a director of the corporation shall not be personally liable to the corporation or its stockholders for monetary damages for breach of fiduciary duties as a director, except for liability for any:

• transaction from which the director derives an improper personal benefit;

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- act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- unlawful payment of dividends or redemption of shares; or
- breach of a director's duty of loyalty to the corporation or its stockholders.

The Registrant's certificate of incorporation includes such a provision. Expenses incurred by any officer or director in defending any such action, suit or proceeding in advance of its final disposition shall be paid by the Registrant upon delivery to the Registrant of an undertaking, by or on behalf of such director or officer, to repay all amounts so advanced if it shall ultimately be determined that such director or officer is not entitled to be indemnified by the Registrant.

As permitted by the Delaware General Corporation Law, the Registrant intends to enter into, indemnification agreements with its directors and executive officers. These agreements, among other things, will require the Registrant to indemnify each director and officer to the fullest extent permitted by law and advance expenses to each indemnitee in connection with any proceeding in which indemnification is available.

At present, there is no pending litigation or proceeding involving any of our directors or executive officers as to which indemnification is required or permitted, and the Registrant is not aware of any threatened litigation or proceeding that may result in a claim for indemnification.

The Registrant has an insurance policy covering our officers and directors with respect to certain liabilities, including liabilities arising under the Securities Act of 1933, as amended, or the Securities Act, or otherwise.

The form of underwriting agreement will provide for indemnification by the underwriters named in this registration statement of our executive officers, directors and the Registrant, and by the Registrant of the underwriters named in this registration statement, for certain liabilities, including liabilities arising under the Securities Act, in connection with matters specifically provided in writing for inclusion in this registration statement.

## Item 15. Recent sales of unregistered securities.

The following sets forth information regarding all unregistered securities sold by the Registrant since January 1, 2015:

### Series A-3 Preferred Interests Issuance

In December 2015, Aquestive, LLC, our parent and predecessor, issued 5,055,000 Series A-3 Preferred Interests to certain accredited investors for \$5,055,000. The Series A-3 Preferred Interests contain a conversion option exercisable upon the offering, giving the holder the right to convert the interests into shares of our common stock.

#### Perceptive Warrants

In connection with the Credit Agreement and Guaranty we entered into with Perceptive Credit Opportunities Fund, LP, or Perceptive on August 16, 2016, we issued 11,625,437 warrants to purchase shares of our common stock representing 4.5% of our fully diluted common stock on an as converted basis. On January 1, 2018, in connection with our conversion into a Delaware corporation, we exchanged such warrants for new identical warrants that were immediately exercisable upon issuance into shares of our common stock at an exercise price of \$0.01 per share. The warrants issued to Perceptive expire on August 16, 2023 and are subject to anti-dilution adjustments so that, upon exercise, they will represent 4.5% of our fully diluted common stock on an as converted basis. The warrants issued to perceptive will, unless exercised earlier, be automatically exercised as of immediately prior to the effective date of this offering.

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## PUP Plan Issuances

The PUP Plans of Aquestive, LLC were terminated in April 2018, with such termination deemed to be effective as of January 1, 2018. In connection with the termination of the PUP Plans and in lieu of cash, we plan to pay the equivalent value in shares of our common stock. Shares of common stock will be issued to directors, officers and key employees in the following amounts:

Keith J. Kendall	12,338,408
Daniel Barber	1,221,000
Peter Boyd	610,000
John T. Maxwell	1,710,274
A. Mark Schobel	12,338,405
Theresa Wood	978,000
Douglas Bratton	926,421
Gregory Brown, M.D.	926,421
John Cochran	926,426
Santo Costa	213,789
James S. Scibetta	71,263

The recipients of securities in each of these transactions acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof, and appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions had adequate access, through employment, business or other relationships, to information about the Registrant.

Unless otherwise stated, the sales of the above securities were deemed to be exempt from registration under the Securities Act in reliance upon Section 4(a)(2) of the Securities Act (or Regulation D promulgated thereunder), or Rule 701 promulgated under Section 3(b) of the Securities Act in that the transactions were under compensatory benefit plans and contracts relating to compensation as provided under Rule 701.

# Item 16. Exhibits and financial statement schedules.

# (a) Exhibits

See the Exhibit Index attached to this Registration Statement, which is incorporated by reference herein.

# (b) Financial statement schedules

Schedules not listed above have been omitted because the information required to be set forth therein is not applicable or is shown in the consolidated financial statements or notes thereto.

### Item 17. Undertakings.

The undersigned Registrant hereby undertakes to provide to the underwriter at the closing specified in the underwriting agreement certificates in such denominations and registered in such names as required by the underwriter to permit prompt delivery to each purchaser.

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



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The undersigned Registrant hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this Registration Statement as of the time it was declared effective.

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

(3)That, for the purpose of determining liability under the Securities Act to any purchaser, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.

(4)That, for the purpose of determining liability of the registrant under the Securities Act to any purchaser in the initial distribution of the securities:

The undersigned Registrant undertakes that in a primary offering of securities of the undersigned Registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned Registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

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

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

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

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

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# EXHIBIT INDEX

	E			
Exhibit Number		Exhibit Description		
1.1*	Form of Underwriting Agreement.			
3.1	Certificate of Incorporation, as currently in effect.			
3.2	Certificate of Amendment to the Certificate	Certificate of Amendment to the Certificate of Incorporation, as currently in effect.		
3.3	Form of Amended and Restated Certificate of Incorporation, to be in effect upon consummation of this offering.			
3.4	Bylaws, as currently in effect.			
3.5	First Amendment to Bylaws, as currently i			
3.6	Form of Amended and Restated Bylaws, to be in effect upon consummation of this offering.			
4.1*	Form of Common Stock Certificate of the Registrant.			
4.2	Warrant to Purchase 11,625,437 senior common equity interests to Perceptive Credit Holdings, LP, dated as of January 1, 2018.			
4.3*	Registration Rights Agreement by and between Aquestive Partners, LLC and certain of the holders of its membership interests.			
5.1*	Opinion of Dechert LLP.			
10.1		ween Registrant and its directors and officers.		
10.2	Credit Agreement and Guaranty dated August 16, 2016, by and between Monosol Rx, LLC and Perceptive Credit Opportunities Fund, LP.			
10.3	Omnibus Amendment No. 1 dated Januar thereto and Perceptive Credit Holdings, L	y 1, 2018, by and between Monosol Rx, LLC, the Lenders party P.		
10.4	Amendment No. 2 to Credit Agreement ar Therapeutics, Inc. and Perceptive Credit (	nd Guaranty dated May 21, 2018, by and between Aquestive Opportunities Fund, LP.		
10.5*	Employment Agreement dated , 201 Kendall.	8, by and between Aquestive Therapeutics, Inc., LLC and Keith J.		
10.6*	Employment Agreement dated , 201 Barber.	8, by and between Aquestive Therapeutics, Inc., LLC and Daniel		
10.7*	Employment Agreement dated , 201 Maxwell.	.8, by and between Aquestive Therapeutics, Inc., LLC and John T.		
10.8*	Employment Agreement dated , 202 Schobel.	18, by and between Aquestive Therapeutics, Inc., LLC and A. Marl		
10.9†*	Pharmaceuticals Inc., dated August 15, 20	nd between MonoSol Rx, LLC and Reckitt Benckiser 008 (as amended on August 19, 2009, November 13, 2009, March 5, 2010, December 9, 2011, December 1, 2012, October 14, 2013 endum B), and January 12, 2017.		
10.10†*	Agreement by and between MonoSol Rx,	LLC and Indivior UK Limited, dated September 24, 2017.		
10.11†*	Agreement to Terminate CLA by and betw 2012.	een MonoSol Rx, LLC and KemPharm, Inc., dated as of March 20		
10.12†*	License Agreement by and between Mono 2016.	oSol Rx, LLC and Cynapsus Therapeutics Inc., dated as of April 1,		
10.13*	Industrial Lease Agreement by and between Ashland Northwest Partners, L.P. and MonoSol Rx, LLC, dated October 24, 2006 (as amended on October 24, 2011 and February 8, 2018).			
10.14*	Aquestive Therapeutics, Inc., 2018 Equity Incentive Plan and forms of agreement thereunder.			
10.15*	Aquestive Therapeutics, Inc. Employee Stock Purchase Plan.			
10.16*	Aquestive Therapeutics, Inc. Executive Bonus Plan.			
23.1*	Consent of KPMG LLP, Independent Registered Public Accounting Firm.			
23.2*	Consent of Dechert LLP (included in Exhibit 5.1).			

23.2\* Consent of Dechert LLP (included in Exhibit 5.1).
24.1\* Power of Attorney (see signature page of the original filing of this registration statement).

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<sup>\*</sup> To be filed by amendment.

Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment that will be separately filed with the Securities and Exchange Commission.

## SIGNATURES

Pursuant to the requirements of the Securities Act, the Registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the County of Somerset, State of New Jersey, on the day of \_\_\_\_\_\_, 2018.

Aquestive Therapeutics, Inc.

By:

Keith J. Kendall President and Chief Executive Officer

## POWER OF ATTORNEY

KNOW ALL BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Keith J. Kendall and John T. Maxwell, as his true and lawful attorney-in-fact and agent, with the full power of substitution, for him and in his name, place or stead, in any and all capacities, to sign any and all amendments to this registration statement (including post-effective amendments), and to sign any registration statement for the same offering covered by this registration statement that is to be effective upon filing pursuant to Rule 462(b) promulgated under the Securities Act, and all post-effective amendments thereto, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

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

Signature	Title	Date
Keith J. Kendall	President, Chief Executive Officer and Member of the Board of Directors (Principal Executive Officer)	, 2018
John T. Maxwell	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	, 2018
Douglas Bratton	Chairman of the Board of Directors	, 2018
Gregory Brown, M.D.	Member of the Board of Directors	, 2018
John Cochran	Member of the Board of Directors	, 2018
Santo Costa	Member of the Board of Directors	, 2018
Nancy Lurker	Member of the Board of Directors	, 2018
James S. Scibetta	Member of the Board of Directors	, 2018
A. Mark Schobel	Member of the Board of Directors	, 2018
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# The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE DO HEREBY CERTIFY THAT THE ATTACHED IS A TRUE AND CORRECT COPY OF THE CERTIFICATE OF INCORPORATION OF "AQUESTIVE THERAPEUTICS, INC." FILED IN THIS OFFICE ON THE TWENTY-NINTH DAY OF DECEMBER, A.D. 2017, AT 2:25 O`CLOCK P.M.

AND I DO HEREBY FURTHER CERTIFY THAT THE EFFECTIVE DATE OF THE AFORESAID CERTIFICATE OF INCORPORATION IS THE FIRST DAY OF JANUARY, A.D. 2018.

A FILED COPY OF THIS CERTIFICATE HAS BEEN FORWARDED TO THE NEW CASTLE COUNTY RECORDER OF DEEDS.



3753153 8100V SR# 20177853465 You may verify this certificate online at corp.delaware.gov/authver.shtml Authentication: 203858776 Date: 12-29-17

Page 1

## CERTIFICATE OF INCORPORATION OF AQUESTIVE THERAPEUTICS, INC.

The undersigned, in order to form a corporation pursuant to the provisions of the General Corporation Law of the State of Delaware (the "<u>DGCL</u>"), hereby certifies:

# ARTICLE I

The name of this corporation is Aquestive Therapeutics, Inc. (the "Corporation").

## ARTICLE II

The address of the registered office of the Corporation in the State of Delaware is 251 Little Falls Drive, in the City of Wilmington, County of New Castle, Delaware 19801. The name of its registered agent at such address is Corporation Service Company.

# ARTICLE Ill

The purpose of the Corporation is to engage in any lawful act or activity for which corporations may be organized under the DGCL.

# ARTICLE IV

The name and mailing address of the incorporator are as follows:

John Maxwell c/o Aquestive Therapeutics, Inc. 30 Technology Drive Warren, NJ 07059

## ARTICLE V

The total number of shares of capital stock which the Corporation shall have authority to issue is Twenty Five Thousand (25,000) shares of Common Stock par value \$0.001 per share.

# ARTICLE VI

The business and affairs of the Corporation shall be managed by or under the direction of the Board of Directors of the Corporation (the "<u>Board</u>"). The number of directors of the Corporation shall be determined in the manner set forth in the Bylaws of the Corporation. Elections of directors need not be by written ballot unless the Bylaws of the Corporation shall so provide.

State of Delaware Secretary of State Division of Corporations Delivered 02:25PM 1212912017 FILED 02:25PM 12/29/2 017 SR 20177853465 –File Number 3753153

#### ARTICLE VII

In furtherance and not in limitation of the powers conferred by statute, the Board of is expressly authorized to make, alter, amend or repeal the Bylaws of the Corporation, but the stockholders may make additional bylaws and may alter or repeal any bylaw whether adopted by them or otherwise. Elections of directors of the Corporation need not be by written ballot except, and to the extent provided in, the bylaws of the Corporation. Advance notice of new business and stockholder nominations for the election of directors shall be given in the manner and to the extent provided in the Bylaws of the Corporation.

## **ARTICLE VIII**

Meetings of stockholders may be held within or without the State of Delaware, as the Bylaws may provide. The books of the Corporation may be kept outside the State of Delaware at such place or places as may be designated from time to time by the Board or in the Bylaws of the Corporation.

## ARTICLE IX

The Corporation is authorized to provide indemnification of (and advancement of expenses to) every Corporate Agent (as defined below) to the fullest extent authorized by the DGCL, as the same exists or may hereafter be amended (but, in the case of any such amendment, only to the extent that such amendment permits the Corporation to provide broader indemnification rights than such law permitted the Corporation to provide prior to such amendment), and to the fullest extent otherwise permitted by law; *provided*, *however*, that the Corporation shall not indemnify any person seeking indemnification in connection with a proceeding (or part thereof) initiated by such person unless the initiation thereof was approved by the Board, unless such proceeding was brought by a director or officer of the Corporation to enforce such director's or officer's rights to indemnification or, in the case of a director, advancement of expenses in accordance with the Bylaws of the Corporation. As used in this Certificate of Incorporation, the term "<u>Corporate Agent</u>" means any person who was or is a director or officer of the Corporation, is or was serving at the request of the Corporation as a director or officer of another corporation, partnership limited liability company, joint venture or other enterprise, or any other persons to which the DGCL permits the Corporation to provide indemnification. The indemnification of Corporate Agents provided for in this Article IX shall not be deemed exclusive of any other rights to indemnification available to such Corporate Agents, whether through the Bylaws of the Corporation, any agreement with such Corporate Agents, a vote of the stockholders of the Corporation or otherwise.

# ARTICLE X

No director of the Corporation shall be personally liable to the Corporation or its stockholders for monetary damages for breach of fiduciary duty as a director, except for liability: (a) for any breach of the director's duty of loyalty to the Corporation or its stockholders; (b) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law; (c) under Section 174 of the DGCL; or (d) for any transaction from which the director derived an improper personal benefit. If the DGCL or any other law of the State of Delaware is amended after the filing of the Certificate of Incorporation of which this Article is a part to authorize corporate action further eliminating or limiting the personal liability of directors or officers of Delaware corporations, then the liability of the directors and officers of the Corporation shall be eliminated or limited to the fullest extent permitted by the DGCL or such other law of the State of Delaware, as so amended. To the fullest extent permitted by law, a director of the Corporation shall not be personally liable to the Corporation or its stockholders for monetary damages for breach of fiduciary duty as a director.

#### ARTICLE XI

Any repeal or modification of the foregoing Articles IX and/or X of this Certificate of Incorporation by the stockholders of the Corporation shall not adversely affect any right or protection of a Corporate Agent of the Corporation existing at the time of, or increase the liability of any director of the Corporation with respect to any acts or omissions of such director occurring prior to, such repeal or modification.

# ARTICLE XII

Unless the Corporation consents in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware shall be the sole and exclusive forum for: (a) any derivative action or proceeding brought on behalf of the Corporation; (b) any action or proceeding asserting a claim of breach of a fiduciary duty owed by any director, officer, employee or agent of the Corporation to the Corporation or the Corporation's stockholders; (c) any action or proceeding asserting a claim against the Corporation arising pursuant to any provision of the DGCL, this Certificate of Incorporation or the Bylaws of the Corporation; or (d) any action or proceeding asserting a claim governed by the internal affairs doctrine, in each case subject to said Court of Chancery having personal jurisdiction over the indispensable parties named as defendants therein.

## ARTICLE XIII

The Corporation reserves the right to amend, alter, change or repeal any provision contained in this Certificate of Incorporation, in the manner now or hereafter prescribed by statute, and all rights conferred upon stockholders herein are granted subject to this reservation.

## ARTICLE XIV

This Certificate of Incorporation shall have an effective date of January 1, 2018.

[Remainder of Page Intentionally Left Blank; Signature Page Follows]

IN WITNESS WHEREOF, the undersigned has caused this Certificate of Incorporation to be executed as of December 29, 2017.

Mud -By: <u>Y// Y//</u> Name: John Maxwell

Title: Sole Incorporator

SIGNATURE PAGE TO CERTIFICATE OF INCORPORATION OF AQUESTIVE THERAPEUTICS, INC.



# The First State

# I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY THE ATTACHED IS A TRUE AND CORRECT COPY OF THE CERTIFICATE OF AMENDMENT OF "AQUESTIVE THERAPEUTICS, INC.", FILED IN THIS OFFICE ON THE THIRTIETH DAY OF APRIL, A.D. 2018, AT 1:54 O`CLOCK P.M.

A FILED COPY OF THIS CERTIFICATE HAS BEEN FORWARDED TO THE NEW CASTLE COUNTY RECORDER OF DEEDS.



Authentication: 202605879 Date: 04-30-18

3753153 8100 SR# 20183160147 You may verify this certificate online at corp.delaware.gov/authver.shtml Page 1

State of Delaware Secretary of State Division of Corporations Delivered 01:54PM 04/30/2018 FILED 01:54PM 04/30/2018 SR 20183160147 - File Number 3753153

## CERTIFICATE OF AMENDMENT OF THE CERTIFICATE OF INCORPORATION OF AQUESTIVE THERAPUETICS, INC.

Aquestive Therapeutics, Inc., a corporation organized and existing under the General Corporation Law of the State of Delaware (the "<u>Corporation</u>"), does hereby certify as follows:

**FIRST**: The Certificate of Incorporation of the Corporation filed with the Secretary of State of the State of Delaware on January 1, 2018 (the "<u>Certificate of Incorporation</u>") is hereby amended by striking out Article V thereof and by substituting in lieu of said Article the new Article V set forth as follows:

## ARTICLE V

(a) <u>Capital stock</u>. The total number of shares of capital stock which the Corporation shall have authority to issue is Three Hundred Fifty Million (350,000,000) shares, divided into two classes consisting of: (i) Two Hundred Eighty Five Million (285,000,000) shares of Common Stock, par value \$.001 per share "Voting Common Stock"); and (ii) Sixty Five Million (65,000,000) shares of non-voting Common Stock, par value \$.001 per share ("<u>Non-Voting Common Stock</u>"). The rights, preferences, powers, privileges, and the restrictions, qualifications and limitations of the Non-Voting Common Stock are identical with those of the Voting Common Stock other than in respect of the rights as set torth herein.

(b) <u>Forward Stock Split</u>. Upon the effective time (the "<u>Effective Time</u>") of the filing of this Certificate of Amendment, each one (1) share of the Corporation's Common Stock that is issued and outstanding or held by the Corporation as treasury stock immediately prior to the Effective Time (which shall include each fractional interest in Common Stock in excess of one (1) share held by any stockholder), is and shall be subdivided and reclassified into 37,212 fully paid, nonassessable shares of Voting Common Stock (or, with respect to such fractional interests, such lesser number of shares as may be applicable based upon such 37,212~to-one ratio) (the "Forward Stock Split'). The par value per share of the Voting Common Stock shall not be affected by the Forward Stock Split.

# (c) Voting Rights.

(i) *Voting Common Stock*. Except as otherwise required by law or this Certificate of Incorporation, the holders of the Voting Common Stock shall possess exclusively all voting power, and each holder of Voting Common Stock shall have one vote in respect of each share held by such holder of record on the books of the Corporation for the election of directors and on all matters submitted to a vote of stockholders of the Corporation.

(ii) Non-Voting Common Stock. Except as otherwise required by law, shares of Non-Voting Common Stock shan be non-voting.

(d) <u>Dividends</u>. Holders Voting Common Stock and Non-Voting Common Stock shall be entitled to receive dividends (whether as cash payments or distributions of stock or property),(d) <u>Dividends</u>. Holders Voting Common Stock and Non-Voting Common Stock shall be entitled to receive dividends (whether as cash payments or distributions of stock or property), when, as and if declared by the Board; *provided, however*, that the Corporation may not declare or pay or set apart any funds for payment of any dividends or make any other distribution upon the Non-Voting Common Stock, or redeem, purchase or otherwise acquire any Non-Voting Common Stock for any consideration and no monies may be paid to or made available for a sinking fund for the redemption of any shares of any such stock, unless and until the holders of Voting Common Stock shall have received in the aggregate, in one or more distributions on the Voting Common Stock, Thirty Million Dollars (\$30,000,000) (the "<u>Voting-Common Preference Amount</u>"), whereupon the Non-Voting Common Stock shall participate *pari passu* with the Voting Common Stock in any and all dividends thereafter declared by the Board. The balance of the Voting Common Preference Amount then outstanding shall be reduced by the amount of cash received, the face amount of any debt instrument received, and the fair market value any property, rights, securities received holder of Voting Coll1111on Stock from the sale Voting Common Stock prior to the conversion of the Non-Voting Common Stock to Voting Common Stock under clause (e) of this Article V.

#### (e) Mandatory Conversion.

(i) *Trigger Events*. Effective upon the earlier of: (a) the closing of the sale of shares of Voting Common Stock to the public in a firmcommitment underwritten public offering pursuant to an effective registration statement under the Securities Act of 1933, as amended, resulting in the listing of the Voting Common Stock on the New York Stock Exchange, the NASDAQ Global Market or another internationally recognized stock exchange (a) "Qualified IPO"); or (b) a date specified by vote or written consent of the holders of a majority of the then outstanding shares of Voting Common Stock (voting together as a single class), each one (1) share of the Non-Voting Common Stock, whether issued and outstanding or held by the Corporation as treasury stock, shall automatically be converted into one (1) share of Voting Common Stock and such shares of Non-Voting Common Stock may not be reissued by the Corporation (the date of closing of such Qualiiied IPO is referred to herein as the "Mandatory Conversion Date").

(ii) *Procedural Requirements*. All holders of record of shares of Non-Voting Common Stock shall be given written notice of the Mandatory Conversion Date. Such notice need not be given in advance of the occurrence of the Mandatory Conversion Date. Such notice shall be sent by first class or registered mail, postage prepaid, or given by electronic communication in compliance with the provisions of the DGCL, to each record bolder of NonVoting Common Stock. On the Mandatory Conversion Date, all outstanding shares of Non-Voting Common Stock shall be deemed to have been conve1ied into shares of Voting Common Stock, which shall be deemed to be outstanding of record, and all rights with respect to shares of such Non-Voting Common Stock so converted (other than as a holder of Voting Common Stock), will terminate. As soon as practicable after the Mandatory Conversion Date, the Corporation shall cause to be issued uncertificated shares of Voting Common Stock issuable on such conversion in accordance with the provisions hereof. All shares of Non-Voting Common Stock converted in accordance with the provisions hereof shall, from and after the Mandatory Conversion Date, be deemed to have been automatically retired and the shares of Non-Voting Common Stock represented thereby converted into Voting Common Stock for all purposes. Such converted shares of Non-Voting Common Stock shall not be available for reissuance, and the Corporation may thereafter take such appropriate action (without the need for stockholder action) as may be necessary to reduce the authorized number of shares of Non-Voting Common Stock accordingly.

(iii) Voting Common Stock Issuable Upon Conversion. For the avoidance of doubt, in the event that all outstanding shares of Non-Voting Common Stock have been converted into Voting Common Stock, all references in this Article V to "Non-Voting Common Stock" shall mean "Voting Common Stock" from and after such conversion.

SECOND: That, in lieu of a meeting of the stockholders, the sole stockholder of the Corporation has given its consent to the foregoing amendment in accordance with the provisions of Section 228 of the Delaware General Corporation Law.

THIRD: That the foregoing amendment was duly adopted in accordance with the provisions of Sections 228 and 242 of the Delaware General Corporation Law.

IN WITNESS WHEREOF, the Corporation has caused this Certificate of Amendment to be signed by its duly authorized officer as of the 30th day of April, 2018.

**AQUESTIVE THERAPUETICS, INC.** 

By: <u>John Maxwell</u>, Chief Financial Officer

## AMENDED AND RESTATED

## **CERTIFICATE OF INCORPORATION**

OF

## **AQUESTIVE THERAPEUTICS, INC.**

AQUESTIVE THERAPEUTICS, INC., a corporation organized and existing under the laws of the State of Delaware, DOES HEREBY CERTIFY AS FOLLOWS:

1. The name of the corporation is Aquestive Therapeutics, Inc. The original Certificate of Incorporation of the corporation was filed with the Secretary of State of the State of Delaware on December 29, 2017 and was effective as of January 1, 2018 (as in effect immediately prior to the adoption and effectiveness hereof, the "Original Certificate of Incorporation").

2. This Amended and Restated Certificate of Incorporation has been duly adopted in accordance with Sections 242 and 245 of the General Corporation Law of the State of Delaware, and by the written consent of its sole stockholder in accordance with Section 228 of the General Corporation Law of the State of Delaware, and shall be effective as of 11:59 p.m., New York City time, on \_\_\_\_\_\_, 2018.

3. The Original Certificate of Incorporation is hereby amended and restated to read in its entirety as follows:

# ARTICLE I

The name of the corporation (hereinafter called the "Corporation") is Aquestive Therapeutics, Inc.

## ARTICLE II

The address of the Corporation's registered office in the State of Delaware is 251 Little Falls Drive, City of Wilmington, New Castle County, Delaware 19808. The name of the Corporation's registered agent at such address is Corporation Service Company.

# ARTICLE III

The purpose of the Corporation is to engage in any lawful act or activity for which corporations may be organized under the General Corporation Law of the State of Delaware ("DGCL").

## ARTICLE IV

Section 1. The total number of shares of all classes of stock which the Corporation shall have authority to issue is 260,000,000 shares, consisting of (1) 250,000,000 shares of Common Stock, par value \$0.001 per share ("Common Stock"), and (2) 10,000,000 shares of Preferred Stock, par value \$0.001 per share ("Preferred Stock"). The number of authorized shares of either Preferred Stock or Common Stock may be increased or decreased (but not below the number of shares thereof then outstanding) by the affirmative vote of the holders of a majority in voting power of the stock of the Corporation entitled to vote thereon irrespective of the provisions of Section 242(b)(2) of the DGCL (or any successor provision thereto), and no vote of the holders of either Preferred Stock or Common Stock voting separately as a class shall be required therefor.

Section 2. The Board of Directors of the Corporation (the "Board of Directors") is hereby expressly authorized, by resolution or resolutions, to provide, out of the unissued shares of Preferred Stock, for series of Preferred Stock and, with respect to each such series, to fix the number of shares constituting such series and the designation of such series, the voting powers (if any) of the shares of such series, and the preferences and relative, participating, optional or other special rights, if any, and any qualifications, limitations or restrictions thereof, of the shares of such series, including without limitation thereof, dividend rights, conversion rights, redemption privileges and liquidation preferences, as shall be stated and expressed in such resolution or resolutions, all to the full extent now or hereafter permitted by the DGCL. The powers, preferences and relative, participating, optional and other special rights of each series of Preferred Stock, and the qualifications, limitations or restrictions thereof, if any, may differ from those of any and all other series at any time outstanding. Except as otherwise provided in this Amended and Restated Certificate of Incorporation, no vote of the holders of Preferred Stock or Common Stock shall be a prerequisite to the designation or issuance of any shares of any series of Preferred Stock authorized by and complying with the conditions of this Amended and Restated Certificate of Incorporation, with the right to have such vote being expressly waived by all present and future holders of the capital stock of the Corporation. Different series of Preferred Stock shall not be construed to constitute different classes of shares for the purposes of voting by classes unless expressly provided in the certificate of designation or any resolution or resolutions providing for the issuance of such series adopted by the Board of Directors. The Board of Directors is further authorized to increase (but not above the total number of authorized shares of the class) or decrease (but not below the number of shares of any such series then outstanding) the number of shares of any series, the number of which was fixed by it, subsequent to the issuance of shares of such series then outstanding, subject to the powers, preferences and rights and the qualifications, limitations and restrictions thereof stated in the Amended and Restated Certificate of Incorporation or the resolution or resolutions of the Board of Directors originally fixing the number of shares of such series. If the number of shares of any series is so decreased, then the shares constituting such decrease shall resume the status which they had prior to the adoption of the resolution originally fixing the number of shares of such series. Any shares of Preferred Stock which may be redeemed, purchased or acquired by the Corporation may be reissued except as otherwise provided by law.

Section 3. (a) Each holder of Common Stock, as such, shall be entitled to one vote for each share of Common Stock held of record by such holder on all matters on which stockholders generally are entitled to vote; provided, however, that, except as otherwise required by law, holders of Common Stock, as such, shall not be entitled to vote on any amendment to this Amended and Restated Certificate of Incorporation (which, as used herein shall mean this Amended and Restated Certificate of Incorporation as amended and/or restated from time to time including the terms of any certificate of designation of any series of Preferred Stock) that relates solely to the terms of one or more outstanding series of Preferred Stock if the holders of such affected series are entitled, either separately or together with the holders of one or more other such series, to vote thereon pursuant to this Amended and Restated Certificate of Incorporation or pursuant to the DCGL. The holders of Common Stock shall have no preemptive rights to subscribe for any shares of any class of stock of the Corporation whether now or hereafter authorized. There shall be no cumulative voting.

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(b) Subject to applicable law and the rights of the holders of any outstanding series of Preferred Stock, dividends may be declared and paid on Common Stock at such times and in such amounts as the Board of Directors in its discretion shall determine.

(c) Upon the dissolution, liquidation or winding up of the Corporation, subject to the rights of the holders of any outstanding series of Preferred Stock, the holders of Common Stock, as such, shall be entitled to receive the assets of the Corporation available for distribution to its stockholders ratably in proportion to the number of shares held by them.

## ARTICLE V

Section 1. (a) The business and affairs of the Corporation shall be managed by or under the direction of the Board of Directors. Except as otherwise fixed pursuant to the terms of any outstanding series of Preferred Stock pursuant to this Amended and Restated Certificate of Incorporation, the number of directors of the Corporation shall be fixed from time to time solely by resolution adopted by the affirmative vote of a majority of such directors then in office. In no event shall a decrease in the number of directors constituting the Board of Directors shorten the term of any incumbent director.

(b) The directors, other than those who may be elected by the holders of any series of Preferred Stock voting separately pursuant to this Amended and Restated Certificate of Incorporation, shall be elected by the stockholders entitled to vote thereon at each annual meeting of stockholders. The election of directors need not be by written ballot.

Subject to the rights of holders of any outstanding series of Preferred Stock to elect directors, and effective upon the effectiveness of (c) this Amended and Restated Certificate of Incorporation, the Board of Directors shall be and is divided into three classes, designated as Class I, Class II and Class III, and each class shall consist, as nearly as may be possible, of one-third of the total number of directors constituting the entire Board of Directors. The Board of Directors is authorized to assign members of the Board of Directors already in office to Class I, Class II or Class III at the time such classification becomes effective. Subject to the rights of holders of any outstanding series of Preferred Stock to elect directors, each director shall serve for a term ending on the date of the third annual meeting of stockholders following the annual meeting of stockholders at which such director was elected; provided that each director initially assigned to Class I shall serve for a term expiring at the Corporation's first annual meeting of stockholders held after the effectiveness of this Amended and Restated Certificate of Incorporation; each director initially assigned to Class II shall serve for a term expiring at the Corporation's second annual meeting of stockholders held after the effectiveness of this Amended and Restated Certificate of Incorporation; and each director initially assigned to Class III shall serve for a term expiring at the Corporation's third annual meeting of stockholders held after the effectiveness of this Amended and Restated Certificate of Incorporation; provided further that the term of each director shall continue until the election and qualification of his or her successor and be subject to his or her earlier death, resignation or removal. In the case of any increase or decrease, from time to time, in the number of directors (other than directors elected by the holders of any series of Preferred Stock), any such increase or decrease shall be apportioned by the Board of Directors among the classes so as to maintain the number of directors in each class as nearly equal as possible, and any such additional director of any class elected to fill a vacancy resulting from an increase in such class shall hold office for a term that shall coincide with the remaining term of that class.

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Section 2. Advance notice of nominations for the election of directors shall be given in the manner and to the extent provided in the Bylaws of the Corporation.

Section 3. (a) Except as otherwise provided for or fixed by or pursuant to the provisions of this Amended and Restated Certificate of Incorporation relating to the rights of the holders of any series of Preferred Stock, newly created directorships resulting from any increase in the number of directors and any vacancies on the Board of Directors resulting from death, resignation, removal or other cause shall be filled only by the Board of Directors by the affirmative vote of a majority of the remaining directors then in office, even though less than a quorum of the Board of Directors, or by a sole remaining director and shall not be filled by stockholders. Any director elected in accordance with the first sentence of this Section 3 shall hold office for a term that shall coincide with the remaining term of the class such director is elected to and until such director's successor shall have been duly elected and qualified or until his or her earlier death, resignation or removal.

(b) Subject to the rights of holders of any outstanding series of Preferred Stock to elect directors and to remove any director whom the holders of any such series have the right to elect, any director (including persons elected by directors to fill vacancies in the Board of Directors) may be removed from office (i) only with cause and (ii) only by the affirmative vote of the holders of at least 66 2/3% of the voting power of the then outstanding stock of the Corporation entitled to vote generally in the election of directors of the Corporation, voting as a single class. At least forty-five (45) days prior to any annual or special meeting of stockholders at which it is proposed that any director be removed from office, written notice of such proposed removal and the alleged grounds thereof shall be sent to the director whose removal will be considered at the meeting.

## ARTICLE VI

Subject to the rights of the holders of any outstanding series of Preferred Stock pursuant to the provisions of this Amended and Restated Certificate of Incorporation (including any certificate of designation relating to such series of Preferred Stock), any action required or permitted to be taken by the stockholders of the Corporation must be effected only at a duly called annual or special meeting of stockholders of the Corporation and may not be effected by any consent in writing by such stockholders.

## ARTICLE VII

Except as otherwise required by law and subject to the rights of the holders of any outstanding series of Preferred Stock pursuant to the provisions of this Amended and Restated Certificate of Incorporation (including any certificate of designation relating to such series of Preferred Stock), special meetings of stockholders of the Corporation for any purpose or purposes may be called only by the Board of Directors pursuant to a resolution approved by a majority of the members of the Board of Directors then in office or by the Chairman of the Board of Directors. Only such business shall be conducted at a special meeting of stockholders as shall have been brought before the meeting pursuant to the Corporation's notice of meeting.

#### ARTICLE VIII

The Corporation reserves the right to amend, alter or repeal any provision contained in this Amended and Restated Certificate of Incorporation, in the manner now or hereafter prescribed by statute, and all rights conferred upon stockholders herein are subject to this reservation; provided, however, that, in addition to any requirements of law and any other provision of this Amended and Restated Certificate of Incorporation, and notwithstanding any other provision of this Amended and Restated Certificate of Incorporation or any provision of law which might otherwise permit a lesser vote or no vote, the affirmative vote of the holders of at least 66-2/3% of the voting power of the then outstanding stock of the Corporation entitled to vote generally in the election of directors of the Corporation, voting together as a single class, shall be required to amend or repeal, or to adopt any provision or Bylaw inconsistent with, Articles V, VI, VII, VIII, IX, X or XI of this Amended and Restated Certificate of Incorporation.

## ARTICLE IX

In furtherance and not in limitation of the powers conferred upon it by law, the Board of Directors is expressly authorized to adopt, repeal, alter or amend the Bylaws of the Corporation by the vote of a majority of the members of the Board of Directors then in office. In addition to any requirements of law and any other provision of this Amended and Restated Certificate of Incorporation and notwithstanding the fact that a lesser percentage may be specified by law, the affirmative vote of the holders of at least 66-2/3% of the voting power of the then outstanding stock of the Corporation entitled to vote generally in the election of directors of the Corporation, voting together as a single class, shall be required for stockholders to adopt, amend, alter or repeal any provision of the Bylaws of the Corporation.

## ARTICLE X

Section 1. To the fullest extent that the DGCL or any other law of the State of Delaware, as it exists or as it may hereafter be amended, permits the limitation or elimination of the liability of directors, no director of the Corporation shall be liable to the Corporation or its stockholders for monetary damages for breach of fiduciary duty as a director.

Section 2. To the fullest extent permitted by applicable law, the Corporation shall provide indemnification (and advancement of expenses) to directors and officers of the Corporation through Bylaw provisions, agreements with such directors and officers, vote of stockholders or disinterested directors, or otherwise.

Section 3. To the fullest extent permitted by applicable law, the Corporation may provide indemnification (and advancement of expenses) to employees and agents of the Corporation, and to any other persons to which the DGCL or any other law of the State of Delaware, as it exists or as it may hereafter be amended, permits, through Bylaw provisions, agreements with such employees and agents, vote of stockholders or disinterested directors, or otherwise.

Section 4. No amendment to or repeal of any Section of this Article X, nor the adoption of any provision of this Amended and Restated Certificate of Incorporation inconsistent with this Article X, shall eliminate or reduce the effect of this Article X in respect of any matter occurring, or any action or proceeding accruing or arising, prior to such amendment, repeal or adoption of an inconsistent provision.

### ARTICLE XI

The Court of Chancery of the State of Delaware shall, to the fullest extent permitted by law, be the sole and exclusive forum for (i) any derivative action or proceeding brought on behalf of the Corporation, (ii) any action asserting a claim of breach of a fiduciary duty owed by any director, officer, employee or stockholder of the Corporation to the Corporation or the Corporation's stockholders, (iii) any action asserting a claim against the Corporation or any director or officer of the Corporation arising pursuant to any provision of the DGCL or this Amended and Restated Certificate of Incorporation or the Bylaws of the Corporation (as either may be amended and/or restated from time to time) or (iv) any action asserting a claim governed by the internal affairs doctrine. Any person or entity purchasing or otherwise acquiring any interest in shares of stock of the Corporation shall be deemed to have notice of and consented to the provisions of this Article XI.

## ARTICLE XII

If any provision or provisions of this Amended and Restated Certificate of Incorporation shall be held to be invalid, illegal or unenforceable as applied to any circumstance for any reason whatsoever: (i) the validity, legality and enforceability of such provisions in any other circumstance and of the remaining provisions of this Amended and Restated Certificate of Incorporation (including, without limitation, each portion of any paragraph of this Amended and Restated Certificate of Incorporation envisions held to be invalid, illegal or unenforceable that is not itself held to be invalid, illegal or unenforceable) shall not in any way be affected or impaired thereby and (ii) to the fullest extent possible, the provisions of this Amended and Restated Certificate of Incorporation (including, without limitation, each such portion of any paragraph of this Amended and Restated Certificate of Incorporation (including, without limitation, each such portion of any paragraph of this Amended and Restated Certificate of Incorporation (including, without limitation, each such portion of any paragraph of this Amended and Restated Certificate of Incorporation (including, without limitation, each such portion of any paragraph of this Amended and Restated Certificate of Incorporation containing any such provision held to be invalid, illegal or unenforceable) shall be construed so as to permit the Corporation to protect its directors, officers, employees and agents from personal liability in respect of their good faith service to or for the benefit of the Corporation to the fullest extent permitted by law.

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AQUESTIVE THERAPEUTICS, INC.

By:

Name: Title:

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## BYLAWS OF Aquestive Therapeutics, Inc.,

a Delaware corporation (the "<u>Corporation</u>")

Effective as of January 1, 2018

# **ARTICLE I: STOCKHOLDERS**

Section 1. <u>Annual Meeting of Stockholders</u>. The annual meeting of stockholders shall be held each year on such date, and at such time and place, as may be designated by the Board of Directors of the Corporation (the "<u>Board of Directors</u>"). The annual meeting of stockholders shall be held at the principal office of the Corporation or such other place as shall be specified in the notice of meeting. The Board of Directors may, in its sole discretion, determine that the meeting shall not be held at any place, but may instead be held solely by means of remote communication as provided under the Delaware General Corporation Law ("<u>DGCL</u>").

Section 2. <u>Special Meetings of Stockholders</u>. Special meetings of stockholders may be called for any purpose or purposes by the Board of Directors or by any member of the Board of Directors. Special meetings of stockholders shall be held at the principal office of the Corporation or at such other place as shall be held at such place, on such date, and at such time as the Board of Directors shall fix.

## Section 3. Notice of Meetings; Adjournments.

(a) Whenever stockholders are required or permitted to take any action at a meeting, a written notice of such meeting shall be given which shall state the place, date and hour of such meeting, and, in the case of a special meeting, the purpose or purposes for which such meeting is called. The written notice of any stockholders meeting shall be given not less than ten (10) nor more than sixty (60) days before the date of such meeting to each stockholder entitled to vote at such meeting. If mailed, notice is given when deposited in the United States mail, postage prepaid, directed to the stockholder at such stockholder's address as it appears on the records of the Corporation. Without limiting the manner by which notice otherwise may be given effectively to stockholders, any notice to stockholders may be given by electronic mail or other electronic transmission, in the manner provided in Section 232 of the DGCL. An affidavit of the Secretary or an Assistant Secretary or of the transfer agent of the Corporation that the notice has been given shall, in the absence of fraud, be prima facie evidence of the facts stated therein.

(b) When any stockholders meeting is adjourned to another time or place, notice need not be given of the adjourned meeting if: (i) the time and place to which the meeting is adjourned and the means of remote communications (if any) by which stockholders may be deemed to be present and vote at such adjourned meeting are announced at the meeting at which the adjournment is taken; (ii) the period of adjournment does not exceed thirty (30) days in any one adjournment; (iii) no new record date is fixed for the adjourned meeting; and (iv) at the adjourned meeting only such business is transacted as might have been transacted at the original meeting.

Section 4. <u>Quorum</u>. The holders of a majority of interest of all stock issued, outstanding and entitled to vote at a meeting, present in person or represented by proxy, shall constitute a quorum. Any meeting may be adjourned from time to time by a majority of the votes properly cast upon the question, whether or not a quorum is present. The stockholders present at a duly constituted meeting may continue to transact business until adjournment notwithstanding the withdrawal of enough stockholders to reduce the voting shares below a quorum.

Section 5. <u>Voting and Proxies</u>. Except as otherwise provided by the Certificate of Incorporation (as may be amended from time to time, the "<u>Certificate of Incorporation</u>") or by law, each stockholder entitled to vote at any meeting of stockholders shall be entitled to one vote for each share of stock held by such stockholder which has voting power upon the matter in question. Each stockholder entitled to vote at a meeting of stockholder by either written proxy or by a transmission permitted by Section 212(c) of the DGCL, but no proxy shall be voted or acted upon after three years from its date, unless the proxy provides for a longer period or is irrevocable and coupled with an interest. Proxies shall be filed with the Secretary of the meeting, or of any adjournment thereof. Except as otherwise limited therein, proxies shall entitle the persons authorized thereby to vote at any adjournment of such meeting.

Section 6. <u>Action at Meeting</u>. When a quorum is present, any matter before the meeting shall be decided by vote of the holders of a majority of the shares of stock voting on such matter except where a larger vote is required by law, by the Certificate of Incorporation or by these Bylaws. Any election of directors by stockholders shall be determined by a plurality of the votes cast, except where a larger vote is required by law, by the Certificate of Incorporation or by these Bylaws. The Corporation shall not directly or indirectly vote any share of its own stock; provided, however, that the Corporation may vote shares which it holds in a fiduciary capacity to the extent permitted by law.

Section 7. <u>Waiver of Notice</u>. Whenever notice is required to be given under any provision of the DGCL or of the Certificate of Incorporation or these Bylaws, a written waiver thereof, signed by the person entitled to notice, or waiver by electronic mail or other electronic transmission by such person, whether before or after the time stated therein, shall be deemed equivalent to notice. Attendance of a stockholder at a meeting shall constitute a waiver of notice of such meeting, except when such stockholder attends a meeting for the express purpose of objecting, and does so object, at the beginning of such meeting, to the transaction of any business because such meeting is not lawfully called or convened. Neither the business to be transacted at, nor the purpose of, any stockholders meeting need be specified in the notice or waiver of notice of such meeting.

# Section 8. <u>Consent of Stockholders in Lieu of Meeting</u>.

(a) Unless otherwise provided in the Certificate of Incorporation, as it may be amended from time to time, or by applicable Delaware law, any action required or permitted to be taken at a meeting of stockholders may be taken without a meeting, without prior notice and without a vote, if a consent or consents in writing, setting forth the action so taken, shall be signed by the holders of outstanding stock having not less than the minimum number of votes that would be necessary to authorize or take such action at a meeting at which all shares entitled to vote thereon were present and voted and shall be delivered to the Corporation by delivery to its registered office in Delaware, its principal place of business, or an officer or agent of the Corporation having custody of the book in which proceedings of meetings of stockholders are recorded.

(b) Every written consent shall bear the date of signature of each stockholder who signs the consent and no written consent shall be effective to take the corporate action referred to therein unless, within sixty (60) days of the date the earliest dated consent is delivered to the Corporation, a written consent or consents signed by a sufficient number of holders to take action are delivered to the Corporation in the manner prescribed in this Section. A facsimile, electronic mail or other electronic transmission consenting to an action to be taken and transmitted by a stockholder or proxyholder, or by a person or persons authorized to act for a stockholder or proxyholder, shall be deemed to be written, signed and dated for purposes of this Section to the extent permitted by law. Any such consent shall be delivered in accordance with Section 228(d)(1) of the DGCL.

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(c) Any copy, facsimile or other reliable reproduction of a consent in writing may be substituted or used in lieu of the original writing for any and all purposes for which the original writing could be used, provided that such copy, facsimile or other reproduction shall be a complete reproduction of the entire original writing.

(d) Prompt notice of the taking of the corporate action without a meeting by less than unanimous written consent shall be given to those stockholders who have not consented in writing (including by electronic mail or other electronic transmission as permitted by law). If the action which is consented to is such as would have required the filing of a certificate under any section of the DGCL if such action had been voted on by stockholders at a meeting thereof, then the certificate filed under such section shall state, in lieu of any statement required by such section concerning any vote of stockholders, that written notice and written consent have been given as provided in Section 228 of the DGCL.

# ARTICLE II: DIRECTORS

Section 1. <u>Board of Directors Generally; Committees</u>. The business and affairs of the Corporation shall be managed by or under the direction of its Board of Directors. From time to time, the Board of Directors may create or abolish committees of the Board of Directors and appoint from among its members to serve on such committees. The committees so designated may include an executive committee to function between meetings of the Board of Directors. Each committee shall have such powers and perform such duties as shall be authorized by the resolution of the Board of Directors appointing it or by any amendment to that resolution; but no such committee shall have power or authority in reference to the following: (i) approving or adopting, or recommending to the stockholders, any action or matter required to be submitted to stockholders for approval; or (ii) adopting, amending or repealing any bylaw of the Corporation. Each committee shall keep regular minutes of its meetings and report the same to the Board of Directors when required.

Section 2. <u>Number and Term of Directors; Regular Meetings</u>. The number of directors shall be no more than nine and no less than one less than one, or as may be determined from time to time by a majority of the entire Board of Directors. The term of office of each director shall be from the time of election and qualification until such director's successor shall have been elected and shall have qualified, or until the earlier death, resignation or removal of such director. Directors need not be stockholders unless so required by the Certificate of Incorporation or these Bylaws, wherein other qualifications for directors may be prescribed. Unless otherwise specified in the Certificate of Incorporation, elections of directors need not be by written ballot. A regular meeting of the Board of Directors for the election of officers and such other business as may come before such meeting shall be held without notice immediately following the annual meeting of stockholders at the same place. The Board of Directors may provide, by resolution adopted at any time by the Board of Directors, for additional regular meetings which may be held without notice, which may be within or outside the state of Delaware.

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Section 3. <u>Special Meetings of the Board of Directors</u>. Special meetings of the Board of Directors for any purpose or purposes may be called at any time by the Chief Executive Officer, President or by a majority of the directors then serving on the Board of Directors. Such meetings shall be held upon at least (i) two days' notice given personally or by telephone, or (ii) two days' notice given by e-mail or facsimile, receipt of which is electronically or orally confirmed, or (iii) four business days' notice given by depositing notice in the mails, postage prepaid. Such notice shall specify the time and place of such meeting, which may be within or outside the state of Delaware. Any oral notice given personally or by telephone may be communicated either to the director or to a person at the office of the director who the person giving the notice has reason to believe will promptly communicate it to the director.

Section 4. <u>Organization of Meeting</u>. Such person as the Board of Directors may have designated or, in the absence of such a person, the Chief Executive Officer, or in his or her absence, the President or, in his or her absence, such person as may be chosen by the holders of a majority of the shares entitled to vote who are present shall call to order any meeting of the stockholders and act as chairman of the meeting. In the absence of the Secretary of the Corporation, the Secretary of the meeting shall be such person as the chairman of the meeting appoints. The chairman of any meeting of stockholders shall determine the order of business and the procedure at the meeting, including the manner of voting and the conduct of business. The date and time of opening and closing of the polls for each matter upon which the stockholders will vote at the meeting shall be announced at the meeting.

Section 5. <u>Waiver of Notice of Board of Directors Meetings; Notice of Purpose; Adjournment</u>. A written waiver, signed by a director entitled to notice of a Board of Directors meeting, or waiver by electronic mail or other electronic transmission by a director, whether before or after such meeting, shall be deemed equivalent to notice. Attendance of a director at a meeting shall constitute a waiver of notice of such meeting, except when such director attends a meeting for the express purpose of objecting, and does so object, at the beginning of such meeting, to the transaction of any business because such meeting is not lawfully called or convened. Neither the business to be transacted at, nor the purpose of, any regular or special meeting of the Board of Directors need be specified in any notice or waiver of notice of such meeting. Unless otherwise indicated in the notice thereof, any and all business may be transacted at a special meeting. Notice of an adjourned meeting need not be given if the time and place are fixed at the meeting adjourning and if the period of adjournment does not exceed 30 days in any one adjournment.

Section 6. <u>Action Without Meeting</u>. The Board of Directors or any committee thereof may act without a meeting if, prior or subsequent to such action, each member of the Board of Directors or of such committee, as the case may be, shall consent in writing or by electronic transmission to such action and the writing or writings or electronic transmission or electronic transmissions are filed with the minutes of the proceedings of the Board of Directors or such committee, as the case may be. Such filing shall be in paper form if the minutes are maintained in paper form and shall be in electronic form if the minutes are maintained in electronic form. Any copy, facsimile or other reliable reproduction of a consent in writing may be substituted or used in lieu of the original writing for any and all purposes for which the original writing could be used, provided that such copy, facsimile or other reproduction shall be a complete reproduction of the entire original writing.

Section 7. <u>Telephone Conference Meetings of the Board of Directors</u>. Any or all directors may participate in any meeting of the Board of Directors or any committee of the Board of Directors by means of conference telephone or similar communications equipment by means of which all persons participating in such meeting can hear each other, and participation in a meeting pursuant to this paragraph shall constitute presence in person at such meeting.

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Section 8. <u>Quorum of Board of Directors and Committees</u>. One director shall constitute a quorum of the Board of Directors or any committee thereof for the transaction of business unless the Board of Directors or such committee, as the case may be, consists of two directors, in which case two directors shall constitute a quorum of the Board of Directors or such committee, and unless the Board of Directors or such committee, as the case may be, consists of three or more directors, in which case a majority of the directors then serving on the Board of Directors shall constitute a quorum. A meeting at which a quorum is initially present may continue to transact business notwithstanding the withdrawal of directors, if any action taken is approved by at least a majority of the required quorum for that meeting.

Section 9. <u>Vacancies in the Board of Directors</u>. Unless otherwise provided in the Certificate of Incorporation, any vacancy in the Board of Directors, including a vacancy caused by an increase in the number of directorships, may be filled by the majority of the directors then in office, although less than a quorum, or a sole remaining director.

Section 10. <u>Removal, Resignation</u>. Unless otherwise provided in the Certificate of Incorporation, any director or the entire Board of Directors may be removed, with or without cause, by the holders of a majority of the shares then entitled to vote at an election of directors. Any director may resign at any time by written notice to the Chief Executive Officer, President or the Secretary of the Corporation. Resignations shall take effect at the time therein specified and, unless otherwise expressly set forth in the resignation, the Board of Directors' acceptance of the resignation shall not be necessary to make it effective. No reduction of the authorized number of directors shall have the effect of removing any director prior to the expiration of such director's term of office.

Section 11. <u>Fees and Compensation of Directors</u>. Unless otherwise restricted by the Certificate of Incorporation or these Bylaws, the Board of Directors shall have the authority to fix the compensation of directors. No such compensation shall preclude any director from serving the Corporation in any other capacity and receiving compensation therefor.

# **ARTICLE III: OFFICERS**

Section 1. Officers. At its regular meeting following the annual meeting of stockholders, the Board of Directors shall elect a Chief Executive Officer, President, a Treasurer, a Secretary, and such other officers as it shall deem necessary or appropriate. Any vacancy occurring in any office of the Corporation shall be filled by the Board of Directors. No officer need be a stockholder or director of the Corporation. One person may hold two or more offices but no officer shall execute, acknowledge or verify any instrument in more than one capacity if such instrument is required by law or by these Bylaws to be executed, acknowledged or verified by two or more officers. The duties and authority of the officers shall be determined from time to time by the Board of Directors. Subject to any such determination, the officers shall have the following duties and authority:

(a) Subject to such supervisory powers (if any) as may be given by the Board of Directors, the Chief Executive Officer of the Corporation (if such an officer is appointed) shall, subject to the control of the Board of Directors, have general supervision, direction, and control of the business and the officers of the Corporation and shall have the general powers and duties of management usually vested in the office of Chief Executive Officer of a corporation and shall have such other powers and duties as may be prescribed by the Board of Directors or these Bylaws. The person serving as Chief Executive Officer shall also be the acting President of the Corporation whenever no other person is then serving in such capacity.

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(b) Subject to such supervisory powers (if any) as may be given by the Board of Directors to the chairman of the Board of Directors (if any) or the Chief Executive Officer, the President shall have general supervision, direction, and control of the business and other officers of the Corporation. He or she shall have the general powers and duties of management usually vested in the office of President of a corporation and such other powers and duties as may be prescribed by the Board of Directors or these Bylaws. The President may enter into and execute in the name of the Corporation contracts or other instruments not in the regular course of business which are authorized, either generally or specifically, by the Board of Directors. The President may delegate from time to time to any other officer, any or all of the duties and authority of the President contemplated in this paragraph. The person serving as President shall also be the acting Chief Executive Officer, Secretary or Treasurer of the Corporation, as applicable, whenever no other person is then serving in such capacity.

(c) Vice Presidents (including, without limitation, executive, senior or other Vice Presidents), if elected, shall have such duties and possess such authority as may be assigned or delegated to them by the President or assigned to them by the Board of Directors. In the absence or disability of the Chief Executive Officer (if any) and President, the Vice Presidents in order of their rank as fixed by the Board of Directors or, if not ranked, a Vice President designated by the Board of Directors, shall perform all the duties of the President and when so acting shall have all the powers of, and be subject to all the restrictions upon, the President.

(d) The Treasurer shall have the custody of the funds and securities of the Corporation and shall keep or cause to be kept regular books of account for the Corporation. The Treasurer shall perform such other duties and possess such other authority as are incident to the office of Treasurer or as may be assigned or delegated to the Treasurer by the President or assigned to the Treasurer by the Board of Directors.

(e) Assistant Treasurers, if elected, shall have such duties and possess such authority as may be delegated to them by the Treasurer or assigned or delegated to them by the President or assigned to them by the Board of Directors.

(f) The Secretary shall cause notices of all meetings to be served as prescribed in these Bylaws and shall keep or cause to be kept the minutes of all meetings of the stockholders and the Board of Directors. The Secretary shall have charge of the seal of the Corporation and shall perform such other duties and possess such authority as are incident to the office of Secretary or as may be assigned or delegated to the Secretary by the President or assigned to the Secretary by the Board of Directors.

(g) Assistant Secretaries, if elected, shall have such duties and possess such authority as may be delegated to them by the Secretary or assigned or delegated to them by the President or assigned to them by the Board of Directors.

(h) Subject to these Bylaws, each officer of the Corporation shall have in addition to the duties and powers specifically set forth in these Bylaws, such duties and powers as are customarily incident to such officer's office, and such duties and powers as may be designated from time to time by the Board of Directors.

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Section 2. <u>Tenure</u>. Except as otherwise provided by the Certificate of Incorporation or these Bylaws, each of the officers of the Corporation shall hold office from the time of election and qualification until such officer's successor shall have been elected and shall have qualified, or until the earlier death, resignation or removal of such officer.

Section 3. <u>Removal, Resignation</u>. Unless otherwise provided in the Certificate of Incorporation or these Bylaws, any officer may be removed, with or without cause, by the vote of a majority of the directors then in office. Any officer may resign at any time by written notice to the Chief Executive Officer, President or the Secretary of the Corporation. Resignations shall take effect immediately, unless otherwise specified.

# ARTICLE IV: CAPITAL STOCK

Section 1. <u>Certificates of Stock</u>. Each stockholder shall be entitled to a certificate of the capital stock of the Corporation in such form as may from time to time be prescribed by the Board of Directors. Such certificate shall be signed by a President or a Vice President, and by the Treasurer or an Assistant Treasurer, or the Secretary or an Assistant Secretary. Such signatures may be a facsimile. In case any officer, transfer agent or registrar who has signed or whose facsimile signature has been placed on such certificate shall have ceased to be such officer, transfer agent or registrar before such certificate is issued, it may be issued by the Corporation with the same effect as if such person were such officer, transfer agent or registrar at the time of its issue. Every certificate for shares of stock which are subject to any restriction on transfer and every certificate issued when the Corporation is authorized to issue more than one class or series of stock shall contain such legend with respect thereto as is required by law. The Corporation shall be permitted to issue fractional shares.

Section 2. <u>Transfers</u>. Subject to any restrictions on transfer, shares of stock may be transferred on the books of the Corporation by the surrender to the Corporation or its transfer agent of the certificate therefor properly endorsed or accompanied by a written assignment or power of attorney properly executed, with transfer stamps (if necessary) affixed, and with such proof of the authenticity of signature as the Corporation or its transfer agent may reasonably require.

Section 3. <u>Record Holders</u>. Except as may otherwise be required by law, by the Certificate of Incorporation or by these Bylaws, the Corporation shall be entitled to treat the record holder of stock as shown on its books as the owner of such stock for all purposes, including the payment of dividends and the right to vote with respect thereto, regardless of any transfer, pledge or other disposition of such stock, until the shares have been transferred on the books of the Corporation in accordance with the requirements of these Bylaws. It shall be the duty of each stockholder to notify the Corporation of such stockholder's post office address.

Section 4. <u>Record Date</u>. In order that the Corporation may determine the stockholders entitled to notice of or to vote at any meeting of stockholders or any adjournment thereof, or to consent to corporate action in writing without a meeting, or entitled to receive payment of any dividend or other distribution or allotment of any rights, or entitled to exercise any rights in respect of any change, conversion or exchange of stock or for the purpose of any other lawful action, the Board of Directors may fix, in advance, a record date, which shall not precede the date on which it is established, and which shall not be more than sixty (60) nor less than ten (10) days before the date of such meeting, more than ten (10) days after the date on which the record date for stockholder consent without a meeting is established, nor more than sixty (60) days prior to any other action. In such case only stockholders of record on such record date shall be so entitled notwithstanding any transfer of stock on the books of the Corporation after the record date.

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If no record date is fixed, (a) the record date for determining stockholders entitled to notice of or to vote at a meeting of stockholders shall be at the close of business on the day next preceding the day on which notice is given, or, if notice is waived, at the close of business on the day next preceding the day on which the meeting is held, (b) the record date for determining stockholders entitled to consent to corporate action in writing without a meeting, when no prior action by the Board of Directors is necessary, shall be the first date on which a signed written consent setting forth the action taken or proposed to be taken is delivered to the Corporation by delivery to its registered office in this state, to its principal place of business, or to an officer or agent of the Corporation having custody of the book in which proceedings of meetings of stockholders are recorded, and (c) the record date for determining stockholders for any other purpose shall be at the close of business on the day on which the Board of Directors adopts the resolution relating thereto.

Section 5. <u>Lost Certificates</u>. The Corporation may issue a new certificate of stock in the place of any certificate theretofore issued by it, alleged to have been lost, stolen or destroyed, and the Corporation may require the owner of the lost, stolen or destroyed certificate, or his legal representative, to give the Corporation a bond sufficient to indemnify it against any claim that may be made against it on account of the alleged loss, theft or destruction of any such certificate or the issuance of such new certificate.

# ARTICLE V: INDEMNIFICATION

Section 1. <u>Definitions</u>. For purposes of this Article V:

(a) "<u>Corporate Status</u>" describes the status of a person who is serving or has served (i) as a Director of the Corporation, (ii) as an Officer of the Corporation, or (iii) as a director, partner, trustee, officer, employee or agent of any other corporation, partnership, joint venture, trust, employee benefit plan or other enterprise which such person is or was serving at the request of the Corporation. For purposes of this Section 1(a), an Officer or Director of the Corporation who is serving or has served as a director, partner, trustee, officer, employee or agent of a Subsidiary shall be deemed to be serving at the request of the Corporation. Notwithstanding the foregoing, "Corporate Status" shall not include the status of a person who is serving or has served as a director, officer, employee or agent of a constituent corporation absorbed in a merger or consolidation transaction with the Corporation with respect to such person's activities prior to said transaction, unless specifically authorized by the Board of Directors or the stockholders of the Corporation;

(b) "Director" means any person who serves or has served the Corporation as a director on the Board of Directors of the Corporation;

(c) "<u>Disinterested Director</u>" means, with respect to each Proceeding in respect of which indemnification is sought hereunder, a Director of the Corporation who is not and was not a party to such Proceeding;

(d) "<u>Expenses</u>" means all reasonable attorneys' fees, retainers, court costs, transcript costs, fees of expert witnesses, private investigators and professional advisors (including, without limitation, accountants and investment bankers), travel expenses, duplicating costs, printing and binding costs, costs of preparation of demonstrative evidence and other courtroom presentation aids and devices, costs incurred in connection with document review, organization, imaging and computerization, telephone charges, postage, delivery service fees, and all other disbursements, costs or expenses of the type customarily incurred in connection with prosecuting, defending, preparing to prosecute or defend, investigating, being or preparing to be a witness in, settling or otherwise participating in, a Proceeding;

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(e) "<u>Non-Officer Employee</u>" means any person who serves or has served as an employee or agent of the Corporation, but who is not or was not a Director or Officer;

(f) "<u>Officer</u>" means any person who serves or has served the Corporation as an officer appointed by the Board of Directors of the Corporation;

(g) "<u>Proceeding</u>" means any threatened, pending or completed action, suit, arbitration, alternate dispute resolution mechanism, inquiry, investigation, administrative hearing or other proceeding, whether civil, criminal, administrative, arbitrative or investigative; and

(h) "<u>Subsidiary</u>" shall mean any corporation, partnership, limited liability company, joint venture, trust or other entity of which the Corporation owns (either directly or through or together with another Subsidiary of the Corporation) either (i) a general partner, managing member or other similar interest or (ii) (A) 50% or more of the voting power of the voting capital equity interests of such corporation, partnership, limited liability company, joint venture or other entity, or (B) 50% or more of the outstanding voting capital stock or other voting equity interests of such corporation, partnership, limited liability company, joint venture or other entity.

Section 2. Indemnification of Directors and Officers. Subject to the operation of Section 4 of this Article V of these Bylaws, each Director and Officer shall be indemnified and held harmless by the Corporation to the fullest extent authorized by the DGCL, as the same exists or may hereafter be amended (but, in the case of any such amendment, only to the extent that such amendment permits the Corporation to provide broader indemnification rights than such law permitted the Corporation to provide prior to such amendment) against any and all Expenses, judgments, penalties, fines and amounts reasonably paid in settlement that are incurred by such Director or Officer or on such Director's or Officer's behalf in connection with any threatened, pending or completed Proceeding or any claim, issue or matter therein, which such Director or Officer is, or is threatened to be made, a party to or participant in by reason of such Director's or Officer's Corporate Status, if such Director or Officer acted in good faith and in a manner such Director or Officer reasonably believed to be in or not opposed to the best interests of the Corporation and, with respect to any criminal proceeding, had no reasonable cause to believe his or her conduct was unlawful. The rights of indemnification provided by this Section 2 shall continue as to a Director or Officer after he or she has ceased to be a Director or Officer and shall inure to the benefit of his or her heirs, executors, administrators and personal representatives. Notwithstanding the foregoing, the Corporation shall indemnify any Director or Officer seeking indemnification in connection with a Proceeding was brought to enforce an Officer or Director's rights to indemnification or, in the case of Directors, advancement of Expenses under these Bylaws in accordance with the provisions set forth herein.

Section 3. Indemnification of Non-Officer Employees. Subject to the operation of Section 4 of this Article V of these Bylaws, each Non-Officer Employee may, in the discretion of the Board of Directors of the Corporation, be indemnified by the Corporation to the fullest extent authorized by the DGCL, as the same exists or may hereafter be amended, against any or all Expenses, judgments, penalties, fines and amounts reasonably paid in settlement that are incurred by such Non-Officer Employee or on such Non-Officer Employee's behalf in connection with any threatened, pending or completed Proceeding, or any claim, issue or matter therein, which such Non-Officer Employee is, or is threatened to be made, a party to or participant in by reason of such Non-Officer Employee's Corporate Status, if such Non-Officer Employee acted in good faith and in a manner such Non-Officer Employee reasonably believed to be in or not opposed to the best interests of the Corporation and, with respect to any criminal proceeding, had no reasonable cause to believe his or her conduct was unlawful. The rights of indemnification provided by this Section 3 shall exist as to a Non-Officer Employee after he or she has ceased to be a Non-Officer Employee and shall inure to the benefit of his or her heirs, personal representatives, executors and administrators. Notwithstanding the foregoing, the Corporation may indemnify any Non-Officer Employee seeking indemnification in connection with a Proceeding initiated by such Non-Officer Employee only if such Proceeding was authorized by the Board of Directors of the Corporation.

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Section 4. <u>Good Faith</u>. Unless ordered by a court, no indemnification shall be provided pursuant to this Article V to a Director, to an Officer or to a Non-Officer Employee unless a determination shall have been made that such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the Corporation and, with respect to any criminal Proceeding, such person had no reasonable cause to believe his or her conduct was unlawful. Such determination shall be made by (a) a majority vote of the Disinterested Directors, even though less than a quorum of the Board of Directors, (b) a committee comprised of Disinterested Directors, such committee having been designated by a majority vote of the Disinterested Directors (even though less than a quorum), (c) if there are no such Disinterested Directors, or if a majority of Disinterested Directors so directs, by independent legal counsel in a written opinion, or (d) by the stockholders of the Corporation.

## Section 5. Advancement of Expenses to Directors Prior to Final Disposition.

(a) The Corporation shall advance all Expenses incurred by or on behalf of any Director in connection with any Proceeding in which such Director is involved by reason of such Director's Corporate Status, upon the receipt by the Corporation of a written statement from such Director requesting such advance or advances from time to time, whether prior to or after final disposition of such Proceeding. Such statement or statements shall reasonably evidence the Expenses incurred by such Director and shall be preceded or accompanied by an undertaking by or on behalf of such Director to repay any Expenses so advanced if it shall ultimately be determined that such Director is not entitled to be indemnified against such Expenses.

(b) In any suit brought by the Corporation to recover an advancement of expenses pursuant to the terms of an undertaking, the Corporation shall be entitled to recover such expenses upon a final adjudication that the Director has not met any applicable standard for indemnification set forth in the DGCL.

# Section 6. <u>Advancement of Expenses to Officers and Non-Officer Employees Prior to Final Disposition</u>.

(a) The Corporation may, at the discretion of the Board of Directors of the Corporation, advance any or all Expenses incurred by or on behalf of any Officer and Non-Officer Employee in connection with any Proceeding in which such is involved by reason of the Corporate Status of such Officer or Non-Officer Employee upon the receipt by the Corporation of a statement or statements from such Officer or Non-Officer Employee upon the receipt by the Corporation of a statement or statements from such Officer or Non-Officer Employee requesting such advance or advances from time to time, whether prior to or after final disposition of such Proceeding. Such statement or statements shall reasonably evidence the Expenses incurred by such Officer and Non-Officer Employee and shall be preceded or accompanied by an undertaking by or on behalf of such to repay any Expenses so advanced if it shall ultimately be determined that such Officer or Non-Officer Employee is not entitled to be indemnified against such Expenses.

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(b) In any suit brought by the Corporation to recover an advancement of expenses pursuant to the terms of an undertaking, the Corporation shall be entitled to recover such expenses upon a final adjudication that the Officer or Non-Officer Employee has not met any applicable standard for indemnification set forth in the DGCL.

# Section 7. <u>Contractual Nature of Rights</u>.

(a) The foregoing provisions of this Article V shall be deemed to be a contract between the Corporation and each Director and Officer entitled to the benefits hereof at any time while this Article V is in effect, and any repeal or modification thereof shall not affect any rights or obligations then existing with respect to any state of facts then or theretofore existing or any Proceeding theretofore or thereafter brought based in whole or in part upon any such state of facts.

(b) If a claim for indemnification hereunder by a Director or Officer is not paid in full by the Corporation within 60 days after receipt by the Corporation of a written claim for indemnification, such Director or Officer may at any time thereafter bring suit against the Corporation to recover the unpaid amount of the claim, and if successful in whole or in part, such Director or Officer shall also be entitled to be paid the expenses of prosecuting such claim. The failure of the Corporation (including its Board of Directors or any committee thereof, independent legal counsel, or stockholders) to make a determination concerning the permissibility of such indemnification under this Article V shall not be a defense to the action and shall not create a presumption that such indemnification is not permissible. The burden of proving that a Director or Officer is not entitled to indemnification shall be on the Corporation.

(c) In any suit brought by a Director or Officer to enforce a right to indemnification hereunder, it shall be a defense that such Director or Officer has not met any applicable standard for indemnification set forth in the DGCL.

Section 8. <u>Non-Exclusivity of Rights</u>. The rights to indemnification and advancement of Expenses set forth in this Article V shall not be exclusive of any other right which any Director, Officer, or Non-Officer Employee may have or hereafter acquire under any statute, provision of the Certificate or these Bylaws, agreement, vote of stockholders or Disinterested Directors or otherwise.

Section 9. <u>Insurance</u>. The Corporation may maintain insurance, at its expense, to protect itself and any Director, Officer or Non-Officer Employee against any liability of any character asserted against or incurred by the Corporation or any such Director, Officer or Non-Officer Employee, or arising out of any such person's Corporate Status, whether or not the Corporation would have the power to indemnify such person against such liability under the DGCL or the provisions of this Article V.

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Section 10. <u>Other Indemnification</u>. The Corporation's obligation, if any, to indemnify any person under this Article V as a result of such person serving, at the request of the Corporation, as a director, partner, trustee, officer, employee or agent of another corporation, partnership, joint venture, trust, employee benefit plan or other enterprise shall be reduced by any amount such person may collect as indemnification from such other corporation, partnership, joint venture, trust, employee benefit plan or enterprise.

## ARTICLE VI: MISCELLANEOUS

Section 1. <u>Fiscal Year</u>. Except as otherwise determined by the Board of Directors, the fiscal year of the Corporation shall end on December 31st of each year.

Section 2. <u>Seal</u>. The Board of Directors shall have power to adopt and alter the seal of the Corporation.

Section 3. <u>Execution of Instruments</u>. Subject to any limitations which may be set forth in a resolution of the Board of Directors, all deeds, leases, transfers, contracts, bonds, notes and other obligations to be entered into by the Corporation in the ordinary course of its business without director action may be executed on behalf of the Corporation by, a President, or by any other officer, employee or agent of the Corporation as the Board of Directors may authorize.

Section 4. <u>Representation of Shares of Other Corporations</u>. The chairman of the Board of Directors, the Chief Executive Officer, the President, any Vice President, the Secretary or Assistant Secretary of this corporation, or any other person authorized by the Board of Directors or the Chief Executive Officer or the President or a Vice President, is authorized to vote, represent, and exercise on behalf of this corporation all rights incident to any and all shares of any other corporation or corporations standing in the name of this corporation.

Section 5. <u>Resident Agent</u>. The Board of Directors may appoint a resident agent upon whom legal process may be served in any action or proceeding against the Corporation.

Section 6. <u>Corporate Records</u>. The original or attested copies of the Certificate of Incorporation, By laws and records of all meetings of the incorporators, stockholders and the Board of Directors and the stock and transfer records, which shall contain the names of all stockholders, their record addresses and the amount of stock held by each, shall be kept at the principal office of the Corporation, at the office of its counsel, or at an office of its transfer agent.

Section 7. <u>Amendment of Bylaws</u>. These Bylaws may be altered, amended or repealed, and new Bylaws may be adopted, by the stockholders or by the Board of Directors; provided, that (a) the Board of Directors may not alter, amend or repeal any provision of these Bylaws which by law, by the Certificate of Incorporation or by these Bylaws requires action by the stockholders and (b) any alteration, amendment or repeal of these Bylaws by the Board of Directors may be altered, amended or repealed by the stockholders.

Section 8. <u>Force and Effect of Bylaws</u>. These Bylaws are subject to the provisions of the DGCL and the Certificate of Incorporation, as they may be amended from time to time. If any provision in these Bylaws is inconsistent with a provision in the DGCL or the Certificate of Incorporation, the provision of the DGCL or the Certificate of Incorporation shall govern to the extent of such inconsistency.

Adopted January 1, 2018

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#### FIRST AMENDMENT TO BYLAWS OF AQUESTIVE THERAPEUTICS, INC.

The Bylaws of the Aquestive Therapeutics, Inc. (the "<u>Bylaws</u>") are hereby amended as follows:

1. Article IV, Section 1, of the Bylaws is hereby amended to read in its entirety as follows:

Section 1. <u>Certificates of Stock</u>. Unless otherwise required by applicable law or authorized by the Board of Directors, all shares of stock of the Corporation shall be issued, recorded, and transferred exclusively in uncertificated book-entry form, as provided by DGCL. Every certificate in respect of shares of stock which are subject to any restriction on transfer and every certificate or notice (in respect of uncertificated stock) issued when the Corporation is authorized to issue more than one class or series of stock shall contain such legend with respect thereto as is required by law. The Corporation shall be permitted to issue fractional shares.

2. Article IV, Section 2, of the Bylaws is hereby amended to read in its entirety as follows:

Section 2. <u>Transfers</u>. Subject to any restrictions on transfer, shares of stock may be transferred on the books of the Corporation by the surrender to the Corporation or its transfer agent of the certificate therefor properly endorsed or accompanied by a written assignment or power of attorney properly executed, with transfer stamps (if necessary) affixed, and with such proof of the authenticity of signature as the Corporation or its transfer agent may reasonably require, or in the case of uncertificated shares of stock, in accordance with customary procedures for transferring shares in uncertificated form. Written notice of the transfer shall be given by the Corporation to the extent required by applicable law.

3. Article IV, Section 5, of the Bylaws is hereby amended to read in its entirety as follows:

Section 5. <u>Lost Certificates</u>. The Corporation may issue uncertificated shares of stock in the place of any certificate theretofore issued by it which are alleged to have been lost, stolen or destroyed, and the Corporation may require the owner of the lost, stolen or destroyed certificate, or his or her legal representative, to give the Corporation a bond sufficient to indemnify it against any claim that may be made against it on account of the alleged loss, theft or destruction of any such certificate or the issuance of such uncertificated shares of stock.

#### AMENDED AND RESTATED

#### BYLAWS

## OF

# **AQUESTIVE THERAPEUTICS, INC.**

### ARTICLE I STOCKHOLDERS

Section 1. The annual meeting of the stockholders of Aquestive Therapeutics, Inc. (the "Corporation") for the purpose of electing directors and for the transaction of such other business as may properly be brought before the meeting shall be held on such date, and at such time and place, if any, within or without the State of Delaware as may be determined exclusively from time to time by the Board of Directors of the Corporation (the "Board"). The Corporation may postpone, reschedule or cancel any annual meeting of stockholders previously scheduled.

Section 2. Except as otherwise required by law or the certificate of incorporation of the Corporation, and subject to the rights of the holders of one or more series of Preferred Stock (as defined in the certificate of incorporation of the Corporation), special meetings of the stockholders of the Corporation may be called only by or at the direction of the Board, acting pursuant to a resolution adopted by the affirmative vote of the majority of the members of the Board then in office or by the Chairman of the Board. The Corporation may postpone, reschedule or cancel any special meeting of stockholders previously scheduled.

Section 3. Except as otherwise provided by law, the certificate of incorporation of the Corporation or these Bylaws, notice of the date, time, place (if any), the means of remote communications, if any, by which stockholders and proxy holders may be deemed to be present in person and vote at such meeting, the record date for determining the stockholders entitled to vote at the meeting (if such date is different from the record date for stockholders entitled to notice of the meeting) and, in the case of a special meeting, the purpose or purposes of the meeting of stockholders, shall be given not more than sixty (60) nor less than ten (10) days before the date of each meeting of stockholders of the Corporation, to each stockholder entitled to vote at the meeting as of the record date for determining stockholders entitled to notice of the meeting at such address as appears on the records of the Corporation.

Section 4. The holders of a majority in voting power of the stock issued and outstanding and entitled to vote thereat, present in person or represented by proxy, shall constitute a quorum at all meetings of the stockholders for the transaction of business, except as otherwise provided in these Bylaws, by law or by the certificate of incorporation of the Corporation; but, if at any meeting of stockholders there shall be less than a quorum present, the chairman of the meeting or, by a majority in voting power thereof, the stockholders present may, to the extent permitted by law, adjourn the meeting from time to time without further notice other than announcement at such meeting of the date, time and place, if any, of the adjourned meeting, until a quorum shall be present or represented by proxy. At any adjourned meeting at which a quorum shall be present or represented by proxy, any business may be transacted which might have been transacted at the original meeting. Notice need not be given of any adjourned meeting if the time and place thereof are announced at the meeting at which the adjournment is taken; provided, however, that if the adjournment is for more than thirty (30) days, a notice of the adjourned meeting shall be given to each stockholder of record entitled to vote at the meeting.

Section 5. The Chairman of the Board, or in the Chairman's absence or at the Chairman's direction, the Chief Executive Officer, or in the Chief Executive Officer's absence or at the Chief Executive Officer's direction, any officer of the Corporation, shall call all meetings of the stockholders to order and shall act as chairman of any such meetings. The Secretary of the Corporation or, in such officer's absence, an Assistant Secretary, shall act as secretary of the meeting. If neither the Secretary nor an Assistant Secretary is present, the chairman of the meeting shall appoint a secretary of the meeting. The Board may adopt such rules and regulations for the conduct of the meeting of stockholders as it shall deem appropriate. Unless otherwise determined by the Board prior to the meeting, the chairman of the meeting, including, without limitation, convening the meeting and adjourning the meeting (whether or not a quorum is present), announcing the date and time of the opening and the closing of the polls for each matter upon which the stockholders will vote, imposing restrictions on the persons (other than stockholders of record of the Corporation or their duly appointed proxies) who may attend any such meeting, establishing procedures for the transaction of business at the meeting after the time fixed for commencement thereof, limiting the circumstances in which any person may make a statement or ask questions at any meeting of stockholders, and limitations on the time allotted to questions or comments by participants at such meeting.

Section 6. At all meetings of stockholders, any stockholder entitled to vote thereat shall be entitled to vote in person or by proxy, but no proxy shall be voted after three years from its date, unless such proxy provides for a longer period. Without limiting the manner in which a stockholder may authorize another person or persons to act for the stockholder as proxy pursuant to the General Corporation Law of the State of Delaware (the "DGCL"), the following shall constitute a valid means by which a stockholder may grant such authority: (i) a stockholder may execute a writing authorizing another person or persons to act for the stockholder as proxy, and execution of the writing may be accomplished by the stockholder or the stockholder's authorized officer, director, employee or agent signing such writing or causing his or her signature to be affixed to such writing by any reasonable means including, but not limited to, by facsimile or electronic signature; or (ii) a stockholder may authorize another person or persons to act for the stockholder as proxy by transmitting or authorizing by means of electronic transmission to the person who will be the holder of the proxy or to a proxy solicitation firm, proxy support service organization or like agent duly authorized by the person who will be the holder of the proxy to receive such transmission; provided that any such means of electronic transmission must either set forth or be submitted with information from which it can be determined that the electronic transmission was authorized by the stockholder. If it is determined that such electronic transmissions are valid, the inspector or inspectors of stockholder votes or, if there are no such inspectors, such other persons making that determination shall specify the information upon which they relied.

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A proxy shall be irrevocable if it states that it is irrevocable and if and only as long as it is coupled with an interest sufficient in law to support an irrevocable power. A stockholder may revoke any proxy which is not irrevocable by attending the meeting and voting in person or by delivering to the Secretary of the Corporation a revocation of the proxy or a new proxy bearing a later date.

Any copy, facsimile telecommunication or other reliable reproduction of the writing or transmission created pursuant to the first paragraph of this Section 6 may be substituted or used in lieu of the original writing or transmission for any and all purposes for which the original writing or transmission could be used, provided that such copy, facsimile telecommunication or other reproduction shall be a complete reproduction of the entire original writing or transmission.

Proxies shall be filed with the secretary of the meeting prior to or at the commencement of the meeting to which they relate.

Section 7. When a quorum is present at any meeting of stockholders, the vote of the holders of a majority of the votes cast shall decide any question brought before such meeting, unless the question is one upon which by express provision of the certificate of incorporation of the Corporation, these Bylaws or the DGCL a different vote is required, in which case such express provision shall govern and control the decision of such question. Notwithstanding the foregoing in this Section 7, where a separate vote by a class or series or classes or series is required and a quorum is present, the affirmative vote of a majority of the votes cast by shares of such class or series or classes or series shall be the act of such class or series or classes or series, unless the question is one upon which by express provision of the certificate of incorporation, these Bylaws or the DGCL a different vote is required, in which case such express provision of the Corporation, these Bylaws or the DGCL a different vote is required, in which case such express provision of the certificate of incorporation of the Corporation, these Bylaws or the DGCL a different vote is required, in which case such express provision shall govern and control the decision of such question.

Section 8. (A) In order that the Corporation may determine the stockholders entitled to notice of any meeting of stockholders or any adjournment thereof, the Board may fix a record date, which record date shall not precede the date upon which the resolution fixing the record date is adopted by the Board, and which record date shall, unless otherwise required by law, not be more than sixty (60) nor less than ten (10) days before the date of such meeting. If the Board so fixes a date, such date shall also be the record date for determining the stockholders entitled to vote at such meeting unless the Board determines, at the time it fixes such record date for determining stockholders entitled to notice of or to vote at a meeting of stockholders shall be at the close of business on the day next preceding the day on which notice is given, or, if notice is waived, at the close of business on the day next preceding the day on which notice is given, or, if notice of or to vote at a meeting of stockholders shall apply to any adjournment of the meeting; provided, however, that the Board may fix a new record date for determination of stockholders entitled to vote at the adjourned meeting, and in such case shall also fix as the record date for stockholders entitled to notice of such adjourned meeting the same or an earlier date as that fixed for determination of stockholders entitled to vote in accordance herewith at the adjourned meeting.

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(B) In order that the Corporation may determine the stockholders entitled to receive payment of any dividend or other distribution or allotment of any rights, or entitled to exercise any rights in respect of any change, conversion or exchange of stock or for the purpose of any other lawful action, the Board may fix a record date, which record date shall not precede the date on which the resolution fixing the record date is adopted and which record date shall not be more than sixty (60) days prior to such other action. If no such record date is fixed, the record date for determining stockholders for any such purpose shall be at the close of business on the day on which the Board adopts the resolution relating thereto.

Section 9. The officer who has charge of the stock ledger of the Corporation shall prepare and make, at least ten (10) days before every meeting of stockholders, a complete list of the stockholders entitled to vote at the meeting (provided, however, if the record date for determining the stockholders entitled to vote is less than ten (10) days before the date of the meeting, the list shall reflect the stockholders entitled to vote as of the tenth (10th) day before the meeting date), arranged in alphabetical order, and showing the address of each stockholder and the number of shares registered in the name of each stockholder, as both appears on the records of the Corporation. Such list shall be open to the examination of any stockholder for any purpose germane to the meeting for a period of at least ten (10) days prior to the meeting; (i) on a reasonably accessible electronic network, provided that the information required to gain access to such list is provided with the notice of the meeting; or (ii) during ordinary business hours, at the principal plàce of business of the Corporation. In the event that the Corporation determines to make the list available on an electronic network, the Corporation may take reasonable steps to ensure that such information is available only to stockholders of the Corporation. If the meeting is to be held at a place, then a list of stockholder who is present. If the meeting is to be held solely by means of remote communication, then the list shall also be open to the examination of any stockholder during the whole time of the meeting on a reasonably accessible electronic network, and the information required to access such list shall be provided with the notice of the meeting during the whole time thereof, and may be inspected by any stockholder who is present. If the meeting is to be held solely by means of remote communication, then the list shall also be open to the examination of any stockholder during the whole time of the meeting on a reasonably accessible electronic network

Section 10. The Board, in advance of all meetings of the stockholders, may (and, if required by law, shall) appoint one or more inspectors of stockholder votes to make a written report thereof, who may be employees or agents of the Corporation or stockholders or their proxies, but who shall not be directors of the Corporation or candidates for election as directors. In the event that the Board fails to so appoint one or more inspectors of stockholder votes or, in the event that one or more inspectors of stockholder votes previously designated by the Board fails to appear or act at the meeting of stockholders, the chairman of the meeting may appoint one or more inspectors of stockholder votes to fill such vacancy or vacancies or such position or positions. Inspectors of stockholder votes appointed to act at any meeting of the stockholders, before entering upon the discharge of their duties, shall take and sign an oath to faithfully execute the duties of inspector of stockholder votes with strict impartiality and according to the best of their ability and the oath so taken shall be subscribed by them. Inspectors of stockholder votes shall take all actions required under the applicable provisions of the DGCL and any other applicable law, rule or regulation.

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# Section 11. (A) Annual Meetings of Stockholders.

1. Nominations of persons for election to the Board and the proposal of other business to be considered by the stockholders may be made at an annual meeting of stockholders only (a) pursuant to the Corporation's notice of meeting (or any supplement thereto) delivered pursuant to Article I, Section 3 of these Bylaws, (b) by or at the direction of the Board or any authorized committee thereof or (c) by any stockholder of the Corporation who is entitled to vote on such election or such other business at the meeting, who complied with the notice procedures set forth in subparagraphs (2) and (3) of this paragraph (A) and who was a stockholder of record at the time such notice is delivered to the Secretary of the Corporation.

2. For nominations or other business to be properly brought before an annual meeting by a stockholder, the stockholder must have given timely notice thereof in writing to the Secretary of the Corporation, and, in the case of business other than nominations of persons for election to the Board, such other business must constitute a proper matter for stockholder action. To be timely, a stockholder's notice shall be delivered to the Secretary of the Corporation at the principal place of business of the Corporation not less than ninety (90) days nor more than one hundred twenty (120) days prior to the first anniversary of the preceding year's annual meeting; provided, however, that, in the event that the date of the annual meeting is advanced by more than twenty (20) days, or delayed by more than seventy (70) days, from the anniversary date of the previous year's meeting, or if no annual meeting was held in the preceding year (including for the Corporation's first annual meeting of stockholders after shares of its Common Stock (as defined in the certificate of incorporation of the Corporation) are first publicly traded), notice by the stockholder to be timely must be so delivered not earlier than the close of business on the one hundred and twentieth (120th) day prior to such annual meeting and not later than the close of business on the later of the ninetieth (90th) day prior to such annual meeting or the tenth (10th) day following the day on which public announcement of the date of such meeting is first made. For purposes of the application of Rule 14a-4(c) of the Securities Exchange Act of 1934, as amended (the "Exchange Act") (or any successor provision), the date for notice specified in this paragraph (A)(2) shall be the earlier of the date calculated as hereinbefore provided or the date specified in paragraph (c)(1) of Rule 14a-4 of the Exchange Act. Such stockholder's notice shall set forth: (a) as to each person whom the stockholder proposes to nominate for election or re-election as a director (1) all information relating to such person that is required to be disclosed in solicitations of proxies for election of directors, or is otherwise required, in each case pursuant to Section 14(a) of the Exchange Act and the rules and regulations promulgated thereunder, including such person's written consent to being named in the proxy statement as a nominee and to serving as a director if elected, and (2) a description of all direct and indirect compensation and other material monetary agreements, assignments and understandings during the past three years, and any other material relationships, between or among the stockholders giving the notice of such nomination, the beneficial owner on whose behalf the nomination is made and any of its or their affiliates or associates and/or others on whose behalf the nomination is made ("nominating person"), on the one hand, and such proposed nominee and his or her respective affiliates and associates, on the other hand, including without limitation, all information that would be required to be disclosed pursuant to Item 404 under Regulation S-K promulgated by the Securities and Exchange Commission if such nominating person was the "registrant" for purposes of such rule and the proposed nominee was a director or executive officer of such registrant; (b) as to any other business that the stockholder proposes to bring before the meeting, a brief description of the business desired to be brought before the meeting, the text of the proposal or business (including the text of any resolutions proposed for consideration and, in the event that such business includes a proposal to amend these Bylaws, the language of the proposed amendment), the reasons for conducting such business at the meeting and any material interest in such business of such stockholder and the beneficial owner, if any, on whose behalf the proposal is made; (c) as to the stockholder giving the notice and the beneficial owner, if any, on whose behalf the nomination or proposal is made (i) the name and address of such stockholder, as they appear on the records of the Corporation, and of such beneficial owner, (ii) the class or series and number of shares of capital stock of the Corporation which are owned directly or indirectly, beneficially and of record, by such stockholder and such beneficial owner, (iii) a representation that the stockholder is a holder of record of the stock of the Corporation at the time of the giving of the notice, will be entitled to vote at such meeting and will appear in person or by proxy at the meeting to propose such business or nomination, (iv) a representation whether the stockholder or the beneficial owner, if any, will be or is part of a group which will (A) deliver a proxy statement and/or form of proxy to holders of at least the percentage of the voting power of the Corporation's outstanding capital stock required to approve or adopt the proposal or elect the nominee and/or (B) otherwise solicit proxies or votes from stockholders in support of such proposal or nomination, (v) a certification regarding whether such stockholder and beneficial owner, if any, have complied with all applicable federal, state and other legal requirements in connection with the stockholder's and/or beneficial owner's acquisition of shares of capital stock or other securities of the Corporation and/or the stockholder's and/or beneficial owner's acts or omissions as a stockholder of the Corporation and (vi) any other information relating to such stockholder and beneficial owner, if any, required to be disclosed in a proxy statement or other filings required to be made in connection with solicitations of proxies for the proposal and/or, if a nominee is being so proposed, for the election of directors in an election contest pursuant to and in accordance with Section 14(a) of the Exchange Act and the rules and regulations promulgated thereunder; (d) a description of any agreement, arrangement or understanding with respect to the nomination or proposal and/or the voting of shares of any class or series of stock of the Corporation between or among the stockholder giving the notice, the beneficial owner, if any, on whose behalf the nomination or proposal is made, any of their respective affiliates or associates and/or any others acting in concert with any of the foregoing (collectively, "proponent persons"); and (e) a description of any agreement, arrangement or understanding (including without limitation any contract to purchase or sell, acquisition or grant of any option, right or warrant to purchase or sell, swap or other instrument) to which any proponent person is a party, the intent or effect of which may be (i) to transfer to or from any proponent person, in whole or in part, any of the economic consequences of ownership of any security of the Corporation, (ii) to increase or decrease the voting power of any proponent person with respect to shares of any class or series of stock of the Corporation and/or (iii) to provide any proponent person, directly or indirectly, with the opportunity to profit or share in any profit derived from, or to otherwise benefit economically from, any increase or decrease in the value of any security of the Corporation. A stockholder providing notice of a proposed nomination for election to the Board or other business proposed to be brought before a meeting (whether given pursuant to this paragraph (A)(2) or paragraph (B) of this Section 11 of these Bylaws) shall update and supplement such notice from time to time to the extent necessary so that the information provided or required to be provided in such notice shall be true and correct as of the record date for determining stockholders entitled to notice of the meeting and as of the date that is fifteen (15) days prior to the meeting or any adjournment or postponement thereof, provided that, if the record date for determining the stockholders entitled to vote at the meeting is less than fifteen (15) days prior to the meeting or any adjournment or postponement thereof, the information shall be supplemented and updated as of such later date. Any such update and supplement shall be delivered in writing to the Secretary of the Corporation at the principal place of business of the Corporation not later than five (5) days after the record date for determining stockholders entitled to notice of the meeting (in the case of any update or supplement required to be made as of the record date for determining stockholders entitled to notice of the meeting), not later than ten (10) days prior to the date for the meeting or any adjournment or postponement thereof (in the case of any update or supplement required to be made as of fifteen (15) days prior to the meeting or any adjournment or postponement thereof) and not later than five (5) days after the record date for determining the stockholders entitled to vote at the meeting, but no later than the day prior to the meeting or any adjournment or postponement thereof (in the case of any update and supplement required to be made as of a date less than fifteen (15) days prior the date of the meeting or any adjournment or postponement thereof). The Corporation may require any proposed nominee to furnish such other information as it may reasonably require to determine the eligibility of such proposed nominee to serve as a director of the Corporation and to determine the independence of such director under the Exchange Act and rules and regulations thereunder and applicable stock exchange rules.

3. Notwithstanding anything in the second sentence of paragraph (A)(2) of this Section 11 of these Bylaws to the contrary, in the event that the number of directors to be elected to the Board is increased, effective after the time period for which nominations would otherwise be due under paragraph (A) (2) of this Section 11 of these Bylaws, and there is no public announcement naming all of the nominees for director or specifying the size of the increased Board made by the Corporation at least one hundred (100) days prior to the first anniversary of the preceding year's annual meeting, a stockholder's notice required by this Bylaw shall also be considered timely, but only with respect to nominees for any new positions created by such increase, if it shall be delivered to the Secretary at the principal executive offices of the Corporation not later than the close of business on the tenth (10th) day following the day on which a public announcement of such increase is first made by the Corporation; provided that, if no such announcement is made at least ten (10) days before the meeting, then no such notice shall be required.

(B) Special Meetings of Stockholders. Only such business shall be conducted at a special meeting of stockholders as shall have been brought before the meeting pursuant to the Corporation's notice of meeting pursuant to Article I, Section 3 of these Bylaws. Nominations of persons for election to the Board may be made at a special meeting of stockholders at which directors are to be elected (i) pursuant to the Corporation's notice of meeting, by any at the direction of the Board or a committee thereof or (b) provided that the Board has determined that directors shall be elected at such meeting, by any stockholder of the Corporation who is entitled to vote on such election at the meeting who complies with the notice procedures set forth in this Section 11 of these Bylaws and who is a stockholder of record at the time such notice is delivered to the Secretary of the Corporation. In the event the Corporation calls a special meeting of stockholders for the purpose of electing one or more directors to the Board, any such stockholder entitled to vote in such election of directors may nominate a person or persons (as the case may be) for election to such position(s) as specified in the Corporation's notice of meeting if the stockholder's notice, containing the same information required by, and which notice to be updated and supplemented in the same manner and at the same time or times as set forth in, paragraph (A)(2) of this Section 11 of these Bylaws, shall be delivered to the Secretary at the principal place of business of the Corporation not earlier than the close of business on the one hundred twentieth (120th) day prior to such special meeting and not later than the close of business on the later of the ninetieth (90th) day prior to such special meeting or the tenth (10th) day following the day on which public announcement is first made of the date of the special meeting and of the nominees proposed by the Board to be elected at such meeting. The Corporation may require any proposed nominee to furnish such other i

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(C) (1) Only persons who are nominated in accordance with the procedures set forth in this Section 11 of these Bylaws shall be eligible to be elected at an annual or special meeting of stockholders of the Corporation to serve as directors and only such business shall be conducted at a meeting of stockholders as shall have been brought before the meeting in accordance with the procedures set forth in this Section 11 of these Bylaws. Except as otherwise provided by law, the certificate of incorporation of the Corporation or these Bylaws, the chairman of the meeting shall, in addition to making any other determination that may be appropriate for the conduct of the meeting, have the power and duty to determine whether a nomination or any business proposed to be brought before the meeting was made in accordance with the procedures set forth in these Bylaws and, if any proposed nomination or business is not in compliance with these Bylaws, to declare that such defective proposal or nomination shall be disregarded or that such proposed business shall not be transacted.

Notwithstanding the foregoing provisions of this Section 11, if the stockholder (or a qualified representative of the stockholder) does not appear at the annual or special meeting of stockholders of the Corporation to present a nomination or business, such nomination shall be disregarded and such proposed business shall not be transacted, notwithstanding that proxies in respect of such vote may have been received by the Corporation. For purposes of this Section 11, to be considered a qualified representative of the stockholder, a person must be a duly authorized officer, manager or partner of such stockholder or must be authorized by a writing executed by such stockholder or an electronic transmission delivered by such stockholder to act for such stockholder as proxy at the meeting of stockholders and such person must produce such writing or electronic transmission, or a reliable reproduction of the writing or electronic transmission, at the meeting of stockholders.

(2) For purposes of this Bylaw, "public announcement" shall mean disclosure (a) in a press release released by the Corporation; provided such press release is released by the Corporation following its customary procedures, is reported by the Dow Jones News Service, Associated Press or comparable national news service, or is generally available on internet news sites, (b) in a document publicly filed or furnished by the Corporation with the Securities and Exchange Commission pursuant to Section 13,14 or 15(d) of the Exchange Act or (c) otherwise disseminated in a manner constituting "public disclosure" under Regulation FD promulgated by the Securities and Exchange Commission.

(3) For purposes of this Section 11, no adjournment or postponement or notice of adjournment or postponement of any meeting shall be deemed to constitute a new notice of such meeting for purposes of this Section 11, and in order for any notification required to be delivered by a stockholder pursuant to this Section 11 to be timely, such notification must be delivered within the periods set forth above with respect to the originally scheduled meeting.

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(4) Notwithstanding the foregoing provisions of this Section 11, a stockholder shall also comply with all applicable requirements of the Exchange Act and the rules and regulations thereunder with respect to the matters set forth in this Section 11; provided, however, that, to the fullest extent permitted by law, any references in these Bylaws to the Exchange Act or the rules and regulations promulgated thereunder are not intended to and shall not limit any requirements applicable to nominations or proposals as to any other business to be considered pursuant to this Section 11 (including paragraphs (A) (1)(c) and (B) hereof), and compliance with paragraphs (A)(1)(c) and (B) of this Section 11 shall be the exclusive means for a stockholder to make nominations or submit other business at such meeting.

(5) Nothing in this Section 11 shall be deemed to affect any rights (i) of stockholders to request inclusion of proposals in the Corporation's proxy statement pursuant to Rule 14a-8 under the Exchange Act or (ii) of the holders of any series of Preferred Stock if and to the extent provided for under law, the certificate of incorporation of the Corporation or these Bylaws. Nothing in this Section 11 shall apply to the right, if any, of the holders of any series of Preferred Stock to elect directors pursuant to any applicable provisions of the certificate of incorporation.

#### ARTICLE II BOARD OF DIRECTORS

Section 1. The Board shall consist, subject to the certificate of incorporation of the Corporation, of such number of directors as shall from time to time be fixed exclusively by resolution adopted by the Board. Directors shall (except as hereinafter provided for the filling of vacancies and newly created directorships and except as otherwise expressly provided in the certificate of incorporation of the Corporation) be elected by the holders of a plurality of the votes cast by the holders of shares present in person or represented by proxy at the meeting and entitled to vote on the election of such directors. A majority of the total number of directors then in office shall constitute a quorum for the transaction of business. Except as otherwise provided by law, these Bylaws or by the certificate of incorporation of the Corporation, the act of a majority of the directors present at any meeting at which there is a quorum shall be the act of the Board. Directors need not be stockholders. If a quorum shall not be present at any meeting of the Board or of any committee thereof, a majority of the directors present thereat may adjourn the meeting from time to time, without notice other than announcement at the meeting, until a quorum shall be present.

Section 2. Subject to the certificate of incorporation of the Corporation, unless otherwise required by the DGCL, any newly created directorship on the Board that results from an increase in the number of directors and any vacancy occurring in the Board (whether by death, resignation, removal, retirement, disqualification or otherwise) shall be filled only by a majority of the directors then in office, even if less than a quorum, or by a sole remaining director.

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Section3. Meetings of the Board shall be held at such place, if any, within or without the State of Delaware as may from time to time be fixed by resolution of the Board or as may be specified in the notice of any meeting. Regular meetings of the Board shall be held without notice at such times as may from time to time be fixed by resolution of the Board and special meetings may be held at any time upon the call of the Chairman of the Board, the Chief Executive Officer of the Corporation or by a majority of the Board, by oral or written notice, including, without limitation, facsimile, email or other means of electronic transmission, duly served on or sent and delivered to each director to such director's address, e-mail address or telephone or telecopy number as shown on the books of the Corporation not less than twenty-four (24) hours before the meeting. The notice of any meeting of the Board need not specify the purposes thereof. A meeting of the Board may be held without notice immediately after the annual meeting of stockholders at the same place, if any, at which such meeting is held.

Section 4. If at any meeting for the election of directors, the Corporation has outstanding more than one class of stock, and one or more such classes or series thereof are entitled to vote separately as a class to elect directors, and there shall be a quorum of only one such class or series of stock, that class or series of stock shall be entitled to elect its quota of directors notwithstanding the absence of a quorum of the other class or series of stock.

Section 5. The Board may from time to time establish one or more committees of the Board to serve at the pleasure of the Board, which shall be composed of one or more members of the Board and have such duties as the Board shall from time to time determine; but no such committee shall have the power or authority in reference to amending the certificate of incorporation of the Corporation, adopting an agreement of merger or consolidation, recommending to the stockholders the sale, lease or exchange of all or substantially all of the Corporation's property and-assets, recommending to the stockholders a dissolution or a revocation of a dissolution or amending these Bylaws; and, unless the resolution expressly so provides, no such committee shall have the power or authority to declare a dividend or to authorize the issuance of stock or to adopt a certificate of ownership and merger. Any director may belong to any number of committees of the Board. The Board may designate one or more directors as alternate members of any committee, who may replace any absent or disqualified member at any meeting of the committee. In the absence or disqualification of a member of a committee, the member or members present at any meeting and not disqualified from voting, whether or not such member or members constitute a quorum, may unanimously appoint another member of the Board to act at the meeting in the place of any such absent or disqualified member. Each such committee shall keep minutes and make such reports as the Board may from time to time request. Except as the Board may otherwise determine, any committee may make rules for the conduct of its business, but unless otherwise provided by the directors or in such rules, its business shall be conducted as nearly as possible in the same manner as is provided in this Article II of these Bylaws for the Board.

Unless otherwise provided in the certificate of incorporation of the Corporation, these Bylaws or the resolution of the Board designating the committee, a committee may create one or more subcommittees, each subcommittee to consist of one or more members of the committee, and may delegate to a subcommittee any or all of the powers and authority of the committee.

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Section 6. Unless otherwise restricted by the certificate of incorporation of the Corporation or these Bylaws, any action required or permitted to be taken at any meeting of the Board or of any committee thereof may be taken without a meeting if all members of the Board or such committee, as the case may be, consent thereto in writing or by electronic transmission, and the writing or writings or electronic transmission or transmissions are filed with the minutes of proceedings of the Board or such committee, as the case may be.

Section 7. The members of the Board or any committee thereof may participate in a meeting of the Board or such committee, as the case may be, by means of conference telephone or other communications equipment by means of which all persons participating in the meeting can hear each other, and participation in a meeting pursuant to this subsection shall constitute presence in person at such a meeting.

Section 8. The Board may establish policies for the compensation of directors and for the reimbursement of the expenses of directors, in each case, in connection with services provided by directors to the Corporation.

#### ARTICLE III OFFICERS

Section 1. The Board shall elect officers of the Corporation, including a Chief Executive Officer, President and a Secretary. The Board may also from time to time elect such other officers (including, without limitation, a Chief Financial Officer, a Chief Operating Officer, a General Counsel, one or more Vice Presidents, a Treasurer, one or more Assistant Vice Presidents, one or more Assistant Secretaries and one or more Assistant Treasurers) as it may deem proper and the Chief Executive Officer of the Corporation shall also have the power to appoint and remove any such other officers (other than the Chief Executive Officer, any President, any Chief Financial Officer, any Chief Operating Officer, any General Counsel, or any Executive Vice President) (collectively, "Other Officers") and to prescribe the respective terms of office, authorities and duties of any such Other Officers. Any Vice President may be designated Executive, Senior or Corporate, or may be given such other designation or combination of designations as the Board or the Chief Executive Officer may determine. Any two or more offices may be held by the same person. The Board may also elect or appoint a Chairman of the Board, who may or may not also be an officer of the Corporation. The Board may elect or appoint co-Chairmen of the Board, co-Presidents or co-Chief Executive Officers and, in such case, references in thêse Bylaws to the Chairman of the Board, the President or the Chief Executive Officer shall refer to either such co-Chairman of the Board, the President or the Chief Executive Officer shall refer to either such co-Chairman of the Board, the President or the Chief Executive Officer shall refer to either such co-Chairman of the Board, co-President or co-Chief Executive Officer, as the case may be.

Section 2. The officers of the Corporation shall hold their offices for such terms and shall exercise such powers and perform such duties as shall be determined from time to time by the Board. All officers of the Corporation elected by the Board shall hold office for such terms as may be determined by the Board or, in the case of any Other Officers, the Chief Executive Officer, or until their respective successors are chosen and qualified or until his or her earlier resignation or removal. Any officer may be removed from office at any time either with or without cause by the affirmative vote of a majority of the members of the Board then in office, or, in the case of any Other Officers, by the Chief Executive Officer.

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Section 3. Each of the officers of the Corporation elected by the Board or appointed by the Chief Executive Officer in accordance with these Bylaws shall have the powers and duties prescribed by law, by these Bylaws or by the Board or, in the case of Other Officers, by the Chief Executive Officer, and, unless otherwise prescribed by these Bylaws or by the Board or, in the case of Other Officers, by the Chief Executive Officer, shall have such further powers and duties as ordinarily pertain to that office.

Section 4. Unless otherwise provided in these Bylaws, in the absence or disability of any officer of the Corporation, the Board or the Chief Executive Officer may, during such period, delegate such officer's powers and duties to any other officer or to any director of the Board and the person to whom such powers and duties are delegated shall, for the time being, hold such office.

## ARTICLE IV CAPITAL STOCK

Section 1. <u>Issuance of Stock</u>. Unless otherwise voted by the stockholders and subject to the provisions of the certificate of incorporation of the Corporation, the whole or any part of any unissued balance of the authorized capital stock of the Corporation or the whole or any part of any shares of the authorized capital stock of the Corporation held in the Corporation's treasury may be issued, sold, transferred or otherwise disposed of by vote of the Board in such manner, for such lawful consideration and on such terms as the Board may determine.

Section 2. <u>Uncertificated Shares; Certificates of Stock</u>. The shares of stock of the Corporation shall be uncertificated, provided that the Board may provide by resolution or resolutions that some or all of any or all classes or series of its stock shall be represented by certificates. Notwithstanding the foregoing, nothing contained in this Section 2 of Article IV shall apply to shares represented by a certificate as of the date of adoption of these Bylaws until such certificate is surrendered to the Corporation. If shares are represented by certificates, such certificates shall be in the form, other than bearer form, approved by the Board. Every holder of stock represented by certificates shall be entitled to have a certificate, certifying the number of shares owned by such holder in the Corporation, signed by, or in the name of the Corporation by, any two authorized officers of the Corporation in accordance with the DGCL. Any or all signatures on any such certificate may be a facsimile or other electronic reproduction. In case any officer, transfer agent or registrar who has signed, whose facsimile or electronic signature has been used on or who has duly affixed a facsimile or electronic signatures to any such certificate or certificates or certificates shall cease to be such officer, transfer agent or registrar of the Corporation whether because of death, resignation or otherwise before such certificate or certificates have been issued by the Corporation, such certificate or signatures have been used thereon or who duly affixed a facsimile or electronic signature or who duly affixed a facsimile or signature or signatures thereon had not ceased to be such officer, transfer agent or registrar of the Corporation. Every certificate for shares of stock which are subject to any restriction on transfer and every certificate issued when the Corporation is authorized to issue more than one class or series of stock shall contain such legend with respect thereto as is required by law. The rights and obligations of st

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Section 3. <u>Transfers</u>. Except as otherwise established by rules and regulations adopted by the Board, and subject to applicable law, shares of stock may be transferred on the books of the Corporation by the surrender to the Corporation or its transfer agent of the certificate representing such shares properly endorsed or accompanied by a written assignment or power of attorney properly executed, and with such proof of authority or the authenticity of signature as the Corporation or its transfer agent may reasonably require. Shares of stock that are not represented by a certificate may be transferred on the books of the Corporation or its transfer agent such evidence of transfer and following such other procedures as the Corporation or its transfer agent may require.

Section 4. <u>Record Holders</u>. Except as may be otherwise required by law, by the certificate of incorporation of the Corporation or by these Bylaws, the Corporation shall be entitled to treat the record holder of stock as shown on the Corporation's stock ledger as the owner of such stock for all purposes, including the payment of dividends and the right to vote with respect to such stock, regardless of any transfer, pledge or other disposition of such stock until the shares have been transferred on the Corporation's stock ledger in accordance with the requirements of these Bylaws.

Section 5. Lost, Stolen or Destroyed Certificates. The Corporation may issue or direct a new certificate or certificates to be issued in place of any previously issued certificate or certificates alleged to have been lost, stolen or destroyed, upon such terms and conditions as the Corporation may prescribe, including the presentation of reasonable evidence of such loss, theft or destruction and the giving of such indemnity and posting of such bond sufficient to indemnify the Corporation against any claim that may be made against it on account of such alleged loss, theft or destruction of any such certificate or the issuance of a new certificate for the protection of the Corporation or any transfer agent or registrar.

#### ARTICLE V EXECUTION OF CORPORATE INSTRUMENTS AND VOTING OF SECURITIES OWNED BY THE CORPORATION

Section 1. <u>Execution of Corporate Instruments</u>. The Board may, in its discretion, determine the method and designate the signatory officer or officers, or other person or persons, to execute on behalf of the Corporation any corporate instrument or document, or to sign on behalf of the Corporation the corporate name without limitation, or to enter into contracts on behalf of the Corporation, except where otherwise provided by law or these Bylaws, and such execution or signature shall be binding upon the Corporation.

Unless authorized or ratified by the Board or within the agency power of an officer, no officer, agent or employee shall have any power or authority to bind the Corporation by any contract or engagement or to pledge its credit or to render it liable for any purpose or for any amount.

Section 2. <u>Voting of Securities Owned By the Corporation</u>. All stock and other securities of other Corporations owned or held by the Corporation for itself, or for other parties in any capacity, shall be voted, and all proxies with respect thereto shall be executed, by the person authorized so to do by resolution of the Board, or, in the absence of such authorization, by the Chairman of the Board, the Chief Executive Officer, or any Vice President.

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#### ARTICLE VI INDEMNIFICATION AND ADVANCEMENT OF EXPENSES

Section 1. Each person who was or is made a party or is threatened to be made a party to or is otherwise involved in any action, suit or proceeding, whether civil, criminal, administrative or investigative (hereinafter a "proceeding"), by reason of the fact that he or she is or was a director or an officer of the Corporation or, while a director or officer of the Corporation, is or was serving at the request of the Corporation as a director, officer, employee, agent, fiduciary or trustee of another corporation or of a partnership, joint venture, trust or other enterprise, including service with respect to an employee benefit plan (hereinafter an "indemnitee"), whether the basis of such proceeding is alleged action in an official capacity as a director, officer, employee, agent, fiduciary or trustee or in any other capacity while serving as a director, officer, employee, agent, fiduciary or trustee, shall be indemnified and held harmless by the Corporation to the fullest extent permitted by Delaware law, as the same exists or may hereafter be amended (but, in the case of any such amendment, only to the extent that such amendment permits the Corporation to provide broader indemnification rights than such law permitted the Corporation to provide prior to such amendment), against all expense, liability and loss (including attorneys' fees, judgments, fines, ERISA excise taxes or penalties and amounts paid in settlement) reasonably incurred or suffered by such indemnification or advancement of expenses or with respect to any compulsory counterclaim brought by such indemnitee, or as may otherwise be expressly approved by the Board or a committee thereof, the Corporation shall indemnify any such indemnitee in connection with a proceeding (or part thereof) initiated by such indemnitee only if such proceeding (or part thereof) was authorized by the Board.

Section 2. In addition to the right to indemnification conferred in Section 1 of this Article VI, an indemnitee shall also have the right to be paid by the Corporation the expenses (including attorneys' fees) incurred in appearing at, participating in or defending any such proceeding in advance of its final disposition or in connection with a proceeding brought to establish or enforce a right to indemnification or advancement of expenses under this Article VI (which shall be governed by Section 3 of this Article VI) (hereinafter an "advancement of expenses"); provided, however, that if (x) the DGCL requires or (y) in the case of an advance made in a proceeding brought to establish or enforce a right to indemnification or advancement, an advancement of expenses incurred by an indemnitee in his or her capacity as a director or officer of the Corporation (and not in any other capacity in which service was or is rendered by such indemnitee, including, without limitation, service to an employee benefit plan) shall be made solely upon delivery to the Corporation of an undertaking (hereinafter an "undertaking"), by or on behalf of such indemnitee, to repay all amounts so advanced if it shall ultimately be determined by final judicial decision from which there is no further right to appeal (hereinafter a "final adjudication") that such indemnitee is not entitled to be indemnified or entitled to advancement of expenses under Section 1 or 2 of this Article VI or otherwise.

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Section 3. If a claim under Section 1 or 2 of this Article VI is not paid in full by the Corporation within (i) sixty (60) days after a written claim for indemnification has been received by the Corporation or (ii) twenty (20) days after a claim for an advancement of expenses has been received by the Corporation, the indemnitee may at any time thereafter bring suit against the Corporation to recover the unpaid amount of the claim or to obtain advancement of expenses, as applicable. To the fullest extent permitted by law, if the indemnitee is successful in whole or in part in any such suit or in a suit brought by the Corporation to recover an advancement of expenses, the indemnitee shall be entitled to be paid also the expense of prosecuting or defending such suit (including, without limitation, attorneys' fees). In (i) any suit brought by the indemnitee to enforce a right to indemnification hereunder (but not in a suit brought by the indemnitee to enforce a right to an advancement of expenses) it shall be a defense that, and (ii) any suit brought by the Corporation to recover an advancement of expenses, the Corporation shall be entitled to recover such expenses upon a final adjudication that, the indemnitee has not met any applicable standard for indemnification set forth in the DGCL. Neither the failure of the Corporation (including by its directors who are not parties to such action, a committee of such directors, independent legal counsel, or its stockholders) to have made a determination prior to the commencement of such suit that indemnification of the indemnitee is proper in the circumstances because the indemnitee has met the applicable standard of conduct set forth in the DGCL, nor an actual determination by the Corporation (including by its directors who are not parties to such action, a committee of such directors, independent legal counsel, or its stockholders) that the indemnitee has not met such applicable standard of conduct, shall create a presumption that the indemnitee has not met the applicable standard of conduct or, in the case of such a suit brought by the indemnitee, be a defense to such suit. In any suit brought by the indemnitee to enforce a right to indemnification or to an advancement of expenses hereunder, or brought by the Corporation to recover an advancement of expenses, the burden of proving that the indemnitee is not entitled to be indemnified, or to such advancement of expenses, under this Article VI or otherwise shall be on the Corporation.

Section 4. The provision of indemnification to or the advancement of expenses and costs to any indemnitee under this Article VI, or the entitlement of any indemnitee to indemnification or advancement of expenses under this Article VI, shall not limit or restrict in any way the power of the Corporation to indemnify or advance expenses to such indemnitee in any other way permitted by law or be deemed exclusive of, or invalidate, any right to which any indemnitee seeking indemnification or advancement of expenses may be entitled under any law, agreement, vote of stockholders or disinterested directors or otherwise, both as to action in such indemnitee's capacity as an officer, director, employee, agent, fiduciary or trustee of the Corporation and as to action in any other capacity.

Section 5. The rights conferred upon indemnitees in this Article VI shall be contract rights and such rights shall continue as to an indemnitee who has ceased to be an officer, director, employee, agent, fiduciary or trustee of the Corporation and shall inure to the benefit of the indemnitee's heirs, executors and administrators. Any amendment, alteration or repeal of this Article VI that adversely affects any right of an indemnitee or its heirs, executors, administrators, and successors, as the case may be, shall be prospective only and shall not limit, eliminate, or impair any such right with respect to any proceeding involving any occurrence or alleged occurrence of any action or omission to act that took place prior to such amendment or repeal.

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Section 6. The Corporation may purchase and maintain insurance, at its expense, to protect itself and any director, officer, employee, agent, fiduciary and trustee of the Corporation or another corporation, partnership, joint venture, trust or other enterprise against any expense, liability or loss, whether or not the Corporation would have the power to indemnify such person against such expense, liability or loss under the DGCL.

Section 7. The Corporation may, to the extent authorized from time to time by the Board, grant rights to indemnification and to the advancement of expenses to any employee or agent of the Corporation to the fullest extent of the provisions of this Article VI with respect to the indemnification and advancement of expenses of directors and officers of the Corporation.

#### ARTICLE VII CORPORATE BOOKS

The books of the Corporation may be kept inside or outside of the State of Delaware at such place or places as the Board may from time to time determine.

# ARTICLE VIII FISCAL YEAR

The fiscal year of the Corporation shall be, unless otherwise determined by resolution of the Board, the calendar year ending on December 31.

### ARTICLE IX CORPORATE SEAL

The corporate seal shall have inscribed thereon the name of the Corporation. In lieu of the corporate seal, when so authorized by the Board or a duly empowered committee thereof a facsimile thereof may be impressed or affixed or reproduced.

#### ARTICLE X GENERAL PROVISIONS

Section 1. Whenever notice is required to be given by law or under any provision of the certificate of incorporation of the Corporation or these Bylaws, notice of any meeting need not be given to any person who shall attend such meeting (except when the person attends a meeting for the express purpose of objecting, at the beginning of the meeting, to the transaction of any business because the meeting is not lawfully called or convened), or who shall waive notice thereof before or after such meeting, in writing (including by electronic transmission).

Section 2. <u>Form of Notice</u>. Notices to directors and stockholders other than notices to directors of special meetings of the Board which may be given by any means stated in Section 3 of Article II, shall be in writing and, in addition to any other method of notice permitted by applicable law, may be delivered personally, mailed to the directors or stockholders at their addresses appearing on the books of the Corporation or transmitted to any director via electronic mail to an electronic mail address appearing on the books or as part of the records of the Corporation or transmitted to any stockholder via electronic mail address at which the stockholder has consented to receive notice. Notice by mail shall be deemed to be given at the time when the same shall be mailed. Notice to directors may also be given by telegram.

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Section 3. Section headings in these Bylaws are for convenience of reference only and shall not be given any substantive effect in limiting or otherwise construing any provision herein.

Section 4. In the event that any provision of these Bylaws is or becomes inconsistent with any provision of the certificate of incorporation of the Corporation or the DGCL, the provision of these Bylaws shall not be given any effect to the extent of such inconsistency but shall otherwise be given full force and effect.

# ARTICLE XI AMENDMENTS

These Bylaws may be made, amended, altered, changed, added to or repealed as set forth in the certificate of incorporation of the Corporation and these Bylaws.

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# WARRANT CERTIFICATE AND AGREEMENT

This WARRANT AGREEMENT (this "*Agreement*"), dated as of January 1, 2018 (the "*Issue Date*"), is among AQUESTIVE PARTNERS, LLC, a Delaware limited liability company (the "*Company*"), and each holder listed on **Schedule A** attached hereto (each, a "*Holder*" and, collectively, the "*Holders*"). Unless otherwise defined herein, capitalized terms have the meanings ascribed thereto in **Section 13** of this Agreement.

#### RECITALS

WHEREAS Aquestive Therapeutics, Inc. (formerly known as MonoSol Rx, LLC) (the "**Borrower**") and each Holder (or one of such Holder's Affiliates) have entered into that certain Credit and Guaranty Agreement, dated as of the August 16, 2016, as amended by Omnibus Amendment No. 1 being executed and delivered as of the date hereof (as the same may be further amended or otherwise modified from time to time, the "**Credit Agreement**"), among the Borrower, as borrower, certain subsidiaries of the Company from time to time parties thereto as guarantors, the Holders and certain other entities, as lenders (the "**Lenders**"), and Perceptive Credit Holdings, LP, a Delaware limited partnership, not in its individual capacity but as administrative agent on behalf of itself and lenders (in such capacity, "**Agent**"); and

WHEREAS, the Borrower requested that the Agent and the Lenders consent to (x) the Borrower converting from a Delaware limited liability company into a Delaware corporation and (y) a contribution by all the Persons (as defined in the Credit Agreement) who own any Equity Interests in the Borrower of their Equity Interests in the Borrower in exchange for equivalent percentage of Equity Interests in the Company, resulting in the Company directly owning 100% of the Equity Interests of the Borrower (collectively, the "*Conversion Transaction*"); and

WHEREAS, as a condition precedent to the Agent's and the Lenders' consent to the Conversion Transaction, the Agent and the Lenders require that Company issue to the Holders warrants (individually a "*Warrant*" and collectively "*Warrants*") that, when taken together, are exercisable into an aggregate number of Senior Common Interests equal to four and one half percent (4.5%) of the aggregate issued and outstanding Membership Interests of the Company, in all cases determined on a fully-diluted basis, subject to the exceptions set forth in this Agreement; and

WHEREAS, in exchange for the execution and delivery of this Agreement and the issuance of the Warrants hereunder, the parties have agreed that the Warrant Certificate and Agreement dated as of August 16, 2016 among the Borrower and each holder listed on Schedule A thereto shall be terminated and the warrant certificate issued in connection therewith shall be delivered by the Agent to the Borrower for cancellation.

NOW, THEREFORE, in consideration of the premises and the mutual agreements herein set forth, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:

# AGREEMENT

Section 1. *Warrant Certificates*. The Company hereby issues the Warrants to the Holders in the amounts set forth opposite the name of each Holder on **Schedule A** attached hereto. Simultaneously upon entering into this Agreement, the Company shall deliver a duly executed certificate (a "*Warrant Certificate*") to each Holder evidencing the Warrant issued to such Holder hereunder. Such Warrant Certificate and any other certificates evidencing a Warrant issued under this Agreement shall be in registered as set forth in **Section 3** below and shall be substantially in the form set forth as **Exhibit A** attached hereto. Each Warrant Certificate shall be dated the Issue Date.

Section 2. *Execution of a Warrant Certificate*. Each Warrant Certificate shall be signed on behalf of the Company by its Manager or an authorized officer of the Company.

Section 3. *Warrant Register*. Upon issuance of each Warrant Certificate the Company shall number and record such Warrant Certificate in a warrant register (the "*Warrant Register*") which the Company shall maintain for so long as any Warrant Certificates remain outstanding. The Warrant Register shall be made available to the Holders, upon request, at reasonable times and intervals during normal business hours. The Company may deem and treat the registered holder(s) of a Warrant Certificate (as set forth in the Warrant Register) as the absolute owner(s) thereof (notwithstanding any notation of ownership or other writing on such certificate made by anyone) for all purposes and shall not be affected by any notice to the contrary, unless in writing from the applicable Holder or its permitted transferee or assign. The Company shall maintain an address for each Holder in the Warrant Register. On the Issue Date, the Warrant Certificates shall be registered initially in the names of each Holder as set forth on Schedule A attached hereto.

Section 4. *Exercise of Warrants.* 

(a) A Warrant may be exercised by a Holder from time to time on any Business Day, in whole or in part, on or prior to August 16, 2023 (the "*Expiration Date*"), upon:

(i) delivery to the Company at its then registered office of an Exercise Certificate in substantially the form attached hereto as **Exhibit B** (each, an "*Exercise Certificate*"), duly executed and completed (including specifying the number or percentage of Senior Common Interests to be purchased and the Aggregate Exercise Price); and

(ii) simultaneously with the delivery of the Exercise Certificate, payment to the Company of the Aggregate Exercise Price in accordance with **Section 4(c)** below; <u>provided</u> that, notwithstanding anything to the contrary herein, in no event shall the Exercise Price with respect to any Senior Common Interest be lower than the par value thereof (or equivalent).

(b) Notwithstanding the foregoing, each Holder shall be deemed to have automatically exercised in full (and not in part) all of its unexercised Warrants outstanding pursuant to any Warrant Certificate on the Business Day immediately preceding the earlier of (i) the Expiration Date (unless prior thereto such Holder has provided written notice to the Company of its election not to exercise), and (ii) the effective date of a Qualified IPO (unless prior thereto an Early Redemption election has been made). In the event of an automatic exercise pursuant to this **Section 4(b)**, no Exercise Certificate shall be required (or any other written or oral notice) to be delivered to any Person, and the Holder shall be deemed to have elected to pay the Aggregate Exercise Price pursuant to the payment option described in **Section 4(c)(ii)** below.

(c) Payment of the Aggregate Exercise Price shall be made, at the option of the Holder as expressed in the Exercise Certificate, by any of the following methods:

(i) by delivery to the Company of a certified or official bank check payable to the order of the Company or by wire transfer of immediately available funds to an account designated in writing by the Company, in the amount of such Aggregate Exercise Price; or

(ii) by instructing the Company to withhold a number of units of Senior Common Interests then issuable upon exercise of this Warrant Certificate with an aggregate Fair Market Value as of the Exercise Date equal to such Aggregate Exercise Price. In the event of any withholding of Senior Common Interests pursuant to **Section 4(c)(ii)** (solely to the extent of such withholding, a "*Cashless Exercise*") where the number of units of Senior Common Interests whose value is equal to the Aggregate Exercise Price is not a whole number, the number of such units withheld by the Company shall be rounded up to the nearest whole unit and the Company shall make a cash payment to the Holder (by delivery of a certified or official bank check or by wire transfer of immediately available funds) based on the incremental fraction of a Senior Common Interest unit being so withheld by the Company in an amount equal to the product of (x) such incremental fraction of a unit being so withheld multiplied by (y) the Fair Market Value per unit of Senior Common Interest as of the Exercise Date.

(d) With respect to any exercise of any Warrant Certificate by its Holder, upon receipt by the Company of an Exercise Certificate and delivery of the Aggregate Exercise Price, the Company shall, within five (5) Business Days, deliver in accordance with the terms hereof to or upon the order of the Holder that number, or percentage of Senior Common Interests for the portion of such Warrant Certificate so exercised on such date, together with cash in lieu of any fraction of a unit, as provided in **Section 4(e)**. If the Senior Common Interests of the Company are issued in certificate form, the Company shall deliver a certificate or certificates, to the extent possible, representing the number of Senior Common Interests as the exercising Holder shall request in the Exercise Certificate. If the Senior Common Interests of the Company are issued in uncertificated form, the Company shall deliver upon request a confirmation evidencing the issuance and registration of such Senior Common Interests in the share register of the Company. Unless otherwise provided herein, a Warrant Certificate shall be deemed to have been exercised, in whole are in part, as the case may be, and Senior Common Interests shall be deemed to have become a holder of record of such Senior Common Interests for all purposes as of the Exercise Date; <u>provided</u> that for purposes of Rule 144 the Holder shall be deemed to be the holder of such Senior Common Interests as of the Issue Date.

(e) The Company shall not be required to issue fractional units of Senior Common Interests upon exercise of any Warrant Certificate. As to any fraction of a Senior Common Interests that the Holder would otherwise be entitled to receive upon such exercise, the Company shall pay to such Holder an amount in cash (by delivery of a certified or official bank check or by wire transfer of immediately available funds) equal to the product of (i) such fraction multiplied by (ii) the Fair Market Value of one Senior Common Interest unit on the Exercise Date.

A Holder shall not be required to physically surrender its Warrant Certificate to the Company until its Warrant Certificate has (f) been exercised in full by the Holder, at which time, the Holder shall, at the written request of the Company, surrender its Warrant Certificate to the Company for cancellation within three (3) Business Days after the date the final Exercise Certificate is delivered to the Company. Partial exercises of a Warrant Certificate resulting in subscriptions of a portion of the total number or percentages of Senior Common Interests available thereunder shall have the effect of lowering the outstanding number and percentage of Senior Common Interests purchasable pursuant to such Warrant Certificate by an amount equal to the applicable number or percentage of Senior Common Interests purchased. The Holder and the Company shall maintain records showing the number and percentage of Senior Common Interests subscribed for and the date of such purchases. The Holder and any assignee, by acceptance of a Warrant Certificate, acknowledge and agree that, by reason of the provisions of this Section 4(f), following the purchase of a portion of the Senior Common Interests thereunder, the number and percentage of Senior Common Interests available for purchase thereunder at any given time may be fewer than the amount stated on the face of such Warrant Certificate. Notwithstanding the foregoing, to the extent that there are unexpired and unexercised Senior Common Interests remaining under any Warrant Certificate, the Holder may request that, upon its surrender to the Company of such Warrant Certificate, the Company (and the Company shall), at the time of delivery of issuance of the Senior Common Interests being issued in accordance with Section 4(d), deliver to the Holder one or more new Warrant Certificates evidencing the rights of the Holder to subscribe for the unexpired and unexercised Senior Common Interests called for by such surrendered Warrant Certificate. Unless otherwise agreed upon by the Holder in its sole discretion, any such new Warrant Certificate shall in all other respects be identical to the surrendered Warrant Certificate.

(g) The Company shall pay all reasonable expenses, Taxes and other charges payable in connection with the preparation, execution and delivery of certificates evidencing Senior Common Interests, if any, pursuant to this **Section 4**, regardless of the name or names in which such certificates shall be registered. Upon exercise by any Holder of its Warrant Certificate, the Company shall take all necessary action to admit such Holder as a Member and holder of Senior Common Interests in accordance with the terms of the Operating Agreement, and such Holder shall execute the Operating Agreement (or a joinder thereto) and become bound by its terms as a Member and holder of Senior Common Interests.

(h) Notwithstanding any other provision of this Agreement, if an exercise of all or any portion of any Warrant or Warrant Certificate is to be made in connection with a Public Offering, any sale of the Company or all sale of or substantially all assets of the Company and its Subsidiaries (pursuant to a merger, sale of stock, sale of assets or otherwise) or any event or transaction described in **Sections 7**, **8 or 11**(c) **hereof**, such exercise may, at the election of the Holder, be conditioned upon the consummation of such event or transaction, in which case such exercise shall not be deemed to be effective until immediately prior to the consummation of such transaction; <u>provided</u> that, with respect to any automatic exercise of any Warrant pursuant to **Section 4(b)** above in connection with a proposed Qualified IPO, the Company and the Holder hereby agree that such automatic conversion is conditioned upon the consummation.

(i) With respect to the exercise of this Warrant Certificate, the Company hereby represents, covenants and agrees:

(i) This Warrant Certificate is, and any Warrant Certificate issued in substitution for or replacement of this Warrant Certificate shall be, upon issuance, duly authorized and validly issued.

(ii) All Senior Common Interests issuable upon the exercise of this Warrant Certificate (or any substitute or replacement Warrant Certificate) pursuant to the terms hereof shall be, upon issuance, and the Company shall take all such actions as may be necessary or appropriate in order that such Senior Common Interests are, validly issued, fully paid, non-assessable and issued without violation of any preemptive or similar rights of any equityholder of the Company, free and clear of all Taxes, Liens and charges.

(iii) The Company shall take all such actions as may be necessary to ensure that all such Senior Common Interests are issued without violation by the Company of any applicable Requirement of Law or Governmental Regulation.

(iv) The Company is a limited liability company duly organized and validly existing under the laws of Delaware and has the capacity and corporate power and authority to enter into this Agreement.

(v) The Company has taken all action required to be taken to authorize the execution, delivery and performance of this Agreement and the Warrant Certificates to be delivered hereunder.

(vi) This Agreement and the Warrant Certificates to be delivered hereunder has been duly executed by the Company.

(vii) The obligations of the Company under this Agreement are legal, valid and binding obligations of the Company, enforceable in accordance with the terms hereof (to the maximum extent permitted by applicable Requirements of Law).

Section 5. *Reservation.* The Company will at all times prior to the Expiration Date reserve and keep available, out of the aggregate of its authorized but unissued Membership Interests, such number of authorized Senior Common Interests solely for the purpose of delivery upon the exercise of the rights represented by the Warrant Certificates, as may at any time be deliverable (based upon the Senior Common Interests and Membership Interests outstanding at any such time) upon the exercise of any Warrant.

#### Section 6. Dilution and Protection Against Dilution; Other Covenants of the Company.

Dilution and Dilution Protection. Each Warrant issued pursuant to this Agreement shall entitle the Holder to purchase Senior (a) Common Interests in the Company representing the percentage of total Membership Interests specified in the related Warrant Certificate. None of such Senior Common Interests to be issued upon exercise of any Warrant shall be subject to any dilution for any reason (including, but not limited to, the conversion of any Equity Interests or other securities of the Company into additional Membership Interests of whatever class or series, the issuance of any Equity Interests or other securities of the Company for any purpose, or the consummation of any transaction or event of the type described in Sections 7, 8 or 11(c) hereof) other than (i) the issuance by the Company after the Issue Date of Senior Common Interests issued to a Holder in connection with the exercise of any Warrant, (ii) the issuance of any Senior Common Interests, Common Interests or Preferred Interests to any director, employee or consultant of the Company pursuant to a Company equity-based compensation plan, arrangement or agreement approved by the Board of Directors of the Company, or (iii) the issuance of any Senior Common Interests, Common Interests or Preferred Interests to a Holder or its Affiliates as additional consideration in connection with any debt financing for the Company involving such Holder or its Affiliates, either directly or through the exercise of any warrant or option agreement (each of the issuances described in clauses (i), (ii) and (iii) above being an "Excluded Issuance"). Any term or provision hereof to the contrary notwithstanding: (A) any Qualified Private Placement of Borrower Equity Interests (as defined in the Omnibus Amendment) that occurs prior to a Qualified IPO Restructuring (as defined in the Omnibus Amendment) shall be deemed to be a dilutive issuance (and not an Excluded Issuance) for the purposes of this Section 6(a), and, upon giving effect to the related Qualified IPO Restructuring, the Holder shall be entitled to the benefits of this Section 6(a) with respect to preserving against dilution its percentage of Equity Interests of the surviving or resulting entity of such Qualified IPO Restructuring issuable upon exercise of this Warrant, as if such deemed dilutive issuance was made by the Company; and (B) in the event that, prior to a Qualified IPO Restructuring, Borrower converts or replaces any of its existing phantom equity compensation plans into or with one or more equity-based compensation plans, arrangements or agreements (each, a "Borrower Equity Compensation Plan") any Equity Interests issued pursuant to any such Borrower Equity Compensation Plan shall be deemed to be a dilutive issuance (and not an Excluded Issuance) for the purposes of this Section 6(a) to the extent (but only to the extent) the aggregate economic value of the Equity Interests of Borrower issued pursuant to all such Borrower Equity Compensation Plans exceeds the aggregate economic impact of Borrower's phantom equity plans in place as of the Issue Date, and in such case and to such extent, upon giving effect to the related Qualified IPO Restructuring, the Holder shall be entitled to the benefits of this Section 6(a) with respect to preserving against dilution its percentage of Equity Interests of the surviving or resulting entity of such Qualified IPO Restructuring issuable upon exercise of the Warrant, as if such deemed dilutive issuance was made by the Company.

(b) *Member Notices.* In the event the Company's obligations under the Credit Agreement are extinguished prior to the Expiration Date, then, for so long as any Warrant shall remain outstanding through the Expiration Date, the Company shall deliver to each Holder a copy of each notice or other information sent to members or other Persons holding any Membership Interests in the Company.

Section 7. Mergers, Consolidations, Sales. In the case of any consolidation, amalgamation or merger of the Company with another Person, or the sale of all or substantially all of its assets to another Person, or any reorganization or reclassification of the Equity Interests of the Company, then, as a condition of such consolidation, merger, sale, reorganization or reclassification, lawful and adequate provision shall be made whereby the Holder of any Warrant shall thereafter have the right to receive upon the basis and upon the terms and conditions specified herein and in lieu of the Senior Common Interests immediately theretofore purchasable hereunder, such Equity Interests, shares of stock, securities or assets as may (by virtue of such consolidation, amalgamation, merger, sale, reorganization or reclassification) be issued or payable with respect to or in exchange for the Senior Common Interests for which such Warrant is exercisable immediately prior to such event (collectively, "Substitute Interests"), and in any such case appropriate provisions shall be made with respect to the rights and interests of the Holder of such Warrant so that the provisions of this Agreement and the Warrant Certificate applicable to such Warrant shall thereafter be applicable, as nearly as may be, in relation to any Substitute Interests, thereafter deliverable upon exercise of such Warrant. The Company shall not effect any such consolidation, amalgamation, merger or sale, unless prior to or simultaneously with the consummation thereof, the successor entity (if other than the Company) resulting from such consolidation, amalgamation, or merger or the entity purchasing such assets shall assume by written instrument executed and mailed or delivered to the Holder of each Warrant, the obligations set forth in this Section 7, as well as each and every other covenant and condition of this Agreement to be performed and observed by the Company and all the obligations and liabilities hereunder, including (without limitation) Section 6(a) above. The Company shall give written notice to the Holders of any event contemplated by the first sentence of this Section 7 at least thirty days prior to such event. Such notice shall set forth in reasonable detail the terms of any such event. Nothing contained in this Section 7 shall permit a merger, amalgamation, or consolidation or a sale of the assets of the Company otherwise prohibited by the provisions of any other agreement to which the Company and any Holder of a Warrant are a party, including, but not limited to, the Credit Agreement.

Section 8. *Dissolution or Liquidation.* In the event of any proposed distribution of the properties or assets of the Company in connection with a dissolution or liquidation (exclusive, however, of any event or transaction covered by **Section 7**), the Company shall deliver notice thereof to each Holder and shall make no distribution to Members or any other Persons until the expiration of thirty days from the date of mailing of the aforesaid notice and, in any such case, each Holder shall have the right to exercise its purchase rights with respect to its Warrants within sixty days from the date of mailing such notice and all rights herein granted not so exercised within such sixty-day period shall thereafter become null and void.

Section 9. *Certain Rights as a Member.* Except as expressly provided in this Agreement or in the Operating Agreement, no Holder, as such, shall be: (i) entitled to vote, or receive any allocations or distributions on account of, or be deemed the holder of, any Membership Interests or any other Equity Interests of the Company which may at any time be issuable on the exercise hereof for any purpose; (ii) entitled to any of the rights of a Member of the Company or any right to vote upon any matter submitted to the Members at any meeting thereof, or to receive notice of meetings, or to receive allocations, distributions or otherwise, except to the extent such Holder's Warrant Certificate shall have been exercised pursuant to **Section 4** of this Agreement and such Holder shall have executed the Operating Agreement and become bound by its terms as a Member and a holder of Senior Common Interests; or (iii) obligated in respect of any obligations or liabilities of a Member under the Operating Agreement, including (without limitation) any capital contributions or similar obligations of the type described in Section 3.02(b) of the Operating Agreement.

Section 10. *Fully Paid Senior Common Interests; Taxes.* The Company covenants that each Warrant is, and that all Senior Common Interests issued upon exercise of such Warrant, upon payment of the applicable Exercise Price and issue thereof and the Holder of such Warrant having executed the Operating Agreement and becoming bound by its terms as a Member and a holder of Senior Common Interests, will be, validly authorized and issued, fully paid, non-assessable, free of preemptive rights and free from all Taxes and Liens with respect to the issue thereof, except as provided in the Operating Agreement. The Company further covenants and agrees that it will pay when due and payable any and all federal, state and local Taxes (other than income Taxes) which may be payable by the Company in respect of any Warrant or any Senior Common Interests or other Equity Interests or certificates therefor upon the exercise of the Warrant pursuant to the provisions hereof.

#### Section 11. Transferability.

(a) In General. Notwithstanding any provision of the Operating Agreement to the contrary, prior to any Holder's exercise in full of all Warrants issued to such Holder hereunder, upon delivery to the Company by the Holder of a duly executed assignment in substantially the form set forth as **Exhibit C** hereto (the "Assignment"), each Warrant Certificate shall be transferable, in a transaction exempt from the registration provisions of the Securities Act (or any similar federal statute at the time in effect) and any applicable state securities laws, to any Person to whom a Lender could transfer its interest in a Loan under the Credit Agreement in accordance with the provisions of Section 14.05 thereof; <u>provided</u>, that any such assignment or an Affiliate of a Lender, or is receiving such assignment in connection with becoming Lender under the Credit Agreement. The Holder of each Warrant Certificate, by its acceptance thereof, agrees to sell or otherwise transfer such Warrant Certificate and any Senior Common Interest issuable upon exercise thereof in compliance with all applicable Requirements of Law (and, following the exercise of its Warrants, the Operating Agreement as in effect on the date hereof). Upon a permitted assignment of a Warrant Certificate, the original assigned Warrant Certificate shall be surrendered at the principal office of the Company and the Company shall issue one or more new Warrant Certificates as provided in such Assignment.

(b) *Restrictive Legend*. Each Warrant Certificate shall bear on the face thereof a legend substantially in the form set forth on the first page of the form of Warrant Certificate attached hereto as **Exhibit A**.

(c) *Tag Along and Drag Along Rights*. The Company shall deliver to the Holder of each Warrant a copy of any "Drag Along Exercise Notice" or "Sale Notice" (each, as defined in the Operating Agreement as in effect on the date hereof) received by the Company pursuant to Section 6.02 and 6.04 (as applicable) of the Operating Agreement as in effect on the date hereof, following which such Holder shall have the following rights and obligations:

(i) If the Drag Along Right is applicable, the Holder of each Warrant and the Senior Common Interest issuable thereunder shall be subject to the provisions of Section 6.02 of the Operating Agreement as in effect on the date hereof, with such Warrant being deemed exercised effective immediately prior to the closing of the transaction.

(ii) If the Tag Along Right is applicable, the Holder may elect to exercise such Warrants and participate in the sale to the third party as set forth in Section 6.04 of the Operating Agreement by exercising such Warrants and delivering notice in accordance with 6.04 of the Operating Agreement.

(d) *Early Redemption.* Upon the occurrence of a Redemption Event, a Holder may, at its option exercised by delivery of written notice to the Company within thirty (30) days of written notification from the Company of such Redemption Event (a "*Redemption Notice*"), *elect* to terminate its Warrant Certificate (in whole and not in part) and demand a redemption of the then unexercised portion of such Holder's Warrants (an "*Early Redemption*"). Upon any such Holder's election to cause an Early Redemption Amount (determined on the basis of such Holder, in full satisfaction of the Company's obligations hereunder); <u>provided</u> that, to the extent such Holder has timely exercised any of its Warrants in part (and not in whole) prior to its exercise of its Early Redemption election, the Redemption Amount payable to such Holder shall be prorated to reflect the proportionate share of such Holder's Warrants that remain unexercised. The Redemption Amount shall be payable in cash, by wire transfer of immediately available funds to the account of the Holder electing such Early Redemption, within ten (10) Business Days following the date of delivery of the Redemption Notice by the Holder. To the extent the Redemption Amount is not paid in full when due, the unpaid portion thereof shall accrue interest at a rate of 11.75% per annum until paid in full.

Section 12. *Rule 144 Compliance*. At all times after the effectiveness of any Public Offering of the Company's Equity Interests, with a view to making available to the Holders the benefits of Rule 144 under the Securities Act and any other rule or regulation of the SEC that may at any time permit a holder to sell securities of the Company to the public without registration or pursuant to a Registration Statement, the Company shall:

(a) make and keep public information available, as those terms are understood and defined in Rule 144 under the Securities Act;

(b) use reasonable commercial efforts to file with the SEC in a timely manner all reports and other documents required of the Company under the Securities Act and the Exchange Act; and

(c) furnish to the Holder so long as the Holder owns Equity Interests of the Company not covered for sale pursuant to a Registration Statement, promptly upon request, a written statement by the Company as to its compliance with the reporting requirements of Rule 144 under the Securities Act and of the Securities Act and the Exchange Act, a copy of the most recent annual or quarterly report of the Company, and such other reports and documents so filed or furnished by the Company as such holder may reasonably request in connection with the sale of Equity Interests of the Company, without registration.

Section 13. *Definitions*.

(a) Unless otherwise defined herein, capitalized terms used in this Agreement have the meanings ascribed to such terms in the Credit Agreement (as in effect on the date hereof).

(b) The following terms have the following meanings: "*Agent*" has the meaning ascribed thereto in the recitals of this Agreement.

"Agreement" has the meaning ascribed thereto in the introductory paragraph of this Agreement.

*"Aggregate Exercise Price"* means, with respect to any exercise of any Warrant for Senior Common Interests, an amount equal to the product of (i) the number of units of Senior Common Interests in respect of which such Warrant is then being exercised pursuant to **Section 4**, multiplied by (ii) the Exercise Price.

"Assignment" has the meaning ascribed thereto in Section 11(a).

"Board of Directors" means the board of directors (or equivalent governing body) of the Company.

*"Cashless Exercise"* has the meaning ascribed thereto in **Section 4(c)** of this Agreement. *"Common Interest"* has the meaning ascribed thereto in the Operating Agreement. *"Company"* has the meaning ascribed thereto in the introductory paragraph of this Agreement.

"Credit Agreement" has the meaning ascribed thereto in the recitals of this Agreement.

"Drag Along Right" has the meaning ascribed thereto in the Operating Agreement.

"Early Redemption" has the meaning ascribed thereto in Section 11(d).

"Equity Interest" has the meaning ascribed thereto in the Credit Agreement (as in effect on the date hereof).

*"Exchange Act"* means the Securities Exchange Act of 1934, as amended.

*"Exercise Certificate"* has the meaning ascribed thereto in **Section 4(a)(i)** of this Agreement.

"Exercise Price" means a price per unit of Senior Common Interests equal to \$0.01.

"*Expiration Date*" has the meaning ascribed thereto in **Section 4(a)** of this Agreement.

*"Fair Market Value"* means, as of any particular Business Day and with respect to any Membership Interests, the fair market value per unit of any such Membership Interest as determined by the Board of Directors in good faith, subject to **Section 21(b)**.

"Holder" has the meaning ascribed thereto in the introductory paragraph of this Agreement.

"Issue Date" has the meaning ascribed thereto in the introductory paragraph of this Agreement.

"Manager" has the meaning ascribed thereto in the Operating Agreement.

"Member" has the meaning ascribed thereto in the Operating Agreement.

"Membership Interest" has the meaning ascribed thereto in the Operating Agreement.

"Non-Qualified Reorganization" means a Qualified Reorganization (as defined in the Operating Agreement) pursuant to or as a result of which the Holders, after giving effect to the implementation of clauses (a) and (b) of Section 3.05(c)(iv) of the Operating Agreement in connection with such Qualified Reorganization, would fail to hold beneficially and of record Equity Interests of the Company (or its successor, survivor, transferee or assign resulting from such Qualified Reorganization) aggregating at least 4.5% of all issued and outstanding common Equity Interests of such Person, determined on a fully diluted basis, immediately prior to the consummation of the Public Offering contemplated in connection with such Qualified Reorganization.

"Omnibus Amendment" means the Omnibus Amendment No. 1, dated as of the date hereof, among MonoSol Rx, LLC (to be renamed Aquestive Therapeutics, Inc. upon consummation of the Conversion Transaction referred to therein), the Lenders party thereto and Perceptive Credit Holdings, LP, as administrative agent and collateral agent.

"Operating Agreement" means the Limited Liability Company Agreement of Aquestive Partners, LLC, dated as of January 1, 2018, as it may be amended from time to time in accordance with its terms and in accordance with the terms hereof.

*"Redemption Amount"* means, at all times prior to the first anniversary of the Issue Date, \$3,000,000, and at all times on or after the first anniversary of the Issue Date, \$5,000,000.

*"Redemption Event"* means (i) the occurrence of any Non-Qualified Reorganization, (ii) any consolidation, amalgamation or merger of the Company with another Person, or the sale of all or substantially all of the Company's assets or properties to another Person, or any reorganization or reclassification of the Equity Interests of the Company, (iii) any distribution of the properties or assets of the Company in connection with a dissolution or liquidation of the Company, (iv) any transaction or event as a result of which any Holder or any of its Warrants would be subject to Section 6.02 of the Operating Agreement, or (v) any other transaction or event that would require or cause any Warrants to be exercised (or deemed be exercised).

"*Redemption Notice*" has the meaning ascribed thereto in **Section 11(d)**.

"Rule 144" means Rule 144 promulgated under the Securities Act.

"SEC" means the Securities and Exchange Commission or any successor thereto.

"Senior Common Interest" has the meaning ascribed thereto in the Operating Agreement.

"Substitute Interests" has the meaning ascribed thereto in Section 7 of this Agreement.

*"Tag Along Right"* means the right of any Holder to participate in the transfer of Membership Interests of the Company pursuant to the terms and provisions of Section 6.04 of the Operating Agreement.

*"Warrant Certificate"* has the meaning ascribed thereto in **Section 1** of this Agreement and shall include any replacement, alternative or substitute Warrant Certificates delivered pursuant to **Sections 4(1), 11(a)** or **14**.

"Warrant Register" has the meaning ascribed thereto in Section 3 of this Agreement.

"Warrant" has the meaning ascribed thereto in the recitals of this Agreement.

Section 14. No Impairment.

(a) The Company shall not, by way of amendment, waiver, consent or other modification of the Operating Agreement or its bylaws (or equivalent), through any resolution of its Board of Directors, by way of any voting or similar agreement, through any reorganization, transfer of assets, consolidation, merger, dissolution, issue or sale of securities, through any other voluntary action, or otherwise, avoid or seek to avoid the observance or performance of any of the terms to be observed or performed by it under this Agreement, or seek to diminish, impair or adversely affect any rights or benefits of the Holders hereunder, but shall instead at all times in good faith assist in the carrying out of all the provisions of this Agreement, including the taking of all such actions as may reasonably be requested by a Holder in order to protect such Holder's exercise rights and liquidation priority of such Holder, redemption rights, rights against dilution and other rights hereunder, consistent with the tenor and purpose of this Agreement.

(b) Any term or provision of the Operating Agreement to the contrary notwithstanding, the Company shall not, without the prior written consent of the majority of all Holders (determined on a fully diluted basis), (i) alter or change the rights, preferences or privileges of the Senior Common Interests so as to adversely affect the Senior Common Interests or any holder thereof (determined on a fully-diluted basis), or (ii) alter, amend, adopt or repeal any provision of the Operating Agreement or any by-laws (or equivalent), voting agreements or similar arrangements of the Company in a manner that adversely affects the Senior Common Interests or holders of the Senior Common Interests.

(c) Notwithstanding anything to the contrary set forth in this **Section 14**, the Company shall be free at any time to authorize or issue, or obligate itself to issue, any other Equity Interests, other than Disqualified Equity Interests (including any Equity Interests convertible into or exchangeable for any other securities), having a preference over, or being on a parity with, the Senior Common Interests with respect to voting, dividends, redemption, conversion or liquidation; provided, that the preference of the Senior Common Interests over the Common Interests set forth in the Operating Agreement is maintained, subject in any such case to **Section 6** hereof.

Section 15. *Lost, Stolen Warrant Certificates, Etc.* In case any Warrant Certificate shall be mutilated, lost, stolen or destroyed, the Company may issue a new Warrant Certificate of like date, tenor and denomination and deliver the same in exchange and substitution for and upon surrender and cancellation of the mutilated Warrant Certificate, or in lieu of the Warrant Certificate lost, stolen or destroyed, upon receipt of evidence satisfactory to the Company of the loss, theft or destruction of such Warrant Certificate, and with respect to a lost, stolen or destroyed Warrant Certificate, reasonable indemnity or bond with respect thereto, if requested by the Company; in each case, such bond and indemnity to be in form and substance reasonably satisfactory to the Company.

Section 16. *Severability.* Should any part of this Agreement for any reason be declared invalid, such decision shall not affect the validity of any remaining portion, which remaining portion shall remain in force and effect.

Section 17. *Notices.* All communications provided for hereunder shall be in writing and, if to the Holder of any Warrant or Senior Common Interests issued thereunder, delivered or mailed prepaid by registered or certified mail or overnight air courier, or by facsimile communication, in each case addressed to the address of such Holder appearing in the Warrant Register (in the case of the initial Holder of the Warrants evidenced by the Warrant Certificates issued hereunder) or such other address as such Holder or any subsequent Holder of any Warrant evidenced by the Warrant Certificates issued hereunder or any such Senior Common Interests may designate to the Company in writing, and if to the Company, delivered or mailed by registered or certified mail or overnight air courier, or by facsimile communication, in each cased addressed to the address of the Company appearing in the Credit Agreement, or to such other address as the Company may in writing designate to any such Holder; provided that a notice to any Holder of a Warrant or any Senior Common Interests issued hereunder by facsimile communication shall only be effective if confirmed by transmission of a copy thereof by prepaid overnight air courier, or, in either case, as any such Holder may designate to the Company in writing.

Section 18. *GOVERNING LAW.* THIS AGREEMENT SHALL BE GOVERNED BY AND CONSTRUED IN ACCORDANCE WITH THE INTERNAL LAWS OF THE STATE OF NEW YORK.

SUBMISSION TO JURISDICTION; WAIVER OF VENUE; WAIVER OF JURY TRIAL. TO THE MAXIMUM EXTENT Section 19. PERMITTED BY APPLICABLE REQUIREMENTS OF LAW, EACH OF THE PARTIES HERETO IRREVOCABLY AND UNCONDITIONALLY SUBMITS, FOR ITSELF AND ITS PROPERTY, TO THE NONEXCLUSIVE JURISDICTION OF THE COURTS OF THE SUPREME COURT OF THE STATE OF NEW YORK SITTING IN NEW YORK COUNTY IN THE BOROUGH OF MANHATTAN AND OF THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK, AND ANY APPELLATE COURT FROM ANY THEREOF, IN ANY ACTION OR PROCEEDING ARISING OUT OF OR RELATING TO THIS AGREEMENT OR ANY WARRANT CERTIFICATE, OR FOR RECOGNITION OR ENFORCEMENT OF ANY JUDGMENT, AND EACH OF THE PARTIES HERETO IRREVOCABLY AND UNCONDITIONALLY AGREES THAT ALL CLAIMS IN RESPECT OF ANY SUCH ACTION OR PROCEEDING MAY BE HEARD AND DETERMINED IN SUCH STATE COURTS OR, TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE REQUIREMENTS OF LAW, IN SUCH FEDERAL COURTS. TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE REQUIREMENTS OF LAW, EACH OF THE PARTIES HERETO AGREES THAT A FINAL JUDGMENT IN ANY SUCH ACTION OR PROCEEDING SHALL BE CONCLUSIVE AND MAY BE ENFORCED IN OTHER JURISDICTIONS BY SUIT ON THE JUDGMENT OR IN ANY OTHER MANNER PROVIDED BY LAW. NOTHING IN THIS AGREEMENT OR IN ANY WARRANT CERTIFICATE SHALL AFFECT ANY RIGHT THAT ANY PARTY HERETO MAY OTHERWISE HAVE TO BRING ANY ACTION OR PROCEEDING RELATING TO THIS AGREEMENT OR ANY WARRANT CERTIFICATE IN THE COURTS OF ANY OTHER JURISDICTION. EACH OF THE PARTIES HERETO IRREVOCABLY AND UNCONDITIONALLY WAIVES, TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAW, ANY OBJECTION THAT IT MAY NOW OR HEREAFTER HAVE TO THE LAYING OF VENUE OF ANY ACTION OR PROCEEDING ARISING OUT OF OR RELATING TO THIS AGREEMENT OR ANY WARRANT CERTIFICATE IN ANY COURT REFERRED TO IN THIS SECTION, EACH OF THE PARTIES HERETO HEREBY IRREVOCABLY WAIVES, TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAW, THE DEFENSE OF AN INCONVENIENT FORUM TO THE MAINTENANCE OF SUCH ACTION OR PROCEEDING IN ANY SUCH COURT. TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAWS, EACH OF THE PARTIES HERETO H EREBY WAIVES ITS RIGHT TO A JURY TRIAL OF ANY ACTION, CLAIM OR PROCEEDING ARISING OR RELATING TO THIS AGREEMENT, ANY WARRANT CERTIFICATE OR THE TRANSACTIONS CONTEMPLATED BY ANY OF THE FOREGOING.

Section 20. *Captions*. The descriptive headings of the various sections of this Agreement are for convenience only and shall not affect the meaning or construction of the provisions hereof.

Section 21. *Exercise of Remedies; Dispute Resolution, Etc.* 

(a) In the event that the Company shall fail to observe any provision contained in this Agreement or any Warrant Certificate, the Holder of any Warrant issued hereunder may enforce its rights hereunder by suit in equity, by action at law, or by any other appropriate proceedings in aid of the exercise of any power granted in this Agreement and, without limiting the foregoing, such Holder shall be entitled to make application for a decree for specific performance and to such other and further relief as such court may decree.

(b) In the case of any dispute as to the determination of the amount, percentage or number of units of any Senior Common Interests or other Membership Interests issuable upon exercise of any Warrant, the calculation of the Aggregate Exercise Price, the determination of Fair Market Value, the calculation of the Redemption Amount (or any Holder's proportionate share of the Redemption Amount) or any other computation or valuation required to be made hereunder or in connection with any Warrant, in the event the Holder, on the one hand, and the Board of Directors or the Company, on the other hand, are unable to settle such dispute within five (5) Business Days, then either party may elect to submit the disputed matter(s) for resolution by KPMG or another firm as may be mutually agreed upon by the Holder and the Board of Directors. Such firm's determination of such disputed matter(s) shall be binding upon all parties absent demonstrable error, and the Company and the Holder shall each pay one half of the fees and costs of such firm.

Section 22. *Successors and Assigns.* This Agreement shall be binding upon each of the Company and each Holder of a Warrant Certificate and each of their permitted respective successors and assigns.

Section 23. *Amendments.* This Agreement and the Warrant Certificates may only be amended or modified, and any provision hereof may only be waived, by an instrument in writing signed by the Company and agreed or consented to by the Holder.

Section 24. *Survival*. The provisions of this Agreement which by their terms or context are to remain applicable after the exercise of each Warrant shall survive the exercise hereof; *provided* that, following the exercise in full by a Holder of its Warrant pursuant to **Section 4** of this Agreement and such Holder having executed the Operating Agreement and become bound by its terms as a Member and a holder of Senior Common Interests, the provisions of Sections 4, 6, 7, 8 and 11 shall be of no further force and effect with respect to such Holder or the Company.

Section 25. *No Third Party Beneficiaries.* Except as expressly provided herein, there are no third party beneficiaries, expressed or implied, of this Agreement.

Section 26. *Entire Agreement.* This Agreement constitutes the entire agreement of the Company and the Holder (and each of its successors and assigns) with respect to the subject matter hereof, and supersedes all prior oral and written agreements concerning or relating to the subject matter hereof.

[Document continues with signature page.]



IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed by their respective duly authorized representative as of the date first written above.

# AQUESTIVE PARTNERS, LLC

By: /s/ John Maxwell

Name: John Maxwell Title: CFO

[Signature Page to Warrant Certificate and Agreement]

# PERCEPTIVE CREDIT HOLDINGS, LP

# By Perceptive Credit Opportunities GP, LLC, its general partner

By: /s/ Sandeep Dixit Name: Sandeep Dixit Title: Chief Credit Officer

By: /s/ Sam Chawla

Name: Sam Chawla Title: Portfolio Manager

[Signature Page to Warrant Certificate and Agreement]

# SCHEDULE OF HOLDERS

Warrant Holders	Number of Senior Common Interests Issuable Upon Exercise	Percentage of Membership Interests in Company Represented by Senior Common Interests
Perceptive Credit Holdings, LP	11,625,437	4.5%
TOTAL:	100%	

#### FORM OF WARRANT CERTIFICATE

NEITHER THIS WARRANT CERTIFICATE NOR THE SECURITIES UNDERLYING THIS WARRANT CERTIFICATE HAVE BEEN THE SUBJECT OF REGISTRATION UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "SECURITIES ACT"), OR UNDER APPLICABLE STATE SECURITIES LAWS. THIS WARRANT CERTIFICATE HAS BEEN TAKEN BY THE REGISTERED OWNER FOR INVESTMENT PURPOSES ONLY AND NOT WITH A CURRENT VIEW TOWARD RESALE OR DISTRIBUTION HEREOF. THIS WARRANT CERTIFICATE MAY NOT BE TRANSFERRED OR DISPOSED OF TO ANY NON-AFFILIATE OF THE HOLDER WITHOUT AN OPINION OF COUNSEL REASONABLY SATISFACTORY TO THE ISSUER HEREOF THAT SUCH TRANSFER OR DISPOSITION DOES NOT VIOLATE THE SECURITIES ACT, THE RULES AND REGULATIONS THEREUNDER, OR APPLICABLE STATE SECURITIES LAWS. IN CONNECTION WITH COMPLIANCE WITH THE SECURITIES ACT AND APPLICABLE STATE SECURITIES LAWS, NO EXERCISE, TRANSFER OR DISPOSITION OF THIS WARRANT OR THE SECURITIES UNDERLYING THIS WARRANT CERTIFICATE SHALL BE MADE UNLESS THE CONDITIONS SPECIFIED HEREIN ARE SATISFIED.

Warrant Certificate No. \_\_\_\_\_ Issue Date: \_\_\_\_\_ Percentage of Aggregate Membership Interests: \_\_\_\_\_

#### WARRANT CERTIFICATE

Reference is made to that certain Warrant Certificate and Agreement, dated as of January 1, 2018 (as amended or otherwise modified, the "*Warrant Agreement*"), among Aquestive Partners, LLC (the "*Company*") and each holder listed on **Schedule A** of the Warrant Agreement (together with their permitted transferees and assigns, the "*Holders*"). Unless otherwise defined herein, capitalized terms used herein have the meanings ascribed thereto in the Warrant Agreement.

This Warrant Certificate certifies that \_\_\_\_\_\_, or its successors, is the registered holder of a Warrant (the "*Warrant*") entitling such holder to purchase Senior Common Interests of the Company representing \_\_\_\_% of the aggregate issued and outstanding Membership Interests of the Company (determined on a fully-diluted basis as of the date of exercise of the Warrant). Exercise of the Warrant shall be subject to delivery of an Exercise Certificate, at the office of the Company designated for such purpose, but only subject to the conditions set forth herein and in the Warrant Agreement. The number of units of Senior Common Interests issuable upon exercise of the Warrant is subject to anti-dilution protections as set forth in the Warrant Agreement.

The Warrant evidenced by this Warrant Certificate is part of a duly authorized issue of Warrants issued pursuant to the Warrant Agreement, the terms and provisions of which are incorporated herein by reference in and made a part of this instrument and are hereby referred to for a description of the rights, limitation of rights, obligations, duties, and immunities thereunder of the Company and the holders (the words "*holders*" or "*holder*" meaning the registered holders or registered holder) of the Warrant. A copy of the Warrant Agreement may be obtained by the holder hereof upon written request to the Company.

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The Warrant evidenced by this Warrant Certificate shall only be exercisable at the times and subject to the satisfaction of the conditions on exercise set forth in **Section 4** of the Warrant Agreement.

This Warrant Certificate, when surrendered at the office of the Company by the registered holder thereof may be exchanged, in the manner and subject to the limitations provided in the Warrant Agreement, but without payment of any service charge, for another Warrant Certificate or Warrant Certificates of like tenor evidencing one or more Warrants that would allow for the purchase of Senior Common Interests that, in the aggregate, represent the percentage of the aggregate issued and outstanding Membership Interests eligible to be purchased pursuant to this Warrant Certificate immediately prior to such exchange.

The Company may deem and treat the registered holder(s) hereof as the absolute owner(s) of this Warrant Certificate (notwithstanding any notation of ownership or other writing hereon made by anyone), for the purpose of any exercise hereof, of any distribution to the holder(s) hereof, and for all other purposes, and the Company shall not be affected by any notice to the contrary (unless in writing by the registered holder hereof). Exempt as expressly provided in the Warrant Agreement, neither the Warrant nor this Warrant Certificate entitles any holder hereof to any rights of an equity holder of the Company.

IN WITNESS WHEREOF, this Warrant Certificate is duly executed on behalf of \_\_\_\_\_as of the \_\_\_\_\_ day of \_\_\_\_\_, 201\_\_.

AQUESTIVE PARTNERS, LLC

By:

Name: Title:

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## FORM OF EXERCISE CERTIFICATE

## AQUESTIVE PARTNERS, LLC

Reference is made to Warrant Certificate No. [\_\_\_\_\_] (the "*Warrant Certificate*"), issued pursuant to that certain Warrant Certificate and Agreement, dated as of January 1, 2018 (as amended or otherwise modified, the "*Warrant Agreement*"), between AQUESTIVE PARTNERS, LLC and [Name(s) of Holder(s)]. Unless otherwise defined, capitalized terms used herein have the meanings ascribed thereto in the Warrant Agreement.

The undersigned, \_\_\_\_\_\_, pursuant to the provisions of the Warrant Agreement and the Warrant Certificate, hereby elects to purchase [[\_\_\_\_] units of Senior Common Interests][a number of units of Senior Common Interests equal to [\_\_%] of the aggregate issued and outstanding Membership Interests of the Company, determined on a fully-diluted basis as of the date hereof].

The undersigned further elects to make payment of the Aggregate Exercise Price for the Senior Common Interests it is electing to purchase pursuant to this Exercise Certificate by the following method:

(Check all that apply):

	(check if applicable) The undersigned hereby elects to make payment of the Aggregate Exercise Price of [	_ Dollars (\$[	)]
for [([	] Senior Common Interests using the method described in <b>Section 4(c)(i)</b> of the Warrant Agreement.		

(check if applicable) The undersigned hereby elects to make payment of the Aggregate Exercise Price of [[\_\_\_\_\_\_ Dollars (\$[\_\_\_\_\_]] for [([\_\_\_\_\_]] Senior Common Interests using the method described in **Section 4(c)(ii)** of the Warrant Agreement.

\_\_\_\_\_ (check if applicable) The undersigned hereby elects to make payment of the Aggregate Exercise Price of [\_\_\_\_\_\_ Dollars (\$[\_\_\_\_\_]] for [([\_\_\_\_\_])] Senior Common Interests using the method described in **Section 4(c)(iii)** of the Warrant Agreement.

The undersigned hereby directs that the Senior Common Interests being purchased pursuant hereto be registered as follows:

NAME

ADDRESS

**B-1** 

By signing below, the undersigned agrees to become a Member in the Company on the terms and conditions of the Operating Agreement.

Taxpayer ID				
	Signature:			
	Address:			
Dated:				

#### [FORM OF WARRANT ASSIGNMENT]

Dated:

Reference is made to that certain Warrant Certificate and Agreement, dated as of January 1, 2018 (as amended or otherwise modified, the "*Warrant Agreement*"), among Aquestive Partners, LLC (the "*Company*") and each holders listed on **Schedule A** of the Warrant Agreement. Unless otherwise defined herein, capitalized terms used herein have the meanings ascribed thereto in the Warrant Agreement.

The undersigned is the holder (in such capacity, the "**Holder**") of a Warrant Certificate issued by the Company pursuant to the Warrant Agreement, bearing Warrant Certificate No. [\_\_\_] (the "*Warrant Certificate*"), entitling the Holder to purchase a number of units of Senior Common Interests of the Company representing [\_\_\_]% of the aggregate Membership Interests of the Company (determined on a fully-diluted basis).

FOR VALUE RECEIVED, the Holder hereby sells, assigns and transfers to [NAME OF ASSIGNEE] (the "Assignee") the right to acquire [all Senior Common Interests entitled to be purchased upon exercise of the Warrant Certificate [\_\_\_] units of Senior Common Interests entitled to be purchased upon exercise of the Warrant Certificate, representing \_\_% of the aggregate Membership Interests of the Company (determined on a fully-diluted basis)]. In furtherance of the foregoing assignment, the Holder hereby irrevocably instructs the Company to (i) memorialize such assignment on the Warrant Register as required pursuant to Section 3 of the Warrant Agreement, and (ii) pursuant to Section 11(a) of the Warrant Agreement, execute and deliver to the Assignee [and the Holder] [a new Warrant Certificate][new Warrant Certificate] reflecting the foregoing assignment ([each] a "Substitute Warrant Certificate").

The Assignee acknowledges and agrees that its Substitute Warrant Certificate and the Senior Common Interests to be issued upon exercise thereof are being acquired for investment and that the Assignee will not offer, sell or otherwise dispose of its Substitute Warrant Certificate or any Senior Common Interests to be issued upon exercise or conversion thereof, except under circumstances which will not result in a violation of the Securities Act or any applicable state securities laws. The Assignee represents and warrants for the benefit of the Company that the Assignee is an "accredited investor" within the meaning of Rule 501 of Regulation D promulgated under the Securities Act of 1933, as amended.

The Assignee acknowledges and agrees that a restrictive legend shall be applied to the Assignee's Substitute Warrant Certificate substantially consistent with the legend described and referenced in **Section 11(b)** of the Warrant Agreement.

[SIGNATURE PAGE FOLLOWS]

#### C-1

[Name of Holder]

By

Name: Title:

Accepted and agreed,

[NAME OF ASSIGNEE]

By

Name: Title:

C-2

#### INDEMNIFICATION AGREEMENT

This Indemnification Agreement (the "<u>Agreement</u>") is made and entered into this \_\_\_\_\_ day of \_\_\_\_\_, 2018, by and between Aquestive Therapeutics, Inc., a Delaware corporation (the "<u>Company</u>," which term shall include, where appropriate, any Enterprise (as hereinafter defined) controlled directly or indirectly by the Company), and \_\_\_\_\_\_ (the "<u>Indemnitee</u>").

WHEREAS, the Company desires to attract and retain the services of highly qualified individuals, such as Indemnitee, to serve the Company;

WHEREAS, in order to induce Indemnitee to continue to provide services to the Company, the Company wishes to provide for the indemnification of, and advancement of expenses to, Indemnitee to the maximum extent permitted by law;

WHEREAS, the Amended and Restated Certificate of Incorporation (the "<u>Charter</u>") and the Amended and Restated Bylaws (the "<u>Bylaws</u>") of the Company require indemnification of the officers and directors of the Company, and Indemnitee may also be entitled to indemnification pursuant to the General Corporation Law of the State of Delaware (the "<u>DGCL</u>");

WHEREAS, the Charter, the Bylaws and the DGCL expressly provide that the indemnification provisions set forth therein are not exclusive, and thereby contemplate that contracts may be entered into between the Company and members of the board of directors, officers and other persons with respect to indemnification;

WHEREAS, the Board of Directors of the Company (the "**<u>Board</u>**") has determined that the increased difficulty in attracting and retaining highly qualified persons such as Indemnitee is detrimental to the best interests of the Company's stockholders;

WHEREAS, it is reasonable and prudent for the Company contractually to obligate itself to indemnify, and to advance expenses on behalf of, such persons to the fullest extent permitted by applicable law, regardless of any amendment or revocation of the Charter or the Bylaws, so that they will serve or continue to serve the Company free from undue concern that they will not be so indemnified; and

WHEREAS, this Agreement is a supplement to and in furtherance of the indemnification provided in the Charter, the Bylaws and any resolutions adopted pursuant thereto, and shall not be deemed a substitute therefor, nor to diminish or abrogate any rights of Indemnitee thereunder.

NOW, THEREFORE, in consideration of the premises and the covenants contained herein, the Company and Indemnitee do hereby covenant and agree as follows:

1. <u>Services to the Company</u>. Indemnitee agrees to serve as an [officer] [director] of the Company. Indemnitee may at any time and for any reason resign from such position (subject to any other contractual obligation or any obligation imposed by operation of law), in which event the Company shall have no obligation under this Agreement to continue Indemnitee in such position. This Agreement shall not be deemed an employment contract between the Company (or any of its subsidiaries or any Enterprise) and Indemnitee. Indemnitee specifically acknowledges that Indemnitee's employment with the Company (or any of its subsidiaries or any Enterprise), if any, is at will, and the Indemnitee may be discharged at any time for any reason, with or without cause, except as may be otherwise provided in any written employment contract between Indemnitee and the Company (or any of its subsidiaries or any Enterprise), other applicable formal severance policies duly adopted by the Board, or, with respect to service as a director or officer of the Company, by the Certificate of Incorporation, the Company's Bylaws, and the DGCL. The foregoing notwithstanding, this Agreement shall continue in force after Indemnitee has ceased to serve as an [officer] [director] of the Company, as provided in <u>Section 16</u> hereof.

### 2. <u>Definitions</u>

As used in this Agreement:

(a) **"Agent**" means any person who is or was a director, officer, or employee of the Company or a subsidiary of the Company or other person authorized by the Company to act for the Company, to include such person serving in such capacity as a director, officer, employee, fiduciary or other official of another corporation, partnership, limited liability company, joint venture, trust or other enterprise at the request of, for the convenience of, or to represent the interests of the Company or a subsidiary of the Company.

(b) A "**Change in Control**" shall be deemed to occur upon the earliest to occur after the date of this Agreement of any of the following events:

- (i) <u>Acquisition of Stock by Third Party</u>. Any Person (as defined below) is or becomes the Beneficial Owner (as defined below), directly or indirectly, of securities of the Company representing fifty percent (50%) or more of the combined voting power of the Company's then outstanding securities unless the change in relative Beneficial Ownership of the Company's securities by any Person results solely from a reduction in the aggregate number of outstanding shares of securities entitled to vote generally in the election of directors;
- (ii) <u>Change in Board of Directors</u>. During any period of two (2) consecutive years (not including any period prior to the execution of this Agreement), individuals who at the beginning of such period constitute the Board, and any new director (other than a director designated by a person who has entered into an agreement with the Company to effect a transaction described in <u>Sections 2(b)(i)</u>, <u>2(b)(iii)</u> or <u>2(b)(iv)</u>) whose election by the Board or nomination for election by the Company's stockholders was approved by a vote of at least two-thirds of the directors then still in office who either were directors at the beginning of the period or whose election or nomination for election was previously so approved, cease for any reason to constitute at least a majority of the members of the Board;
- (iii) <u>Corporate Transactions</u>. The effective date of a merger or consolidation of the Company with any other entity, other than a merger or consolidation which would result in the voting securities of the Company outstanding immediately prior to such merger or consolidation continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity or its ultimate parent, as applicable) more than fifty percent (50%) of the combined voting power of the voting securities of the surviving entity outstanding immediately after such merger or consolidation and with the power to elect at least a majority of the board of directors or other governing body of such surviving entity or its ultimate parent, as applicable;
- (iv) <u>Liquidation</u>. The approval by the stockholders of the Company of a complete liquidation of the Company or an agreement for the sale or disposition by the Company of all or substantially all of the Company's assets; and
- (v) <u>Other Events</u>. There occurs any other event of a nature that would be required to be reported in response to Item 6(e) of Schedule 14A of Regulation 14A (or a response to any similar item on any similar schedule or form) promulgated under the Exchange Act (as defined below), whether or not the Company is then subject to such reporting requirement.

For purposes of this <u>Section 2(b)</u>, the following terms shall have the following meanings:

(A) "Exchange Act" shall mean the Securities Exchange Act of 1934, as amended from time to time.

(B) "**Person**" shall have the meaning as set forth in Sections 13(d) and 14(d) of the Exchange Act; provided, however, that Person shall exclude (i) the Company, (ii) any trustee or other fiduciary holding securities under an employee benefit plan of the Company, and (iii) any corporation owned, directly or indirectly, by the stockholders of the Company in substantially the same proportions as their ownership of stock of the Company.

(C) "**Beneficial Owner**" shall have the meaning given to such term in Rule 13d-3 under the Exchange Act; provided, however, that Beneficial Owner shall exclude any Person otherwise becoming a Beneficial Owner by reason of the stockholders of the Company approving a merger of the Company with another entity.

(c) "Corporate Status" describes the status of a person who is or was a director, officer, employee or agent of the Company or of any other corporation, limited liability company, partnership or joint venture, trust or other enterprise which such person is or was serving at the request of the Company.

(d) "<u>Disinterested Director</u>" shall mean a director of the Company who is not and was not a party to the Proceeding in respect of which indemnification is sought by Indemnitee.

(e) "<u>Enterprise</u>" shall mean the Company and any other corporation, limited liability company, partnership, joint venture, trust or other enterprise of which Indemnitee is or was serving at the request of the Company as a director, officer, trustee, partner, managing member, employee, agent or fiduciary.

(f) "Expenses" shall include all reasonable attorneys' fees, retainers, court costs, transcript costs, fees of experts and other professionals, witness fees, travel expenses, duplicating costs, printing and binding costs, telephone charges, postage, delivery service fees, any federal, state, local or foreign taxes imposed on Indemnitee as a result of the actual or deemed receipt of any payments under this Agreement, ERISA excise taxes and penalties, and all other disbursements or expenses of the types customarily incurred in connection with prosecuting, defending, preparing to prosecute or defend, investigating, being or preparing to be a witness in, or otherwise participating in, a Proceeding. Expenses also shall include: (i) Expenses incurred in connection with any appeal resulting from any Proceeding, including without limitation the premium, security for, and other costs relating to any cost bond, supersedeas bond, or other appeal bond or its equivalent, and (ii) for purposes of <u>Section 14(d)</u> only, Expenses incurred by Indemnitee in connection with the interpretation, enforcement or defense of Indemnitee's rights under this Agreement, by litigation or otherwise. The parties agree that for the purposes of any advancement of Expenses for which Indemnitee has made written demand to the Company in accordance with this Agreement, all Expenses included in such demand that are certified by affidavit of Indemnitee's counsel as being reasonable shall be presumed conclusively to be reasonable. Expenses, however, shall not include amounts paid in settlement by Indemnitee or the amount of judgments or fines against Indemnitee.

(g) "Independent Counsel" shall mean a law firm, or a member of a law firm, that is experienced in matters of corporation law and neither presently is, nor in the past five years has been, retained to represent: (i) the Company or Indemnitee in any matter material to either such party (other than with respect to matters concerning the Indemnitee under this Agreement, or of other indemnitees under similar indemnification agreements), or (ii) any other party to the Proceeding giving rise to a claim for indemnification hereunder. Notwithstanding the foregoing, the term "Independent Counsel" shall not include any person who, under the applicable standards of professional conduct then prevailing, would have a conflict of interest in representing either the Company or Indemnitee in an action to determine Indemnitee's rights under this Agreement. The Company agrees to pay the reasonable fees and expenses of the Independent Counsel referred to above and to fully indemnify such counsel against any and all Expenses, claims, liabilities and damages arising out of or relating to this Agreement or its engagement pursuant hereto.

(h) The term "**Proceeding**" shall include any threatened, pending or completed action, suit, claim, counterclaim, cross claim, arbitration, mediation, alternate dispute resolution mechanism, investigation, inquiry, administrative hearing or any other actual, threatened or completed proceeding, whether brought in the right of the Company or otherwise and whether of a civil, criminal, administrative, legislative, or investigative (formal or informal) nature, including any appeal therefrom, in which Indemnitee was, is or will be involved as a party, potential party, non-party witness or otherwise by reason of the fact that Indemnitee is or was a director or officer of the Company, by reason of any action taken by him (or a failure to take action by him) or of any action (or failure to act) on his part while acting pursuant to his Corporate Status, in each case whether or not serving in such capacity at the time any liability or Expense is incurred for which indemnification, reimbursement, or advancement of Expenses can be provided under this Agreement. If the Indemnitee believes in good faith that a given situation may lead to or culminate in the institution of a Proceeding, this shall be considered a Proceeding under this paragraph.

(i) Reference to "other enterprise" shall include employee benefit plans; references to "fines" shall include any excise tax assessed with respect to any employee benefit plan; references to "serving at the request of the Company" shall include any service as a director, officer, employee or agent of the Company which imposes duties on, or involves services by, such director, officer, employee or agent with respect to an employee benefit plan, its participants or beneficiaries; and a person who acted in good faith and in a manner he reasonably believed to be in the best interests of the participants and beneficiaries of an employee benefit plan shall be deemed to have acted in manner "not opposed to the best interests of the Company" as referred to in this Agreement.

3. Indemnity in Third-Party Proceedings. The Company shall indemnify Indemnitee in accordance with the provisions of this Section 3 if Indemnitee is, or is threatened to be made, a party to or a participant in any Proceeding, other than a Proceeding by or in the right of the Company to procure a judgment in its favor. Pursuant to this Section 3, Indemnitee shall be indemnified to the fullest extent permitted by applicable law against all Expenses, judgments, fines and amounts paid in settlement (including all interest, assessments and other charges paid or payable in connection with or in respect of such Expenses, judgments, fines and amounts paid in settlement) actually and reasonably incurred by Indemnitee or on his behalf in connection with such Proceeding or any claim, issue or matter therein, if Indemnitee acted in good faith and in a manner he reasonably believed to be in or not opposed to the best interests of the Company and, in the case of a criminal Proceeding had no reasonable cause to believe that his conduct was unlawful. The parties hereto intend that this Agreement shall provide to the fullest extent permitted by law for indemnification in excess of that expressly permitted by statute, including, without limitation, any indemnification provided by the Certificate of Incorporation, the Bylaws, vote of its stockholders or disinterested directors or applicable law.

4. Indemnity in Proceedings by or in the Right of the Company. The Company shall indemnify Indemnitee in accordance with the provisions of this Section 4 if Indemnitee is, or is threatened to be made, a party to or a participant in any Proceeding by or in the right of the Company to procure a judgment in its favor. Pursuant to this Section 4, Indemnitee shall be indemnified to the fullest extent permitted by applicable law against all Expenses actually and reasonably incurred by him or on his behalf in connection with such Proceeding or any claim, issue or matter therein, if Indemnitee acted in good faith and in a manner he reasonably believed to be in or not opposed to the best interests of the Company. No indemnification for Expenses shall be made under this Section 4 in respect of any claim, issue or matter as to which Indemnitee shall have been finally adjudged by a court to be liable to the Company, unless and only to the extent that the Delaware Court (as hereinafter defined) or any court in which the Proceeding was brought shall determine upon application that, despite the adjudication of liability but in view of all the circumstances of the case, Indemnitee is fairly and reasonably entitled to indemnification.

5. <u>Indemnification for Expenses of a Party Who is Wholly or Partly Successful</u>. Notwithstanding any other provisions of this Agreement, to the fullest extent permitted by applicable law and to the extent that Indemnitee is a party to (or a participant in) and is successful, on the merits or otherwise, in any Proceeding or in defense of any claim, issue or matter therein, in whole or in part, the Company shall indemnify Indemnitee against all Expenses actually and reasonably incurred by him in connection therewith. If Indemnitee is not wholly successful in such Proceeding but is successful, on the merits or otherwise, as to one or more but less than all claims, issues or matters in such Proceeding, the Company shall indemnify Indemnitee against all Expenses actually and reasonably incurred by him or on his behalf in connection with or related to each successfully resolved claim, issue or matter to the fullest extent permitted by law. For purposes of this Section and without limitation, the termination of any claim, issue or matter in such a Proceeding by dismissal, with or without prejudice, shall be deemed to be a successful result as to such claim, issue or matter.

6. <u>Indemnification For Expenses of a Witness</u>. Notwithstanding any other provision of this Agreement, to the fullest extent permitted by applicable law and to the extent that Indemnitee is, by reason of his Corporate Status, a witness or otherwise asked to participate in any Proceeding to which Indemnitee is not a party, he shall be indemnified against all Expenses actually and reasonably incurred by him or on his behalf in connection therewith.

7. <u>Partial Indemnification</u>. If Indemnitee is entitled under any provision of this Agreement to indemnification by the Company for some or a portion of Expenses, but not, however, for the total amount thereof, the Company shall nevertheless indemnify Indemnitee for the portion thereof to which Indemnitee is entitled.

## 8. <u>Additional Indemnification</u>.

(a) Notwithstanding any limitation in <u>Sections 3</u>, 4, or <u>5</u>, the Company shall indemnify Indemnitee to the fullest extent permitted by applicable law if Indemnitee is a party to or threatened to be made a party to any Proceeding (including a Proceeding by or in the right of the Company to procure a judgment in its favor) against all Expenses, judgments, fines and amounts paid in settlement (including all interest, assessments and other charges paid or payable in connection with or in respect of such Expenses, judgments, fines and amounts paid in settlement) actually and reasonably incurred by Indemnitee in connection with the Proceeding.

limited to:

(b)

- For purposes of Section 8(a), the meaning of the phrase "to the fullest extent permitted by applicable law" shall include, but not be
- (i) to the fullest extent permitted by the provision of the DGCL that authorizes or contemplates additional indemnification by agreement, or the corresponding provision of any amendment to or replacement of the DGCL, and
- (ii) to the fullest extent authorized or permitted by any amendments to or replacements of the DGCL adopted after the date of this Agreement that increase the extent to which a corporation may indemnify its officers and directors.

9. <u>Exclusions</u>. Notwithstanding any provision in this Agreement, the Company shall not be obligated under this Agreement to make any indemnification payment in connection with any claim made against Indemnitee:

(a) for which payment has actually been made to or on behalf of Indemnitee under any insurance policy or other indemnity provision, except with respect to any excess beyond the amount paid under any insurance policy or other indemnity provision; or

(b) for (i) an accounting of profits made from the purchase and sale (or sale and purchase) by Indemnitee of securities of the Company within the meaning of Section 16(b) of the Exchange Act (as defined in <u>Section 2(b)</u> hereof) or similar provisions of state statutory law or common law, or (ii) any reimbursement of the Company by the Indemnitee of any bonus or other incentive-based or equity-based compensation or of any profits realized by the Indemnitee from the sale of securities of the Company, as required in each case under the Exchange Act (including any such reimbursements that arise from an accounting restatement of the Company pursuant to Section 304 of the Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act"), or the payment to the Company of profits arising from the purchase and sale by Indemnitee of securities in violation of Section 306 of the Sarbanes-Oxley Act); or

(c) except as provided in <u>Section 14(d)</u> of this Agreement, in connection with any Proceeding (or any part of any Proceeding) initiated by Indemnitee, including any Proceeding (or any part of any Proceeding) initiated by Indemnitee against the Company or its directors, officers, employees or other indemnities, unless (i) the Board authorized the Proceeding (or any part of any Proceeding) prior to its initiation or (ii) the Company provides the indemnification, in its sole discretion, pursuant to the powers vested in the Company under applicable law.

(d) to provide any indemnification or advancement of expenses that is prohibited by applicable law (as such law exists at the time payment would otherwise be required pursuant to this Agreement).

10. Advances of Expenses. Notwithstanding any provision of this Agreement to the contrary (other than Section 14(d)), the Company shall advance, to the extent not prohibited by law, the Expenses incurred by Indemnitee in connection with any Proceeding (or any part of any Proceeding) not initiated by Indemnitee, and such advancement shall be made within thirty (30) days after the receipt by the Company of a statement or statements requesting such advances from time to time, whether prior to or after final disposition of any Proceeding. Advances shall be unsecured and interest free. Advances shall be made without regard to Indemnitee's ability to repay the Expenses and without regard to Indemnitee's ultimate entitlement to indemnification under the other provisions of this Agreement. In accordance with Section 14(d), advances shall include any and all reasonable Expenses incurred pursuing an action to enforce this right of advancement, including Expenses incurred preparing and forwarding statements to the Company to support the advances claimed. The Indemnitee shall qualify for advances upon the execution and delivery to the Company of this Agreement, which shall constitute an undertaking providing that the Indemnitee undertakes to repay the amounts advanced (without interest) to the extent that it is ultimately determined that Indemnitee is not entitled to be indemnified by the Company. No other form of undertaking shall be required other than the execution of this Agreement. This Section 10 shall not apply to any claim made by Indemnitee for which indemnity is excluded pursuant to Section 9.



#### 11. <u>Procedure for Notification and Defense of Claim</u>

(a) Indemnitee shall notify the Company in writing of any matter with respect to which Indemnitee intends to seek indemnification or advancement of Expenses hereunder as soon as reasonably practicable following the receipt by Indemnitee of written notice thereof. The written notification to the Company shall include a description of the nature of the Proceeding and the facts underlying the Proceeding. To obtain indemnification under this Agreement, Indemnitee shall submit to the Company a written request, including therein or therewith such documentation and information as is reasonably available to Indemnitee and is reasonably necessary to determine whether and to what extent Indemnitee is entitled to indemnification following the final disposition of such Proceeding. The omission by Indemnitee to notify the Company hereunder will not relieve the Company from any liability which it may have to Indemnitee hereunder or otherwise than under this Agreement, and any delay in so notifying the Company shall not constitute a waiver by Indemnitee of any rights under this Agreement. The Secretary of the Company shall, promptly upon receipt of such a request for indemnification, advise the Board in writing that Indemnitee has requested indemnification.

(b) In the event that the Company shall be obligated hereunder to provide indemnification for or make any advancement of Expenses with respect to any Proceeding, the Company shall be entitled to assume the defense of such Proceeding, or any claim, issue or matter therein, with counsel approved by Indemnitee (which approval shall not be unreasonably withheld or delayed) upon the delivery to Indemnitee of written notice of the Company's election to do so. After delivery of such notice, approval of such counsel by Indemnitee and the retention of such counsel by the Company, the Company will not be liable to Indemnitee under this Agreement for any fees or expenses of separate counsel subsequently employed by or on behalf of Indemnitee with respect to the same Proceeding; provided that (i) Indemnitee shall have the right to employ separate counsel in any such Proceeding at Indemnitee's expense and (ii) if (A) the employment of separate counsel by Indemnitee has been previously authorized by the Company, (B) Indemnitee shall have reasonably concluded that there may be a conflict of interest between the Company and Indemnitee in the conduct of such defense, or (C) the Company shall not continue to retain such counsel to defend such Proceeding, then the reasonable fees and expenses actually and reasonably incurred by Indemnitee with respect to his or her separate counsel shall be Expenses hereunder.

(c) In the event that the Company does not assume the defense in a Proceeding pursuant to <u>Section 11(b)</u> above, then the Company will be entitled to participate in the Proceeding at its own expense.

(d) The Company shall not be liable to indemnify Indemnitee under this Agreement for any amounts paid in settlement of any Proceeding effected without its prior written consent (which consent shall not be unreasonably withheld or delayed). The Company shall not, without the prior written consent of Indemnitee (which consent shall not be unreasonably withheld or delayed), enter into any settlement which (i) includes an admission of fault of Indemnitee, any non-monetary remedy imposed on Indemnitee or any monetary damages for which Indemnitee is not wholly and actually indemnified hereunder or (ii) with respect to any Proceeding with respect to which Indemnitee may be or is made a party or may be otherwise entitled to seek indemnification hereunder, does not include the full release of Indemnitee from all liability in respect of such Proceeding.

#### 12. <u>Procedure Upon Application for Indemnification</u>.

Upon written request by Indemnitee for indemnification pursuant to Section 11(a), a determination, if required by applicable law, (a) with respect to Indemnitee's entitlement thereto shall be made in the specific case: (i) if a Change in Control shall have occurred, by Independent Counsel in a written opinion to the Board, a copy of which shall be delivered to Indemnitee; or (ii) if a Change in Control shall not have occurred, (A) by a majority vote of the Disinterested Directors, even though less than a quorum of the Board, (B) by a committee of Disinterested Directors designated by a majority vote of the Disinterested Directors, even though less than a quorum of the Board, (C) if there are no such Disinterested Directors or, if such Disinterested Directors so direct, by Independent Counsel in a written opinion to the Board, a copy of which shall be delivered to Indemnitee or (D) if so directed by the Board, by the stockholders of the Company; and, if it is so determined that Indemnitee is entitled to indemnification, payment to Indemnitee shall be made within ten (10) days after such determination. Indemnitee shall cooperate with the person, persons or entity making such determination with respect to Indemnitee's entitlement to indemnification, including providing to such person, persons or entity upon reasonable advance request any documentation or information which is not privileged or otherwise protected from disclosure and which is reasonably available to Indemnitee and reasonably necessary to such determination. Any costs or Expenses (including attorneys' fees and disbursements) incurred by Indemnitee in so cooperating with the person, persons or entity making such determination shall be borne by the Company (irrespective of the determination as to Indemnitee's entitlement to indemnification) and the Company hereby indemnifies and agrees to hold Indemnitee harmless therefrom. The Company promptly will advise Indemnitee in writing with respect to any determination that Indemnitee is or is not entitled to indemnification, including a description of any reason or basis for which indemnification has been denied.

(b) In the event the determination of entitlement to indemnification is to be made by Independent Counsel pursuant to Section 12(a) hereof, the Independent Counsel shall be selected as provided in this Section 12(b). If a Change in Control shall not have occurred, the Independent Counsel shall be selected by the Board, and the Company shall give written notice to Indemnitee advising him of the identity of the Independent Counsel so selected. If a Change in Control shall have occurred, the Independent Counsel shall be selected by Indemnitee (unless Indemnitee shall request that such selection be made by the Board, in which event the preceding sentence shall apply), and Indemnitee shall give written notice to the Company advising it of the identity of the Independent Counsel so selected. In either event, Indemnitee or the Company, as the case may be, may, within ten (10) days after such written notice of selection shall have been given, deliver to the Company or to Indemnitee, as the case may be, a written objection to such selection; provided, however, that such objection may be asserted only on the ground that the Independent Counsel so selected does not meet the requirements of "Independent Counsel" as defined in Section 2 of this Agreement, and the objection shall set forth with particularity the factual basis of such assertion. Absent a proper and timely objection, the person so selected shall act as Independent Counsel. If such written objection is so made and substantiated, the Independent Counsel so selected may not serve as Independent Counsel unless and until such objection is withdrawn or the Delaware Court has determined that such objection is without merit. If, within twenty (20) days after the later of submission by Indemnitee of a written request for indemnification pursuant to Section 11(a) hereof and the final disposition of the Proceeding, no Independent Counsel shall have been selected and not objected to, either the Company or Indemnitee may petition the Delaware Court for resolution of any objection which shall have been made by the Company or Indemnitee to the other's selection of Independent Counsel and/or for the appointment as Independent Counsel of a person selected by such court or by such other person as such court shall designate, and the person with respect to whom all objections are so resolved or the person so appointed shall act as Independent Counsel under Section 12(a) hereof. Upon the due commencement of any judicial proceeding or arbitration pursuant to Section 14(a) of this Agreement, Independent Counsel shall be discharged and relieved of any further responsibility in such capacity (subject to the applicable standards of professional conduct then prevailing).

#### 13. <u>Presumptions and Effect of Certain Proceedings</u>.

(a) In making a determination with respect to entitlement to indemnification hereunder, the person or persons or entity making such determination shall, to the fullest extent not prohibited by law, presume that Indemnitee is entitled to indemnification under this Agreement if Indemnitee has submitted a request for indemnification in accordance with Section 11(a) of this Agreement, and the Company shall, to the fullest extent not prohibited by law, have the burden of proof to overcome that presumption in connection with the making by any person, persons or entity of any determination contrary to that presumption. Neither the failure of the Company (including by its directors or Independent Counsel) to have made a determination prior to the commencement of any action pursuant to this Agreement that indemnification is proper in the circumstances because Indemnitee has met the applicable standard of conduct, nor an actual determination by the Company (including by its directors or Independent Counsel) that Indemnitee has not met such applicable standard of conduct, shall be a defense to the action or create a presumption that Indemnitee has not met the applicable standard of conduct.

(b) Subject to Section 14(f), if the person, persons or entity empowered or selected under Section 12 of this Agreement to determine whether Indemnitee is entitled to indemnification shall not have made a determination within sixty (60) days after receipt by the Company of the request therefor, the requisite determination of entitlement to indemnification shall, to the fullest extent not prohibited by law, be deemed to have been made and Indemnitee shall be entitled to such indemnification, absent (i) a misstatement by Indemnitee of a material fact, or an omission of a material fact necessary to make Indemnitee's statement not materially misleading, in connection with the request for indemnification, or (ii) a prohibition of such indemnification under applicable law; provided, however, that such 60-day period may be extended for a reasonable time, not to exceed an additional thirty (30) days, if the person, persons or entity making the determination with respect to entitlement to indemnification in good faith requires such additional time for the obtaining or evaluating of documentation and/or information relating thereto; and provided, further, that the foregoing provisions of this <u>Section 13(b)</u> shall not apply (i) if the determination of entitlement to indemnification is to be made by the stockholders pursuant to <u>Section 12(a)</u> of this Agreement and if (A) within fifteen (15) days after receipt by the Company of the request for such determination the Board has resolved to submit such determination to the stockholders for their consideration at an annual meeting thereof to be held within seventy-five (75) days after such receipt and such determination, such meeting is held for such purpose within sixty (60) days after having been so called and such determination is made thereat, or (ii) if the determination of entitlement to indemnification is to be made by Independent Counsel pursuant to <u>Section 12(a)</u> of this Agreement.

(c) The termination of any Proceeding or of any claim, issue or matter therein, by judgment, order, settlement or conviction, or upon a plea of guilty, *nolo contendere* or its equivalent, shall not (except as otherwise expressly provided in this Agreement) of itself adversely affect the right of Indemnitee to indemnification or create a presumption that Indemnitee did not act in good faith and in a manner which he or she reasonably believed to be in or not opposed to the best interests of the Company or, with respect to any criminal Proceeding, that Indemnitee had reasonable cause to believe that his or her conduct was unlawful.

(d) For purposes of any determination of good faith, Indemnitee shall be deemed to have acted in good faith if Indemnitee's action is based on the records or books of account of the Enterprise, including financial statements, or on information supplied to Indemnitee by the directors or officers of the Enterprise in the course of their duties, or on the advice of legal counsel for the Enterprise or on information or records given or reports made to the Enterprise by an independent certified public accountant or by an appraiser or other expert selected with the reasonable care by the Enterprise. The provisions of this Section 13(d) shall not be deemed to be exclusive or to limit in any way the other circumstances in which the Indemnitee may be deemed to have met the applicable standard of conduct set forth in this Agreement.

(e) The knowledge and/or actions, or failure to act, of any director, officer, trustee, partner, managing member, fiduciary, agent or employee of the Enterprise shall not be imputed to Indemnitee for purposes of determining the right to indemnification under this Agreement.

## 14. <u>Remedies of Indemnitee</u>.

(a) Subject to Section 14(e), in the event that (i) a determination is made pursuant to Section 12 of this Agreement that Indemnitee is not entitled to indemnification under this Agreement, (ii) advancement of Expenses is not timely made pursuant to Section 10 of this Agreement, (iii) no determination of entitlement to indemnification shall have been made pursuant to Section 12(a) of this Agreement within ninety (90) days after receipt by the Company of the request for indemnification, (iv) payment of indemnification is not made pursuant to Section 5, 6 or 7 or the last sentence of Section 12(a) of this Agreement within ten (10) days after receipt by the Company of a written request therefor, (v) payment of indemnification, or (vi) in the event that the Company or any other person takes or threatens to take any action to declare this Agreement void or unenforceable, or institutes any litigation or other action or Proceeding designed to deny, or to recover from, the Indemnitee the benefits provided or intended to be provided to the Indemnitee hereunder, Indemnitee shall be entitled to an adjudication by a court of his entitlement to such indemnification or advancement of Expenses. Alternatively, Indemnitee, at his option, may seek an award in arbitration to be conducted by a single arbitrator pursuant to the Commercial Arbitration Rules of the American Arbitration Association. Indemnitee shall commence such proceeding pursuant to this <u>Section 14(a)</u>; provided, however, that the foregoing clause shall not apply in respect of a proceeding brought by Indemnitee to enforce his rights under <u>Section 5</u> of this Agreement. The Company shall not oppose Indemnitee's right to seek any such adjudication or award in arbitration.

(b) In the event that a determination shall have been made pursuant to <u>Section 12(a)</u> of this Agreement that Indemnitee is not entitled to indemnification, any judicial proceeding or arbitration commenced pursuant to this <u>Section 14</u> shall be conducted in all respects as a de novo trial, or arbitration, on the merits and Indemnitee shall not be prejudiced by reason of that adverse determination. In any judicial proceeding or arbitration commenced pursuant to this <u>Section 14</u> shall be conducted in all respects as a de novo trial, or arbitration to this <u>Section 14</u> the Company shall have the burden of proving Indemnitee is not entitled to indemnification or advancement of Expenses, as the case may be.

(c) If a determination shall have been made pursuant to <u>Section 12(a)</u> of this Agreement that Indemnitee is entitled to indemnification, the Company shall be bound by such determination in any judicial proceeding or arbitration commenced pursuant to this <u>Section 14</u>, absent (i) a misstatement by Indemnitee of a material fact, or an omission of a material fact necessary to make Indemnitee's statement not materially misleading, in connection with the request for indemnification, or (ii) a prohibition of such indemnification under applicable law.

(d) The Company shall, to the fullest extent not prohibited by law, be precluded from asserting in any judicial proceeding or arbitration commenced pursuant to this Section 14 that the procedures and presumptions of this Agreement are not valid, binding and enforceable and shall stipulate in any such court or before any such arbitrator that the Company is bound by all the provisions of this Agreement. It is the intent of the Company that, to the fullest extent permitted by law, the Indemnitee not be required to incur legal fees or other Expenses associated with the interpretation, enforcement or defense of Indemnitee's rights under this Agreement by litigation or otherwise because the cost and expense thereof would substantially detract from the benefits intended to be extended to the Indemnitee hereunder. The Company shall, to the fullest extent permitted by law, indemnify Indemnitee against any and all Expenses and, if requested by Indemnitee, shall (within ten (10) days after receipt by the Company of a written request therefor) advance, to the extent not prohibited by law, such Expenses to Indemnitee, which are incurred by Indemnitee in connection with any action brought by Indemnitee for indemnification or advance of Expenses from the Company under this Agreement or under any directors' and officers' liability insurance policies maintained by the Company if, in the case of indemnification, Indemnitee is wholly successful on the underlying claims; if Indemnitee is not wholly successful on the underlying claims, then such indemnification shall be only to the extent Indemnitee is successful on such underlying claims or otherwise as permitted by law, whichever is greater.

(e) Notwithstanding anything in this Agreement to the contrary, no determination as to entitlement of Indemnitee to indemnification under this Agreement shall be required to be made prior to the final disposition of the Proceeding.

## 15. <u>Non-exclusivity; Survival of Rights; Insurance; Subrogation</u>.

(a) The rights of indemnification and to receive advancement of Expenses as provided by this Agreement shall not be deemed exclusive of any other rights to which Indemnitee may at any time be entitled under applicable law, the Certificate of Incorporation, the By-laws, any agreement, a vote of stockholders or a resolution of directors, or otherwise. No amendment, alteration or repeal of this Agreement or of any provision hereof shall limit or restrict any right of Indemnitee under this Agreement in respect of any action taken or omitted by such Indemnitee in his Corporate Status prior to such amendment, alteration or repeal. To the extent that a change in Delaware law, whether by statute or judicial decision, permits greater indemnification or advancement of Expenses than would be afforded currently under the Certificate of Incorporation and this Agreement, it is the intent of the parties hereto that Indemnitee shall enjoy by this Agreement the greater benefits so afforded by such change. No right or remedy herein conferred is intended to be exclusive of any other right or remedy, and every other right and remedy shall be cumulative and in addition to every other right and remedy given hereunder or now or hereafter existing at law or in equity or otherwise. The assertion or employment of any right or remedy hereunder, or otherwise, shall not prevent the concurrent assertion or employment of any right or remedy.

(b) To the extent that the Company maintains an insurance policy or policies providing liability insurance for directors, officers, employees, or agents of the Enterprise, Indemnitee shall be covered by such policy or policies in accordance with its or their terms to the maximum extent of the coverage available for any such director, officer, employee or agent under such policy or policies. If, at the time of the receipt of a notice of a claim pursuant to the terms hereof, the Company has director and officer liability insurance in effect, the Company shall give prompt notice of such claim or of the commencement of a Proceeding, as the case may be, to the insurers in accordance with the procedures set forth in the respective policies. The Company shall thereafter take all necessary or desirable action to cause such insurers to pay, on behalf of the Indemnitee, all amounts payable as a result of such Proceeding in accordance with the terms of such policies.

(c) In the event of any payment under this Agreement, the Company shall be subrogated to the extent of such payment to all of the rights of recovery of Indemnitee, who shall execute all papers required and take all action necessary to secure such rights, including execution of such documents as are necessary to enable the Company to bring suit to enforce such rights.

(d) The Company shall not be liable under this Agreement to make any payment of amounts otherwise indemnifiable (or for which advancement is provided hereunder) hereunder if and to the extent that Indemnitee has otherwise actually received such payment under any insurance policy, contract, agreement or otherwise.

(e) The Company's obligation to indemnify or advance Expenses hereunder to Indemnitee who is or was serving at the request of the Company as a director, officer, trustee, partner, managing member, fiduciary, employee or agent of any other corporation, limited liability company, partnership, joint venture, trust, employee benefit plan or other enterprise shall be reduced by any amount Indemnitee has actually received as indemnification or advancement of Expenses from such other corporation, limited liability company, partnership, joint venture, trust or other enterprise.

16. <u>Duration of Agreement</u>. This Agreement shall continue until and terminate upon the later of: (a) ten (10) years after the date that Indemnitee shall have ceased to serve as a [officer] [director] of the Company or (b) one (1) year after the final termination of any Proceeding then pending in respect of which Indemnitee is granted rights of indemnification or advancement of Expenses hereunder and of any proceeding commenced by Indemnitee pursuant to <u>Section 14</u> of this Agreement relating thereto. The indemnification and advancement of expenses rights provided by or granted pursuant to this Agreement shall be binding upon and be enforceable by the parties hereto and their respective successors and assigns (including any direct or indirect successor by purchase, merger, consolidation or otherwise to all or substantially all of the business or assets of the Company), shall continue as to an Indemnitee who has ceased to be a director, officer, employee or agent of the Company or of any other Enterprise, and shall inure to the benefit of Indemnitee and his or her spouse, assigns, heirs, devisees, executors and administrators and other legal representatives.

17. <u>Severability</u>. If any provision or provisions of this Agreement shall be held to be invalid, illegal or unenforceable for any reason whatsoever: (a) the validity, legality and enforceability of the remaining provisions of this Agreement (including without limitation, each portion of any Section of this Agreement containing any such provision held to be invalid, illegal or unenforceable, that is not itself invalid, illegal or unenforceable) shall not in any way be affected or impaired thereby and shall remain enforceable to the fullest extent permitted by law; (b) such provision or provisions shall be deemed reformed to the extent necessary to conform to applicable law and to give the maximum effect to the intent of the parties hereto; and (c) to the fullest extent possible, the provisions of this Agreement (including, without limitation, each portion of any Section of this Agreement containing any such provision held to be invalid, illegal or unenforceable) shall be doemed reformed to the extent necessary to conform to applicable law and to give the maximum effect to the intent of the parties hereto; and (c) to the fullest extent possible, the provisions of this Agreement (including, without limitation, each portion of any Section of this Agreement containing any such provision held to be invalid, illegal or unenforceable, that is not itself invalid, illegal or unenforceable) shall be construed so as to give effect to the intent manifested thereby.

#### 18. Enforcement.

(a) The Company expressly confirms and agrees that it has entered into this Agreement and assumed the obligations imposed on it hereby in order to induce Indemnitee to serve as a director or officer of the Company, and the Company acknowledges that Indemnitee is relying upon this Agreement in serving as a director or officer of the Company.

(b) This Agreement constitutes the entire agreement between the parties hereto with respect to the subject matter hereof and supersedes and replaces all prior agreements and understandings, oral, written and implied, between the parties hereto with respect to the subject matter hereof, including any indemnification agreement previously entered into between the Company and the Indemnitee; provided, however, that this Agreement is a supplement to and in furtherance of the Certificate of Incorporation, the By-laws and applicable law, and shall not be deemed a substitute therefor, nor to diminish or abrogate any rights of Indemnitee thereunder.

19. <u>Modification and Waiver</u>. No supplement, modification or amendment, or waiver of any provision, of this Agreement shall be binding unless executed in writing by the parties thereto. No waiver of any of the provisions of this Agreement shall be deemed or shall constitute a waiver of any other provisions of this Agreement nor shall any waiver constitute a continuing waiver. No supplement, modification or amendment of this Agreement or of any provision hereof shall limit or restrict any right of Indemnitee under this Agreement in respect of any action taken or omitted by such Indemnitee prior to such supplement, modification or amendment.

20. <u>Notice by Indemnitee</u>. Indemnitee agrees promptly to notify the Company in writing upon being served with any summons, citation, subpoena, complaint, indictment, information or other document relating to any Proceeding or matter which may be subject to indemnification or advancement of Expenses covered hereunder. The failure of Indemnitee to so notify the Company shall not relieve the Company of any obligation which it may have to the Indemnitee under this Agreement or otherwise.

21. <u>Notices</u>. All notices, requests, demands and other communications under this Agreement shall be in writing and shall be deemed to have been duly given if (a) delivered by hand and receipted for by the party to whom said notice or other communication shall have been directed, (b) mailed by certified or registered mail with postage prepaid, on the third business day after the date on which it is so mailed, (c) mailed by reputable overnight courier and receipted for by the party to whom said notice or other communication shall have been directed or (d) sent by facsimile transmission, with receipt of oral confirmation that such transmission has been received:

(a) If to Indemnitee, at the address indicated on the signature page of this Agreement, or such other address as Indemnitee shall provide to the Company.

(b) If to the Company, to:

Aquestive Therapeutics, Inc. 30 Technology Drive Warren, NJ 07059 Attn: Keith Kendall, Chief Executive Officer

or to any other address as may have been furnished to Indemnitee by the Company.

22. <u>Contribution</u>. To the fullest extent permissible under applicable law, if the indemnification provided for in this Agreement is unavailable to Indemnitee for any reason whatsoever, the Company, in lieu of indemnifying Indemnitee, shall contribute to the amount incurred by Indemnitee, whether for judgments, fines, penalties, excise taxes, amounts paid or to be paid in settlement and/or for Expenses, in connection with any claim relating to an indemnifiable event under this Agreement, in such proportion as is deemed fair and reasonable in light of all of the circumstances of such Proceeding in order to reflect (i) the relative benefits received by the Company, on the one hand, and Indemnitee, on the other hand, as a result of the event(s) and/or transaction(s) giving cause to such Proceeding; and/or (ii) the relative fault of the Company (and its other directors, officers, employees and agents), on the one hand, and Indemnitee, on the other hand, in connection with such event(s) and/or transaction(s).

23. <u>Internal Revenue Code Section 409A</u>. The Company intends for this Agreement to comply with the Indemnification exception under Section 1.409A-1(b)(10) of the regulations promulgated under the Internal Revenue Code of 1986, as amended (the "**Code**"), which provides that indemnification of, or the purchase of an insurance policy providing for payments of, all or part of the expenses incurred or damages paid or payable by Indemnitee with respect to a bona fide claim against Indemnitee or the Company do not provide for a deferral of compensation, subject to Section 409A of the Code, where such claim is based on actions or failures to act by Indemnitee in his or her capacity as a service provider of the Company. The parties intend that this Agreement be interpreted and construed with such intent.

24. <u>Applicable Law and Consent to Jurisdiction</u>. This Agreement and the legal relations among the parties shall be governed by, and construed and enforced in accordance with, the laws of the State of Delaware, without regard to its conflict of laws rules. Except with respect to any arbitration commenced by Indemnitee pursuant to <u>Section 14(a)</u> of this Agreement, the Company and Indemnitee hereby irrevocably and unconditionally (i) agree that any action or proceeding arising out of or in connection with this Agreement shall be brought only in the Chancery Court of the State of Delaware (the "Delaware Court"), and not in any other state or federal court in the United States of America or any court in any other country, (ii) consent to submit to the exclusive jurisdiction of the Delaware Court for purposes of any action or proceeding arising out of or in connection with this Agreement, irrevocably RL&F Service Corp., 920 North King Street, 2nd Floor, Wilmington, New Castle County, Delaware 19801 as its agent in the State of Delaware as such party's agent for acceptance of legal process in connection with any such action or proceeding against such party with the same legal force and validity as if served upon such party personally within the State of Delaware, (iv) waive any objection to the laying of venue of any such action or proceeding in the Delaware Court, and (v) waive, and agree not to plead or to make, any claim that any such action or proceeding brought in the Delaware Court has been brought in an improper or inconvenient forum.

25. <u>Headings</u>. The headings of the paragraphs of this Agreement are inserted for convenience only and shall not be deemed to constitute part of this Agreement or to affect the construction thereof.

26. <u>Identical Counterparts</u>. This Agreement may be executed in one or more counterparts, each of which shall for all purposes be deemed to be an original but all of which together shall constitute one and the same Agreement. Only one such counterpart signed by the party against whom enforceability is sought needs to be produced to evidence the existence of this Agreement.

27. <u>Miscellaneous</u>. Use of the masculine pronoun shall be deemed to include usage of the feminine pronoun where appropriate. The headings of this Agreement are inserted for convenience only and shall not be deemed to constitute part of this Agreement or to affect the construction thereof.

## [The remainder of this page is intentionally blank]

IN WITNESS WHEREOF, the parties hereto have executed this Indemnification Agreement as of the day and year first above written.

## AQUESTIVE THERAPEUTICS, INC.

By:

Name: Title:

## INDEMNITEE

Name:

[Signature Page to Aquestive Indemnification Agreement]

Exhibit 10.2

**Execution Version** 

## CREDIT AGREEMENT AND GUARANTY

dated as of

August 16, 2016

between

## MONOSOL RX, LLC as Borrower,

The Subsidiary Guarantors from Time to Time Party Hereto,

The Lenders from Time to Time Party Hereto,

and

**PERCEPTIVE CREDIT HOLDINGS, LP,** as Administrative Agent and Collateral Agent

U.S. \$50,000,000

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#### **CREDIT AGREEMENT AND GUARANTY**

Credit Agreement and Guaranty, dated as of August 16, 2016 (this "*Agreement*"), among MonoSol Rx, LLC, a Delaware limited liability company ("*Borrower*"), the Subsidiary Guarantors from time to time parties hereto, the Lenders from time to time parties hereto and Perceptive Credit Holdings, LP, a Delaware limited partnership, as administrative agent and collateral agent for the Lenders (in such capacity, together with its successors and assigns, "*Administrative Agent*").

#### WITNESSETH:

WHEREAS, Borrower has requested that the Lenders provide a senior secured term loan facility to Borrower in an aggregate principal amount of \$50,000,000 (with up to \$45,000,000 to be available on the Closing Date and up to \$5,000,000 to be available on the Delayed Draw Date, in each case subject to the terms and conditions set forth herein); and

WHEREAS, the Lenders are willing, on the terms and subject to the conditions set forth herein, to extend the Commitment and make the Loans to Borrower.

NOW, THEREFORE, the parties hereto agree as follows:

#### SECTION 1. DEFINITIONS

**1.01** Certain Defined Terms. As used herein, the following terms have the following respective meanings:

"Act" has the meaning set forth in Section 14.17.

"Acquisition" means any transaction, or any series of related transactions, by which any Person directly or indirectly, by means of a take-over bid, tender offer, amalgamation, merger, purchase of assets, or similar transaction having the same effect as any of the foregoing, (i) acquires any business or all or substantially all of the assets of any Person engaged in any business, (ii) acquires control of securities of a Person engaged in a business representing more than 50% of the ordinary voting power for the election of directors or other governing body if the business affairs of such Person are managed by a board of directors or other governing body, or (iii) acquires control of more than 50% of the ownership interest in any Person engaged in any business that is not managed by a board of directors or other governing body.

"Administrative Agent" has the meaning set forth in the introduction hereto.

"Affected Lender" has the meaning set forth in Section 2.07(a).

"Affiliate" means, with respect to a specified Person, another Person that directly, or indirectly through one or more intermediaries, Controls or is Controlled by or is under common Control with the Person specified.

"Agreement" has the meaning set forth in the introduction hereto.

"Applicable Margin" means 9.75%, as may be increased pursuant to Section 3.02(b).

"Asset Sale" has the meaning set forth in Section 9.09.

*"Assignment and Assumption"* means an assignment and assumption entered into by a Lender and an assignee of such Lender substantially in the form of **Exhibit F.** 

"Bailee Letter" means a bailee letter substantially in the form of Exhibit F to the Security Agreement.

"Bankruptcy Code" means Title 11 of the United States Code entitled "Bankruptcy."

"Benefit Plan" means any employee benefit plan as defined in Section 3(3) of ERISA (whether governed by the laws of the United States or otherwise) to which any Obligor or Subsidiary thereof incurs or otherwise has any obligation or liability, contingent or otherwise.

"Borrower" has the meaning set forth in the introduction hereto.

"Borrower Party" has the meaning set forth in Section 14.03(b).

"Borrowing" means, as the context may require, either the borrowing of the Initial Loans on the Closing Date or the borrowing of the Delayed Draw Loans on the Delayed Draw Date.

"Borrowing Date" means, with respect to the Initial Loan, the Closing Date, and with respect to the Delayed Draw Loan, the Delayed Draw Date.

"Borrowing Notice" means a written notice substantially in the form of Exhibit B.

"Business Day" means a day (other than a Saturday or Sunday) on which commercial banks are not authorized or required to close in New York City.

"Calculation Date" has the meaning set forth in Section 10.02.

*"Capital Lease Obligations"* means, as to any Person, the obligations of such Person to pay rent or other amounts under a lease of (or other agreement conveying the right to use) real and/or personal property, which obligations are required to be classified and accounted for as a capital lease on a balance sheet of such Person under GAAP and, for purposes of this Agreement, the amount of such obligations shall be the capitalized amount thereof, determined in accordance with GAAP.

"Casualty Event" means the damage, destruction or condemnation, as the case may be, of property of any Person or any of its Subsidiaries.

*"Change of Control"* means (i) the acquisition of ownership, directly or indirectly, beneficially or of record, by any Person or group of Persons acting jointly or otherwise in concert of Equity Interests representing more than 40% of the aggregate ordinary voting power represented by the issued and outstanding Equity Interests of Borrower, (ii) during any period of 12 consecutive calendar months, the occupation of a majority of the seats (other than vacant seats) on the board of directors of Borrower by Persons who were neither (x) nominated by the board of directors of Borrower, nor (y) appointed by directors so nominated, (iii) the acquisition of direct or indirect Control of Borrower by any Person or group of Persons acting jointly or otherwise in concert; in each case whether as a result of a tender or exchange offer, open market purchases, privately negotiated purchases or otherwise, (iv) the sale, conveyance or disposal of all or substantially all of the property or business of Borrower and its Subsidiaries, taken as a whole or (v) Borrower shall cease to own, directly or indirectly, beneficially and of record, 100% of the issued and outstanding Equity Interests of each of its Subsidiaries, free and clear of all Liens.

*"Claims"* includes claims, demands, complaints, grievances, actions, applications, suits, causes of action, orders, charges, indictments, prosecutions, informations (brought by a public prosecutor without grand jury indictment) or other similar processes, assessments or reassessments.

"Closing Date" means August 16, 2016.

### "Closing Date Certificate" has the meaning set forth in Section 6.01(b).

"Code" means the Internal Revenue Code of 1986, as amended from time to time, and the rules and regulations promulgated thereunder from time to time.

"*Collateral*" means any property in which a Lien is purported to be granted under any of the Security Documents (or all such property, as the context may require).

*"Commitment"* means, with respect to each Lender, the obligation of such Lender to make Loans to Borrower in accordance with the terms and conditions of this Agreement, which commitment is in the amount set forth opposite such Lender's name on **Schedule 1** under the caption "Commitment", as such Schedule may be amended from time to time pursuant to an Assignment and Assumption or otherwise. The aggregate Commitments on the date hereof equal \$50,000,000.

"Commodity Account" is defined in the Security Agreement.

"Compliance Certificate" has the meaning set forth in Section 8.01(d).

"Contracts" means contracts, licenses, leases, agreements, obligations, promises, undertakings, understandings, arrangements, documents, commitments, entitlements or engagements under which a Person has, or will have, any liability or contingent liability (in each case, whether written or oral, express or implied).

"Control" means, in respect of a particular Person, the possession, directly or indirectly, of the power to direct or cause the direction of the management or policies of such Person, whether through the ability to exercise voting power, by contract or otherwise. "Controlling" and "Controlled" have meanings correlative thereto.

"Controlled Account" has the meaning set forth in Section 8.18(a).

"Copyright" is defined in the Security Agreement.

"Default" means any Event of Default and any event that, upon the giving of notice, the lapse of time or both, would constitute an Event of Default.

## "Default Rate" has the meaning set forth in Section 3.02(b).

**"Defaulting Lender"** means, subject to **Section 2.06**, any Lender that (i) has failed to perform any of its funding obligations hereunder, including in respect of its Loans, within three Business Days of the date required to be funded by it hereunder, (ii) has notified Borrower or any Lender that it does not intend to comply with its funding obligations or has made a public statement to that effect with respect to its funding obligations hereunder or under other agreements in which it commits to extend credit, or (iii) has, or has a direct or indirect parent company that has, (x) become the subject of an Insolvency Proceeding, (y) had a receiver, conservator, trustee, administrator, assignee for the benefit of creditors or similar Person charged with reorganization or liquidation of its business or a custodian appointed for it, or (z) taken any action in furtherance of, or indicated its consent to, approval of or acquiescence in any such proceeding or appointment; provided that a Lender shall not be a Defaulting Lender solely by virtue of the ownership or acquisition of any equity interest in that Lender or any direct or indirect parent company thereof by a Governmental Authority.

## "Delayed Draw Certificate" has the meaning set forth in Section 6.02(a).

"Delayed Draw Date" means the date of the making of the Delayed Draw Loan hereunder, which shall be no sooner than the date on which each of the conditions precedent set forth in Section 6.02 shall have been satisfied.

"Delayed Draw Loan" means the term loan made by the Lenders on the Delayed Draw Date in an aggregate principal amount not to exceed \$5,000,000.

"Deposit Account" is defined in the Security Agreement.

"Designated Jurisdiction" means any country or territory to the extent that such country or territory is the subject of any Sanction.

"Disqualified Equity Interests" means, with respect to any Person, any Equity Interest of such Person that, by its terms (or by the terms of any security or other Equity Interest into which it is convertible or for which it is exchangeable), or upon the happening of any event or condition (i) matures or is mandatorily redeemable (other than solely for Qualified Equity Interests), including pursuant to a sinking fund obligation or otherwise, (ii) is redeemable at the option of the holder thereof (other than solely for Qualified Equity Interests), in whole or in part, (iii) provides for the scheduled payments of dividends in cash, or (iv) is or becomes convertible into or exchangeable for Indebtedness or any other Equity Interests that would constitute Disqualified Equity Interests, in each case, prior to the date that is 91 days after all monetary Obligations are satisfied in full in cash.

"Dollars" and "\$" means lawful money of the United States of America.

"Domestic Subsidiary" means any Subsidiary that is a corporation, limited liability company, partnership or similar business entity incorporated, formed or organized under the laws of the United States, any State of the United States or the District of Columbia.

*"Eligible Transferee"* means and includes (i) any commercial bank, (ii) any insurance company, (iii) any finance company, (iv) any financial institution, (v) any investment fund that invests in loans, (vi) with respect to any Lender, any of its Affiliates, and (vii) any other "accredited investor" (as defined in Regulation D of the Securities Act) that is principally in the business of managing investments or holding assets for investment purposes; <u>provided</u>, that an Eligible Transferee shall expressly exclude any of the foregoing that is a competitor of any Obligor.

*"Environmental Law"* means any federal, state, provincial or local governmental law, rule, regulation, order, writ, judgment, injunction or decree relating to pollution or protection of the environment or the treatment, storage, disposal, release, threatened release or handling of hazardous materials, and all local laws and regulations related to environmental matters and any specific agreements entered into with any competent authorities which include commitments related to environmental matters.

*"Equity Interest"* shall mean, with respect to any Person, any and all shares, interests, participations or other equivalents, including membership interests (however designated, and whether voting or nonvoting), of equity of such Person, including, if such Person is a partnership, partnership interests (whether general or limited) and any other interest or participation that confers on another Person the right to receive a share of the profits and losses of, or distributions of property of, such Person, but excluding debt securities convertible or exchangeable into such equity.

*"Equivalent Amount"* means, with respect to an amount denominated in one currency, the amount in another currency that could be purchased by the amount in the first currency determined by reference to the Exchange Rate at the time of determination.

"ERISA" means the United States Employee Retirement Income Security Act of 1974, as amended.

*"ERISA Affiliate"* means, collectively, any Obligor, Subsidiary thereof, and any Person under common control, or treated as a single employer, with any Obligor or Subsidiary thereof, within the meaning of Section 414(b), (c), (m) or (o) of the Code.

"ERISA Event" means (i) a reportable event as defined in Section 4043 of ERISA with respect to a Title IV Plan, excluding, however, such events as to which the PBGC by regulation has waived the requirement of Section 4043(a) of ERISA that it be notified within 30 days of the occurrence of such event; (ii) the applicability of the requirements of Section 4043(b) of ERISA with respect to a contributing sponsor, as defined in Section 4001(a)(13) of ERISA, to any Title IV Plan where an event described in paragraph (9), (10), (11), (12) or (13) of Section 4043(c) of ERISA is reasonably expected to occur with respect to such plan within the following 30 days; (iii) a withdrawal by any Obligor or any ERISA Affiliate thereof from a Title IV Plan or the termination of any Title IV Plan resulting in liability under Sections 4063 or 4064 of ERISA; (iv) the withdrawal of any Obligor or any ERISA Affiliate thereof in a complete or partial withdrawal (within the meaning of Section 4203 and 4205 of ERISA) from any Multiemployer Plan if there is any potential liability therefore, or the receipt by any Obligor or any ERISA Affiliate thereof of notice from any Multiemployer Plan that it is in reorganization or insolvency pursuant to Section 4241 or 4245 of ERISA; (v) the filing of a notice of intent to terminate, the treatment of a plan amendment as a termination under Section 4041 or 4041A of ERISA, or the commencement of proceedings by the PBGC to terminate a Title IV Plan or Multiemployer Plan; (vi) the imposition of liability on any Obligor or any ERISA Affiliate thereof pursuant to Sections 4062(e) or 4069 of ERISA or by reason of the application of Section 4212(c) of ERISA; (vii) the failure by any Obligor or any ERISA Affiliate thereof to make any required contribution to a Plan, or the failure to meet the minimum funding standard of Section 412 of the Code with respect to any Title IV Plan (whether or not waived in accordance with Section 412(c) of the Code) or the failure to make by its due date a required installment under Section 430 of the Code with respect to any Title IV Plan or the failure to make any required contribution to a Multiemployer Plan; (viii) the determination that any Title IV Plan is considered an at-risk plan or a plan in endangered to critical status within the meaning of Sections 430, 431 and 432 of the Code or Sections 303, 304 and 305 of ERISA; (ix) an event or condition which might reasonably be expected to constitute grounds under Section 4042 of ERISA for the termination of, or the appointment of a trustee to administer, any Title IV Plan or Multiemployer Plan; (x) the imposition of any liability under Title I or Title IV of ERISA, other than PBGC premiums due but not delinquent under Section 4007 of ERISA, upon any Obligor or any ERISA Affiliate thereof; (xi) an application for a funding waiver under Section 303 of ERISA or an extension of any amortization period pursuant to Section 412 of the Code with respect to any Title IV Plan; (xii) the occurrence of a non-exempt prohibited transaction under Sections 406 or 407 of ERISA for which any Obligor or any Subsidiary thereof may be directly or indirectly liable; (xiii) a violation of the applicable requirements of Section 404 or 405 of ERISA or the exclusive benefit rule under Section 401(a) of the Code by any fiduciary or disgualified person for which any Obligor or any ERISA Affiliate thereof. may be directly or indirectly liable; (xiv) the occurrence of an act or omission which could give rise to the imposition on any Obligor or any ERISA Affiliate thereof of fines, penalties, taxes or related charges under Chapter 43 of the Code or under Sections 409, 502(c), (i) or (1) or 4071 of ERISA; (xv) the assertion of a material claim (other than routine claims for benefits) against any Plan or the assets thereof, or against any Obligor or any Subsidiary thereof in connection with any such plan; (xvi) receipt from the IRS of notice of the failure of any Qualified Plan to qualify under Section 401(a) of the Code, or the failure of any trust forming part of any Qualified Plan to fail to qualify for exemption from taxation under Section 501(a) of the Code; (xvii) the imposition of any lien (or the fulfillment of the conditions for the imposition of any lien) on any of the rights, properties or assets of any Obligor or any ERISA Affiliate thereof, in either case pursuant to Title I or IV, including Section 302(f) or 303(k) of ERISA or to Section 401(a)(29) or 430(k) of the Code; or (xviii) the establishment or amendment by any Obligor or any Subsidiary thereof of any "welfare plan", as such term is defined in Section 3(1) of ERISA, that provides post-employment welfare benefits in a manner that would increase the liability of any Obligor.

*"ERISA Funding Rules"* means the rules regarding minimum required contributions (including any installment payment thereof) to Title IV Plans, as set forth in Sections 412, 430, 431, 432 and 436 of the Code and Sections 302, 303, 304 and 305 of ERISA.

#### "Event of Default" has the meaning set forth in Section 11.01.

*"Exchange Rate"* means, as of any date, the rate at which any currency may be exchanged into another currency, as set forth on the relevant Reuters screen at or about 11:00 a.m. (Eastern time) on such date. In the event that such rate does not appear on the Reuters screen, the "Exchange Rate" shall be determined by reference to such other publicly available service for displaying exchange rates as may be agreed upon by Borrower and Administrative Agent or, in the absence of such agreement, such Exchange Rate shall instead be determined by Administrative Agent by any reasonable method that it deems applicable to determine such rate, and such determination shall be conclusive absent manifest error.

*"Excluded Taxes"* means any of the following Taxes imposed on or with respect to a Recipient or required to be withheld or deducted from a payment to a Recipient: (i) Taxes imposed on or measured by net income (however denominated), franchise Taxes and branch profits Taxes, in each case imposed as a result of such Recipient being organized under the laws of, or having its principal office or, in the case of any Lender, its applicable lending office located in, the jurisdiction imposing such Tax, (ii) Other Connection Taxes, (iii) U.S. federal withholding Taxes that are imposed on amounts payable to a Lender to the extent that the obligation to withhold amounts existed on the date that such Lender became a "Lender" under this Agreement, except in each case to the extent such Lender is a direct or indirect assignee of any other Lender that was entitled, at the time the assignment of such other Lender became effective, to receive additional amounts under **Section 5.03**,(iv) any Taxes imposed in connection with FATCA, and (v) Taxes attributable to such Recipient's failure to comply with **Section 5.03(e)**.

*"Existing Credit Agreement"* means the Amended and Restated Loan and Security Agreement, dated as of December 18, 2013, among MonoSol Rx, LLC, as Borrower, the subsidiaries of Borrower from time to time party thereto, the entities from time to time party thereto as lenders, and White Oak Global Advisors, LLC, as Agent, as may be amended or otherwise modified.

*"FATCA"* means Sections 1471 through 1474 of the Code, as of the date of this Agreement (or any amended or successor version that is substantively comparable and not more onerous to comply with), any regulations or official interpretations thereof and any agreements entered into pursuant to Section 1471(b)(1) of the Code.

"FD&C Act" means the U.S. Food, Drug and Cosmetic Act of 1938 (or any successor thereto), as amended from time to time, and the rules and regulations promulgated thereunder.

"FDA" means the U.S. Food and Drug Administration and any successor entity.

"Fee Letter" means the Fee Letter Agreement, dated as of the Closing Date, between Borrower and Administrative Agent.

"Foreign Lender" means a Lender that is not a U.S. Person.

"Foreign Subsidiary" means a Subsidiary of Borrower that is not a Domestic Subsidiary or a Permitted Foreign Subsidiary.

*"GAAP"* means generally accepted accounting principles in the United States of America, as in effect from time to time, set forth in the opinions and pronouncements of the Accounting Principles Board and the American Institute of Certified Public Accountants, in the statements and pronouncements of the Financial Accounting Standards Board and in such other statements by such other entity as may be in general use by significant segments of the accounting profession that are applicable to the circumstances as of the date of determination. Subject to **Section 1.02**, all references to "GAAP" shall be to GAAP applied consistently with the principles used in the preparation of the financial statements described in **Section 7.04(a)**.

"Governmental Approval" means any consent, authorization, approval, order, license, franchise, permit, certificate, accreditation, registration, filing or notice, of, issued by, from or to, or other act by or in respect of, any Governmental Authority.

*"Governmental Authority"* means any nation, government, branch of power (whether executive, legislative or judicial), state, province or municipality or other political subdivision thereof and any entity exercising executive, legislative, judicial, monetary, regulatory or administrative functions of or pertaining to government, including without limitation regulatory authorities, governmental departments, agencies, commissions, bureaus, officials, ministers, courts, bodies, boards, tribunals and dispute settlement panels, and other law-, rule- or regulation-making organizations or entities of any State, territory, county, city or other political subdivision of any country, including the United States.

*"Guarantee*" of or by any Person (the *"guarantor"*) means any obligation, contingent or otherwise, of the guarantor guaranteeing or having the economic effect of guaranteeing any Indebtedness or other obligation of any other Person (the *"primary obligor"*) in any manner, whether directly or indirectly, and including any obligation of the guarantor, direct or indirect, (i) to purchase or pay (or advance or supply funds for the purchase or payment of) such Indebtedness or other obligation or to purchase (or to advance or supply funds for the purchase of) any security for the payment thereof, (ii) to purchase or lease property, securities or services for the purpose of assuring the owner of such Indebtedness or other obligation of the guarant condition or liquidity of the primary obligor so as to enable the primary obligor to pay such Indebtedness or other obligation or (iv) as an account party in respect of any letter of credit or letter of guaranty issued to support such Indebtedness or obligation; provided, that the term Guarantee shall not include endorsements for collection or deposit in the ordinary course of business.

*"Guarantee Assumption Agreement"* means a Guarantee Assumption Agreement substantially in the form of **Exhibit A** by an entity that, pursuant to **Section 8.12(a)**, is required to become a "Subsidiary Guarantor."

"Guaranteed Obligations" has the meaning set forth in Section 13.01.

"Hazardous Material" means any substance, element, chemical, compound, product, solid, gas, liquid, waste, by-product, pollutant, contaminant or material which is hazardous or toxic, and includes, without limitation, (i) asbestos, polychlorinated biphenyls and petroleum (including crude oil or any fraction thereof) and (ii) any material classified or regulated as "hazardous" or "toxic" or words of like import pursuant to an Environmental Law.

"Hedging Agreement" means any interest rate exchange agreement, foreign currency exchange agreement, commodity price protection agreement or other interest or currency exchange rate or commodity price hedging arrangement.

*"IND"* means (i) (x) an investigational new drug application (as defined in the FD&C Act) that is required to be filed with the FDA before beginning clinical testing in human subjects, or any successor application or procedure and (y) any similar application or functional equivalent relating to any investigational new drug application applicable to or required by any country, jurisdiction or Governmental Authority other than the U.S. and (ii) all supplements and amendments that may be filed with respect to the foregoing.

"Indebtedness" of any Person means, without duplication, (i) all obligations of such Person for borrowed money or obligations of such Person with respect to deposits or advances of any kind by third parties, (ii) all obligations of such Person evidenced by bonds, debentures, notes or similar instruments, (iii) all obligations of such Person upon which interest charges are customarily paid, (iv) all obligations of such Person under conditional sale or other title retention agreements relating to property acquired by such Person, (v) all obligations of such Person in respect of the deferred purchase price of property or services (excluding current accounts payable incurred in the ordinary course of business), (vi) all Indebtedness of others secured by (or for which the holder of such Indebtedness has an existing right, contingent or otherwise, to be secured by) any Lien on property owned or acquired by such Person, whether or not the Indebtedness secured thereby has been assumed, (vii) all Guarantees by such Person of Indebtedness of others, (viii) all Capital Lease Obligations of such Person, (ix) all obligations, contingent or otherwise, of such Person as an account party in respect of letters of credit and letters of guaranty, (x) obligations under any Hedging Agreement, currency swaps, forwards, futures or derivatives transactions, (xi) all obligations, contingent or otherwise, of such Person in respect of bankers' acceptances, (xii) all obligations of such Person under license or other agreements containing a guaranteed minimum payment or purchase by such Person, (xiii) all other obligations required to be classified as indebtedness of such Person under GAAP, excluding any of the foregoing to the extent comprised of an obligation in respect of a trade payable, a commercial letter of credit supporting one or more trade payables or similar obligations to a trade creditor, in each case in the ordinary course of business and (xiv) any Disgualified Equity Interests. The Indebtedness of any Person shall include the Indebtedness of any other entity (including any partnership in which such Person is a general partner) to the extent such Person is liable therefor as a result of such Person's ownership interest in or other relationship with such entity, except to the extent the terms of such Indebtedness provide that such Person is not liable therefor.

"Indemnified Party" has the meaning set forth in Section 14.03(b).

*"Indemnified Taxes"* means (i) Taxes, other than Excluded Taxes, imposed on or with respect to any payment made by or on account of any Obligation and (ii) to the extent not otherwise described in **clause (i)**, Other Taxes.

"Initial Loan" means the term loan made by the Lenders on the Closing Date in an aggregate principal amount not to exceed \$45,000,000.

*"Insolvency Proceeding"* means (i) any case, action or proceeding before any court or other Governmental Authority relating to bankruptcy, reorganization, insolvency, liquidation, receivership, dissolution, winding-up or relief of debtors, or (ii) any general assignment for the benefit of creditors, composition, marshaling of assets for creditors, or other, similar arrangement in respect of any Person's creditors generally or any substantial portion of such Person's creditors, in each case undertaken under U.S. Federal, state or foreign law, including the Bankruptcy Code.

*"Intellectual Property"* means all Patents, Trademarks, Copyright, and Technical Information, whether registered or not, domestic and foreign. Intellectual Property shall include all:

- (a) applications or registrations relating to such Intellectual Property;
- (b) rights and privileges arising under any Requirement of Law with respect to such Intellectual Property;
- (c) rights to sue for past, present or future infringements of such Intellectual Property; and
- (d) rights of the same or similar effect or nature in any jurisdiction corresponding to such Intellectual Property throughout the world.

"Interest-Only Period" means the period from and including the Closing Date through and including December 31, 2018.

*"Interest Period"* means, with respect to any Borrowing, (i) initially, the period commencing on (and including) the Borrowing Date thereof and ending on (and including) the last Business Day of the calendar month in which such Borrowing was made, and (ii) thereafter, the period beginning on (and including) the first day following the last day of the preceding Interest Period and ending on the earlier of (and including) (x) the last Business Day of the calendar month next following such preceding Interest Period and (y) the Maturity Date.

*"Interest Rate"* means the sum of (i) the Applicable Margin plus (ii) the greater of (x) One-Month LIBOR and (y) 2.00%; provided that if Administrative Agent is at any time unable to determine One-Month LIBOR, One-Month LIBOR shall be deemed to be 2.00%.

"Invention" means any novel, inventive and useful art, apparatus, method, process, machine (including article or device), manufacture or composition of matter, or any novel, inventive and useful improvement in any art, method, process, machine (including article or device), manufacture or composition of matter.

*"Investment"* means, for any Person, any direct or indirect acquisition or investment by such Person, whether by means of (i) the purchase or other acquisition of Equity Interests or other securities of another Person, (ii) a loan, advance or capital contribution to, Guarantee or assumption of debt of, or purchase or other acquisition of any other debt or equity participation or interest in, another Person, including any partnership or joint venture interest in such other Person and any arrangement pursuant to which the investor Guarantees any Indebtedness of such other Person, or (iii) the purchase or other acquisition (in one transaction or a series of transactions) of assets of another Person that constitute a business unit. For purposes of covenant compliance hereunder or under any other Loan Document, the amount of any Investment shall be the amount actually invested, without adjustment for subsequent increases or decreases in the value of such Investment.

"IRS" means the U.S. Internal Revenue Service or any successor agency, and to the extent relevant, the U.S. Department of the Treasury.

*"Key Persons"* means (i) Keith Kendall, in his capacity as Chief Executive Officer of Borrower, and (ii) Mark Schobel, in his capacity as Chief Technology Officer of Borrower.

*"Key Person Event"* means, at any time prior to the occurrence of a Qualified IPO, that any of the following events or circumstances occurs or continues for a period of 60 consecutive days (or such longer period as the Administrative Agent may agree to in its sole discretion): (i) Mr. Kendall has not held the office of Chief Executive Officer and Mr. Schobel has not held the office of Chief Technology Officer, (ii) Mr. Kendall fails to possess the power and authority typically associated with individuals holding the office of Chief Executive Officer at companies similar to Borrower and Mr. Schobel fails to possess the power and authority typically associated with individuals holding the office of Chief Technology Officer at companies similar to Borrower, (iii) both Key Persons fail to be directly and actively involved in the day to day management and direction of Borrower, or (iv) neither Key Person is devoting his full working time and efforts to the business and affairs of Borrower; <u>provided</u> that, for the purposes **of clauses (iii)** and **(iv)** hereof, each Key Person may manage his personal investments and may engage in civic, educational, religious, charitable or other community activities, and may serve as a member of one or more advisory boards or boards of directors of companies or organizations as long as such activities do not pose an actual or apparent conflict of interest and do not materially interfere with such Key Person's performance of his full-time duties as Chief Executive Officer or Chief Technology Officer, as the case may be.

"Landlord Consent" means a landlord consent substantially in the form of Exhibit E to the Security Agreement.

*"Laws"* means, collectively, all international, foreign, federal, state, provincial, territorial, municipal and local statutes, treaties, rules, guidelines, regulations, ordinances, codes and administrative or judicial precedents or authorities, including the interpretation or administration thereof by any Governmental Authority charged with the enforcement, interpretation or administration thereof, and all applicable administrative orders, directed duties, requests, licenses, authorizations and permits of, and agreements with, any Governmental Authority, in each case whether or not having the force of law.

"Lenders" means Perceptive Credit Holdings, LP and each other entity identified under the caption "LENDERS" on the signature pages hereto, as well as any successor entities thereof, and each assignee of any Lender who has executed an Assignment and Assumption pursuant to Section 14.05(b), and "Lender" means any one of them.

"Lien" means any mortgage, lien, pledge, charge or other security interest, or any lease, title retention agreement, mortgage, restriction, easement, right-of-way, option or adverse claim (of ownership or possession) or other encumbrance of any kind or character whatsoever or any preferential arrangement that has the practical effect of creating a security interest.

"LLC Agreement" means Borrower's Fourth Amended and Restated Limited Liability Company Agreement, made and entered into as of August 20, 2015.

"Loans" means the Initial Loan and the Delayed Draw Loan.

*"Loan Documents"* means, collectively, this Agreement, the Notes, the Security Documents, the Warrant Agreement, each Warrant, the Fee Letter and any subordination agreement, intercreditor agreement or other present or future document, instrument, agreement or certificate delivered to Administrative Agent or any Lender in connection with this Agreement or any of the other Loan Documents, in each case, as amended or otherwise modified.

"Loss" means judgments, debts, liabilities, expenses, costs, damages or losses, contingent or otherwise, whether liquidated or unliquidated, matured or unmatured, disputed or undisputed, contractual, legal or equitable, including loss of value, professional fees, including fees and disbursements of legal counsel on a full indemnity basis, and all costs incurred in investigating or pursuing any Claim or any proceeding relating to any Claim.

"*Majority Lenders*" means, at any time, Lenders having at such time in excess of 50% of the aggregate Commitments (or, if such Commitments are terminated, the outstanding principal amount of the Loans) then in effect, ignoring, in such calculation, the Commitments of and outstanding Loans owing to any Defaulting Lender.

*"Manufacturing Revenue"* means, with respect to Borrower, any Obligor or any of their respective Subsidiaries, all revenue generated by such Person as a result of the ordinary course manufacturing and sale of Products that, in accordance with GAAP, would be classified as net revenue, excluding upfront payments, milestones and royalties revenue generated by such Person that are not related to the sale of products or services.

"Margin Stock" means "margin stock" within the meaning of Regulations U and X.

*"Material Adverse Change"* and *"Material Adverse Effect"* mean a material adverse change in or effect on (i) the business, condition (financial or otherwise), operations, performance, property or prospects of Borrower and its Subsidiaries taken as a whole, (ii) the ability of any Obligor to perform its obligations under the Loan Documents, or (iii) the legality, validity, binding effect or enforceability of the Loan Documents or the rights and remedies of Administrative Agent or the Lenders under any of the Loan Documents.

*"Material Agreements"* means (i) the agreements which are listed in **Schedule 7.14**,(ii) all other agreements to which any Obligor is a party or a beneficiary from time to time, the absence or termination of which would reasonably be expected to result in a Material Adverse Effect, and (iii) all agreements and documents directly or indirectly associated with contract manufacturing, distribution of Products and the payment of royalties by the Obligors to third parties, if any.

*"Material Indebtedness"* means, at any time, any Indebtedness of any Obligor, the outstanding principal amount of which, individually or in the aggregate, exceeds \$250,000 (or the Equivalent Amount in other currencies).

*"Material Intellectual Property"* means, the Obligor Intellectual Property described in **Schedule 7.05(c)** and any other Obligor Intellectual Property after the date hereof the loss of which could reasonably be expected to have a Material Adverse Effect.

"Maturity Date" means the fourth anniversary of the Closing Date.

"Membership Interest" has the meaning set forth in the LLC Agreement (as in effect on the date hereof).

*"Multiemployer Plan"* means any multiemployer plan, as defined in Section 400l(a)(3) of ERISA, to which any ERISA Affiliate incurs or otherwise has any obligation or liability, contingent or otherwise.

*"NDA"* means (i) (x) a new drug application (as defined in the FD&C Act) and (y) any similar application or functional equivalent relating to any new drug application applicable to or required by any country, jurisdiction or Governmental Authority other than the United States and (ii) all supplements and amendments that may be filed with respect to the foregoing.

"Non-Consenting Lender" has the meaning set forth in Section 2.07(a).

*"Note"* means a promissory note, in substantially the form attached hereto as **Exhibit C**, executed and delivered by Borrower in accordance with **Section 2.04**.

"NYUCC" means the Uniform Commercial Code as in effect from time to time in the State of New York.

"Obligations" means, with respect to any Obligor, all amounts, obligations, liabilities, covenants and duties of every type and description owing by such Obligor to any Lender, any other indemnitee hereunder or any participant, arising out of, under, or in connection with, any Loan Document, whether direct or indirect (regardless of whether acquired by assignment), absolute or contingent, due or to become due, whether liquidated or not, now existing or hereafter arising and however acquired, and whether or not evidenced by any instrument or for the payment of money, including, without duplication, (i) if such Obligor is Borrower, all Loans, (ii) all interest, whether or not accruing after the filing of any petition in bankruptcy or after the commencement of any insolvency, reorganization or similar proceeding, and whether or not a claim for post-filing or post-petition interest is allowed in any such proceeding, and (iii) all other fees, expenses (including fees, charges and disbursement of counsel), interest, commissions, charges, costs, disbursements, indemnities and reimbursement of amounts paid and other sums chargeable to such Obligor under any Loan Document.

"Obligor Intellectual Property" means Intellectual Property owned by or licensed to any of the Obligors.

"Obligors" means, collectively, Borrower and the Subsidiary Guarantors and their respective successors and permitted assigns.

**"One-Month LIBOR"** means, with respect to any applicable Interest Period hereunder, the one-month London Interbank Offered Rate for deposits in Dollars at approximately 11:00 a.m. (London, England time), as determined by Administrative Agent from the appropriate Bloomberg or Telerate page selected by Administrative Agent (or any successor thereto or similar source reasonably determined by Administrative Agent from time to time), which shall be that one-month London Interbank Offered Rate for deposits in Dollars in effect two Business Days prior to the first day of such Interest Period rounded up to the nearest l/16 of l%. Administrative Agent's determination of interest rates shall be determinative in the absence of manifest error.

"Organic Document" means, for any Person, its certificate of incorporation, by-laws, certificate of partnership, partnership agreement, certificate of formation, limited liability company agreement, operating agreement and all shareholder agreements, voting trusts and similar arrangements applicable to such Person's Equity Interests.

"Other Connection Taxes" means, with respect to any Recipient, Taxes imposed as a result of a present or former connection between such Recipient and the jurisdiction imposing such Tax (other than connections arising from such Recipient having executed, delivered, become a party to, performed its obligations under, received payments under, received or perfected a security interest under, engaged in any other transaction pursuant to or enforced any Loan Document, or sold or assigned an interest in any Loan or Loan Document).

*"Other Taxes"* means all present or future stamp, court or documentary, intangible, recording, filing or similar Taxes that arise from any payment made under, from the execution, delivery, performance, enforcement or registration of, from the receipt or perfection of a security interest under, or otherwise with respect to, any Loan Document, except any such Taxes that are Other Connection Taxes imposed with respect to an assignment (other than an assignment made pursuant to **Section 5.03(g)**).

"Participant" has the meaning set forth in Section 14.05(e).

"Patents" is defined in the Security Agreement.

"Payment Date" means (i) the last day of each Interest Period and (ii) the Maturity Date.

**"PBGC"** means the United States Pension Benefit Guaranty Corporation referred to and defined in ERISA and any successor entity performing similar functions.

*"Permitted Acquisition"* means any acquisition by Borrower or any of its Subsidiaries, whether by purchase, merger or otherwise, of all or substantially all of the assets of, all of the Equity Interests of, or a business line or unit or a division of, any Person; <u>provided</u> that:

(a) immediately prior to, and after giving effect thereto, no Default shall have occurred and be continuing or would result therefrom;

(b) all transactions in connection therewith shall be consummated, in all material respects, in accordance with all Requirements of Law and in conformity with all applicable Governmental Approvals;

(c) in the case of the acquisition of all of the Equity Interests of such Person, all of the Equity Interests (except for any such securities in the nature of directors' qualifying shares required pursuant to any Requirement of Law) acquired, or otherwise issued by such Person or any newly formed Subsidiary of Borrower in connection with such acquisition, shall be owned 100% by an Obligor or any other Subsidiary, and Borrower shall have taken, or caused to be taken, as of the date such Person becomes a Subsidiary of Barrower, each of the actions set forth in **Section 8.12**, if applicable;

(d) such Person (in the case of an acquisition of Equity Interests) or assets (in the case of an acquisition of assets or a division) (i) shall be engaged or used, as the case may be, in the same business or lines of business in which Borrower and/or its Subsidiaries are engaged or (ii) shall have a similar customer base as Borrower and/or its Subsidiaries;

(e) on a *pro forma* basis after giving effect to such acquisition, Borrower and its Subsidiaries shall be in compliance with the financial covenants set forth in **Section 10**; and

(f) such acquisition (i) when taken with together all other acquisitions consummated or effected in the prior l2-month period, does not exceed \$2,000,000 in the aggregate, and (ii) when taken together with all other acquisitions consummated or effected since the Closing Date, does not exceed \$5,000,000 in the aggregate.

*"Permitted Cash Equivalent Investments"* means (i) marketable direct obligations issued or unconditionally guaranteed by the United States or any agency or any State thereof having maturities of not more than two years from the date of acquisition and (ii) commercial paper maturing no more than one year after its creation and having the highest rating from either Standard & Poor's Ratings Group or Moody's Investors Service, Inc.

"Permitted Foreign Subsidiary" means any Subsidiary of Borrower organized under the Laws of the Cayman Islands.

"Permitted Indebtedness" means any Indebtedness permitted under Section 9.01.

"Permitted Liens" means any Liens permitted under Section 9.02.

*"Permitted Priority Liens"* means (i) Liens permitted under Section 9.02(c), (d), (e), (f) or (i), and (ii) Liens permitted under Section 9.02(b); <u>provided</u> that such Liens are also of the type described in Section 9.02(c), (d), (e), (f) or (i).

"Permitted Refinancing" means, with respect to any Indebtedness, any extensions, renewals and replacements of such Indebtedness; provided that such extension, renewal or replacement (i) shall not increase the outstanding principal amount of such Indebtedness, (ii) contains terms relating to outstanding principal amount, amortization, maturity, collateral (if any) and subordination (if any), and other material terms taken as a whole no less favorable in any material respect to Borrower and its Subsidiaries or the Secured Parties than the terms of any agreement or instrument governing such existing Indebtedness, (iii) shall have an applicable yield which does not exceed the yield of the Indebtedness being replaced, (iv) shall not contain any new requirement to grant any lien or security or to give any guarantee that was not an existing requirement of such Indebtedness, and (v) after giving effect to such extension, renewal or replacement, no Default shall have occurred as a result thereof.

*"Person"* means any individual, corporation, company, voluntary association, partnership, limited liability company, joint venture, trust, unincorporated organization or Governmental Authority or other entity of whatever nature.

*"Plan"* means any employee pension benefit plan (other than a Multiemployer Plan) subject to the provisions of Title IV of ERISA or Section 412 of the Code or Section 302 of ERISA, and in respect of which Borrower or any ERISA Affiliate is (or, if such plan were terminated, would under Section 4069 of ERISA be deemed to be) an "employer" as defined in Section 3(5) of ERISA.

*"Prepayment Premium"* means, (i) with respect to any prepayment pursuant to Section 3.03(a) or (b) occurring on or prior to the first anniversary of the Closing Date, an amount equal to 5.00% of the aggregate outstanding principal amount of the Loans being prepaid on such Redemption Date; (ii) with respect to any prepayment pursuant to Section 3.03(a) or (b) occurring after the first anniversary of the Closing Date and on or prior to the second anniversary of the Closing Date, an amount equal to 3.00% of the aggregate outstanding principal amount of the Loans being prepaid on such Redemption Date; (iii) with respect to any prepayment pursuant to Section 3.03(a) or (b) occurring after the second anniversary of the Closing Date and on or prior to the third anniversary of the Closing Date, an amount equal to 2.00% of the aggregate outstanding principal amount of the Loans being prepaid on such Redemption Date; (iii) with respect to any prepayment pursuant to Section 3.03(a) or (b) occurring after the second anniversary of the Closing Date and on or prior to the third anniversary of the Closing Date, an amount equal to 2.00% of the aggregate outstanding principal amount of the Loans being prepaid on such Redemption Date; and (iv) with respect to any prepayment pursuant to Section 3.03(a) or (b) occurring at any time after the third anniversary of the Closing Date, an amount equal to 1.00% of the aggregate outstanding principal amount of the Loans being prepaid on such Redemption Date.

"Products" means Suboxone, Zuplenz, Diazepam, Riluzole, Clobazam or Epinephrine, and each of their respective successors, and any other current or future product developed, manufactured, licensed, marketed, sold or otherwise commercialized by any Obligor, including any such product in development or which may be developed.

"Product Authorizations" means any and all approvals (including applicable supplements, amendments, pre and post approvals, drug master files, governmental price and reimbursement approvals and approvals of applications for regulatory exclusivity), licenses, registrations or authorizations of any Governmental Authority necessary for the manufacture, development, distribution, use, storage, import, export, transport, promotion, marketing, sale or other commercialization of a Product in any country or jurisdiction, including without limitation INDs, NDAs or similar applications.

"Product Development and Commercialization Activities" means, with respect to any Product, any combination of research, development, manufacture, importation, use, sale, storage, design, labeling, marketing, promotion, supply, distribution, testing, packaging, purchasing or other commercialization activities, receipt of payment in respect of any of the foregoing, or like activities the purpose of which is to commercially exploit such Product.

"Prohibited Payment" means any bribe, rebate, payoff, influence payment, kickback or other payment or gift of money or anything of value (including meals or entertainment) to any officer, employee or ceremonial office holder of any government or instrumentality thereof, political party or supra-national organization (such as the United Nations), any political candidate, any royal family member or any other person who is connected or associated personally with any of the foregoing that is prohibited under any Requirement of Law for the purpose of influencing any act or decision of such payee in his official capacity, inducing such payee to do or omit to do any act in violation of his lawful duty, securing any improper advantage or inducing such payee to use his influence with a government or instrumentality thereof to affect or influence any act or decision of such government or instrumentality.

*"Proportionate Share"* means, with respect to any Lender, the percentage obtained by dividing (i) the sum of the Commitment (or, if the Commitments are terminated, the outstanding principal amount of the Loans) of such Lender then in effect by (ii) the sum of the Commitments (or, if the Commitments are terminated, the outstanding principal amount of the Loans) of all Lenders then in effect.

*"Public Offering"* means any sale of Equity Interests of a Person pursuant to an offering that is underwritten on a firm commitment basis by a nationally recognized investment banking firm and, as a result of which, such Person becomes subject to the reporting requirements of Section 13 or Section 15 of the Securities Act immediately following such offering.

"Qualified Equity Interest" means, with respect to any Person, any Equity Interest of such Person that is not a Disqualified Equity Interest.

"Qualified IPO" means Borrower's initial Public Offering of its common Equity Interests, as a result of which such Equity Interests are listed on either the New York Stock Exchange or the NASDAQ National Market.

*"Qualified Plan"* means an employee benefit plan (as defined in Section 3(3) of ERISA) other than a Multiemployer Plan (i) that is or was at any time maintained or sponsored by any Obligor or any ERISA Affiliate thereof or to which any Obligor or any ERISA Affiliate thereof has ever made, or was ever obligated to make, contributions, and (ii) that is intended to be tax qualified under Section 401(a) of the Code.

*"Real Property Security Documents"* means any Landlord Consents, Bailee Letters and any mortgage or deed of trust or any other real property security document executed or required hereunder to be executed by any Obligor and granting a security interest in real property owned or leased (as tenant) by any Obligor in favor of Administrative Agent for the benefit of the Secured Parties.

"Recipient" means any Lender or any other recipient of any payment to be made by or on account of any Obligation.

*"Redemption Date"* has the meaning set forth in Section 3.03(a)(i).

"Redemption Price" has the meaning set forth in Section 3.03(a)(i).

"*Register*" has the meaning set forth in Section 14.05(d).

"Regulation T" means Regulation T of the Board of Governors of the Federal Reserve System, as amended.

"Regulation U" means Regulation U of the Board of Governors of the Federal Reserve System, as amended.

"Regulation X" means Regulation X of the Board of Governors of the Federal Reserve System, as amended.

*"Regulatory Approvals"* means (i) any registrations, licenses, authorizations, permits or approvals issued by any Governmental Authority and applications or submissions related to any of the foregoing and (ii) with respect to any Product, all approvals, clearances, authorizations, orders, exemptions, registrations, certifications, licenses and Permits granted by any Regulatory Authorities, including all NDAs and Product Authorizations held by any Obligor or any of their respective licensors, as applicable, or that are pending before the FDA or equivalent non-U.S. Governmental Entity with respect to the Products.

*"Regulatory Authority"* means any Governmental Authority that is concerned with or has regulatory oversight with respect to the use, control, safety, efficacy, reliability, manufacturing, marketing, distribution, sale or other Product Development and Commercialization Activities relating to any Product of an Obligor, including the FDA and all equivalents of such agencies in other jurisdictions.

## "Related Parties" has the meaning set forth in Section 14.16.

*"Requirement of Law"* means, as to any Person, any statute, law, treaty, rule or regulation or determination, order, injunction or judgment of an arbitrator or a court or other Governmental Authority, in each case applicable to or binding upon such Person or any of its properties or revenues.

*"Responsible Officer"* means (i) with respect to Borrower in connection with any Borrowing Notice, any Compliance Certificate or any other certificate or notice pertaining to any financial information required to be delivered by Borrower hereunder, the chief financial officer, treasurer or controller of Borrower, and (ii) otherwise, with respect to Borrower or any Subsidiary Guarantor, the chief executive officer, president, chief financial officer, treasurer or controller of such Person.

*"Restricted Payment"* means any dividend or other distribution (whether in cash, securities or other property) with respect to any Equity Interest of Borrower or any of its Subsidiaries, or any payment (whether in cash, securities or other property), including any sinking fund or similar deposit, on account of the purchase, redemption, retirement, acquisition, cancellation or termination of any such shares of capital stock of Borrower or any of its Subsidiaries or any option, warrant or other right to acquire any such shares of capital stock of Borrower or any of its Subsidiaries.

*"Restrictive Agreement"* means any indenture, agreement, instrument or other arrangement that prohibits, restricts or imposes any condition upon (i) the ability of Borrower or any Subsidiary to create, incur or permit to exist any Lien upon any of its property or assets (other than (x) customary provisions in Contracts (including without limitation leases and licenses of Intellectual Property) restricting the assignment thereof and (y) restrictions or conditions imposed by any agreement governing secured Permitted Indebtedness permitted under **Section 9.01(g)**, to the extent that such restrictions or conditions apply only to the property or assets securing such Indebtedness), or (i) the ability of any Subsidiary to pay dividends or other distributions with respect to any shares of its capital stock or to make or repay loans or advances to Borrower or any other Subsidiary or to Guarantee Indebtedness of Borrower or any other Subsidiary.

*"Revenue"* of a Person means all receipts received by such Person resulting from the sale or outbound license of Products that, in accordance with GAAP, would be classified as revenue, less all rebates, discounts and other price allowances applicable thereto.

## "Revenue Covenant Cure" has the meaning set forth in Section 10.03.

*"Sanction"* means any international economic sanction administered or enforced by the United States Government (including, without limitation, OFAC), the United Nations Security Council, the European Union or its Member States, Her Majesty's Treasury or other relevant sanctions authority.

"Secured Parties" means the Lenders, Administrative Agent, each other Indemnified Party and any other holder of any Obligation.

"Securities Act" means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

*"Security Agreement"* means the Security Agreement, dated as of the date hereof, among the Obligors and Administrative Agent, granting a security interest in the Obligors' personal property in favor of Administrative Agent, for the benefit of the Secured Parties, and in substantially the form attached hereto as **Exhibit H**.

*"Security Documents"* means, collectively, the Security Agreement, each Short-Form IP Security Agreement, each Real Property Security Document, and each other security document, control agreement or financing statement required or recommended to perfect Liens in favor of the Secured Parties.

"Securities Account" has the meaning set forth in the Security Agreement.

"Senior Common Interest" has the meaning set forth in the LLC Agreement (as in effect on the date hereof).

"Shortfall Default" has the meaning set forth in Section 10.03.

"Short-Form IP Security Agreements" means short-form copyright, patent or trademark (as the case may be) security agreements, dated as of the date hereof and substantially in the form attached as Exhibits B, C, and D to the Security Agreement, entered into by one or more Obligors in favor of Administrative Agent, for the benefit of the Secured Parties, each in form and substance satisfactory to the Majority Lenders (and as amended, modified or replaced from time to time).

"Solvent" means, with respect to any Person at any time, that (i) the present fair saleable value of the property of such Person is greater than the total amount of liabilities (including contingent liabilities) of such Person, (ii) the present fair saleable value of the property of such Person is not less than the amount that will be required to pay the probable liability of such Person on its debts as they become absolute and matured, (iii) such Person has not incurred and does not intend to, and does not believe that it will, incur debts or liabilities beyond such Person's ability to pay as such debts and liabilities mature and (iv) such Person would be able to obtain a letter from its auditors that did not contain a going concern qualification.

"Subsidiary" means, with respect to any Person (the "parent") at any date, any corporation, limited liability company, partnership, association or other entity the accounts of which would be consolidated with those of the parent in the parent's consolidated financial statements if such financial statements were prepared in accordance with GAAP as of such date, as well as any other corporation, limited liability company, partnership, association or other entity (i) of which securities or other ownership interests representing more than 50% of the equity or more than 50% of the ordinary voting power or, in the case of a partnership, more than 50% of the general partnership interests are, as of such date, owned, controlled or held, or (ii) that is, as of such date, otherwise Controlled, by the parent or one or more subsidiaries of the parent or by the parent and one or more subsidiaries of the parent.

*"Subsidiary Guarantors"* means each of the Subsidiaries of Borrower identified under the caption "SUBSIDIARY GUARANTORS" on the signature pages hereto and each Subsidiary of Borrower that becomes, or is required to become, a "Subsidiary Guarantor" after the date hereof pursuant to **Section 8.12(a)**.

"Substitute Lender" has the meaning set forth in Section 2.07(a).

*"Taxes"* means all present or future taxes, levies, imposts, duties, deductions, withholdings (including backup withholding), assessments, fees or other charges imposed by any Governmental Authority, including any interest, additions to tax or penalties applicable thereto.

*"Technical Information"* means all trade secrets and other proprietary or confidential information, public information, non-proprietary know-how, any information of a scientific, technical, or business nature in any form or medium, standards and specifications, conceptions, ideas, innovations, discoveries, Invention disclosures, all documented research, developmental, demonstration or engineering work and all other information, data, plans, specifications, reports, summaries, experimental data, manuals, models, samples, know-how, technical information, systems, methodologies, computer programs, information technology and any other information.

*"Title IV Plan"* means an employee benefit plan (as defined in Section 3(3) of ERISA) other than a Multiemployer Plan (i) that is or was at any time maintained or sponsored by any Obligor or any ERISA Affiliate thereof or to which any Obligor or any ERISA Affiliate thereof has ever made, or was obligated to make, contributions, and (ii) that is or was subject to Section 412 of the Code, Section 302 of ERISA or Title IV of ERISA.

"Trademarks" is defined in the Security Agreement.

*"Transactions"* means the execution, delivery and performance by each Obligor of this Agreement and the other Loan Documents to which such Obligor is intended to be a party, and the Borrowings (and the use of the proceeds of the Loans).

"United States" or "U.S." means the United States of America.

"U.S. Person" means a "United States Person" within the meaning of Section 7701(a)(30) of the Code.

"U.S. Tax Compliance Certificate" has the meaning set forth in Section 5.03(e)(ii)(B)(3).

*"UCC"* means the Uniform Commercial Code as in effect in the applicable jurisdiction, as may be modified from time to time.

*"Warrant Agreement"* means that that certain Warrant Certificate and Agreement, dated as of the date hereof, by and between the Borrower and Perceptive Credit Holdings, LP, and in substantially the form attached hereto as **Exhibit I**.

*"Warrant"* means one or more warrants, issued pursuant to the Warrant Agreement, exercisable into an aggregate number of Senior Common Interests equal to four and half percent (4.5%) of the aggregate issued and outstanding Membership Interests of Borrower, in each case determined on a fully-diluted basis. Each Warrant shall be exercisable at \$0.01 per unit of Senior Common Interests and shall be subject to the terms and conditions of the Warrant Agreement.

"Warrant Obligations" means, with respect to any Obligor, all Obligations arising out of, under or in connection with, any Warrant.

*"Withdrawal Liability"* means, at any time, any liability incurred (whether or not assessed) by any ERISA Affiliate and not yet satisfied or paid in full at such time with respect to any Multiemployer Plan pursuant to Section 4201 of ERISA.

**1.02** Accounting Terms and Principles. Unless otherwise specified, all accounting terms used in each Loan Document shall be interpreted, and all accounting determinations and computations thereunder (including under Section 10 and any definitions used in such calculations) shall be made, in accordance with GAAP. Unless otherwise expressly provided, all financial covenants and defined financial terms shall be computed on a consolidated basis for Borrower and its Subsidiaries, in each case without duplication.

1.03 Interpretation. For all purposes of this Agreement, except as otherwise expressly provided herein or unless the context otherwise requires,

- (a) the terms defined in this Agreement include the plural as well as the singular and vice versa;
- (b) words importing gender include all genders;
- (c) any reference to a Section, Annex, Schedule or Exhibit refers to a Section of, or Annex, Schedule or Exhibit to, this Agreement;

(d) any reference to "this Agreement" refers to this Agreement, including all Annexes, Schedules and Exhibits hereto, and the words herein, hereof, hereto and hereunder and words of similar import refer to this Agreement and its Annexes, Schedules and Exhibits as a whole and not to any particular Section, Annex, Schedule, Exhibit or any other subdivision;

- (e) references to days, months and years refer to calendar days, months and years, respectively;
- (f) all references herein to "include" or "including" shall be deemed to be followed by the words "without limitation";
- (g) the word "from" when used in connection with a period of time means "from and including" and the word "until" means "to but not including";

(h) the words "asset" and "property" shall be construed to have the same meaning and effect and to refer broadly to any and all assets and properties, whether tangible or intangible, real or personal, including cash, securities, rights under contractual obligations and permits and any right or interest in any such assets or property; and

(i) accounting terms not specifically defined herein (other than "property" and "asset") shall be construed in accordance with GAAP.

Unless otherwise expressly provided herein, references to organizational documents, agreements (including the Loan Documents) and other contractual instruments shall be deemed to include all subsequent amendments, restatements, extensions, supplements and other modifications thereto permitted by the Loan Documents.

## SECTION 2. THE COMMITMENT AND THE LOANS

### 2.01 Loans.

(a) On the terms and subject to the conditions of this Agreement, the Lenders agree to make the Initial Loan available to Borrower in a single Borrowing on the Closing Date.

(b) On the terms and subject to the conditions of this Agreement, the Lenders agree to make the Delayed Draw Loan to Borrower in a single Borrowing on the Delayed Draw Date.



#### (c) No amounts paid or prepaid with respect to any Loan may be reborrowed.

(d) Any term or provision hereof (or of any other Loan Document) to the contrary notwithstanding, Loans made to Borrower will be denominated solely in Dollars and will be repayable solely in Dollars and no other currency.

### 2.02 Borrowing Procedures.

(a) At least three (but not more than five) Business Days prior to the proposed Borrowing Date, Borrower shall deliver to Administrative Agent an irrevocable Borrowing Notice (which notice, if received by Administrative Agent on a day that is not a Business Day or after 10:00 A.M. Eastern time on a Business Day, shall be deemed to have been delivered on the next Business Day).

(b) Upon receipt of a Borrowing Notice, Administrative Agent shall promptly notify each Lender thereof. No later than (i) 12:00 Noon Eastern time on the anticipated Borrowing Date, each Lender shall make available to Administrative Agent an amount in immediately available funds equal to the Loan to be made by such Lender.

# 2.03 [Reserved]

**2.04** Notes. If requested by any Lender, the Loans of such Lender shall be evidenced by one or more Notes. Borrower shall prepare, execute and deliver to Administrative Agent such promissory note(s) payable to the Lenders (or, if requested by the Lenders, to the Lenders and their registered assigns) and substantially in the form attached hereto as **Exhibit C**. Thereafter, the Loans and interest thereon shall at all times (including after assignment pursuant to **Section 14.05**) be represented by one or more promissory notes in such form payable to the payee named therein (or, if such promissory note is a registered note, to such payee and its registered assigns).

**2.05** Use of Proceeds. Borrower shall use the proceeds of the Loans first, to pay in full all amounts outstanding under the Existing Credit Agreement and terminate all commitments thereunder to make future credit extensions, and, thereafter, for general business purposes, including the payment of fees and expenses associated with this Agreement.

# 2.06 Defaulting Lenders.

(a) **Adjustments.** Notwithstanding anything to the contrary contained in this Agreement, if any Lender becomes a Defaulting Lender, then, until such time as that Lender is no longer a Defaulting Lender, to the extent permitted by Requirements of Law:

(i) **Waivers and Amendments.** Such Defaulting Lender's right to approve or disapprove any amendment, waiver or consent with respect to this Agreement shall be restricted as set forth in **Section 14.04**.

(ii) **Reallocation of Payments.** Any payment of principal, interest, fees or other amounts received by the Lenders for the account of such Defaulting Lender (whether voluntary or mandatory, at maturity, pursuant to **Section 11** or otherwise), shall be applied at such time or times as follows: first, as Borrower may request (so long as no Default exists), to the funding of any Loan in respect of which such Defaulting Lender has failed to fund its portion thereof as required by this Agreement; second, if so determined by the Majority Lenders and Borrower, to be held in a non-interest bearing deposit account and released in order to satisfy obligations of such Defaulting Lender to fund Loans under this Agreement; third, to the payment of any amounts owing to the Lenders as a result of any judgment of a court of competent jurisdiction obtained by any Lender against such Defaulting Lender as a result of such Defaulting Lender's breach of its obligations under this Agreement; fourth, so long as no Default exists, to the payment of any amounts owing to Borrower as a result of a court of competent jurisdiction obtained by Borrower against such Defaulting Lender as a result of such Defaulting Lender's breach of its obligations under this Agreement; and fifth, to such Defaulting Lender or as otherwise directed by a court of competent jurisdiction; provided that if (x) such payment is a payment of the principal amount of any Loans in respect of which such Defaulting Lender has not fully funded its appropriate share and (y) such Loans were made at a time when the conditions set forth in **Section 6** were satisfied or waived, such payment shall be applied solely to pay the Loans of all non-Defaulting Lender son a *pro rata* basis prior to being applied to the payment of any Loans of such Defaulting Lender. Any payments, prepayments or other amounts paid or payable to a Defaulting Lender that are applied (or held) to pay amounts owed by a Defaulting Lender pursuant to this **Section 2.06(a)** (ii) shall be deemed p

(b) **Defaulting Lender Cure.** If Borrower and the Majority Lenders agree in writing in their sole discretion that a Defaulting Lender should no longer be deemed to be a Defaulting Lender, that Lender will, to the extent applicable, purchase that portion of outstanding Loans of the other Lenders or take such other actions as necessary to cause the Loans to be held on a *pro rata* basis by the Lenders in accordance with their Proportionate Share, whereupon that Lender will cease to be a Defaulting Lender; <u>provided</u> that no adjustments will be made retroactively with respect to fees accrued or payments made by or on behalf of Borrower while that Lender was a Defaulting Lender; and <u>provided</u>, <u>further</u>, that except to the extent otherwise expressly agreed by the affected parties, no change hereunder from Defaulting Lender to Lender will constitute a waiver or release of any claim of any party hereunder arising from that Lender's having been a Defaulting Lender.

## 2.07 Substitution of Lenders.

(a) **Substitution Right.** If any Lender (an "*Affected Lender*"), (i) becomes a Defaulting Lender or (ii) does not consent to any amendment, waiver or consent to any Loan Document for which the consent of the Majority Lenders is obtained but that requires the consent of other Lenders (a "*Non-Consenting Lender*"), then (x) Borrower may elect to pay in full such Affected Lender with respect to all Obligations (other than Warrant Obligations) due to such Affected Lender or (y) either Borrower or the Majority Lenders shall identify any willing Lender or Affiliate of any Lender or Eligible Transferee (in each case, a "Substitute Lender") to substitute for such Affected Lender; <u>provided</u> that any substitution of a Non-Consenting Lender shall occur only with the consent of Administrative Agent and the Majority Lenders.

(b) **Procedure.** To substitute such Affected Lender or pay in full all Obligations (other than Warrant Obligations) owed to such Affected Lender, Borrower shall deliver a notice to such Affected Lender. The effectiveness of such payment or substitution shall be subject to the delivery by Borrower (or, as may be applicable in the case of a substitution, by the Substitute Lender) of (i) payment for the account of such Affected Lender, of, to the extent accrued through, and outstanding on, the effective date for such payment or substitution, all Obligations (other than Warrant Obligations) owing to such Affected Lender (which shall not include any Prepayment Premium) and (ii) in the case of a substitution, an Assignment and Assumption executed by the Substitute Lender, which shall thereunder, among other things, agree to be bound by the terms of the Loan Documents.

(c) **Effectiveness.** Upon satisfaction of the conditions set forth in **Sections 2.07(a)** and **(b)**, Administrative Agent shall record such substitution or payment in the Register, whereupon (i) in the case of any payment in full of an Affected Lender, such Affected Lender's Commitments shall be terminated and (ii) in the case of any substitution of an Affected Lender, (x) such Affected Lender shall sell and be relieved of, and the Substitute Lender shall purchase and assume, all rights and claims of such Affected Lender the Loan Documents, except that the Affected Lender shall retain such rights under the Loan Documents that expressly provide that they survive the repayment of the Obligations and the termination of the Commitments, (y) such Affected Lender shall no longer constitute a "Lender" hereunder and such Substitute Lender shall become a "Lender" hereunder and (z) such Affected Lender shall execute and deliver an Assignment and Assumption to evidence such substitution; provided that the failure of any Affected Lender to execute any such Assignment and Assumption shall not render such sale and purchase (or the corresponding assignment) invalid.

## SECTION 3. PAYMENTS OF PRINCIPAL AND INTEREST

### 3.01 Repayment.

(a) During the Interest-Only Period, no payments of principal shall be due.

(b) Subject to **clause (e)** below, during the period commencing on January 1, 2019 and ending on July 31, 2019, Borrower shall make monthly scheduled repayments of the Loans in an amount equal to \$550,000, such repayments to be made on the Payment Date of each calendar month ending during such period.

(c) Subject to **clause (e)** below, during the period commencing on August l, 2019 and ending on July 31, 2020, Borrower shall make monthly scheduled repayments of the Loans in an amount equal to \$750,000, such repayments to be made on the Payment Date of each calendar month ending during such period.

(d) Borrower shall repay the entire remaining outstanding balance of the Loans on the Maturity Date.

(e) In the event that, on or before the last day of the eighteenth (18th) calendar month following the Closing Date, Borrower has made more than \$10,000,000 in optional or mandatory pre-payments of the Loans pursuant to **Section 3.03**,Borrower and Administrative Agent shall negotiate in good faith for a period of no more than five (5) Business Days whether a mutually satisfactory reduction of the monthly scheduled repayments (required pursuant to **Sections 3.01(b)** and **3.01(c)** above) is warranted; <u>provided</u> that if Borrower and Administrative Agent are unable to mutually agree upon any such reduction the amount of such monthly scheduled repayments shall remain as in effect on the date hereof.

## 3.02 Interest.

(a) **Interest Generally.** The outstanding principal amount of the Loans, as well as all other outstanding Obligations, shall accrue interest at the Interest Rate.

(b) **Default Interest.** Notwithstanding the foregoing, upon the occurrence and during the continuance of any Event of Default, the Applicable Margin shall increase automatically by 3.00% *per annum* (the Interest Rate, as increased pursuant to this **Section 3.02(b)**, being the **"Default Rate"**). If any Obligation is not paid when due under any applicable Loan Document, the amount thereof shall accrue interest at the Default Rate.

(c) **Interest Payment Dates.** Accrued interest on the Loans shall be payable in arrears on each Payment Date in cash, and upon the payment or prepayment of the Loans (on the principal amount being so paid or prepaid); <u>provided</u> that interest payable at the Default Rate shall also be payable from time to time on demand by Administrative Agent or the Majority Lenders.

## 3.03 Prepayments.

# (a) **Optional Prepayments.**

(i) Subject to prior written notice pursuant to **clause (ii)** below, Borrower shall have the right to optionally prepay in whole or in part the outstanding principal amount of the Loans on any Business Day (a *"Redemption Date"*) for an amount equal to the sum of (x) the aggregate principal amount of the Loans being prepaid, (y) the applicable Prepayment Premium on the principal amount of the Loans being prepaid and (z) any accrued but unpaid interest on the principal amount of the Loans being prepaid (such aggregate amount, the *"Redemption Price"*).

(ii) A notice of optional prepayment shall be effective only if received by Administrative Agent not later than 2:00 p.m. (Eastern time) on a date not less than three (nor more than five) Business Days prior to the proposed date of prepayment. Each notice of optional prepayment shall specify the Redemption Price and the principal amount to be prepaid, as well as the date of prepayment.

(b) **Mandatory Prepayments.** Upon the occurrence of a Casualty Event or an initial Public Offering, Borrower shall make a mandatory prepayment of the Loans as set forth below:

(i) in the event of any Casualty Event, Borrower shall mandatorily prepay the outstanding principal amount of the Loans in an amount equal to the sum of (i) 100% of the net insurance or other proceeds received by Borrower with respect thereto, (ii) the applicable Prepayment Premium on the principal amount of the Loans being prepaid and (iii) any accrued but unpaid interest on any principal amount of the Loans being prepaid; <u>provided</u> that the Borrower may, upon notice to Administrative Agent, use such proceeds to acquire or repair fixed or capital assets useful in Borrower's or its Subsidiaries' businesses, as long as such investment is made within six months of the Casualty Event; and

(ii) in the event of an initial Public Offering, Borrower shall mandatorily prepay the outstanding principal amount of the Loans in an amount equal to the sum of (i) 25% of the net cash proceeds thereof; (ii) the applicable Prepayment Premium on the principal amount of the Loans being prepaid and (iii) any accrued but unpaid interest on any principal amount of the Loans being prepaid.

- (c) **Application.** All prepayments made pursuant to **clauses (a)** or **(b)** above shall be applied as follows:
  - (i) first, in reduction of Borrower's obligation to pay any unpaid interest and any fees then due and owing;
  - (ii) second, in reduction of Borrower's obligation to pay any costs or expenses referred to in Section 14.03 then due and owing;
  - (iii) third, in reduction of Borrower's obligation to pay any amounts due and owing on account of the unpaid principal amount of the Loans;
  - (iv) fourth, in reduction of any other Obligation then due and owing, including payment of the Prepayment Premium; and
  - (v) fifth, to Borrower or such other Persons as may lawfully be entitled to or directed by Borrower to receive the remainder.

## SECTION 4. PAYMENTS, ETC.

#### 4.01 Payments.

(a) **Payments Generally.** Each payment of principal, interest and other amounts to be made by the Obligors under this Agreement or any other Loan Document shall be made in Dollars, in immediately available funds, without deduction, set off or counterclaim, to an account to be designated by Administrative Agent by notice to Borrower, not later than 2:00 p.m. (Eastern time) on the date on which such payment shall become due (each such payment made after such time on such due date to be deemed to have been made on the next succeeding Business Day).

(b) **Application of Payments.** Unless otherwise agreed by Administrative Agent or as otherwise set forth in **Section 3.03(c)**, all payments and prepayments made in respect of the Loans will be applied *pro rata* against outstanding Initial Loans and Delayed Draw Loans in reverse order of scheduled amortization. If at any time insufficient funds are received by and available to Administrative Agent to pay fully all amounts of principal, interest and fees then due hereunder, such funds will be applied (i) first, towards payment of fees then due hereunder, ratably (to the extent provided herein) among the parties entitled thereto in accordance with the amount of fees then due to such parties, and (ii) second, towards payment of interest then due hereunder in respect of the Loans, ratably (to the extent provided herein) among the parties and (iii) third, towards payment of principal then due hereunder in respect of the Loans, ratably (to the extent provided herein) among the parties and (iii) third, towards payment of principal due to such parties.

(c) **Non-Business Days.** If the due date of any payment under this Agreement would otherwise fall on a day that is not a Business Day, such date shall be extended to the next succeeding Business Day, and, in the case of any payment accruing interest, interest thereon shall be payable for the period of such extension.

**4.02 Computations.** All computations of interest and fees hereunder shall be computed on the basis of a year of 360 days and actual days elapsed during the period for which payable.

#### 4.03 [Reserved].

#### 4.04 Set-Off.

(a) **Set-Off Generally.** Upon the occurrence and during the continuance of any Event of Default, each of Administrative Agent, each Lender and each of their Affiliates is hereby authorized at any time and from time to time, to the fullest extent permitted by law, to set off and apply any and all deposits (general or special, time or demand, provisional or final) at any time held and other indebtedness at any time owing by Administrative Agent, any Lender and any of their Affiliates to or for the credit or the account of any Obligor against any and all of the Obligations, whether or not such Person shall have made any demand and although such obligations may be unmatured. Administrative Agent and each Lender agree promptly to notify Borrower after any such set-off and application, <u>provided</u> that the failure to give such notice shall not affect the validity of such set-off and application. The rights of Administrative Agent, each Lender and each of their Affiliates under this **Section 4.04** are in addition to other rights and remedies (including other rights of set-off) that such Persons may have.

(b) **Exercise of Rights Not Required.** Nothing contained in **Section 4.04(a)** shall require Administrative Agent, any Lender and any of their Affiliates to exercise any such right or shall affect the right of such Persons to exercise, and retain the benefits of exercising, any such right with respect to any other indebtedness or obligation of any Obligor.

### SECTION 5. YIELD PROTECTION, ETC.

## 5.01 Additional Costs

(a) **Change in Requirements of Law Generally.** If, on or after the date hereof, the adoption of any Requirement of Law, or any change in any Requirement of Law, or any change in the interpretation or administration thereof by any court or other Governmental Authority charged with the interpretation or administration thereof, or compliance by any of the Lenders (or its lending office) with any request or directive (whether or not having the force of law) of any such Governmental Authority, shall impose, modify or deem applicable any reserve (including any such requirement imposed by the Board of Governors of the Federal Reserve System), special deposit, contribution, insurance assessment or similar requirement, in each case that becomes effective after the date hereof, against assets of, deposits with or for the account of, or credit extended by, a Lender (or its lending office) or shall impose on a Lender (or its lending office) any other condition affecting the Loans or the Commitment, and the result of any of the foregoing is to increase the cost to such Lender of making or maintaining the Loans, or to reduce the amount of any sum received or receivable by such Lender under this Agreement or any other Loan Document, by an amount deemed by such Lender to be material (other than (i) Indemnified Taxes and (ii) Taxes described in **clause (iii)** or **(iv)** of the definition of **"Excluded Taxes"**), then, within five (5) Business Days of Borrower's receipt of written notice described in **Section 5.01(b)** below, Borrower shall pay to such Lender such additional amount or amounts as will compensate such Lender for such increased cost or reduction; provided that if such additional amount or amounts exceeds \$250,000 in the aggregate, Borrower's receipt of such written notice from a Lender.

(b) **Notification by Lender.** Each Lender promptly will notify Borrower in writing of any event of which it has knowledge, occurring after the date hereof which will entitle such Lender to compensation pursuant to **Section 5.01(a)**.Before giving any such notice pursuant to this **Section 5.01(b)** such Lender shall designate a different lending office if such designation (x) will, in the reasonable judgment of such Lender, avoid the need for, or reduce the amount of, such compensation and (y) will not, in the reasonable judgment of such Lender, be materially disadvantageous to such Lender. Such written notice delivered to Borrower by such Lender claiming compensation under **Section 5.01(a)**,which notice shall set forth in reasonable detail the additional amount or amounts to be paid to such Lender pursuant to such **Section 5.01(a)**,shall be conclusive and binding on Borrower in the absence of manifest error.

(c) Notwithstanding anything herein to the contrary, (x) the Dodd-Frank Wall Street Reform and Consumer Protection Act and all requests, rules, guidelines or directives thereunder or issued in connection therewith and (y) all requests, rules, guidelines or directives promulgated by the Bank for International Settlements, the Basel Committee on Banking Supervision (or any successor or similar authority) or the United States or foreign regulatory authorities, in each case pursuant to Basel III, shall in each case be deemed to constitute a change in Requirements of Law for all purposes of this **Section 5.01**,regardless of the date enacted, adopted or issued.

**5.02 Illegality.** Notwithstanding any other provision of this Agreement, in the event that on or after the date hereof the adoption of or any change in any Requirement of Law or in the interpretation or application thereof by any competent Governmental Authority shall make it unlawful for a Lender or its lending office to make or maintain the Loans (and, in the opinion of such Lender, the designation of a different lending office would either not avoid such unlawfulness or would be disadvantageous to such Lender), then such Lender shall promptly notify Borrower thereof, following which (i) such Lender's Commitment shall be suspended until such time as such Lender may again make and maintain the Loans hereunder and (ii) if such, Requirement of Law shall so mandate, the Loans shall be prepaid by Borrower on or before such date as shall be mandated by such Requirement of Law in an amount equal to the Redemption Price applicable on the date of such prepayment in accordance with **Section 3.03(a)**.

## 5.03 Taxes.

(a) **Payments Free of Taxes.** Any and all payments by or on account of any Obligation shall be made without deduction or withholding for any Taxes, except as required by any Requirement of Law. If any Requirement of Law requires the deduction or withholding of any Tax from any such payment by an Obligor, then such Obligor shall be entitled to make such deduction or withholding and shall timely pay the full amount deducted or withheld to the relevant Governmental Authority in accordance with Requirements of Law and, if such Tax is an Indemnified Tax, then the sum payable by such Obligor shall be increased as necessary so that after such deduction or withholding has been made (including such deductions and withholdings applicable to additional sums payable under this **Section 5**) the applicable Recipient receives an amount equal to the sum it would have received had no such deduction or withholding been made.

(b) **Payment of Other Taxes by Borrower.** Borrower shall timely pay to the relevant Governmental Authority in accordance with Requirements of Law, or at the option of each Lender, timely reimburse it for, Other Taxes.

(c) **Evidence of Payments.** As soon as practicable after any payment of Taxes by Borrower to a Governmental Authority pursuant to this **Section 5**,Borrower shall deliver to each Lender the original or a certified copy of a receipt issued by such Governmental Authority evidencing such payment.

(d) **Indemnification.** Borrower shall reimburse and indemnify each Recipient, within ten days after demand therefor, for the full amount of any Indemnified Taxes (including Indemnified Taxes imposed or asserted on or attributable to amounts payable under this **Section 5**) payable or paid by such Recipient or required to be withheld or deducted from a payment to such Recipient and any reasonable expenses arising therefrom or with respect thereto, whether or not such Indemnified Taxes were correctly or legally imposed or asserted by the relevant Governmental Authority. A certificate as to the amount of such payment or liability delivered to Borrower by a Lender shall be conclusive absent manifest error.

# (e) Status of Lenders.

(i) Any Lender that is entitled to an exemption from or reduction of withholding Tax with respect to payments made under any Loan Document shall timely deliver to Borrower such properly completed and executed documentation reasonably requested by Borrower as will permit such payments to be made without withholding or at a reduced rate of withholding; <u>provided</u> that, other than in the case of U.S. Federal withholding Taxes, such Lender has received written notice from Borrower advising it of the availability of such exemption or reduction and containing all applicable documentation. In addition, any Lender shall deliver such other documentation prescribed by a Requirement of Law as reasonably requested by Borrower as will enable Borrower to determine whether or not such Lender is subject to backup withholding or information reporting requirements. Notwithstanding anything to the contrary in the preceding two sentences, the completion, execution and submission of such documentation (other than such documentation set forth in **Section 5.03(e)(ii)**)shall not be required if in such Lender's reasonable judgment such completion, execution or submission would subject such Lender to any material unreimbursed cost or expense or would materially prejudice the legal or commercial position of such Lender.

(ii) without limiting the generality of the foregoing, in the event that Borrower is a U.S. Person:

(A) any Lender that is a U.S. Person shall deliver to Borrower on or prior to the date on which such Lender becomes a Lender under this Agreement (and from time to time thereafter upon the reasonable request of Borrower), executed originals of IRS Form W-9 (or successor form) certifying that such Lender is exempt from U.S. Federal backup withholding tax;

(B) any Foreign Lender shall, to the extent it is legally entitled to do so, deliver to Borrower (in such number of copies as shall be requested by the recipient) on or prior to the date on which such Foreign Lender becomes a Lender under this Agreement (and from time to time thereafter upon the reasonable request of Borrower), whichever of the following is applicable:

(1) in the case of a Foreign Lender claiming the benefits of an income tax treaty to which the United States is a party (x) with respect to payments of interest under any Loan Document, executed originals of IRS Form W-8BEN (or successor form) establishing an exemption from, or reduction of, U.S. Federal withholding Tax pursuant to the "interest" article of such tax treaty and (y) with respect to any other applicable payments under any Loan Document, IRS Form W-8BEN (or successor form) establishing an exemption from, or reduction of, U.S. Federal withholding Tax pursuant to the "business profits" or "other income" article of such tax treaty;

(2) executed originals of IRS Form W-8ECI (or successor form);

(3) in the case of a Foreign Lender claiming the benefits of the exemption for portfolio interest under Section 881(c) of the Code, (x) a certificate substantially in the form of **Exhibit D** to the effect that such Foreign Lender is not a "bank" within the meaning of Section 881(c)(3) (A) of the Code, a "10 percent shareholder" of the applicable Borrower within the meaning of Section 881(c)(3)(B) of the Code, or a "controlled foreign corporation" described in Section 881(c)(3)(C) of the Code (a "*U.S. Tax Compliance Certificate*") and (y) executed originals of IRS Form W-8BEN (or successor form); or

(4) to the extent a Foreign Lender is not the beneficial owner, executed originals of IRS Form W-8IMY (or successor form), accompanied by IRS Form W-8ECI (or successor form), IRS Form W-8BEN (or successor form), a U.S. Tax Compliance Certificate, IRS Form W-9 (or successor form), and/or other certification documents from each beneficial owner, as applicable; <u>provided</u> that if the Foreign Lender is a partnership and one or more direct or indirect partners of such Foreign Lender are claiming the portfolio interest exemption, such Foreign Lender may provide a U.S. Tax Compliance Certificate on behalf of each such direct and indirect partner.

(C) any Foreign Lender shall, to the extent it is legally entitled to do so, deliver to Borrower (in such number of copies as shall be requested by the recipient) on or prior to the date on which such Foreign Lender becomes a Lender under this Agreement (and from time to time thereafter upon the reasonable request of Borrower), executed originals of any other form prescribed by Requirements of Law as a basis for claiming exemption from or a reduction in U.S. Federal withholding Tax, duly completed, together with such supplementary documentation as may be prescribed by Requirements of Law to permit Borrower to determine the withholding or deduction required to be made; and

(D) any Foreign Lender shall deliver to Borrower any forms and information necessary to establish that such Foreign Lender is not subject to withholding tax under FATCA.

Each Lender agrees that if any form or certification it previously delivered expires or becomes obsolete or inaccurate in any respect, it shall update such form or certification or promptly notify Borrower in uniting of its legal inability to do so.

(f) **Treatment of Certain Refunds.** If any party to this Agreement determines, in its sole discretion exercised in good faith, that it has received a refund of any Taxes as to which it has been indemnified pursuant to this **Section 5** (including by the payment of additional amounts pursuant to this **Section 5**), it shall pay to the indemnifying party an amount equal to such refund (but only to the extent of indemnifying party and without interest (other than any interest paid by the relevant Governmental Authority with respect to such refund). Such indemnifying party, upon the request of such indemnified party, shall repay to such indemnified party the amount paid over pursuant to this paragraph (plus any penalties, interest or other charges imposed by the relevant Governmental Authority) in the event that such indemnified party is required to repay such refund to such Governmental Authority. Notwithstanding anything to the contrary in this **Section 5.03(f)**, in no event will the indemnified party be required to pay any amount to an indemnified party would have been in if the indemnification payments or additional amounts giving rise to such refund had never been paid. This **Section 5.03(f)** shall not be construed to require any indemnified party to make available its Tax returns (or any other information relating to its Taxes that it deems confidential) to the indemnifying party or any other Person.

(g) **Mitigation Obligations.** If Borrower is required to pay any Indemnified Taxes or additional amounts to any Lender or to any Governmental Authority for the account of any Lender pursuant to **Section 5.01** or this **Section 5.03**, then such Lender shall (at the request of Borrower) use commercially reasonable efforts to designate a different lending office for funding or booking its Loans hereunder or to assign and delegate its rights and obligations hereunder to another of its offices, branches or Affiliates if, in the sole reasonable judgment of such Lender, such designation or assignment and delegation would (i) eliminate or reduce amounts payable pursuant to **Section 5.01** or this **Section 5.03**, as the case may be, in the future, (ii) not subject such Lender to any unreimbursed cost or expense and (iii) not otherwise be disadvantageous to such Lender. Borrower hereby agrees to pay all reasonable costs and expenses incurred by any Lender in connection with any such designation or assignment and delegation.

**5.04 Delay in Requests.** Failure or delay on the part of any Lender to demand compensation pursuant to this **Section 5** shall not constitute a waiver of such Lender's right to demand such compensation; <u>provided</u> that if such Lender has not provided the appropriate notice within nine (9) months of the event or change giving rise to such increased cost or reduction, then Borrower shall not be required to compensate such Lender pursuant to this **Section 5**.

# SECTION 6. CONDITIONS PRECEDENT

**6.01** Conditions to the Borrowing of the Initial Loan. The obligation of each Lender to make the Initial Loan shall be subject to the execution and delivery of this Agreement by the parties hereto, the delivery of a Borrowing Notice as required pursuant to Section 2.02(a), and the prior or concurrent satisfaction of each of the conditions precedent set forth below in this Article.

(a) **Officer's Certificate, Etc.** Administrative Agent shall have received from each Obligor (i) a copy of a good standing certificate, dated a date reasonably close to the Closing Date, for each such Person and (ii) a certificate, dated as of the Closing Date, duly executed and delivered by such Person's secretary, assistant secretary or a Responsible Officer of such Person as to:

(i) resolutions of each such Person's board of directors (or other managing body, in the case of an Obligor other than a corporation) then in full force and effect authorizing the execution, delivery and performance of each Loan Document to be executed by such Person and the Transactions;

(ii) the incumbency and signatures of those of its officers, managing member or general partner, as applicable, authorized to act with respect to each Loan Document to be executed by such Person; and

(iii) the full force and validity of each Organic Document of such Person and copies thereof;

upon which certificates Administrative Agent may conclusively rely until it shall have received a further certificate of the secretary, assistant secretary or Responsible Officer of any such Person cancelling or amending the prior certificate of such Person.

(b) **Closing Date Certificate.** Administrative Agent shall have received a certificate, dated as of the Closing Date and in form and substance satisfactory to Administrative Agent (the "*Closing Date Certificate*"), duly executed and delivered by a Responsible Officer of Borrower, in which certificate Borrower shall agree and acknowledge, among other things, that the statements made therein shall be deemed to be true and correct representations and warranties of Borrower as of such date, and, at the time such certificate is delivered, such statements shall in fact be true and correct, and such statements shall include that (i) both immediately before and after giving effect to the Initial Loan, (x) the representations and warranties set forth in each Loan Document shall, in each case, be true and correct and (y) no Default shall have then occurred and be continuing, or would result from the Initial Loan being advanced on the Closing Date and (ii) all of the conditions set forth in **Section 6.01** have been satisfied. All documents and agreements required to be appended to the Closing Date Certificate, if any, shall be in form and substance satisfactory to Administrative Agent, shall have been executed and delivered by the requisite parties, and shall be in full force and effect.

(c) **Delivery of Notes.** Administrative Agent shall have received a Note for the Loan duly executed and delivered by a Responsible Officer of Borrower.

(d) **Financial Information, Etc.** Administrative Agent shall have received unaudited consolidated balance sheets of Borrower and its Subsidiaries for each Fiscal Quarter ended after December 31, 2015 and at least ten Business Days prior to the Closing Date, together with the related consolidated statement of operations, shareholder's equity and cash flows for such Fiscal Quarter.

(e) **Compliance Certificate.** Administrative Agent shall have received an initial Compliance Certificate, prepared on a pro forma basis as of the Closing Date, giving effect to the Initial Loan, dated as of the Closing Date, duly executed (and with all schedules thereto duly completed) and delivered by the chief financial or accounting Responsible Officer of Borrower, which such Compliance Certificate shall demonstrate Borrower's compliance with the financial covenants contained in **Section 10**, on a pro forma basis.

(f) **Solvency, Etc.** Administrative Agent shall have received a solvency certificate duly executed and delivered by the chief financial or accounting Responsible Officer of Borrower, dated as of the Closing Date, in form and substance satisfactory to Administrative Agent.

(g) **Security Agreement.** Administrative Agent shall have received executed counterparts of the Security Agreement, dated as of the date hereof, duly executed and delivered by each Obligor together with:

(i) delivery of all certificates (in the case of Equity Interests that are securities (as defined in the NYUCC)) evidencing the issued and outstanding Equity Interests owned by each Obligor that are required to be pledged under the Security Agreement, which certificates in each case shall be accompanied by undated instruments of transfer duly executed in blank, or, in the case of Equity Interests that are uncertificated securities (as defined in the NYUCC), confirmation and evidence satisfactory to Administrative Agent that the security interest required to be pledged therein under the Security Agreement has been transferred to and perfected by Administrative Agent in accordance with Articles 8 and 9 of the NYUCC and all laws otherwise applicable to the perfection of the pledge of such Equity Interests;

(ii) financing statements suitable in form for naming each Obligor as a debtor and Administrative Agent as the secured party, or other similar instruments or documents to be filed under the UCC of all jurisdictions as may be necessary or, in the opinion of Administrative Agent, desirable to perfect the security interests of the Lenders pursuant to the Security Agreement; and

(iii) UCC-3 termination statements, if any, necessary to release all Liens and other rights of any Person in any collateral described in the Security Agreement previously granted by any Person.

(h) **Lien Searches.** Administrative Agent shall be satisfied with Lien searches regarding Borrower and its Subsidiaries made within two Business Days prior to the Borrowing of the Initial Loan.

(i) **Short-Form IP Agreements.** Administrative Agent shall have received all Short-Form IP Agreements required to be provided under the Security Agreement, each dated as of the Closing Date, duly executed and delivered by each Obligor that is required to do so under the Security Agreement.

(j) **Warrant Agreement and Warrants.** The Administrative Agent shall have received executed counterparts of the Warrant Agreement, dated as of the Closing Date, and the Lenders shall have received the Warrants, in each case dated as of the Closing Date, duly executed, delivered and validly issued by Borrower.

(k) **Insurance.** Administrative Agent shall have received certified copies of the insurance policies (or binders in respect thereof), from one or more insurance companies satisfactory to Administrative Agent, evidencing coverage required to be maintained pursuant to each Loan Document. All such insurance policies required pursuant to this Section shall (i) name Administrative Agent as mortgagee (in the case of property insurance) or loss payee or additional insured (in the case of liability insurance), as applicable, and provide that no cancellation or modification of the policies will be made without the prior written consent of Administrative Agent and (ii) be in addition to any requirements to maintain specific types of insurance contained in the other Loan Documents.

(l) **Material Agreements.** Administrative Agent shall be satisfied, in its sole discretion, with the terms conditions and other provisions of each Material Agreement.

(m) **Opinions of Counsel.** Administrative Agent shall have received one or more opinions, dated the Closing Date and addressed to Administrative Agent, from independent legal counsel to Borrower and the other Obligors, in form and substance reasonably acceptable to Administrative Agent.

(n) Fee Letter. Administrative Agent shall have received an executed counterpart of the Fee Letter, duly executed and delivered by Borrower.

(o) **Closing Fees, Expenses, Etc.** Administrative Agent shall have received for its own account, all fees, costs and expenses due and payable pursuant to the Fee Letter and Section 14.03, including all reasonable closing costs and fees and all unpaid reasonable expenses of the Lenders incurred in connection with the Transactions (including Administrative Agent's legal fees and expenses).

(p) **Payoff of Existing Credit Agreement.** On the Closing Date, Borrower shall repay the Existing Credit Agreement in full and shall provide to Administrative Agent a payoff letter to that effect, in form and substance reasonably satisfactory to Administrative Agent, which letter shall include a release of all Liens existing under the Existing Credit Agreement, if any.

(q) **Regulatory Approvals.** Administrative Agent shall have received and be satisfied, in its sole discretion, with all regulatory approvals, clinical data valuations, owned and licensed rights to intellectual property, and other arrangements with third parties performed with respect to the Obligors, as well as other financial, legal, insurance and accounting information related to the Obligors.

(r) **Legal Structure.** Administrative Agent shall be satisfied with the legal structure of Borrower and its Subsidiaries, and Administrative Agent shall be satisfied with the nature and status of all securities, labor, tax, litigation, environmental matters and other material matters involving or affecting Borrower and its Subsidiaries.

(s) **Litigation.** The litigation between Borrower, Indivior plc and certain manufacturers of generic pharmaceuticals including, but not limited to, Actavis, Teva and Par Pharmaceuticals, regarding the Suboxone patents, shall have been resolved to the reasonable satisfaction of Administrative Agent.

(t) **Anti-Terrorism Laws.** Administrative Agent shall have received, as applicable, all documentation and other information required by bank regulatory authorities under applicable "know your customer" and anti-money laundering rules and regulations, including the U.S.A. Patriot Act.

(u) **Due Diligence.** Administrative Agent shall have received and be satisfied with all due diligence (including without limitation financial, technical, operational, legal, intellectual property, commercial market forecasts, clinical and regulatory assessments, supply chain, securities, labor, tax, litigation, environmental, reimbursement and regulatory authority matters) in its sole discretion.

(v) **Material Adverse Change.** No Material Adverse Change shall have occurred in the business, financial performance or condition, operations (including the results thereof), assets, properties or prospects of Borrower and its Subsidiaries, taken as a whole, since December 31, 2015.

(w) **Satisfactory Legal Form.** All documents executed or submitted pursuant hereto by or on behalf of each Obligor or any of its respective Subsidiaries shall be satisfactory in form and substance to Administrative Agent and its counsel, and Administrative Agent and its counsel shall have received all information, approvals, resolutions, opinions, documents or instruments as Administrative Agent or its counsel may reasonably request.

**6.02** Conditions to the Borrowing of the Delayed Draw Loan. The obligation of the Lenders to make the Delayed Draw Loan shall be subject to the prior making of the Initial Loan, the delivery of a Borrowing Notice for such Delayed Draw Loan as required pursuant to Section 2.02(a), and the satisfaction of each of the conditions precedent set forth below in this Section 6.02.

(a) **Delayed Draw Certificate.** Administrative Agent shall have received a certificate, dated as of the Delayed Draw Date and in form and substance satisfactory to Administrative Agent (the "*Delayed Draw Certificate*"), duly executed and delivered by a Responsible Officer of Borrower, in which certificate Borrower shall agree and acknowledge, among other things, that the statements made therein shall be deemed to be true and correct representations and warranties of Borrower as of such date, and, at the time such certificate is delivered, such statements shall in fact be true and correct, and such statements shall include that (i) both immediately before and after giving effect to the Delayed Draw Loan (x) the representations and warranties set forth in this Agreement and each other Loan Document shall, in each case, be true and correct and (y) no Default shall have then occurred and be continuing, or would result from the Delayed Draw Loan to be advanced on the Delayed Draw Date, and (ii) all of the conditions set forth in **Section 6.02** have been satisfied. All documents and agreements required to be appended to the Delayed Draw Certificate, if any, shall be in form and substance reasonably satisfactory to Administrative Agent, shall have been executed and delivered by the requisite parties, and shall be in full force and effect.

(b) **Delayed Draw Borrowing Milestone.** On or before the first anniversary of the Closing Date, Borrower shall have delivered to Administrative Agent written evidence, in reasonable detail, which evidence shall be in form and substance satisfactory to the Administrative Agent, that at least one patient has enrolled in a pivotal clinical study for Diazepam (MSRX-203).

(c) **Compliance Certificate.** Administrative Agent shalt have received a Compliance Certificate, prepared on a pro forma basis as if the Delayed Draw Loan had been made as of the first day of the most recently ended Fiscal Quarter for which a report pursuant to **Section 8.01(a)** has been delivered to Administrative Agent, duly executed (and with all schedules thereto duly completed) and delivered by the chief financial or accounting Responsible Officer of each Obligor.

(d) **Closing Fee, Expenses, Etc.** Administrative Agent shall have received for its own account, all fees, costs and expenses due and payable pursuant to **Section 14.03**.

(e) **Delayed Draw Date.** The Delayed Draw Date shall have occurred on or before the date which is 30 days after the date when all conditions precedent set forth in this Section 6.02 have been satisfied; <u>provided</u> that, if such date occurs on or before December 3, 2016, the Delayed Draw Date shall be January 13, 2017.

(f) **Lien Searches.** Borrower and its Subsidiaries shall have delivered lien searches to the Administrative Agent dated as of a date reasonably close to the Delayed Draw Date, and the Administrative Agent shall be satisfied with the results of such searches.

(g) **Satisfactory Legal Form.** All documents executed or submitted pursuant hereto by or on behalf of Borrower or any Subsidiary shall be reasonably satisfactory in form and substance to Administrative Agent and its counsel, and Administrative Agent and its counsel shall have received all information, approvals, resolutions, opinions, documents or instruments as Administrative Agent or its counsel may reasonably request.

### SECTION 7. REPRESENTATIONS AND WARRANTIES

Borrower represents and warrants to Administrative Agent and the Lenders that:

**7.01 Power and Authority.** Each of Borrower and its Subsidiaries (i) is duly organized and validly existing under the laws of its jurisdiction of organization, (ii) has all requisite corporate or other power, and has all Governmental Approvals necessary to own its assets and carry on its business as now being or as proposed to be conducted, except to the extent that failure to have the same could not reasonably be expected to have a Material Adverse Effect, (iii) is qualified to do business and is in good standing in all jurisdictions in which the nature of the business conducted by it makes such qualification necessary and where failure so to qualify (either individually or in the aggregate) could reasonably be expected to have a Material Adverse Effect, and (iv) has full power, authority and legal right to enter into and perform its obligations under each of the Loan Documents to which it is a party and, in the case of Borrower, to borrow the Loans hereunder.

**7.02 Authorization; Enforceability.** The Transactions are within each Obligor's corporate powers and have been duly authorized by all necessary corporate and, if required, by all necessary shareholder action. This Agreement has been duly executed and delivered by each Obligor and constitutes, and each of the other Loan Documents to which it is a party when executed and delivered by such Obligor will constitute, a legal, valid and binding obligation of such Obligor, enforceable against such Obligor in accordance with its terms, except as such enforceability may be limited by (i) bankruptcy, insolvency, reorganization, moratorium or similar laws of general applicability affecting the enforcement of creditors' rights and (ii) the application of general principles of equity (regardless of whether such enforceability is considered in a proceeding in equity or at law).

**7.03 Governmental and Other Approvals; No Conflicts.** The Transactions (i) do not require any Governmental Approval of, registration or filing with, or any other action by, any Governmental Authority or any third party, except for (x) such as have been obtained or made and are in full force and effect and (y) filings and recordings in respect of the Liens created pursuant to the Security Documents, (ii) will not violate any Requirement of Law or the Organic Documents of Borrower and its Subsidiaries or any order of any Governmental Authority, other than any such violations that, individually or in the aggregate, could not reasonably be expected to have a Material Adverse Effect, (iii) will not violate or result in a default under any indenture, agreement or other instrument binding upon Borrower and its Subsidiaries or assets, or give rise to a right thereunder to require any payment to be made by any such Person, and (iv) will not result in the creation or imposition of any Lien (other than Permitted Liens) on any asset of Borrower and its Subsidiaries.

# 7.04 Financial Statements; Material Adverse Change.

(a) **Financial Statements.** Borrower has heretofore furnished to the Lenders certain consolidated financial statements as provided for in **Section 8.01**. Such financial statements, and all other financial statements delivered by Borrower to Administrative Agent (whether prior to the Closing Date or otherwise) present fairly, in all material respects, the consolidated financial position and results of operations and cash flows of Borrower and its Subsidiaries as of such dates and for such periods in accordance with GAAP, subject to year-end audit adjustments and the absence of footnotes in the case of the statements of the type described in **Section 8.01(a)**. Neither Borrower nor any of its Subsidiaries has any material contingent liabilities or unusual forward or long-term commitments not disclosed in the aforementioned financial statements.

# (b) No Material Adverse Change. Since December 31, 2015, there has been no Material Adverse Change.

# 7.05 Properties.

(a) **Property Generally.** Each Obligor has good and marketable fee simple title to, or valid leasehold interests in, all its real and personal property material to its business, subject only to Permitted Liens and except for minor defects in title that do not interfere with its ability to conduct its business as currently conducted or to utilize such properties for their intended purposes.

# (b) Intellectual Property.

(i) Schedule 7.05(b) contains:

(A) a complete and accurate list of all applied for or registered or issued Patents, including the jurisdiction and patent number;

(B) a complete and accurate list of all applied for or registered Trademarks, including the jurisdiction, trademark application or registration number and the application or registration date; and

(C) a complete and accurate list of all applied for or registered Copyrights.

(ii) To the best of each Obligor's knowledge, each Obligor is the absolute beneficial owner of all right, title and interest in and to the Obligor Intellectual Property that it owns, with no breaks in chain of title with good and marketable title, free and clear of any Liens or Claims of any kind whatsoever other than Permitted Liens, and each Obligor has the right to use all Obligor Intellectual Property. Without limiting the foregoing, and except as set forth in **Schedule 7.05(b)**:

(A) other than with respect to the Material Agreements, or as permitted by **Section 9.09**, to the best of each Obligor's knowledge, the Obligors have not transferred ownership of Material Intellectual Property, in whole or in part, to any other Person who is not an Obligor;

(B) to the best of each Obligor's knowledge, other than (i) the Material Agreements, (ii) customary restrictions in in-bound licenses of Intellectual Properly and non disclosure agreements, or (iii) as would have been or is permitted by **Section 9.09**, there are no judgments, covenants not to sue, permits, grants, licenses, Liens (other than Permitted Liens), Claims, or other agreements or arrangements relating to Borrower's Material Intellectual Property, including any development, submission, services, research, license or support agreements, which bind, obligate or otherwise restrict in any material manner any Obligor or any of its Subsidiaries with respect to their Material Intellectual Property;

(C) to the best of each Obligor's knowledge, neither the use by it of any of its Intellectual Property, nor the operations by such Obligor of its business, violates, infringes or interferes with or constitutes a misappropriation of any valid rights arising under any Intellectual Property of any other Person;

(D) except as set forth in **Schedule 7.06(a)**, there are no pending or, to Borrower's knowledge, threatened Claims against the Obligors asserted by any other Person relating to the Obligor Intellectual Property, including any Claims of adverse ownership, invalidity, infringement, misappropriation, violation or other opposition to or conflict with such Intellectual Property; the Obligors have not received any written notice from any Person that Borrower's business, the use of the Obligor Intellectual Property, or the manufacture, use or sale of any product or the performance of any service by Borrower infringes upon, violates or constitutes a misappropriation of, or may infringe upon, violate or constitute a misappropriation of, or otherwise interfere with, any other Intellectual Property of any other Person;

(E) except as set forth in **Schedule 7.06(a)**, the Obligors have no knowledge that the Obligor Intellectual Property is being infringed, violated, misappropriated or otherwise used by any other Person without the express authorization of the Obligors. Without limiting the foregoing, except as set forth in **Schedule 7.06(a)**, the Obligors have not put any other Person on notice of actual or potential infringement, violation or misappropriation of any of the Obligor Intellectual Property; the Obligors have not initiated the enforcement of any Claim with respect to any of the Obligor Intellectual Property;

(F) to the best of each Obligor's knowledge, all relevant current and former employees and contractors of Borrower have executed written confidentiality and invention assignment Contracts with Borrower that irrevocably assign to Borrower or its designee all of their rights to any Inventions relating to Borrower's business;

(G) to the best of each Obligor's knowledge, the Obligor Intellectual Property is all the Intellectual Property necessary for the operation of Borrower's business as it is currently conducted or as currently contemplated to be conducted;

(H) the Obligors have taken reasonable precautions to protect the secrecy, confidentiality and value of its Obligor Intellectual Property consisting of trade secrets and confidential information;

(I) each Obligor has delivered to Administrative Agent accurate and complete copies of all Material Agreements relating to the Obligor Intellectual Property; and

(J) to the best of each Obligor's knowledge, there are no pending or threatened in writing Claims against the Obligors asserted by any other Person relating to the Material Agreements, including any Claims of breach or default under such Material Agreements.

(iii) To the best of each Obligor's knowledge, with respect to the Obligor Intellectual Property consisting of Patents, except as set forth in **Schedule 7.05(b)**, and without limiting the representations and warranties in **Section 7.05(b)(ii)**:

(A) each of the issued claims in such Patents, to Borrower's knowledge, is valid and enforceable;

(B) the named inventors claimed in such Patents have executed written Contracts with Borrower or its predecessor-in-interest that properly and irrevocably assigns to Borrower or predecessor-in-interest all of their rights, title and interest to any of the Inventions claimed in such Patents to the extent permitted by Requirements of Law;

(C) none of the Patents, or the Inventions claimed in them, have been dedicated to the public except as a result of intentional decisions made by the applicable Obligor;

(D) to the best of each Obligor's knowledge, all prior art material to the Patents listed on **Schedule 7.05(b)** was adequately disclosed to or considered by the respective patent offices during prosecution of such Patents to the extent required by Requirements of Law;

(E) subsequent to the issuance of such Patents, neither any Obligor nor its predecessor in interest, have filed any disclaimer or filed any other voluntary reduction in the scope of the Inventions claimed in such Patents;

(F) except as expressly indicated on **Schedule 7.05(b)**, no allowable or allowed subject matter of such Patents, to each Obligor's knowledge, is subject to any competing conception claims of allowable or allowed subject matter of any patent applications or patents of any third party and have not been the subject of any interference, re-examination, opposition or any other post-grant proceedings, nor are the Obligors aware of any basis for any such interference, re-examination, opposition or any other post-grant proceedings;

(G) no such Patents have ever been finally adjudicated to be invalid, unpatentable or unenforceable for any reason in any administrative, arbitration, judicial or other proceeding, and, with the exception of publicly available documents in the applicable patent office recorded with respect to any Patents, the Obligors have not received any notice asserting that such Patents are invalid, unpatentable or unenforceable; if any of such Patents is terminally disclaimed to another patent or patent application, all patents and patent applications subject to such terminal disclaimer are included in the Collateral;

(H) to the best of each Obligor's knowledge, the Obligors have not received an opinion, whether preliminary in nature or qualified in any manner, which concludes that a challenge to the validity or enforceability of any of such Patents is more likely than not to succeed;

(I) the Obligors have no knowledge that they or any prior owner of such Patents or their respective agents or representatives have engaged in any conduct, or omitted to perform any necessary act, the result of which would invalidate or render unpatentable or unenforceable any such Patents; and

(J) all maintenance fees, annuities, and the like due or payable on the Patents have been timely paid or the failure to so pay was the result of an intentional decision by the applicable Obligor or would not reasonably be expected to result in a Material Adverse Change.

(c) **Material Intellectual Property. Schedule 7.05(c)** contains an accurate list of the Obligor Intellectual Property that is material to Borrower's current business with an indication as to whether the applicable Obligor owns or has an exclusive or non-exclusive license to such Obligor Intellectual Property.

## 7.06 No Actions or Proceedings.

(a) **Litigation.** There is no litigation, investigation or proceeding pending or, to Borrower's knowledge, threatened with respect to Borrower and its Subsidiaries by or before any Governmental Authority or arbitrator (i) that either individually or in the aggregate could reasonably be expected to have a Material Adverse Effect, except as specified in **Schedule 7.06(a)** or (ii) that involves this Agreement or the Transactions.

(b) **Environmental Matters.** The operations and property of Borrower and its Subsidiaries comply with all applicable Environmental Laws, except to the extent the failure to so comply (either individually or in the aggregate) could not reasonably be expected to have a Material Adverse Effect.

(c) **Labor Matters.** There are no strikes, lockouts or other material labor disputes against Borrower or any Subsidiary or, to Borrower's knowledge, threatened against or affecting Borrower or any Subsidiary, and no significant unfair labor practice complaint is pending against Borrower or any Subsidiary or, to the knowledge of Borrower, threated against any of them before any Governmental Authority. Except as set forth on **Schedule 7.06(c)**, Borrower is not party to any collective bargaining agreements or contracts, no union representation exists on any facilities of Borrower or any of its Subsidiaries and, to the knowledge of Borrower, no union organizing activities are taking place.

**7.07 Compliance with Laws and Agreements**. Each of the Obligors is in compliance with all Requirements of Law and all indentures, agreements and other instruments binding upon it or its property, except where the failure to do so, individually or in the aggregate, could not reasonably be expected to result in a Material Adverse Effect. No Default has occurred and is continuing. Obligors and their Subsidiaries are in compliance with 21 CFR §§210-211 and 21 CFR §§600-610.

**7.08** Taxes. Except as set forth on Schedule 7.08, each of the Obligors has timely filed or caused to be filed all tax returns and reports required to have been filed and has paid or caused to be paid all taxes required to have been paid by it, except taxes that are being contested in good faith by appropriate proceedings and for which such Obligor has set aside on its books adequate reserves with respect thereto in accordance with GAAP.

**7.09 Full Disclosure.** To the best knowledge of Borrower, none of the representations or warranties made by any Obligor in any of the Loan Documents to which it is a party, as of the date such representations and warranties are made or deemed made, and none of the statements contained in any exhibit, report, statement or certificate furnished by or on behalf of any Obligor in connection with the Loan Documents, contains any untrue statement of a material fact or omits any material fact required to be stated therein or necessary to make the statements made therein, in light of the circumstances under which they are made, not misleading as of the time when made or delivered.

## 7.10 Regulation.

(a) **Investment Company Act.** Neither Borrower nor any of its Subsidiaries is an "investment company" as defined in, or subject to regulation under, the Investment Company Act of 1940.

(b) **Margin Stock.** Neither Borrower nor any of its Subsidiaries is engaged principally, or as one of its important activities, in the business of extending credit for the purpose, whether immediate, incidental or ultimate, of buying or carrying Margin Stock, and no part of the proceeds of the Loans will be used to buy or carry any Margin Stock in violation of Regulation T, U or X.

**7.11 Solvency.** Borrower is and, immediately after giving effect to the Borrowing and the use of proceeds thereof, will be Solvent. Each Subsidiary of Borrower is and, immediately after giving effect to the Borrowing and the use of proceeds thereof, will be Solvent.

**7.12 Subsidiaries.** Set forth on **Schedule 7.12** is a complete and correct list of all Subsidiaries as of the date hereof. Each such Subsidiary is duly organized and validly existing under the jurisdiction of its organization shown in said **Schedule 7.12**, and the percentage ownership by Borrower of each such Subsidiary is as shown in said **Schedule 7.12**. Each Subsidiary that is a Foreign Subsidiary and each Subsidiary that is a Permitted Foreign Subsidiary is designated as such on such Schedule.

**7.13** Indebtedness and Liens. Set forth on Schedule **7.13(a)** is a complete and correct list of all Indebtedness of each Obligor outstanding as of the date hereof. Schedule **7.13(b)** is a complete and correct list of all Liens granted by Borrower and other Obligors with respect to their respective property and outstanding as of the date hereof.

**7.14 Material Agreements.** Set forth on **Schedule 7.14** is a complete and correct list of (i) each Material Agreement and (ii) each agreement creating or evidencing any Material Indebtedness. No Obligor is in material default under any such Material Agreement or agreement creating or evidencing any Material Indebtedness. Except as otherwise disclosed on **Schedule 7.14**, all material vendor purchase agreements and provider Contracts of the Obligors are in full force and effect without material modification from the form in which the same were disclosed to Administrative Agent and the Lenders.

**7.15 Restrictive Agreements.** None of the Obligors is subject to any Restrictive Agreement, except those listed on **Schedule 15** or otherwise permitted under **Section 9.11**.

**Real Property.** Neither Borrower nor any of its Subsidiaries owns or leases (as tenant thereof) any real property, except as described on Schedule 7.16.



**7.17 Pension Matters. Schedule 7.17** sets forth, as of the date hereof, a complete and correct list of, and that separately identifies, (i) all Title IV Plans, (ii) all Multiemployer Plans and (iii) all material Benefit Plans. Each Benefit Plan, and each trust thereunder, intended to qualify for tax exempt status under Section 401 or 501 of the Code or other Requirements of Law so qualifies. Except for those that could not, in the aggregate, have a Material Adverse Effect, (x) each Benefit Plan is in compliance with applicable provisions of ERISA, the Code and other Requirements of Law, (y) there are no existing or pending (or to the knowledge of any Obligor or Subsidiary thereof, threatened) claims (other than routine claims for benefits in the normal course), sanctions, actions, lawsuits or other proceedings or investigation involving any Benefit Plan to which any Obligor or Subsidiary thereof incurs or otherwise has or could have an obligation or any liability or Claim and (z) no ERISA Event is reasonably expected to occur. Borrower and each of its ERISA Affiliates has met all applicable requirements under the ERISA Funding Rules with respect to each Title IV Plan, and no waiver of the minimum funding standards under the ERISA Funding Rules has been applied for or obtained. As of the most recent valuation date for any Title IV Plan, the funding target attainment percentage (as defined in Section 430(d)(2) of the Code) is at least 60%, and neither Borrower nor any of its ERISA Affiliates knows of any facts or circumstances that could reasonably be expected to cause the funding target attainment percentage to fall below 60% as of the most recent valuation date. As of the date hereof, no ERISA Event has occurred in connection with which obligations and liabilities (contingent or otherwise) remain outstanding. No ERISA Affiliate would have any Withdrawal Liability as a result of a complete withdrawal from any Multiemployer Plan on the date this representation is made.

**7.18 Collateral; Security Interest**. Each Security Document is effective to create in favor of the Secured Parties a legal, valid and enforceable security interest in the Collateral subject thereto to the extent required by the applicable Security Document. The Security Documents collectively are effective to create in favor of the Secured Parties a legal, valid and enforceable security interest in the Collateral, which security interests are perfected and first-priority (subject only to Permitted Priority Liens).

## 7.19 Regulatory Approvals.

(a) Each Obligor and each of its Subsidiaries holds, and will continue to hold, either directly or through licensees and agents, all Regulatory Approvals, licenses, permits and similar governmental authorizations of a Governmental Authority necessary or required for Borrower and each of its Subsidiaries to conduct their respective operations and businesses in the manner currently conducted.

(b) Set forth on **Schedule 7.19(b)** is a complete and accurate list as of the date hereof of all material Regulatory Approvals relating to the Obligors and each of their Subsidiaries, the conduct of their business and the Products (on a per Product basis). All such material Regulatory Approvals are (i) legally and beneficially owned exclusively by the Obligors or such Subsidiaries, as the case may be, free and clear of all Liens other than Permitted Liens, (ii) validly registered and on file with the applicable Governmental Authority, in material compliance with all registration, filing and maintenance requirements (including any fee requirements) thereof, and (iii) in good standing, valid and enforceable with the applicable Governmental Authority in all material respects. All required and material notices, registrations and listings, supplemental applications or notifications, reports (including field alerts or other reports of adverse experiences) and other required and material filings with respect to the Products have been filed with the FDA and all other applicable Governmental Authorities.

(c) (i) All material regulatory filings required by any Regulatory Authority or in respect of any Regulatory Approval or Product Authorization with respect to any Product or any Product Development and Commercialization Activities have been made, and all such filings are complete and correct in all material respects and have complied in all material respects with all Requirements of Law, (ii) all clinical and pre-clinical trials, if any, of investigational Products have been and are being conducted by each Obligor according to all Requirements of Law in all material respects along with appropriate monitoring of clinical investigator trial sites for their compliance, and (iii) each Obligor has disclosed to the Lenders all such material regulatory filings and all material communications between representatives of each Obligor and any Regulatory Authority.

(d) Each Obligor and each of its agents are in compliance in all material respects with all applicable Requirements of Law (including all Regulatory Approvals and Product Authorizations) of all applicable Governmental Authorities, including the FDA and all other Regulatory Authorities, with respect to each Product and all Product Development and Commercialization Activities related thereto. Each Obligor has and maintains in full force and effect all the necessary and requisite Regulatory Approvals and Product Authorizations. Each Obligor is in compliance in all material respects with all applicable registration and listing requirements set forth in the FD&C Act or equivalent regulation of each other Governmental Authority having jurisdiction over such Person. Each Obligor adheres in all material respects to all applicable Requirements of Law of all Regulatory Authorities with respect to the Products and all Product Development and Commercialization Activities related thereto.

(e) Except as set forth on **Schedule 7.19(e)**,no Obligor has received from any Regulatory Authority any notice of adverse findings with respect to any Product Development and Commercialization Activities related thereto, including any FDA Form 483 inspectional observations, notices of violations, warning letters, criminal proceeding notices under Section 305 of the FD&C Act, or any other similar communication from any Regulatory Authority. There have been no seizures conducted or, to Borrower's knowledge, threatened by any Regulatory Authority with respect to any Product, and no recalls, market withdrawals, field notifications, notifications of misbranding or adulteration or safety alerts conducted, requested or, to Borrower's knowledge, threatened by any Regulatory Authority relating to any Products. No Obligor has received any written notification that remains unresolved from the FDA or any other Regulatory Authority indicating any breach or violation of any applicable Product Authorization or Regulatory Approval, including that any of the Products is misbranded or adulterated as defined in the FD&C Act or the rules and regulations promulgated thereunder.

(f) Neither any Obligor nor any officer, employee or agent thereof, has made an untrue statement of a material fact or fraudulent statements to the FDA or any other Regulatory Authority, failed to disclose a material fact required to be disclosed to the FDA or any other Regulatory Authority, or committed an act, made a statement, or failed to make a statement that, at the time such disclosure was made (or was not made), could reasonably be expected to provide a basis for the FDA or any other Regulatory Authority to invoke its policy respecting Fraud, Untrue Statements of Material Facts, Bribery and Illegal Gratuities, set forth in 56 Fed. Reg. 46191 (September 10, 1991) or any similar policy.

(g) No Obligor has received any written notice that the FDA or any other applicable Regulatory Authority has commenced or initiated, or, to the knowledge of Borrower or any such Obligor, threatened to commence or initiate, any action to withdraw any Regulatory Approval or Product Authorization or requested the recall of any Products or commenced or initiated or, to the knowledge of Borrower or any such Obligor, threatened to commence or initiate, any action to enjoin any Product Development and Commercialization Activities of Borrower or any such Obligor.

(h) The clinical, preclinical, safety and other studies and tests conducted by or on behalf of or sponsored by each Obligor, or in respect of which any Products or Product candidates under development have participated, were (and if still pending, are) being conducted materially in accordance with standard medical and scientific research procedures and all applicable Product Authorizations. Each Obligor has operated within, and currently is in compliance in all material respects with, all applicable Requirements of Law, Product Authorizations and Regulatory Approvals, as well as the rules and regulations of the FDA and each other Regulatory Authority. No Obligor has received any notices or other correspondence from the FDA or any other Regulatory Authority requiring the termination or suspension of any clinical, preclinical, safety or other studies or tests used to support regulatory clearance of, or any Product Authorization or Regulatory Approval for, any Product.

**7.20** Transactions with Affiliates. Except as set forth on Schedule 7.20, neither Borrower nor any Subsidiary has entered into, renewed, extended or been a part to, any transaction (including the purchase, sale, lease, transfer or exchange of property or assets of any kind or the rendering of services of any kind) with any Affiliate during the three-year period prior to the Closing Date.

**7.21 OFAC.** No Obligor or, to the knowledge of Borrower, any of their respective directors, officers, or employees nor, to the knowledge of Borrower, any agents or other persons acting on behalf of any of the foregoing (i) is currently the target of any Sanctions, (ii) is located, organized or residing in any Designated Jurisdiction, (iii) is or has been (within the previous five years) engaged in any transaction with, or for the benefit of, any Person who is now or was then the target of Sanctions or who is located, organized or residing in any Designated Jurisdiction or (iv) is or has ever been in violation of or subject to an investigation relating to Sanctions. No Loan, nor the proceeds from any Loan, has been or will be used, directly or indirectly, to lend, contribute or provide to, or has been or will be otherwise made available to fund, any activity or business in any Designated Jurisdiction or to fund any activity or business of any Person located, organized or residing in any Designated Jurisdiction, or in any other manner that will result in any violation by any Person (including Administrative Agent and its Affiliates) of Sanctions.

**7.22 Anti-Corruption.** No Obligor or, to the knowledge of Borrower, nor any of their respective directors, officers, or employees nor, to the knowledge of Borrower, any agents or other persons acting on behalf of any of the foregoing, directly or indirectly, has (i) violated or is in violation of any applicable anticorruption law, (ii) made, offered to make, promised to make or authorized the payment or giving of, directly or indirectly, any Prohibited Payment or (iii) been subject to any investigation by any Governmental Authority with regard to any actual or alleged Prohibited Payment.

**7.23 Deposit and Disbursement Accounts. Schedule 7.23** contains a list of all banks and other financial institutions at which any Obligor maintains deposit accounts, lockboxes, disbursement accounts, investment accounts or other similar accounts, and such Schedule correctly identifies the name, address and telephone number of each bank or financial institution, the name in which the account is held, the type of account, and the complete account number therefor.

**7.24** Royalty and Other Payments. Except as set forth on Schedule 7.24, no Obligor is obligated to pay any royalty, milestone payment, deferred payment or any other contingent payment in respect of any Product.

# SECTION 8. AFFIRMATIVE COVENANTS

Each Obligor jointly and severally covenants and agrees with Administrative Agent and the Lenders that, until the Commitments have expired or been terminated and all Obligations (other than Warrant Obligations) have been indefeasibly paid in full in cash:

# 8.01 Financial Statements and Other Information. Borrower will furnish to Administrative Agent:

(a) as soon as available and in any event within 45 days after the end of the first three fiscal quarters of each fiscal year (or 120 days, in the case of the fourth fiscal quarter), the consolidated balance sheets of the Obligors as of the end of such quarter, and the related consolidated statements of income, shareholders' equity and cash flows of Borrower and its Subsidiaries for such quarter and the portion of the fiscal year through the end of such quarter, prepared in accordance with GAAP consistently applied, all in reasonable detail and setting forth in comparative form the figures for the corresponding period in the preceding fiscal year, together with a certificate of a Responsible Officer of Borrower stating that such financial statements fairly present the financial condition of Borrower and its Subsidiaries as at such date and the results of operations of Borrower and its Subsidiaries for the period ended on such date and have been prepared in accordance with GAAP consistently applied, subject to changes resulting from normal, year-end audit adjustments and except for the absence of notes;

(b) other than with respect to the fiscal year ended December 31, 2015 (which shall be governed by **Section 8.20**), as soon as available and in any event within 120 days after the end of each fiscal year, the consolidated balance sheets of Borrower and its Subsidiaries as of the end of such fiscal year, and the related consolidated statements of income, shareholders' equity and cash flows of Borrower and its Subsidiaries for such fiscal year, prepared in accordance with GAAP consistently applied, all in reasonable detail and setting forth in comparative form the figures for the previous fiscal year, accompanied by a report and opinion thereon of KPMG LLP or another firm of independent certified public accountants of recognized national standing acceptable to the Lenders, which report and opinion shall be prepared in accordance with generally accepted auditing standards and shall not be subject to any "going concern" or like qualification or exception or any qualification or exception as to the scope of such audit, and in the case of such consolidating financial statements, certified by a Responsible Officer of Borrower;

(c) as soon as available and in any event within 45 days after the end of each fiscal month of each fiscal year (including the last month of each fiscal quarter and each fiscal year), a consolidated balance sheet for Borrower and its Subsidiaries as at the end of such fiscal month, and the related consolidated statements of income or operations, shareholders' (or members') equity and cash flows for such fiscal month and the portion of Borrower's fiscal year then ended, prepared in accordance with GAAP consistently applied, all in reasonable detail and setting forth in comparative form the figures for the corresponding period in the preceding fiscal year, together with a certificate of a Responsible Officer of Borrower and its Subsidiaries for the previod ended on such date and have been prepared in accordance with GAAP consistently applied, subject to changes resulting from normal, year-end audit adjustments and except for the absence of notes;

(d) together with the financial statements required pursuant to **Sections 8.01(a)**, **(b)** and **(c)**, a compliance certificate of a Responsible Officer as of the end of the applicable accounting period (which delivery may, unless a Lender requests executed originals, be by electronic communication including fax or email and shall be deemed to be an original authentic counterpart thereof for all purposes) substantially in the form of **Exhibit E** (a *"Compliance Certificate"*) including details of any issues that are material that are raised by auditors;

(e) copies of all letters of representation signed by an Obligor to its auditors and, promptly upon receipt thereof, copies of all auditor reports delivered for each fiscal quarter;

(f) as soon as available and in any event no later than 45 days following approval by the Board of Directors (or similar body) of Borrower, copies of all annual financial projections commensurate in form and substance with those provided to Borrower's equity investors;

(g) promptly, and in any event within five Business Days after receipt thereof by an Obligor thereof, copies of each notice or other correspondence received from any securities regulator or exchange to the authority of which Borrower may become subject from time to time concerning any investigation or possible investigation or other inquiry by such agency regarding financial or other operational results of such Obligor;

(h) the information regarding insurance maintained by Borrower and its Subsidiaries as required under **Section 8.05**;

(i) promptly following Administrative Agent's request at any time, proof of Borrower's compliance with **Section 10**;

(j) within five Business Days of delivery, copies of all statements, reports and notices (including board kits) made available to holders of Borrower's Equity Interests; <u>provided</u>that any such material may be redacted by Borrower to exclude information relating to the Lenders (including Borrower's strategy regarding the Loans);

(k) as soon as possible and in any event within ten Business Days after Borrower obtains knowledge of any return, recovery, dispute or claim related to any Product or inventory that involves more than \$1,000,000, written notice thereof from a Responsible Officer of Borrower which notice shall include any statement setting forth details of such return, recovery, dispute or claim; and

(l) such other information respecting the operations, properties, business or condition (financial or otherwise) of the Obligors (including with respect to the Collateral) as the Majority Lenders may from time to time reasonably request.

**8.02** Notices of Material Events. Borrower will furnish to Administrative Agent written notice of the following promptly, but in any event within ten Business Days, after a Responsible Officer first learns of the existence of:

(a) the occurrence of any Default;

(b) notice of the occurrence of any event with respect to its property or assets resulting in an uninsured Loss aggregating \$250,000 (or the Equivalent Amount in other currencies) or more;

(c) (i) any proposed acquisition of stock, assets or property by any Obligor that would reasonably be expected to result in environmental liability under Environmental Laws, and (ii)(x) spillage, leakage, discharge, disposal, leaching, migration or release of any Hazardous Material required to be reported to any Governmental Authority under applicable Environmental Laws, and (y) all actions, suits, claims, notices of violation, hearings, investigations or proceedings pending, or to the best of Borrower's knowledge, threatened against or affecting Borrower or any of its Subsidiaries or with respect to the ownership, use, maintenance and operation of their respective businesses, operations or properties, relating to Environmental Laws or Hazardous Material;

(d) the assertion of any environmental matter by any Person against, or with respect to the activities of, Borrower or any of its Subsidiaries and any alleged violation of or non-compliance with any Environmental Laws or any permits, licenses or authorizations which could reasonably be expected to involve damages in excess of \$250,000 other than any environmental matter or alleged violation that, if adversely determined, could not (either individually or in the aggregate) reasonably be expected to result in a Material Adverse Effect;

(e) the filing or commencement of any action, suit or proceeding by or before any arbitrator or Governmental Authority against or affecting Borrower or any of its Affiliates that, if adversely determined, could reasonably be expected to result in a Material Adverse Effect;

(f) (i) on or prior to any filing by any ERISA Affiliate of any notice of intent to terminate any Title IV Plan, a copy of such notice and (ii) promptly, and in any event within ten days, after any Responsible Officer of any ERISA Affiliate knows or has reason to know that a request for a minimum funding waiver under Section 412 of the Code has been filed with respect to any Title IV Plan or Multiemployer Plan, a notice (which may be made by telephone if promptly confirmed in writing) describing such waiver request and any action that any ERISA Affiliate proposes to take with respect thereto, together with a copy of any notice filed with the PBGC or the IRS pertaining thereto;

(g) (i) the termination of any Material Agreement; (ii) the receipt by Borrower or any of its Subsidiaries of any material notice under any Material Agreement (and a copy thereof); (iii) the entering into of any new Material Agreement by an Obligor (and a copy thereof); or (iv) any material amendment to a Material Agreement (and a copy thereof) that, in the case of clauses (i), (ii) or (iv), could reasonably be expected to result in a Material Adverse Effect;

(h) the reports and notices as required by the Security Documents;

(i) within 30 days of the date thereof, or, if earlier, on the date of delivery of any financial statements pursuant to **Section 8.01**,notice of any material change in accounting policies or financial reporting practices by the Obligors;

(j) promptly after the occurrence thereof, notice of any labor controversy resulting in or threatening to result in any strike, work stoppage, boycott, shutdown or other material labor disruption against or involving an Obligor;

(k) a licensing agreement or arrangement entered into by Borrower or any of its Subsidiaries in connection with (or as a result of) any infringement or alleged infringement by Borrower or any of its Subsidiaries of the Intellectual Property of another Person;

(l) concurrently with the delivery of financial statements under **Section 8.01(b)**, the creation or other acquisition of any Intellectual Property by Borrower or any Subsidiary after the date hereof and during such prior fiscal year which is registered or becomes registered or the subject of an application for registration with the U.S. Copyright Office or the U.S. Patent and Trademark Office, as applicable, or with any other equivalent foreign Governmental Authority;

(m) any change to any Obligor's ownership of Deposit Accounts, Securities Accounts and Commodity Accounts, by delivering Administrative Agent an updated Schedule 7 to the Security Agreement setting forth a complete and correct list of all such accounts as of the date of such change; and

(n) any other development that results in, or could reasonably be expected to result in, a Material Adverse Effect.

Each notice delivered under this **Section 8.02** shall be accompanied by a statement of a financial officer or other executive officer of Borrower setting forth the details of the event or development requiring such notice and any action taken or proposed to be taken with respect thereto.

**8.03** Existence; Conduct of Business. Such Obligor will, and will cause each of its Subsidiaries to, do or cause to be done all things necessary to preserve, renew and keep in full force and effect its legal existence and the rights, licenses, permits, privileges and franchises material to the conduct of its business; provided that the foregoing shall not prohibit any merger, amalgamation, consolidation, liquidation or dissolution permitted under Section 9.03.

**8.04 Payment of Obligations.** Such Obligor will, and will cause each of its Subsidiaries to, pay and discharge its obligations, including (i) all taxes, fees, assessments and governmental charges or levies imposed upon it or upon its properties or assets prior to the date on which penalties attach thereto, and all lawful claims for labor, materials and supplies which, if unpaid, might become a Lien upon any properties or assets of Borrower or any Subsidiary, except to the extent such taxes, fees, assessments or governmental charges or levies, or such claims are being contested in good faith by appropriate proceedings and are adequately reserved against in accordance with GAAP, and (ii) all lawful claims which, if unpaid, would by law become a Lien upon its property not constituting a Permitted Lien.

**8.05 Insurance.** Such Obligor will, and will cause each of its Subsidiaries to maintain, with financially sound and reputable insurance companies, insurance in such amounts and against such risks as are customarily maintained by companies engaged in the same or similar businesses operating in the same or similar locations, and with coverage amounts for property insurance and liability insurance of not less than \$10,000,000 in the aggregate. Upon the request of Administrative Agent or the Majority Lenders, Borrower shall furnish Administrative Agent from time to time with (i) full information as to the insurance carried by it and, if so requested, copies of all such insurance policies and (ii) a certificate from Borrower's insurance broker or other insurance specialist stating that all premiums then due on the policies relating to insurance on the Collateral have been paid, that such policies are in full force and effect. Borrower shall use commercially reasonable efforts to ensure, or cause others to ensure, that all insurance policies required under this **Section 8.05** shall provide that they shall not be terminated or cancelled nor shall any such policy be materially changed in a manner adverse to Borrower without at least 30 days' prior written notice to Borrower and Administrative Agent. Receipt of notice of termination or cancellation of any such insurance policies or reduction of coverages or amounts thereunder shall entitle Secured Parties to renew any such policies, cause the coverages and amounts thereof to be maintained at levels required pursuant to the first sentence of this **Section 8.05** or otherwise to obtain similar insurance in place of such policies, in each case at the expense of Borrower (payable on demand). The amount of any such expenses shall accrue interest at the Default Rate if not paid on demand and shall constitute "Obligations."

**8.06 Books and Records; Inspection Rights.** Such Obligor will, and will cause each of its Subsidiaries to, keep proper books of record and account in which full, true and correct entries are made of all dealings and transactions in relation to its business and activities. Such Obligor will, and will cause each of its Subsidiaries to, permit any representatives designated by Administrative Agent or the Lenders, upon reasonable prior notice, to visit and inspect its properties, to examine and make extracts from its books and records, and to discuss its affairs, finances and condition with its officers and independent accountants, all at such reasonable times (but not more often than once a year unless an Event of Default has occurred and is continuing) as Administrative Agent or the Lenders may request. The Obligors shall pay all costs of all such inspections.

**8.07** Compliance with Laws and Other Obligations. Such Obligor will, and will cause each of its Subsidiaries to, (i) comply in all material respects with all Requirements of Law (including Environmental Laws) and (ii) comply in all material respects with all terms of Indebtedness and all other Material Agreements, except where the failure to do so, individually or in the aggregate, could not reasonably be expected to result in a Material Adverse Effect.

**8.08** Maintenance of Properties, Etc. Such Obligor shall, and shall cause each of its Subsidiaries to, maintain and preserve all of its properties necessary or useful in the proper conduct of its business in good working order and condition in accordance with the general practice of other Persons of similar character and size, ordinary wear and tear and damage from casualty or condemnation excepted.

**8.09** Licenses. Such Obligor shall, and shall cause each of its Subsidiaries to, obtain and maintain all licenses, authorizations, consents, filings, exemptions, registrations and other Governmental Approvals necessary in connection with the execution, delivery and performance of the Loan Documents, the consummation of the Transactions or the operation and conduct of its business and ownership of its properties, except where failure to do so could not reasonably be expected to have a Material Adverse Effect.

**8.10** Action under Environmental Laws. Such Obligor shall, and shall cause each of its Subsidiaries to, upon becoming aware of the presence of any Hazardous Materials or the existence of any environmental liability under applicable Environmental Laws with respect to their respective businesses, operations or properties, take all actions, at their cost and expense, as shall be necessary or advisable to investigate and clean up the condition of their respective businesses, operations or properties, including all required removal, containment and remedial actions, and restore their respective businesses, operations or properties to a condition in compliance with applicable Environmental Laws.

**8.11** Use of Proceeds. The proceeds of the Loans will be used only as provided in Section 2.05. No part of the proceeds of the Loans will be used, whether directly or indirectly, for any purpose that entails a violation of any of the Regulations of the Board of Governors of the Federal Reserve System, including Regulations T, U and X.

### 8.12 Certain Obligations Respecting Subsidiaries; Further Assurances.

(a) Such Obligor will take such action, and will cause each of its Subsidiaries to take such action, from time to time as shall be necessary to ensure that all Subsidiaries that are Domestic Subsidiaries and Permitted Foreign Subsidiaries are "Subsidiary Guarantors" hereunder. Without limiting the generality of the foregoing, in the event that Borrower or any of its Subsidiaries shall form or acquire any new Subsidiary that is a Domestic Subsidiary or a Permitted Foreign Subsidiary, such Obligor and its Subsidiaries concurrently will:

(i) cause such new Subsidiary to become a "Subsidiary Guarantor" hereunder pursuant to a Guarantee Assumption Agreement;

(ii) take such action or cause such Subsidiary to take such action (including joining the Security Agreement, delivering such shares of stock together with undated transfer powers executed in blank) as shall be necessary to create and perfect valid and enforceable first priority (subject to Permitted Priority Liens) Liens on substantially all of the personal property of such new Subsidiary as collateral security for the obligations of such new Subsidiary hereunder;

(iii) to the extent that the parent of such Subsidiary is not a party to the Security Agreement or has not otherwise pledged Equity Interests in its Subsidiaries in accordance with the terms of the Security Agreement and this Agreement, cause the parent of such Subsidiary to execute and deliver a pledge agreement in favor of Administrative Agent, for the benefit of the Secured Parties, in respect of all outstanding issued shares of such Subsidiary; and

(iv) deliver such proof of corporate action, incumbency of officers, opinions of counsel and other documents as is consistent with those delivered by each Obligor pursuant to **Section 6.01** or as Administrative Agent or the Majority Lenders shall have requested.

(b) No Foreign Subsidiary shall be required to become a Subsidiary Guarantor hereunder. Except as set forth on **Schedule 7.12**, Borrower has no Foreign Subsidiaries.

(c) Such Obligor will, and will cause each of its Subsidiaries to, take such action from time to time as shall reasonably be requested by Administrative Agent or the Majority Lenders to effectuate the purposes and objectives of this Agreement.

Without limiting the generality of the foregoing, each Obligor will, and will cause each Person that is required to be a Subsidiary Guarantor to, take such action from time to time (including executing and delivering such assignments, security agreements, control agreements and other instruments) as shall be reasonably requested by Administrative Agent or the Majority Lenders to create, in favor of Administrative Agent, for the benefit of the Secured Parties, perfected security interests and Liens in substantially all of the personal property of such Obligor as collateral security for the Obligations; <u>provided</u> that any such security interest or Lien shall be subject to the relevant requirements of the Security Documents.

**8.13** Termination of Non-Permitted Liens. In the event that Borrower or any of its Subsidiaries shall become aware or be notified by Administrative Agent or any Lender of the existence of any outstanding Lien against any property of Borrower or any of its Subsidiaries, which Lien is not a Permitted Lien, Borrower shall use its best efforts to promptly terminate or cause the termination of such Lien.

**8.14 Intellectual Property.** In the event that the Obligors acquire Obligor Intellectual Property during the term of this Agreement, then the provisions of this Agreement shall automatically apply thereto and any such Obligor Intellectual Property shall automatically constitute part of the Collateral under the Security Documents, without further action by any party, in each case from and after the date of such acquisition (except that any representations or warranties of any Obligor shall apply to any such Obligor Intellectual Property only from and after the date, if any, subsequent to such acquisition that such representations and warranties are brought down or made anew as provided herein).

**8.15** Litigation Cooperation. Borrower shall make available to Administrative Agent, without expense to Administrative Agent, reasonable access to each Obligor and such Obligor's officers, employees and agents and such Obligor's books and records, to the extent that Administrative Agent may deem them reasonably necessary to prosecute or defend any third-party suit or proceeding instituted by or against Administrative Agent or any Lender with respect to any Collateral, the subject of any Loan Document or relating to any Obligor.

8.16 Maintenance of Regulatory Approvals, Contracts, Intellectual Property, Etc. With respect to the Products, Borrower will, and will cause each other Obligor (to the extent applicable) to, (i) maintain in full force and effect all Regulatory Approvals (including all Product Authorizations), contract rights, or other rights necessary for the operations of Borrower's or such Obligor's business, as the case may be, including any Product Development and Commercialization Activities, (ii) notify Administrative Agent, promptly after learning thereof, of (x) any product recalls, safety alerts, corrections, withdrawals, marketing suspensions, removals or the like conducted, to be undertaken or issued by Borrower, any such Obligor or any of their respective suppliers, as the case may be, whether or not at the request, demand or order of any Governmental Authority or otherwise with respect to any Product, or (y) any basis for undertaking or issuing any such action or item, (iii) maintain in full force and effect, and pay all costs and expenses relating to such maintenance, all Intellectual Property owned or controlled by Borrower or any such Obligor that is used in and is necessary for the operations of the business of such Person, including Product Development and Commercialization Activities, and all Material Agreements, (iv) notify Administrative Agent, promptly after learning thereof, of any Infringement or other violation by any Person of Borrower's or any other Obligor's Intellectual Property that is used in the operations of the business of such Person, or in connection with any Product Development and Commercialization Activities, and aggressively pursue any such Infringement or other violation, to the extent Borrower deems it commercially reasonable to do so, (v) use commercially reasonable efforts to pursue and maintain in full force and effect legal protection for all new Intellectual Property developed or controlled by Borrower or any other Obligor, as the case may be, that is used in and necessary for the operations of the business of such Person, or in connection with any Product Development and Commercialization Activities, and (vi) notify Administrative Agent, promptly after learning thereof, of (x) any claim by any Person that the conduct of Borrower's or any such Obligor's business (including any Product Development and Commercialization Activities) Infringes any Intellectual Property of such Person, or (y) any event, circumstance, act or omission that would cause any representation or warranty contained in Section 7.19 to be incorrect in any material respect if such representation or warranty was to be made at the time such Obligor learned of such event, circumstance, act or omission.

**8.17 ERISA Compliance.** Borrower shall comply, and shall cause each of its Subsidiaries to comply, in all material respects, with the provisions of ERISA with respect to any Plans to which Borrower or any Subsidiary is a party as employer.

### 8.18 Cash Management. Each Obligor will:

(a) maintain all deposit accounts, disbursement accounts, investment accounts (and other similar accounts) and lockboxes with a bank or financial institution that has executed and delivered to Administrative Agent an account control agreement, in form and substance reasonably acceptable to Administrative Agent (provided that no account control agreement shall be required for any payroll or payroll tax account of Borrower or any deposit account maintained in connection with any Borrower employee benefit plan, to the extent the funds on deposit therein are held for the benefit of Borrower's employees); each such deposit account, disbursement account, investment account (or similar account) and lockbox (each, a *"Controlled Account"*) shall be a cash collateral account, with all cash, checks and other similar items of payment in such account securing payment of the Obligations, and each Obligor shall have granted a Lien to Administrative Agent over such Controlled Accounts;

(b) deposit promptly, and in any event no later than ten Business Days after the date of receipt thereof, all cash, checks, drafts or other similar items of payment relating to or constituting payments made in respect of any and all accounts and other rights and interests into Controlled Accounts; and

(c) at any time after the occurrence and during the continuance of an Event of Default, at the request of Administrative Agent, each Obligor will cause all payments constituting proceeds of accounts to be directed into lockbox accounts under agreements in form and substance satisfactory to Administrative Agent.

**8.19 Regulatory Milestones.** On or before March 31, 2018, the Borrower shall have filed (or caused to be filed) with the FDA, in accordance with all applicable Requirements of Law, a Form FDA-356h (or successor form thereto) for approval by the FDA of an NDA for at least one of the following Products: Diazepam, Riluzole, Clobazam or Epinephrine.

### 8.20 Post-Closing Obligations.

(a) Borrower shall deliver, or shall cause to be delivered, the following items to the Administrative Agent within 45 days after the Closing Date:

(i) audited consolidated financial statements of Borrower and its Subsidiaries for the Fiscal Year ended December 31, 2015, together with such other information required to be delivered pursuant to **Section 8.01(b)** with respect thereto;

(ii) evidence that all deposit accounts, lockboxes, disbursement accounts, investment accounts or other similar accounts of each Obligor set forth on Schedule 7 to the Security Agreement as of the Closing Date are Controlled Accounts; and

(iii) evidence that all such Controlled Accounts set forth on Schedule 7 to the Security Agreement as of the Closing Date are subject to one or more account control agreements, in favor of, and satisfactory in form and substance to, Administrative Agent.

(b) Borrower shall use commercially reasonable efforts to deliver, or cause to be delivered, executed counterparts of the Landlord Consents for each of the properties listed on Schedule 9 to the Security Agreement as of the Closing Date (other than the leased property identified as "TN Lab" on such Schedule) to the Administrative Agent within 45 days after the Closing Date.

## SECTION 9. NEGATIVE COVENANTS

Each Obligor jointly and severally covenants and agrees with Administrative Agent and the Lenders that, until the Commitments have expired or been terminated and all Obligations (other than Warrant Obligations) have been paid in full indefeasibly in cash:

**9.01** Indebtedness. Such Obligor will not, and will not permit any of its Subsidiaries to, create, incur, assume or permit to exist any Indebtedness, whether directly or indirectly, except:

# (a) the Obligations;

(b) Indebtedness existing on the date hereof and set forth in **Schedule 7.13(a)** and Permitted Refinancings thereof; <u>provided</u>that, in each case, such Indebtedness is subordinated to the Obligations on terms satisfactory to the Majority Lenders;

(c) accounts payable to trade creditors for goods and services and current operating liabilities (not the result of the borrowing of money) incurred in the ordinary course of Borrower's or such Subsidiary's business in accordance with customary terms and paid within the specified time, unless contested in good faith by appropriate proceedings and reserved for in accordance with GAAP;

(d) Indebtedness consisting of guarantees resulting from endorsement of negotiable instruments for collection by any Obligor in the ordinary course of business;

(e) Indebtedness of an Obligor (other than any Foreign Subsidiary) to any other Obligor;

(f) Guarantees by any Obligor of Indebtedness of any other Obligor (other than any Foreign Subsidiary); <u>provided</u> that the aggregate outstanding principal amount of such Indebtedness, when added to the aggregate principal amount of the outstanding Indebtedness permitted in reliance on **Section 9.01(g)**, does not exceed \$250,000 (or the Equivalent Amount in other currencies) at any time;

(g) normal course of business equipment financing; <u>provided</u> that (i) if secured, the collateral therefor consists solely of the assets being financed, the products and proceeds thereof and books and records related thereto, and (ii) the aggregate outstanding principal amount of such Indebtedness, when added to the aggregate principal amount of the outstanding Indebtedness permitted in reliance on **Section 9.01(f)**, does not exceed \$500,000 (or the Equivalent Amount in other currencies) at any time;

(h) Indebtedness under Hedging Agreements permitted by Section 9.05(f); and

(i) Indebtedness approved in advance in writing by Administrative Agent and the Majority Lenders.

**9.02** Liens. Such Obligor will not, and will not permit any of its Subsidiaries to, create, incur, assume or permit to exist any Lien on any property now owned by it, or assign or sell any income or revenues (including accounts receivable) or rights in respect of any thereof, except:

(a) Liens securing the Obligations;

(b) any Lien on any property or asset of Borrower or any of its Subsidiaries existing on the date hereof and set forth in **Schedule 7.13(b)**; <u>provided</u> that (i) no such Lien shall extend to any other property or asset of Borrower or any of its Subsidiaries and (ii) any such Lien shall secure only those obligations which it secures on the date hereof and extensions, renewals and replacements thereof that do not increase the outstanding principal amount thereof;

(c) Liens securing Indebtedness permitted under Section 9.01(g); provided that such Liens are restricted solely to the collateral described in Section 9.01(g);

(d) Liens imposed by law which were incurred in the ordinary course of business, including (but not limited to) carriers', warehousemen's and mechanics' liens and other similar Liens arising in the ordinary course of business and which (x) do not in the aggregate materially detract from the value of the property subject thereto or materially impair the use thereof in the operations of the business of such Person or (y) are being contested in good faith by appropriate proceedings, which proceedings have the effect of preventing the forfeiture or sale of the property subject to such Liens and for which adequate reserves have been made if required in accordance with GAAP;

(e) pledges or deposits made in the ordinary course of business in connection with workers' compensation, unemployment insurance or other similar social security legislation;

(f) Liens securing taxes, assessments and other governmental charges, the payment of which is not yet due or is being contested in good faith by appropriate proceedings promptly initiated and diligently conducted and for which such reserve or other appropriate provisions, if any, as shall be required by GAAP shall have been made;

(g) servitudes, easements, rights of way, restrictions and other similar encumbrances on real property imposed by any Requirement of Law and encumbrances consisting of zoning or building restrictions, easements, licenses, restrictions on the use of property or minor imperfections in title thereto which, in the aggregate, are not material, and which do not in any case materially detract from the value of the property subject thereto or interfere with the ordinary conduct of the business of any of the Obligors;

(h) with respect to any real property, (i) such defects or encroachments as might be revealed by an up-to-date survey of such real property; (ii) the reservations, limitations, provisos and conditions expressed in the original grant, deed or patent of such property by the original owner of such real property pursuant to Requirements of Law; and (iii) rights of expropriation, access or user or any similar right conferred or reserved by or in any Requirement of Law, which, in the aggregate for (i), (ii) and (iii), are not material, and which do not in any case materially detract from the value of the property subject thereto or interfere with the ordinary conduct of the business of any of the Obligors; and

(i) Bankers liens, rights of setoff and similar Liens incurred on deposits made in the ordinary course of business;

provided that no Lien otherwise permitted under any of the foregoing Section 9.02(b) through (i) shall apply to any Material Intellectual Property.

**9.03** Fundamental Changes and Acquisitions. Such Obligor will not, and will not permit any of its Subsidiaries to, (i) enter into any transaction of merger, amalgamation or consolidation, (ii) liquidate, wind up or dissolve itself (or suffer any liquidation or dissolution) or (iii) make any Acquisition or otherwise acquire any business or substantially all the property from, or capital stock of, or be a party to any acquisition of, any Person, except:

(a) Investments permitted under **Section 9.05(e)**;

(b) the merger, amalgamation or consolidation of any Subsidiary Guarantor with or into any other Obligor (other than any Foreign Subsidiary);

(c) the sale, lease, transfer or other disposition by any Subsidiary Guarantor of any or all of its property (upon voluntary liquidation or otherwise) to any other Obligor (other than any Foreign Subsidiary);

(d) the sale, transfer or other disposition of the capital stock of any Subsidiary Guarantor to any other Obligor (other than any Foreign Subsidiary); and

(e) Permitted Acquisitions.

**9.04** Lines of Business. Except as set forth on Schedule 9.04, such Obligor will not, and will not permit any of its Subsidiaries to, engage to any material extent in any business other than the business engaged in or planned to be engaged in on the date hereof by Borrower or any Subsidiary or a business reasonably related thereto.

**9.05 Investments.** Such Obligor will not, and will not permit any of its Subsidiaries to, make, directly or indirectly, or permit to remain outstanding any Investments except:

(a) Investments outstanding on the date hereof and identified in Schedule 9.05;

(b) operating deposit accounts with banks;

(c) extensions of credit in the nature of accounts receivable or notes receivable arising from the sales of goods or services in the ordinary course of business;

(d) Permitted Cash Equivalent Investments;

(e) Investments by any Obligor in the Subsidiary Guarantors;

(f) Hedging Agreements entered into in Borrower's ordinary course of business for the purpose of hedging currency risks (and not for speculative purposes) and in an aggregate notional amount for all such Hedging Agreements not in excess of \$1,500,000 (or the Equivalent Amount in other currencies);

(g) Investments consisting of security deposits with utilities and other like Persons made in the ordinary course of business;

(h) employee loans, travel advances and guarantees in accordance with Borrower's usual and customary practices with respect thereto (if permitted by Requirements of Law) which in the aggregate shall not exceed \$100,000 outstanding at any time (or the Equivalent Amount in other currencies);

(i) Investments received in connection with any Insolvency Proceedings in respect of any customers, suppliers or clients and in settlement of delinquent obligations of, and other disputes with, customers, suppliers or clients; and

### (j) Investments permitted under Section 9.03.

**9.06 Restricted Payments.** Such Obligor will not, and will not permit any of its Subsidiaries to, declare or make, or agree to pay or make, directly or indirectly, any Restricted Payment, other than:

(a) dividends with respect to Borrower's Equity Interests payable solely in additional Equity Interests that constitute common stock (or the equivalent);

(b) Borrower's purchase, redemption, retirement, or other acquisition of its Equity Interests with the proceeds received from a substantially concurrent issue of new shares of its Equity Interests;

(c) dividends paid by any Subsidiary Guarantor to any other Obligor (other than any Foreign Subsidiary); and

(d) if Borrower is at the time taxed as a partnership for federal and state tax income purposes, quarterly cash distributions to the holders of the Equity Interests of Borrower in an aggregate amount not to exceed the amount necessary to pay current year estimated taxes (including self-employment taxes and calculated at a maximum income tax rate equal to the highest effective federal and applicable state marginal income tax rates owing by the holders of Equity Interests of Borrower) attributable to the taxable income of Borrower and its Subsidiaries from and after the Closing Date, plus (x) the amount by which actual taxes, including self-employment taxes, of such holders (calculated on an aggregate basis at such maximum tax rate) exceed estimated taxes, if such actual taxes of such holders are higher than such estimated taxes, and minus (y) the amount by which estimates taxes of such holders exceed actual taxes, including self-employment taxes, of such holders (calculated on an aggregate basis at such maximum income tax rate), if such estimated taxes exceed such actual taxes.

**9.07** Payments of Indebtedness. Such Obligor will not, and will not permit any of its Subsidiaries to, make any payments in respect of any Indebtedness other than (i) payments of the Obligations, (ii) scheduled payments of other Permitted Indebtedness and (iii) repayment of intercompany Indebtedness permitted in reliance upon Section 9.01(e).

**9.08** Change in Fiscal Year. Such Obligor will not, and will not permit any of its Subsidiaries to, change the last day of its fiscal year from that in effect on the date hereof, except to change the fiscal year of a Subsidiary acquired in connection with an Acquisition to conform its fiscal year to that of Borrower.

**9.09** Sales of Assets, Etc. Such Obligor will not, and will not permit any of its Subsidiaries to, sell, lease, license, transfer or otherwise dispose of any of its property (including accounts receivable and Equity Interests of Subsidiaries), or forgive, release or compromise any amount owed to such Obligor or Subsidiary, in each case, in one transaction or series of transactions (any thereof, an "*Asset Sale*"), except:

- (a) sales of inventory in the ordinary course of its business on ordinary business terms;
- (b) the forgiveness, release or compromise of any amount owed to any Obligor or Subsidiary in the ordinary course of business;
- (c) Asset Sales that constitute outbound licenses permitted pursuant to **Section 9.13(b)**;
- (d) transfers of property by any Subsidiary Guarantor to any other Obligor (other than any Foreign Subsidiary);
- (e) dispositions of any property that is obsolete or worn out or no longer used or useful in the Business;
- (f) in connection with any transaction permitted under Section 9.03 or 9.05.

**9.10** Transactions with Affiliates. Such Obligor will not, and will not permit any of its Subsidiaries to, sell, lease, license or otherwise transfer any assets to, or purchase, lease, license or otherwise acquire any assets from, or otherwise engage in any other transactions with, any of its Affiliates, except:

- (a) transactions between or among Obligors (other than any Foreign Subsidiary);
- (b) any transaction permitted under **Section 9.01**, **9.05**, **9.06** or **9.09**;

(c) customary compensation and indemnification of and other employment arrangements with, directors, officers and employees of Borrower or any Subsidiary in the ordinary course of business;

(d) issuances of Equity Interests by Borrower constituting common stock (or the equivalent thereof) to Affiliates in exchange for cash, provided that the terms thereof are no less favorable (including the amount of cash received by Borrower) to Borrower than those that would be obtained in a comparable arm's-length transaction with a Person not an Affiliate of Borrower; and

(e) the transactions set forth on **Schedule 9.10**.

**9.11 Restrictive Agreements.** Such Obligor will not, and will not permit any of its Subsidiaries to, directly or indirectly, enter into, incur or permit to exist any Restrictive Agreement other than (i) restrictions and conditions imposed by law or by the Loan Documents and (ii) Restrictive Agreements listed on **Schedule 7.15**.

**9.12** Modifications and Terminations of Material Agreements and Organic Documents. To the extent such action could reasonably be expected to have or result in a Material Adverse Effect, such Obligor will not, and will not permit any of its Subsidiaries to,

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#### (a) waive, amend or otherwise modify any term or provision of any Organic Document; or

(b) (x) take or omit to take any action that results in the termination of any Material Agreement or (y) take any action that permits any Material Agreement to be terminated by any counterparty thereto prior to its stated date of expiration (in each case, unless such terminated Material Agreement is replaced with another agreement that, viewed as a whole, is on equal or better terms for Borrower or such Subsidiary).

## 9.13 Inbound and Outbound Licenses.

(a) **Inbound Licenses.** No Obligor shall enter into or become or, except as disclosed on **Schedule 9.13(a)**, remain bound by any inbound license agreement requiring any Obligor, during any twelve-month period during the term of such license agreement, to make aggregate payments in excess of \$1,000,000 for any such individual license or agreement or in excess of \$5,000,000 when taken together with all other such licenses agreements, unless (i) no Event of Default has occurred and is continuing and (ii)(x) Borrower has provided prior written notice to Administrative Agent of the material terms of such license or agreement with a description of its anticipated and projected impact on the relevant Obligor's business or financial condition, (y) such license or agreement has been approved pursuant to Borrower's internal customary approval process for inbound licenses, and (z) Borrower has taken such commercially reasonable actions as Administrative Agent may reasonably request to obtain the consent of, or waiver by, any Person whose consent or waiver is necessary for Administrative Agent to be granted a valid and perfected Lien on such license agreement and the right to fully exercise its rights under any of the Loan Documents, including upon the occurrence and continuance of any Event of Default; <u>provided</u> that inbound licenses agreements in the nature of over-the-counter software that is commercially available to the public shall not be prohibited by or subject to this **clause (a)**.

(b) **Outbound Licenses.** No Obligor shall enter into or become or, except as disclosed on **Schedule 9.13(b)**, remain bound by any outbound license of Intellectual Property unless such outbound license (i) is duly authorized by Borrower in accordance with its customary internal approval process for outbound licenses and is entered into on an arm's-length basis and in the ordinary course of business, and (ii) to the extent such Intellectual Property constitutes Collateral, the terms of such license do not impair Administrative Agent or the Lenders from fully exercising their rights under any of the Loan Documents in the event of a disposition or liquidation of the rights, assets or property that is the subject of such license.

**9.14** Sales and Leasebacks. Except as disclosed on Schedule 9.14, such Obligor will not, and will not permit any of its Subsidiaries to, become liable, directly or indirectly, with respect to any lease, whether an operating lease or a Capital Lease Obligation, of any property (whether real, personal, or mixed), whether now owned or hereafter acquired, (i) which Borrower or such Subsidiary has sold or transferred or is to sell or transfer to any other Person and (ii) which Borrower or such Subsidiary intends to use for substantially the same purposes as property which has been or is to be sold or transferred.

**9.15** Hazardous Material. Such Obligor will not, and will not permit any of its Subsidiaries to, use, generate, manufacture, install, treat, release, store or dispose of any Hazardous Material, except in compliance with all applicable Environmental Laws or where the failure to comply could not reasonably be expected to result in a Material Adverse Effect.

**9.16** Accounting Changes. Such Obligor will not, and will not permit any of its Subsidiaries to, make any significant change in accounting treatment or reporting practices, except as required or permitted by GAAP.

**9.17 Compliance with ERISA.** No ERISA Affiliate shall cause or suffer to exist (i) any event that could result in the imposition of a Lien with respect to any Title IV Plan or Multiemployer Plan or (ii) any other ERISA Event that would, in the aggregate, have a Material Adverse Effect. No Obligor or Subsidiary thereof shall cause or suffer to exist any event that could result in the imposition of a Lien with respect to any Benefit Plan.

**9.18 Inconsistent Agreements.** No Obligor will enter into any agreement containing any provision which would (i) be violated or breached by such Obligor hereunder or by the performance by such Obligor of any of its obligations hereunder or under any other Loan Document, (ii) prohibit any such Obligor from granting to Administrative Agent a Lien on any of its assets or (iii) create or permit to exist or become effective any encumbrance or restriction on the ability of any Obligor to (x) pay dividends or make other distributions to Borrower, or pay any Indebtedness owed to Borrower, (y) make loans or advances to Borrower or (z) transfer any of its assets or properties to Borrower.

# SECTION 10. FINANCIAL COVENANTS

**10.01 Minimum Liquidity.** Borrower shall at all times maintain a minimum aggregate balance of \$4,000,000 in cash in one or more Controlled Accounts, which cash and Controlled Accounts shall be free and clear of all Liens, other than Liens granted hereunder in favor of Administrative Agent.

**10.02 Minimum Revenue.** Subject to **Section 10.03** below, on each calculation date set forth below (each, a "*Calculation Date*") Manufacturing Revenue of the Borrower and its Subsidiaries, on a consolidated basis, for the twelve consecutive month period ended on such Calculation Date shall not be less than the amount set forth opposite such Calculation Date:

Calculation Date	Manufacturing Revenue
December 31, 2016	\$24,500,000
March 31, 2017	\$25,400,000
June 30, 2017	\$24,600,000
September 30, 2017	\$22,300,000
December 31, 2017	\$21,300,000

Calculation Date	Manufacturing Revenue
March 31, 2018	\$21,500,000
June 30, 2018	\$22,000,000
September 30, 2018	\$24,500,000
December 31, 2018	\$28,000,000
March 31, 2019	\$32,500,000
June 30, 2019	\$32,500,000
September 30, 2019	\$35,000,000
December 31, 2019	\$35,000,000
March 31, 2020	\$37,500,000
June 30, 2020	\$37,500,000

**10.03 Revenue Covenant Cure.** If as of any Calculation Date set forth above, Manufacturing Revenue as of such Calculation Date is less than the amount required above for such Calculation Date (a "*Shortfall Default*"), such Shortfall Default shall be deemed cured (a "*Revenue Covenant Cure*") if, at all times from such Calculation Date until the next scheduled Calculation Date, Borrower maintains a minimum aggregate balance of \$8,000,000 in cash in one or more Controlled Accounts, which cash and Controlled Accounts are free and clear of all Liens, other than Liens granted hereunder in favor of the Administrative Agent; <u>provided</u> that (a) Borrower shall only be entitled to two Revenue Covenant Cures during the term of this Agreement and (b) Borrower may not use a Revenue Covenant Cure in two consecutive fiscal quarters; <u>provided</u>, <u>further</u> that, at any time during which a Revenue Covenant Cure is in effect, upon the request of the Administrative Agent, Borrower shall, from time to time, provide evidence in written and reasonable detail demonstrating Borrower's maintenance of not less than \$8,000,000 in cash in the Collateral Accounts (as provided above).

# SECTION 11. EVENTS OF DEFAULT

11.01 Events of Default. Each of the following events shall constitute an "Event of Default":

(a) **Principal or Interest Payment Default.** Borrower shall fail to pay: (i) when and as the same shall become due and payable, any amount of principal of on the Loans, whether at the due date thereof or at a date fixed for prepayment thereof or otherwise; or (ii) within three Business Days after the same shall become due and payable, any interest on the Loans.

(b) **Other Payment Defaults.** Any Obligor shall fail to pay any Obligation (other than an amount referred to in **Section 11 .01(a)**)when and as the same shall become due and payable, and such failure shall continue unremedied for a period of five Business Days.

(c) **Representations and Warranties.** Any representation or warranty made or deemed made by or on behalf of Borrower or any of its Subsidiaries in or in connection with this Agreement or any other Loan Document or any amendment or modification hereof or thereof or in any report, certificate, financial statement or other document furnished pursuant to or in connection with this Agreement or any other Loan Document or any amendment or modification hereof or thereof shall: (i) prove to have been incorrect when made or deemed made to the extent that such representation or warranty contains any materiality or Material Adverse Effect qualifier; or (ii) prove to have been incorrect in any material respect when made or deemed made to the extent that such representation or warranty does not otherwise contain any materiality or Material Adverse Effect qualifier.

(d) **Certain Covenants.** Any Obligor shall fail to observe or perform any covenant, condition or agreement contained in **Sections 8.02**, **8.03** (with respect to Borrower's existence), **8.11**, **8.12**, **8.18**, **8.19**, **Section 9** or **Section 10**; <u>provided</u> that, for the avoidance of doubt, **Section 10.02** shall be subject to the Borrower's cure rights expressly set forth in **Section 10.03**.

(e) **Other Covenants.** Any Obligor shall fail to observe or perform any covenant, condition or agreement contained in this Agreement (other than those specified in **Section 11.01(a)**, (b) or (d)) or any other Loan Document, and, in the case of any failure that is capable of cure, such failure shall continue unremedied for a period of 20 or more days.

(f) **Payment Default on Other Indebtedness.** Borrower or any of its Subsidiaries shall fail to make any payment (whether of principal or interest and regardless of amount) in respect of any Material Indebtedness, when and as the same shall become due and payable after giving effect to any applicable grace or cure period as originally provided by the terms of such Indebtedness.

(g) **Other Defaults on Other Indebtedness.** (i) Any material breach of or "event of default" or similar event under, the documentation governing any Material Indebtedness shall occur, or (ii) any event or condition occurs (x) that results in any Material Indebtedness becoming due prior to its scheduled maturity or (y) that enables or permits (with or without the giving of notice, the lapse of time or both) the holder or holders of such Material Indebtedness or any trustee or agent on its or their behalf to cause such Material Indebtedness to become due, or to require the prepayment, repurchase, redemption or defeasance thereof, prior to its scheduled maturity; provided that this **Section 11.01(g)** shall not apply to secured Indebtedness that becomes due as a result of the voluntary sale or transfer of the property or assets securing such Material Indebtedness.

#### (h) Insolvency, Bankruptcy, Etc.

(i) Any Obligor becomes insolvent, or generally does not or becomes unable to pay its debts or meet its liabilities as the same become due, or admits in writing its inability to pay its debts generally, or declares any general moratorium on its indebtedness, or proposes a compromise or arrangement or deed of company arrangement between it and any class of its creditors.

(ii) Any Obligor commits an act of bankruptcy or makes an assignment of its property for the general benefit of its creditors or makes a proposal (or files a notice of its intention to do so).

(iii) Any Obligor institutes any proceeding seeking to adjudicate it an insolvent, or seeking liquidation, dissolution, winding-up, reorganization, compromise, arrangement, adjustment, protection, moratorium, relief, stay of proceedings of creditors generally (or any class of creditors), or composition of it or its debts or any other relief, under any federal, provincial or foreign Law now or hereafter in effect relating to bankruptcy, winding-up, insolvency, reorganization, receivership, plans of arrangement or relief or protection of debtors or at common law or in equity, or files an answer admitting the material allegations of a petition filed against it in any such proceeding.

(iv) Any Obligor applies for the appointment of, or the taking of possession by, a receiver, interim receiver, receiver/manager, sequestrator, conservator, custodian, administrator, trustee, liquidator, voluntary administrator, receiver and manager or other similar official for it or any substantial part of its property.

(v) Any Obligor takes any action, corporate or otherwise, to approve, effect, consent to or authorize any of the actions described in this **Section 11.01(h)**, or otherwise acts in furtherance thereof or fails to act in a timely and appropriate manner in defense thereof.

- (vi) Any petition is filed, application made or other proceeding instituted against or in respect of Borrower or any Subsidiary:
  - (A) seeking to adjudicate it as insolvent;
  - (B) seeking a receiving order against it;

(C) seeking liquidation, dissolution, winding-up, reorganization, compromise, arrangement, adjustment, protection, moratorium, relief, stay of proceedings of creditors generally (or any class of creditors), deed of company arrangement or composition of it or its debts or any other relief under any federal, provincial or foreign law now or hereafter in effect relating to bankruptcy, winding-up, insolvency, reorganization, receivership, plans of arrangement or relief or protection of debtors or at common law or in equity; or

(D) seeking the entry of an order for relief or the appointment of, or the taking of possession by, a receiver, interim receiver, receiver/manager, sequestrator, conservator, custodian, administrator, trustee, liquidator, voluntary administrator, receiver and manager or other similar official for it or any substantial part of its property, and such petition, application or proceeding continues undismissed, or unstayed and in effect, for a period of 60 days after the institution thereof; <u>provided</u> that if an order, decree or judgment is granted or entered (whether or not entered or subject to appeal) against Borrower or such Subsidiary thereunder in the interim, such grace period will cease to apply; <u>provided</u>, <u>further</u>, that if Borrower or such Subsidiary files an answer admitting the material allegations of a petition filed against it in any such proceeding, such grace period will cease to apply.

(vii) Any other event occurs which, under the laws of any applicable jurisdiction, has an effect equivalent to any of the events referred to in **Section 11.01(h)**.

(i) **Judgments.** One or more judgments for the payment of money in an aggregate amount in excess of \$1,000,000 (or the Equivalent Amount in other currencies) shall be rendered against any Obligor or any combination thereof and the same shall remain undischarged for a period of 45 calendar days during which execution shall not be effectively stayed, or any action shall be legally taken by a judgment creditor to attach or levy upon any assets of any Obligor to enforce any such judgment.

(j) **ERISA and Pension Plans.** (i) An ERISA Event shall have occurred that, in the opinion of the Majority Lenders, when taken together with all other ERISA Events that have occurred, could reasonably be expected to result in liability of Borrower and its Subsidiaries in an aggregate amount exceeding (i) \$250,000 in any year or (ii) \$500,000 for all periods until repayment of all Obligations (other than Warrant Obligations).

- (k) Change of Control. A Change of Control shall have occurred.
- (l) Material Adverse Change. A Material Adverse Change shall have occurred and continues for a period of five consecutive days.
- (m) Key Person Event. A Key Person Event shall have occurred.

(n) **Regulatory Matters, Etc.** (i) The FDA or any other Governmental Authority initiates enforcement action against, or issues a warning letter (x) to any Obligor concerning any Product that has generated or is expected to generate at least \$3,000,000 in consolidated revenue for Borrower and its Subsidiaries over any consecutive twelve month period, or (y) concerning any Obligor's manufacturing facilities for any such Product, in each case that causes the marketing of any such Product to be discontinued, causes any such Product to be withdrawn from the market, or causes a delay in the manufacture of any such Product, which discontinuance, withdrawal or delay could reasonably be expected to last for more than 120 days; or (ii) any Obligor enters into a settlement agreement with the FDA or any other Governmental Authority that results in aggregate liability as to any single or related series of transactions, incidents or conditions in excess of \$2,000,000.

(o) **Impairment of Security, Etc.** (i) Any Lien created by any of the Security Documents shall at any time not constitute a valid and perfected Lien on the applicable Collateral in favor of Administrative Agent, for the benefit of the Secured Parties, free and clear of all other Liens (other than Permitted Liens), (ii) except for expiration in accordance with its terms, any of the Security Documents or any Guarantee of any of the Obligations (including that contained in **Section 13**) shall for whatever reason cease to be in full force and effect, (iii) any Obligor shall, directly or indirectly, contest in any manner such effectiveness, validity, binding nature or enforceability, or (iv) any injunction, whether temporary or permanent, shall be rendered against any Obligor that prevents the Obligors from selling or manufacturing the Products or their commercially available successors, or any of their other material and commercially available products in the United States for more than 90 calendar days.

**11.02 Remedies.** Upon the occurrence of any Event of Default, then, and in every such event (other than an Event of Default described in **Section 11.01(h)**), and at any time thereafter during the continuance of such event, Administrative Agent may, by notice to Borrower, take either or both of the following actions, at the same or different times: (i) terminate the Commitments, and thereupon the Commitments shall terminate immediately, and (ii) declare the Loans then outstanding to be due and payable in whole (or in part, in which case any principal not so declared to be due and payable may thereafter be declared to be due and payable), and thereupon the principal of the Loans so declared to be due and payable, together with accrued interest thereon and all fees and other Obligations, shall become due and payable immediately (in the case of the Loans, at the Redemption Price therefor), without presentment, demand, protest or other notice of any kind, all of which are hereby waived by each Obligor; and in case of an Event of Default described in **Section 11.01(h)**, the Commitment shall automatically terminate and the principal of the Loans then outstanding, together with accrued interest thereon and all fees and other Obligations, shall automatically terminate and the principal of the Loans then outstanding, together with accrued interest thereon and all fees and other Obligations, shall automatically terminate and the principal of the Loans then outstanding, together with accrued interest thereon and all fees and other Obligations, shall automatically become due and payable immediately (in the case of the Loans, at the Redemption Price therefor), without presentment, demand, protest or other notice of any kind, all of which are hereby waived by each Obligor.

### SECTION 12. THE ADMINISTRATIVE AGENT

12.1 Appointment and Duties. Subject in all cases to clause(c) below:

(a) **Appointment of Administrative Agent.** Each Lender hereby appoints Perceptive Credit Holdings, LP (together with any successor Administrative Agent pursuant to **Section 12.09**) as Administrative Agent hereunder and authorizes Administrative Agent to (i) execute and deliver the Loan Documents and accept delivery thereof on its behalf from any Obligor or any of its Subsidiaries, (ii) take such action on its behalf and to exercise all rights, powers and remedies and perform the duties as are expressly delegated to Administrative Agent under such Loan Documents and (iii) exercise such powers as are reasonably incidental thereto.

(b) Duties as Collateral and Disbursing Agent. Without limiting the generality of Section 12.01(a), Administrative Agent shall have the sole and exclusive right and authority (to the exclusion of the Lenders), and is hereby authorized, to (i) act as the disbursing and collecting agent for the Lenders with respect to all payments and collections arising in connection with the Loan Documents (including in any proceeding described in Section 11.01(h) or any other bankruptcy, insolvency or similar proceeding), and each Person making any payment in connection with any Loan Document to any Secured Party is hereby authorized to make such payment to Administrative Agent, (ii) file and prove claims and file other documents necessary or desirable to allow the claims of the Secured Parties with respect to any Obligation in any proceeding described in Section 11.01(h) or any other bankruptcy, insolvency or similar proceeding (but not to vote, consent or otherwise act on behalf of such Secured Party), (iii) act as collateral agent for each Secured Party for purposes of the perfection of all Liens created by such agreements and all other purposes stated therein, (iv) manage, supervise and otherwise deal with the Collateral, (v) take such other action as is necessary or desirable to maintain the perfection and priority of the Liens created or purported to be created by the Loan Documents, (vi) except as may be otherwise specified in any Loan Document, exercise all remedies given to Administrative Agent and the other Secured Parties with respect to the Collateral, whether under the Loan Documents, applicable Requirements of Law or otherwise and (vii) execute any amendment, consent or waiver under the Loan Documents on behalf of any Lender that has consented in writing to such amendment, consent or waiver; provided that Administrative Agent hereby appoints, authorizes and directs each Lender to act as collateral sub-agent for Administrative Agent and the Lenders for purposes of the perfection of all Liens with respect to the Collateral, including any deposit account maintained by an Obligor with, and cash and Cash Equivalents held by, such Lender, and may further authorize and direct the Lenders to take further actions as collateral sub-agents for purposes of enforcing such Liens or otherwise to transfer the Collateral subject thereto to Administrative Agent, and each Lender hereby agrees to take such further actions to the extent, and only to the extent, so authorized and directed.

(c) **Limited Duties.** The Lenders and the Obligors hereby each acknowledge and agree that Administrative Agent (i) has undertaken its role hereunder purely as an accommodation to the parties hereto and the Transactions, (ii) is receiving no compensation for undertaking such role and (iii) subject only to the notice provisions set forth in **Section 12.09**, may resign from such role at any time for any reason or no reason whatsoever. Without limiting the foregoing, the parties hereto further acknowledge and agree that under the Loan Documents, Administrative Agent (i) is acting solely on behalf of the Lenders (except to the limited extent provided in **Section 12.11**), with duties that are entirely administrative in nature, notwithstanding the use of the defined term "Administrative Agent," the terms "agent", "administrative agent" and "collateral agent" and similar terms in any Loan Document to refer to Administrative Agent, which terms are used for title purposes only, (ii) is not assuming any obligation under any Loan Document other than as expressly set forth therein or any role as agent, fiduciary or trustee of or for any Lender or any other Secured Party and (iii) shall have no implied functions, responsibilities, duties, obligations or other liabilities under any Loan Document (fiduciary or otherwise), and each Lender hereby waives and agrees not to assert any claim against Administrative Agent based on the roles, duties and legal relationships expressly disclaimed in this **clause (c)**.

**12.02 Binding Effect.** Each Lender agrees that (i) any action taken by Administrative Agent or the Majority Lenders (or, if expressly required hereby, a greater proportion of the Lenders) in accordance with the provisions of the Loan Documents, (ii) any action taken by Administrative Agent in reliance upon the instructions of the Majority Lenders (or, where so required, such greater proportion) and (iii) the exercise by Administrative Agent or the Majority Lenders (or, where so required, such greater proportion) and (iii) the exercise by Administrative Agent or the Majority Lenders (or, where so required, such greater proportion) of the powers set forth herein or therein, together with such other powers as are reasonably incidental thereto, shall be authorized and binding upon all of the Secured Parties.

# 12.3 Use of Discretion.

(a) **No Action without Instructions.** Administrative Agent shall not be required to exercise any discretion or take, or to omit to take, any action, including with respect to enforcement or collection, except (subject to **clause (b)** below) any action it is required to take or omit to take (i) under any Loan Document or (ii) pursuant to instructions from the Majority Lenders (or, where expressly required by the terms of this Agreement, a greater proportion of the Lenders).

(b) **Right Not to Follow Certain Instructions.** Notwithstanding **Section 12.03(a)** or any other term or provision of this **Section 12**, Administrative Agent shall not be required to take, or to omit to take, any action (i) unless, upon demand, Administrative Agent receives an indemnification satisfactory to it from the Lenders (or, to the extent applicable and acceptable to Administrative Agent, any other Secured Party) against all Liabilities that, by reason of such action or omission, may be imposed on, incurred by or asserted against Administrative Agent or any Related Person thereof or (ii) that is, in the opinion of Administrative Agent, in its sole and absolute discretion, contrary to any Loan Document, Requirement of Law or the best interests of Administrative Agent or any of its Affiliates or Related Persons.

**12.04 Delegation of Rights and Duties.** Administrative Agent may, upon any term or condition it specifies, delegate or exercise any of its rights, powers and remedies under, and delegate or perform any of its duties or any other action with respect to, any Loan Document by or through any trustee, co-agent, employee, attorney-in-fact and any other Person (including any Secured Parry). Any such Person shall benefit from this **Section 12** to the extent provided by Administrative Agent.

## 12.05 Reliance and Liability.

(a) Administrative Agent may, without incurring any liability hereunder, (i) consult with any of its Related Persons and, whether or not selected by it, any other advisors, accountants and other experts (including advisors to, and accountants and experts engaged by, any Obligor) and (ii) rely and act upon any document and information and any telephone message or conversation, in each case believed by it to be genuine and transmitted, signed or otherwise authenticated by the appropriate parties.

(b) Neither Administrative Agent nor any of its Related Persons shall be liable for any action taken or omitted to be taken by any of them under or in connection with any Loan Document, and each Lender and Borrower hereby waive and shall not assert (and Borrower shall cause each other Obligor to waive and agree not to assert) any right, claim or cause of action based thereon, except to the extent of liabilities resulting from the gross negligence or fraudulent conduct of Administrative Agent or, as the case may be, such Related Person (each as determined in a final, non-appealable judgment or order by a court of competent jurisdiction) in connection with the duties expressly set forth herein; <u>provided</u> that the resignation of Administrative Agent pursuant to **Section 12.09** at any time, under any circumstance, shall not constitute grossly negligent or fraudulent conduct or behavior. Without limiting the foregoing, Administrative Agent:

(i) shall not be responsible or otherwise incur liability for any action or omission taken in reliance upon the instructions of the Majority Lenders or for the actions or omissions of any of its Related Persons selected with reasonable care (other than employees, officers and directors of Administrative Agent, when acting on behalf of Administrative Agent);

(ii) shall not be responsible to any Secured Party for the due execution, legality, validity, enforceability, effectiveness, genuineness, sufficiency or value of or the attachment, perfection or priority of any Lien created or purported to be created under or in connection with, any Loan Document;

(iii) makes no warranty or representation, and shall not be responsible, to any Secured Party for any statement, document, information, representation or warranty made or furnished by or on behalf of any Related Person, in or in connection with any Loan Document or any transaction contemplated therein, whether or not transmitted by Administrative Agent, including as to completeness, accuracy, scope or adequacy thereof, or for the scope, nature or results of any due diligence performed by Administrative Agent in connection with the Loan Documents; and

(iv) shall not have any duty to ascertain or to inquire as to the performance or observance of any provision of any Loan Document, whether any condition set forth in any Loan Document is satisfied or waived, as to the financial condition of any Obligor or as to the existence or continuation or possible occurrence or continuation of any Default or Event of Default and shall not be deemed to have notice or knowledge of such occurrence or continuation unless it has received a notice from Borrower, any Lender describing such Default or Event of Default clearly labeled "notice of default" (in which case Administrative Agent shall promptly give notice of such receipt to all Lenders).

With respect to each of the items set forth in clauses (i) through (iv) above, each Lender and Borrower hereby waives and agrees not to assert (and Borrower shall cause each other Obligor to waive and agree not to assert) any right, claim or cause of action it might have against Administrative Agent based thereon.

**12.06** Administrative Agent Individually. Administrative Agent and its Affiliates may make loans and other extensions of credit to, acquire stock and stock equivalents of, engage in any kind of business with, any Obligor or Affiliate thereof as though it were not acting Administrative Agent and may receive separate fees and other payments therefor. To the extent Administrative Agent or any of its Affiliates makes any Loan or otherwise becomes a Lender hereunder, it shall have and may exercise the same rights and powers hereunder and shall be subject to the same obligations and liabilities as any other Lender and the terms "Lender", "Majority Lender", and any similar terms shall, except where otherwise expressly provided in any Loan Document, include, without limitation, Administrative Agent or such Affiliate, as the case may be, in its individual capacity as Lender or as one of the Majority Lenders, respectively.

**12.07** Lender Credit Decision. Each Lender acknowledges that it has, independently and without reliance upon Administrative Agent, any Lender or any of their Related Persons or upon any document (including the Disclosure Documents) solely or in part because such document was transmitted by Administrative Agent or any of its Related Persons, conducted its own independent investigation of the financial condition and affairs of each Obligor and has made and continues to make its own credit decisions in connection with entering into, and taking or not taking any action under, any Loan Document or with respect to any transaction contemplated in any Loan Document, in each case based on such documents and information as it shall deem appropriate.

#### 12.08 Expenses; Indemnities.

(a) Each Lender agrees to reimburse Administrative Agent and each of its Related Persons (to the extent not reimbursed by any Obligor) promptly upon demand for such Lender's Pro Rata Share of any costs and expenses (including fees, charges and disbursements of financial, legal and other advisors and Other Taxes paid in the name of, or on behalf of, any Obligor) that may be incurred by Administrative Agent or any of its Related Persons in connection with the preparation, syndication, execution, delivery, administration, modification, consent, waiver or enforcement (whether through negotiations, through any work-out, bankruptcy, restructuring or other legal or other proceeding or otherwise) of, or legal advice in respect of its rights or responsibilities under, any Loan Document.

(b) Each Lender further agrees to indemnify Administrative Agent and each of its Related Persons (to the extent not reimbursed by any Obligor), from and against such Lender's aggregate Pro Rata Share of the Liabilities (including taxes, interests and penalties imposed for not properly withholding or backup withholding on payments made to, on or for the account of any Lender) that may be imposed on, incurred by or asserted against Administrative Agent or any of its Related Persons in any matter relating to or arising out of, in connection with or as a result of any Loan Document, any Related Document or any other act, event or transaction related, contemplated in or attendant to any such document, or, in each case, any action taken or omitted to be taken by Administrative Agent or any of its Related Persons under or with respect to any of the foregoing; provided that no Lender shall be liable to Administrative Agent or any of its Related Persons to the extent such liability has resulted primarily from the gross negligence or willful misconduct of Administrative Agent or, as the case may be, such Related Person, as determined by a court of competent jurisdiction in a final non-appealable judgment or order.

### 12.09 Resignation of Administrative Agent.

(a) At any time upon not less than five Business Days prior written notice, Administrative Agent may resign as the "Administrative Agent" hereunder, in whole or in part (in the sole and absolute discretion of Administrative Agent), effective on the date set forth in such notice, which effective date shall not be less than five (or more than 30) days following delivery of such notice. If Administrative Agent delivers any such notice, the Majority Lenders shall have the right to appoint a successor Administrative Agent; provided that if a successor Administrative Agent has not been appointed on or before the effectiveness of the resignation of the resigning Administrative Agent, then the resigning Administrative Agent may, on behalf of the Lenders, appoint any Person reasonably chosen by it as the successor Administrative Agent.

(b) Effective immediately upon its resignation, (i) the resigning Administrative Agent shall be discharged from its duties and obligations under the Loan Documents to the extent set forth in the applicable resignation notice, (ii) the Lenders shall assume and perform all of the duties of Administrative Agent until a successor Administrative Agent shall have accepted a valid appointment hereunder, (iii) the resigning Administrative Agent and its Related Persons shall no longer have the benefit of any provision of any Loan Document other than with respect to (x) any actions taken or omitted to be taken while such resigning Administrative Agent was, or because such Administrative Agent had been, validly acting as Administrative Agent under the Loan Documents or (y) any continuing duties such resigning Administrative Agent will continue to perform, and (iv) subject to its rights under **Section 12.04**, the resigning Administrative Agent shall take such action as may be reasonably necessary to assign to the successor Administrative Agent, a successor Administrative Agent under the Loan Documents. Effective immediately upon its acceptance of a valid appointment as Administrative Agent, a successor Administrative Agent shall succeed to, and become vested with, all the rights, powers, privileges and duties of the resigning Administrative Agent under the Loan Documents.

**12.10** Release of Collateral or Guarantors. Each Lender hereby consents to the release and hereby directs Administrative Agent to release (or, in the case of Section 12.10 (b)(ii), release or subordinate) the following:

(a) any Subsidiary of Borrower from its guaranty of any Obligation of any Obligor if all of the Equity Interests in such Subsidiary owned by any Obligor or any of its Subsidiaries are disposed of in an Asset Sale permitted under the Loan Documents (including pursuant to a waiver or consent), to the extent that, after giving effect to such Asset Sale, such Subsidiary would not be required to guaranty any Obligations pursuant to **Section 8.12(a)**; and

(b) any Lien held by Administrative Agent for the benefit of the Secured Parties against (i) any Collateral that is disposed of by an Obligor in an Asset Sale permitted by the Loan Documents (including pursuant to a valid waiver or consent), (ii) any property subject to a Lien described in **Section 9.02(c)** and (iii) all of the Collateral and all Obligors, upon (w) termination of the Commitments, (x) payment and satisfaction in full of all Loans and all other Obligations that Administrative Agent has been notified in writing are then due and payable, (y) deposit of cash collateral with respect to all contingent Obligations, in amounts and on terms and conditions and with parties satisfactory to Administrative Agent and each Indemnitee that is owed such Obligations and (z) to the extent requested by Administrative Agent, receipt by the Secured Parties of liability releases from the Obligors each in form and substance acceptable to Administrative Agent.

Each Lender hereby directs Administrative Agent, and Administrative Agent hereby agrees, upon receipt of reasonable advance notice from Borrower, to execute and deliver or file such documents and to perform other actions reasonably necessary to release the guarantees and Liens when and as directed in this **Section 12.10**.

**12.11** Additional Secured Parties. The benefit of the provisions of the Loan Documents directly relating to the Collateral or any Lien granted thereunder shall extend to and be available to any Secured Party that is not a Lender as long as, by accepting such benefits, such Secured Party agrees, as among Administrative Agent and all other Secured Parties, that such Secured Party is bound by (and, if requested by Administrative Agent, shall confirm such agreement in a writing in form and substance acceptable to Administrative Agent) this Section 12 and the decisions and actions of Administrative Agent and the Majority Lenders (or, where expressly required by the terms of this Agreement, a greater proportion of the Lenders) to the same extent a Lender is bound; provided that, notwithstanding the foregoing, (i) such Secured Party shall be bound by Section 12.08 only to the extent of Liabilities, costs and expenses with respect to or otherwise relating to the Collateral held for the benefit of such Secured Party, in which case the obligations of such Secured Party thereunder shall not be limited by any concept of Pro Rata Share or similar concept, (ii) each of Administrative Agent and each Lender shall be entitled to act at its sole discretion, without regard to the interest of such Secured Party, regardless of whether any Obligation to such Secured Party thereafter remains outstanding, is deprived of the benefit of the Collateral, becomes unsecured or is otherwise affected or put in jeopardy thereby, and without any duty or liability to such Secured Party or any such Obligation and (iii) such Secured Party shall not have any right to be notified of, consent to, direct, require or be heard with respect to, any action taken or omitted in respect of the Collateral or under any Loan Document.

## SECTION 13. GUARANTEE

**13.01 The Guarantee.** The Subsidiary Guarantor hereby jointly and severally guarantee to Administrative Agent and the Lenders, and their successors and assigns, the prompt payment in full when due (whether at stated maturity, by acceleration or otherwise) of the principal of and interest on the Loans, all fees and other amounts and Obligations from time to time owing to Administrative Agent or the Lenders by Borrower under this Agreement or under any other Loan Document and by any other Obligor under any of the Loan Documents, in each case strictly in accordance with the terms thereof (such obligations being herein collectively called the *"Guaranteed Obligations"*). The Subsidiary Guarantors hereby further jointly and severally agree that if Borrower shall fail to pay in full when due (whether at stated maturity, by acceleration or otherwise) any of the Guaranteed Obligations, the Subsidiary Guarantors will promptly pay the same, without any demand or notice whatsoever, and that in the case of any extension of time of payment or renewal of any of the Guaranteed Obligations, the same will be promptly paid in full when due (whether at extended maturity, by acceleration or otherwise) in accordance with the terms of such extension or renewal.

**13.02 Obligations Unconditional.** The obligations of the Subsidiary Guarantors under **Section 13.01** are absolute and unconditional, joint and several, irrespective of the value, genuineness, validity, regularity or enforceability of the obligations of Borrower under this Agreement or any other agreement or instrument referred to herein, or any substitution, release or exchange of any other guarantee of or security for any of the Guaranteed Obligations, and, to the fullest extent permitted by Requirements of Law, irrespective of any other circumstance whatsoever that might otherwise constitute a legal or equitable discharge or defense of a surety or guarantor, it being the intent of this **Section 13.02** that the obligations of the Subsidiary Guarantors hereunder shall be absolute and unconditional, joint and several, under any and all circumstances. Without limiting the generality of the foregoing, it is agreed that the occurrence of any one or more of the following shall not alter or impair the liability of the Subsidiary Guarantors hereunder, which shall remain absolute and unconditional as described above:

(a) at any time or from time to time, without notice to the Subsidiary Guarantors, the time for any performance of or compliance with any of the Guaranteed Obligations shall be extended, or such performance or compliance shall be waived;

(b) any of the acts mentioned in any of the provisions of this Agreement or any other agreement or instrument referred to herein shall be done or omitted;

(c) the maturity of any of the Guaranteed Obligations shall be accelerated, or any of the Guaranteed Obligations shall be modified, supplemented or amended in any respect, or any right under this Agreement or any other agreement or instrument referred to herein shall be waived or any other guarantee of any of the Guaranteed Obligations or any security therefor shall be released or exchanged in whole or in part or otherwise dealt with; or

(d) any lien or security interest granted to, or in favor of, the Secured Parties as security for any of the Guaranteed Obligations shall fail to be perfected.

The Subsidiary Guarantors hereby expressly waive diligence, presentment, demand of payment, protest and all notices whatsoever, and any requirement that Administrative Agent or the Lenders exhaust any right, power or remedy or proceed against Borrower under this Agreement or any other agreement or instrument referred to herein, or against any other Person under any other guarantee of, or security for, any of the Guaranteed Obligations.

**13.03 Reinstatement.** The obligations of the Subsidiary Guarantors under this **Section 13** shall be automatically reinstated if and to the extent that for any reason any payment by or on behalf of Borrower in respect of the Guaranteed Obligations is rescinded or must be otherwise restored by any holder of any of the Guaranteed Obligations, whether as a result of any proceedings in bankruptcy or reorganization or otherwise, and the Subsidiary Guarantors jointly and severally agree that they will indemnify Administrative Agent and the Lenders on demand for all reasonable costs and expenses (including fees of counsel) incurred by such Persons in connection with such rescission or restoration, including any such costs and expenses incurred in defending against any claim alleging that such payment constituted a preference, fraudulent transfer or similar payment under any bankruptcy, insolvency or similar law.

**13.04 Subrogation.** The Subsidiary Guarantors hereby jointly and severally agree that, until the payment and satisfaction in full of all Guaranteed Obligations (other than Warrant Obligations) and the expiration and termination of the Commitments, they shall not exercise any right or remedy arising by reason of any performance by them of their guarantee in **Section 13.01**, whether by subrogation or otherwise, against Borrower or any other guarantor of any of the Guaranteed Obligations or any security for any of the Guaranteed Obligations.

**13.05 Remedies.** The Subsidiary Guarantors jointly and severally agree that, as between the Subsidiary Guarantors, on one hand, and Administrative Agent and the Lenders, on the other hand, the obligations of Borrower under this Agreement and under the other Loan Documents may be declared to be forthwith due and payable as provided in **Section 11** (and shall be deemed to have become automatically due and payable in the circumstances provided in **Section 11**) for purposes of **Section 13.01** notwithstanding any stay, injunction or other prohibition preventing such declaration (or such obligations from becoming automatically due and payable) as against Borrower and that, in the event of such declaration (or such obligations being deemed to have become automatically due and payable), such obligations (whether or not due and payable by Borrower) shall forthwith become due and payable by the Subsidiary Guarantors for purposes of **Section 13.01**.

**13.06 Instrument for the Payment of Money.** Each Subsidiary Guarantor hereby acknowledges that the guarantee in this **Section 13** constitutes an instrument for the payment of money, and consents and agrees that Administrative Agent and the Lenders, at their sole option, in the event of a dispute by such Subsidiary Guarantor in the payment of any moneys due hereunder, shall have the right to proceed by motion for summary judgment in lieu of complaint pursuant to N.Y. Civ. Prac. L&R §3213.

13.07 Continuing Guarantee. The guarantee in this Section 13 is a continuing guarantee, and shall apply to all Guaranteed Obligations whenever arising.

**13.08 Rights of Contribution.** The Subsidiary Guarantors hereby agree, as between themselves, that if any Subsidiary Guarantor shall become an Excess Funding Guarantor (as defined below) by reason of the payment by such Subsidiary Guarantor of any Guaranteed Obligations, each other Subsidiary Guarantor shall, on demand of such Excess Funding Guarantor (but subject to the next sentence), pay to such Excess Funding Guarantor an amount equal to such Subsidiary Guarantor) of the Excess Payment (as defined below) in respect of such Guaranteed Obligations. The payment obligation of a Subsidiary Guarantor to any Excess Funding Guarantor under this **Section 13.08** shall be subordinate and subject in right of payment to the prior payment in full of the obligations of such Subsidiary Guarantor under the other provisions of this **Section 13** and such Excess Funding Guarantor shall not exercise any right or remedy with respect to such excess until payment and satisfaction in full of all of such obligations.

For purposes of this **Section 13.08**,(i) "*Excess Funding Guarantor*" means, in respect of any Guaranteed Obligations, a Subsidiary Guarantor that has paid an amount in excess of its Fair Share of such Guaranteed Obligations, (ii) "*Excess Payment*" means, in respect of any Guaranteed Obligations, the amount paid by an Excess Funding Guarantor in excess of its Fair Share of such Guaranteed Obligations and (iii) "*Fair Share*" means, for any Subsidiary Guarantor, the ratio (expressed as a percentage) of (x) the amount by which the aggregate present fair saleable value of all properties of such Subsidiary Guarantor (excluding any shares of stock of any other Subsidiary Guarantor) exceeds the amount of all the debts and liabilities of such Subsidiary Guarantor (including contingent, subordinated, unmatured and unliquidated liabilities, but excluding the obligations of such Subsidiary Guarantor hereunder and any obligations of any other Subsidiary Guarantor that have been Guaranteed by such Subsidiary Guarantor) to (y) the amount by which the aggregate fair saleable value of all properties of all of the Subsidiary Guarantors exceeds the amount of all the debts and liabilities (including contingent, subordinated, unmatured and unliquidated liabilities, but excluding the obligations of Borrower and the Subsidiary Guarantors hereunder and under the other Loan Documents) of all of the Subsidiary Guarantors, determined (A) with respect to any Subsidiary Guarantor that is a party hereto on the Closing Date, as of the Closing Date, and (B) with respect to any other Subsidiary Guarantor, as of the date such Subsidiary Guarantor becomes a Subsidiary Guarantor hereunder.

**13.09** General Limitation on Guarantee Obligations. In any action or proceeding involving any provincial, territorial or state corporate law, or any state or federal bankruptcy, insolvency, reorganization or other law affecting the rights of creditors generally, if the obligations of any Subsidiary Guarantor under Section 13.01 would otherwise, taking into account the provisions of Section 13.08, be held or determined to be void, invalid or unenforceable, or subordinated to the claims of any other creditors, on account of the amount of its liability under Section 13.01, then, notwithstanding any other provision hereof to the contrary, the amount of such liability shall, without any further action by such Subsidiary Guarantor, Administrative Agent, the Lenders or any other Person, be automatically limited and reduced to the highest amount that is valid and enforceable and not subordinated to the claims of other creditors as determined in such action or proceeding.

# SECTION 14. MISCELLANEOUS

**14.01** No Waiver. No failure on the part of Administrative Agent or the Lenders to exercise and no delay in exercising, and no course of dealing with respect to, any right, power or privilege under any Loan Document shall operate as a waiver thereof, nor shall any single or partial exercise of any right, power or privilege under any Loan Document preclude any other or further exercise thereof or the exercise of any other right, power or privilege. The remedies provided herein are cumulative and not exclusive of any remedies provided by law.

**14.02** Notices. All notices, requests, instructions, directions and other communications provided for herein (including any modifications of, or waivers, requests or consents under, this Agreement) shall be given or made in writing (including by telecopy) delivered, if to Borrower, another Obligor, Administrative Agent or any Lender, to its address specified on the signature pages hereto or its Guarantee Assumption Agreement, as the case may be, or at such other address as shall be designated by such party in a written notice to the other parties. Except as otherwise provided in this Agreement, all such communications shall be deemed to have been duly given upon receipt of a legible copy thereof in each case given or addressed as aforesaid. All such communications provided for herein by telecopy shall be confirmed in writing promptly after the delivery of such communication (it being understood that non-receipt of written confirmation of such communication shall not invalidate such communication).

## 14.03 Expenses, Indemnification, Etc.

(a) **Expenses.** Borrower agrees to pay or reimburse (i) Administrative Agent and the Lenders for all of their reasonable out of pocket costs and expenses (including the reasonable fees and expenses of Morrison & Foerster LLP, special counsel to Administrative Agent the Lenders, and any sales, goods and services or other similar taxes applicable thereto, and printing, reproduction, document delivery, communication and travel costs) in connection with (x) the negotiation, preparation, execution and delivery of this Agreement and the other Loan Documents and the making of the Loans (exclusive of post-closing costs), (y) post-closing costs and (z) the negotiation or preparation of any modification, supplement or waiver of any of the terms of this Agreement or any of the other Loan Documents (whether or not consummated) and (ii) Administrative Agent and the Lenders for all of their out of pocket costs and expenses (including the fees and expenses of legal counsel) in connection with any enforcement or collection proceedings resulting from the occurrence of an Event of Default.

Indemnification. Borrower hereby indemnifies Administrative Agent, the Lenders, and their respective Affiliates, directors, officers, (b) employees, attorneys, agents, advisors and controlling parties (each, an "Indemnified Party") from and against, and agrees to hold them harmless against, any and all Claims and Losses of any kind (including reasonable fees and disbursements of counsel), joint or several, that may be incurred by or asserted or awarded against any Indemnified Party, in each case arising out of or in connection with or relating to any investigation, litigation or proceeding or the preparation of any defense with respect thereto arising out of or in connection with or relating to this Agreement or any of the other Loan Documents or the Transactions or any use made or proposed to be made with the proceeds of the Loans, whether or not such investigation, litigation or proceeding is brought by Borrower, any of its shareholders or creditors, an Indemnified Party or any other Person, or an Indemnified Party is otherwise a party thereto, and whether or not any of the conditions precedent set forth in Section 6 are satisfied or the other transactions contemplated by this Agreement are consummated, except to the extent such Claim or Loss is found in a final, non-appealable judgment by a court of competent jurisdiction to have resulted from such Indemnified Party's gross negligence or willful misconduct. No Obligor shall assert any claim against any Indemnified Party, on any theory of liability, for consequential, indirect, special or punitive damages arising out of or otherwise relating to this Agreement or any of the other Loan Documents or any of the Transactions or the actual or proposed use of the proceeds of the Loans. Borrower, its Subsidiaries and Affiliates and their respective directors, officers, employees, attorneys, agents, advisors and controlling parties are each sometimes referred to in this Agreement as a "Borrower Party." No Lender shall assert any claim against any Borrower Party, on any theory of liability, for consequential, indirect, special or punitive damages arising out of or otherwise relating to this Agreement or any of the other Loan Documents or the Transactions or the actual or proposed use of the proceeds of the Loans.

**14.04 Amendments, Etc.** Except as otherwise expressly provided in this Agreement, any provision of this Agreement may be modified or supplemented only by an instrument in writing signed by Borrower and the Majority Lenders; <u>provided</u> that:

(a) no amendment, waiver or consent shall affect the rights or duties under any Loan Document of or any payment to, Administrative Agent (or otherwise modify any provision of **Section 12** or the application thereof) unless in writing and signed by Administrative Agent in addition to any signature otherwise required; and

(b) the consent of all of the Lenders shall be required to:

(i) amend, modify, discharge, terminate or waive any of the terms of this Agreement if such amendment, modification discharge, termination or waiver would increase the amount of the Loans, reduce the fees payable hereunder, reduce interest rates or other amounts payable with respect to the Loans, extend any date fixed for payment of principal, interest or other amounts payable relating to the Loans or extend the repayment dates of the Loans;

(ii) amend the provisions of **Section 6**;

(iii) amend, modify, discharge, terminate or waive any Security Document if the effect is to release a material part of the Collateral subject thereto other than pursuant to the terms hereof or thereof; or

### (iv) amend this Section 14.04;

provided that, notwithstanding anything to the contrary herein, a Defaulting Lender shall not have any right to approve or disapprove any amendment, waiver or consent hereunder (and any amendment, waiver or consent which by its terms requires the consent of all Lenders or each affected Lender may be effected with the consent of the applicable Lenders other than Defaulting Lenders), except that (x) the Commitment of any Defaulting Lender may not be increased or extended without the consent of such Lender and (y) any waiver, amendment or modification requiring the consent of all Lenders or each affected Lender that by its terms affects any Defaulting Lender more adversely than other affected Lenders shall require the consent of such Defaulting Lender.

#### 14.05 Successors and Assigns.

(a) **General.** The provisions of this Agreement and the other Loan Documents shall be binding upon and inure to the benefit of the parties hereto and their respective successors and assigns permitted hereby, except that Borrower may not assign or otherwise transfer any of its rights or obligations hereunder or under any of the other Loan Documents without the prior written consent of Administrative Agent. Any of the Lenders may assign or otherwise transfer any of its rights or obligations hereunder or under any of its rights or obligations hereunder or under any of the other Loan Documents (i) to an assignee in accordance with the provisions of **Section 14.05(b)**, (ii) by way of participation in accordance with the provisions of **Section 14.05(e)** or (iii) by way of pledge or assignment of a security interest subject to the restrictions of **Section 14.05(f)**. Nothing in this Agreement, expressed or implied, shall be construed to confer upon any Person (other than the parties hereto, their respective successors and assigns permitted hereby, Participants to the extent provided in **Section 14.05(e)** and, to the extent expressly contemplated hereby, the Indemnified Parties) any legal or equitable right, remedy or claim under or by reason of this Agreement.

(b) Assignments by Lenders. Any of the Lenders may, with the prior written consent of Administrative Agent (such consent not to be unreasonably withheld, delayed or conditioned), at any time assign to one or more Eligible Transferees (or, if an Event of Default has occurred and is continuing, to any Person, other than a competitor of any Obligor) all or a portion of its rights and obligations under this Agreement (including all or a portion of the Commitment and the Loans at the time owing to it) and the other Loan Documents; <u>provided</u> that no such assignment shall be made to Borrower, an Affiliate of Borrower, or any employees or directors of Borrower at any time. Subject to the recording thereof by the Lenders pursuant to Section 14.05(d), from and after the effective date specified in each Assignment and Assumption, the assignee thereunder shall be a party to this Agreement and, to the extent of the interest assigned by such Assignment and Assumption, have the rights and obligations of the Lenders under this Agreement and the other Loan Documents, and correspondingly the assigning Lender shall, to the extent of the interest assigned by such Assignment (and, in the case of an Assignment and Assumption covering all of a Lender's rights and obligations under this Agreement, such Lender shall cease to be a party hereto) and the other Loan Documents but shall continue to be entitled to the benefits of Section 5 and Section 14.05(b) shall be treated for purposes of this Agreement as a sale by such Lender of a participation in such rights and obligations in accordance with Section 14.05(e).

(c) **Amendments to Loan Documents.** Each of Administrative Agent, the Lenders and the Obligors agrees to enter into such amendments to the Loan Documents, and such additional Security Documents and other instruments and agreements, in each case in form and substance reasonably acceptable to Administrative Agent, the Lenders and the Obligors, as shall reasonably be necessary to implement and give effect to any assignment made under this **Section 14.05**.

(d) **Register.** Administrative Agent, acting solely for this purpose as an agent of Borrower, shall maintain at one of its offices a register for the recordation of the name and address of any assignee of the Lenders and the Commitment and outstanding principal amount of the loans owing thereto (the *"Register"*). The entries in the Register shall be conclusive, absent manifest error, and Borrower shall treat each Person whose name is recorded in the Register pursuant to the terms hereof as the "Lender" hereunder for all purposes of this Agreement, notwithstanding notice to the contrary. The Register shall be available for inspection by Borrower, at any reasonable time and from time to time upon reasonable prior notice.

(e) **Participations.** Any of the Lenders may at any time, without the consent of or notice to, Borrower, sell participations to any Person (other than a natural person or Borrower or any of Borrower's Affiliates or Subsidiaries) (each, a "*Participant*") in all or a portion of such Lender's rights and/or obligations under this Agreement (including all or a portion of the Commitment and/or the Loans owing to it); provided that (i) such Lender's obligations under this Agreement shall remain unchanged, (ii) such Lender shall remain solely responsible to the other parties hereto for the performance of such obligations and (iii) Borrower shall continue to deal solely and directly with the Lenders in connection therewith. Any agreement or instrument pursuant to which a Lender sells such a participation shall provide that such Lender shall retain the sole right to enforce this Agreement and to approve any amendment, modification or waiver of any provision of this Agreement; provided that such agreement or instrument may provide that such Lender will not, without the consent of the Participant, agree to any amendment, modification or waiver that would (i) increase or extend the term of such Lender's Commitment, (ii) extend the date fixed for the payment of principal of or interest on the Loans or any portion of any fee hereunder payable to the Participant, (iii) reduce the amount of any such payment of principal, or (iv) reduce the rate at which interest is payable thereon to a level below the rate at which the Participant is entitled to receive such interest. Subject to Section 14.05(f), Borrower agrees that each Participant shall be entitled to the benefits of Section 5 to the same extent as if it were a Lender and had acquired its interest by assignment pursuant to Section 14.05(b). To the extent permitted by law, each Participant also shall be entitled to the benefits of Section 4.04(a) as though it were the Lender.

(f) **Limitations on Rights of Participants.** A Participant shall not be entitled to receive any greater payment under **Section 5.01** or **5.03** than a Lender would have been entitled to receive with respect to the participation sold to such Participant, unless the sale of the participation to such Participant is made with Borrower's prior written consent.

(g) **Certain Pledges.** The Lenders may at any time pledge or assign a security interest in all or any portion of its rights under this Agreement and any other Loan Document to secure obligations of the Lenders, including any pledge or assignment to secure obligations to a Federal Reserve Bank; <u>provided</u> that no such pledge or assignment shall release the Lenders from any of their obligations hereunder or substitute any such pledgee or assignee for the Lenders as a party hereto.

**14.06** Survival. The obligations of Borrower under Sections 5.01, 5.02, 5.03, 14.03, 14.05, 14.09, 14.10, 14.11, 14.12, 14.13, 14.14 and 14.16, and the obligations of the Subsidiary Guarantors under Section 13 (solely to the extent guaranteeing any of the obligations under the foregoing Sections) shall survive the repayment of the Obligations and the termination of the Commitment and, in the case of the Lenders' assignment of any interest in the Commitment or the Loans hereunder, shall survive, in the case of any event or circumstance that occurred prior to the effective date of such assignment, the making of such assignment, notwithstanding that the Lenders may cease to be "Lenders" hereunder. In addition, each representation and warranty made, or deemed to be made by a Borrowing Notice, herein or pursuant hereto shall survive the making of such representation and warranty.

**14.07** Captions. The table of contents and captions and section headings appearing herein are included solely for convenience of reference and are not intended to affect the interpretation of any provision of this Agreement.

**14.08 Counterparts.** This Agreement may be executed in any number of counterparts, all of which taken together shall constitute one and the same instrument and any of the parties hereto may execute this Agreement by signing any such counterpart. Delivery of an executed signature page of this Agreement by facsimile transmission or electronic transmission (in PDF format) shall be effective as delivery of a manually executed counterpart hereof.

**14.09 Governing Law.** This Agreement and the rights and obligations of the parties hereunder shall be governed by, and construed in accordance with, the law of the State of New York, without regard to principles of conflicts of laws that would result in the application of the laws of any other jurisdiction; provided that Section 5-1401 of the New York General Obligations Law shall apply.

# 14.10 Jurisdiction, Service of Process and Venue.

(a) **Submission to Jurisdiction.** Each Obligor agrees that any suit, action or proceeding with respect to this Agreement or any other Loan Document to which it is a party or any judgment entered by any court in respect thereof may be brought initially in the federal or state courts in New York, New York or in the courts of its own corporate domicile and irrevocably submits to the non-exclusive jurisdiction of each such court for the purpose of any such suit, action, proceeding or judgment. This **Section 14.10(a)** is for the benefit of Administrative Agent and the Lenders only and, as a result, neither Administrative Agent nor any Lender shall be prevented from taking proceedings in any other courts with jurisdiction. To the extent allowed by any Requirement of Law, Administrative Agent and the Lenders may take concurrent proceedings in any number of jurisdictions.

(b) **Alternative Process.** Nothing herein shall in any way be deemed to limit the ability of Administrative Agent or the Lenders to serve any process or summons in any other manner permitted by a Requirement of Law.

(c) **Waiver of Venue, Etc.** Each Obligor irrevocably waives to the fullest extent permitted by law any objection that it may now or hereafter have to the laying of the venue of any suit, action or proceeding arising out of or relating to this Agreement or any other Loan Document and hereby further irrevocably waives to the fullest extent permitted by law any claim that any such suit, action or proceeding brought in any such court has been brought in an inconvenient forum. A final judgment (in respect of which time for all appeals has elapsed) in any such suit, action or proceeding shall be conclusive and may be enforced in any court to the jurisdiction of which such Obligor is or may be subject, by suit upon judgment.

**14.11 Waiver of Jury Trial.** EACH OBLIGOR AND EACH LENDER HEREBY IRREVOCABLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY AND ALL RIGHT TO TRIAL BY JURY IN ANY SUIT, ACTTON OR PROCEEDING ARISING OUT OF OR RELATING TO THIS AGREEMENT, THE OTHER LOAN DOCUMENTS OR THE TRANSACTIONS CONTEMPLATED HEREBY OR THEREBY.

**14.12** Waiver of Immunity. To the extent that any Obligor may be or become entitled to claim for itself or its property or revenues any immunity on the ground of sovereignty or the like from suit, court jurisdiction, attachment prior to judgment, attachment in aid of execution of a judgment or execution of a judgment, and to the extent that in any such jurisdiction there may be attributed such an immunity (whether or not claimed), such Obligor hereby irrevocably agrees not to so claim and hereby irrevocably waives such immunity with respect to its obligations under this Agreement and the other Loan Documents.

**14.13** Entire Agreement. This Agreement and the other Loan Documents constitute the entire agreement among the parties with respect to the subject matter hereof and supersede any and all previous agreements and understandings, oral or written, relating to the subject matter hereof including any confidentiality (or similar) agreements. EACH OBLIGOR ACKNOWLEDGES, REPRESENTS AND WARRANTS THAT IN DECIDING TO ENTER INTO THIS AGREEMENT AND THE OTHER LOAN DOCUMENTS OR IN TAKING OR NOT TAKING ANY ACTION HEREUNDER OR THEREUNDER, IT HAS NOT RELIED, AND WILL NOT RELY, ON ANY STATEMENT, REPRESENTATION, WARRANTY, COVENANT, AGREEMENT OR UNDERSTANDING, WHETHER WRITTEN OR ORAL, OF OR WITH ADMINISTRATIVE AGENT OR THE LENDERS OTHER THAN THOSE EXPRESSLY SET FORTH IN THIS AGREEMENT AND THE OTHER LOAN DOCUMENTS.

**14.14** Severability. If any provision hereof is found by a court to be invalid or unenforceable, to the fullest extent permitted by any Requirement of Law the parties agree that such invalidity or unenforceability shall not impair the validity or enforceability of any other provision hereof.

**14.15** No Fiduciary Relationship. Borrower acknowledges that Administrative Agent and the Lenders have no fiduciary relationship with, or fiduciary duty to, Borrower arising out of or in connection with this Agreement or the other Loan Documents, and the relationship between the Lenders and Borrower is solely that of creditor and debtor. This Agreement and the other Loan Documents do not create a joint venture among the parties.

14.16 Confidentiality. Administrative Agent and each Lender agree to keep confidential all non-public information provided to them by any Obligor pursuant to this Agreement that is designated by such Obligor as confidential in accordance with its customary procedures for handling its own confidential information and use such information solely for purposes of the lending activities of Administrative Agent and each Lender under the Loan Documents; provided that nothing herein shall prevent Administrative Agent or any Lender from disclosing any such information (i) to Administrative Agent, any other Lender, any Affiliate of a Lender or any Eligible Transferee or other assignee permitted under Section 14.05(b), (ii) subject to an agreement to comply with the provisions of this Section, to any actual or prospective direct or indirect counterparty to any Hedging Agreement (or any professional advisor to such counterparty), (iii) to its employees, officers, directors, agents, attorneys, accountants, trustees and other professional advisors or those of any of its affiliates who have a need to know such information (collectively, its "Related Parties"), (iv) upon the request or demand of any Governmental Authority or any regulatory authority purporting to have jurisdiction over such Person or its Related Parties (including any self-regulatory authority, such as the National Association of Insurance Commissioners), (v) in response to any order of any court or other Governmental Authority or as may otherwise be required pursuant to any Requirement of Law, (vi) if required to do so in connection with any litigation or similar proceeding, (vii) that has been publicly disclosed (other than as a result of a disclosure in violation of this Section 14.16), (viii) to the National Association of Insurance Commissioners or any similar organization or any nationally recognized rating agency that requires access to information about a Lender's investment portfolio in connection with ratings issued with respect to such Lender, (ix) in connection with the exercise of any remedy hereunder or under any other Loan Document, (x) on a confidential basis to (A) any rating agency in connection with rating Borrower or its Subsidiaries or the Loan or (B) the CUSIP Service Bureau or any similar agency in connection with the issuance and monitoring of CUSIP numbers of other market identifiers with respect to the Loan or (xi) to any other party hereto; provided, further, that, (1) neither the Administrative Agent nor any Lender shall use any Obligor's non-public information for the purposes of engaging in hedging or short-selling activities of Borrower's Equity Interests and (2) unless specifically prohibited by applicable law or court order, each Lender shall notify Borrower of any request by any Governmental Authority or representative thereof (other than any such request in connection with any examination of the financial condition or other routine examination of such Lender by such Governmental Authority) for disclosure of any such non-public information prior to disclosure of such information.

**14.17 USA PATRIOT Act.** Administrative Agent and the Lenders hereby notify the Obligors that pursuant to the requirements of the USA PATRIOT Act (Title III of Pub. L.107-56 (signed into law October 26, 2001)) (the "*Act*"), they are required to obtain, verify and record information that identifies the Obligors, which information includes the name and address of each Obligor and other information that will allow such Person to identify such Obligor in accordance with the Act.

[Signature Pages Follow]

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be duly executed and delivered as of the day and year first above written.

## BORROWER:

## MONOSOL RX, LLC

By /s/ Keith J. Kendall

Name: Keith J. Kendall Title: Chief Executive Officer

Address for Notices: MonoSol Rx, LLC 30 Technology Drive Warren, NJ 07059 Attn: Chief Financial Officer Tel.: (908) 941-1912 Fax: (908) 561-1209 Email: jleonard@monosolrx.com

## SUBSIDIARY GUARANTORS:

#### MONOSOL RX, INC.

By /s/ Keith J. Kendall Name: Keith J. Kendall Title: President

Address for Notices: c/o MonoSol Rx, LLC 30 Technology Drive Warren, NJ 07059 Attn: Chief Financial Officer Tel.: (908) 941-1912 Fax: (908) 561-1209 Email: jleonard@monosolrx.com

[Signature page to Credit Agreement]

## MSRX US, LLC

By /s/ Keith J. Kendall Name: Keith J. Kendall Title: President

Address for Notices: c/o MonoSol Rx, LLC 30 Technology Drive Warren, NJ 07059 Attn: Chief Financial Officer Tel.: (908) 941-1912 Fax: (908) 561-1209 Email: jleonard@monosolrx.com

[Signature page to Credit Agreement]

## ADMINISTRATIVE AGENT:

## PERCEPTIVE CREDIT HOLDINGS, LP

## By: Perceptive Credit Opportunities GP, LLC, its general partner

By: /s/ Sandeep Dixit Name: Sandeep Dixit Title: Chief Credit Officer

By: /s/ Sam Chawla

Name: Sam Chawla Title: Portfolio Manager

Perceptive Credit Holding, LP c/o Perceptive Advisors LLC 51 Astor Place, 10<sup>th</sup> floor New York, NY 10003 Attn: Sandeep Dixit Email: Sandeep@ Perceptivelife.com

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## COMMITMENTS

Lender	Commitment	<b>Proportionate Share</b>
Perceptive Credit Holdings, LP	\$50,000,000	100%
TOTAL	\$50,000.000	100%

## FORM OF GUARANTEE ASSUMPTION AGREEMENT

GUARANTEE ASSUMPTION AGREEMENT dated as of [DATE] by [NAME OF ADDITIONAL SUBSIDIARY GUARANTOR], a \_\_\_\_\_\_ [corporation][limited liability company] (the "Additional Subsidiary Guarantor"), under that certain Credit Agreement, dated as of August 16, 2016 (as amended or otherwise modified, renewed, refinanced or replaced, the "Credit Agreement"), among MonoSol Rx, LLC, a Delaware limited liability company ("Borrower"), the Subsidiary Guarantors party thereto, the lenders party thereto and Perceptive Credit Holdings, LP, a Delaware limited partnership, as administrative agent and collateral agent for the lenders (in such capacity, together with its successors and assigns, "Administrative Agent").

Pursuant to **Section 8.12(a)** of the Credit Agreement, the Additional Subsidiary Guarantor hereby agrees to become a "Subsidiary Guarantor" for all purposes of the Credit Agreement, and a "Grantor" for all purposes of the Security Agreement. Without limiting the foregoing, the Additional Subsidiary Guarantor hereby, jointly and severally with the other Subsidiary Guarantors, guarantees to the Lenders and its successors and assigns the prompt payment in full when due (whether at stated maturity, by acceleration or otherwise) of all Guaranteed Obligations (as defined in Section 13.01 of the Credit Agreement) in the same manner and to the same extent as is provided in Section 13 of the Credit Agreement. In addition, as of the date hereof, the Additional Subsidiary Guarantor hereby makes the representations and warranties set forth in Section 7 of the Credit Agreement and in Section 3 of the Security Agreement, with respect to itself and its obligations under this Agreement and the other Loan Documents, as if each reference in such Sections to the Loan Documents included reference to this Agreement, such representations and warranties to be made as of the date hereof.

The Additional Subsidiary Guarantor hereby instructs its counsel to deliver the opinions referred to in **Section 8.12(a)** of the Credit Agreement to the Lenders.

IN WITNESS WHEREOF, the Additional Subsidiary Guarantor has caused this Guarantee Assumption Agreement to be duly executed and delivered as of the day and year first above written.

## [ADDITIONAL SUBSIDIARY GUARANTOR]

By

Name: Title:

Exhibit A-1

#### FORM OF BORROWING NOTICE

Date : [\_\_\_\_]

To: Perceptive Credit Holdings, LP, as Administrative Agent c/o Perceptive Advisors LLC 51 Astor place, 10th floor New York, NY 10003 Attn: Sandeep Dixit Email: Sandeep@perceptivelife.com

#### **Re: Borrowing under Credit Agreement**

Ladies and Gentlemen:

The undersigned, MonoSol Rx, LLC, a Delaware limited liability company ("*Borrower*"), refers to the Credit Agreement, dated as of August 16, 2016 (as the same may be amended or otherwise modified from time to time, the "*Credit Agreement*"), among Borrower, the Subsidiary Guarantors party thereto, the Lenders party thereto and Perceptive Credit Holdings, LP, a Delaware limited partnership, as administrative agent and collateral agent for the Lenders (in such capacity, together with its successors and assigns, "*Administrative Agent*"). The terms defined in the Credit Agreement are herein used as therein defined.

Borrower hereby gives you notice irrevocably, pursuant to Section 2.02(a) of the Credit Agreement, of the borrowing of the Loan specified herein:

- 1. The proposed Borrowing Date is [\_\_\_\_\_].
- 2. The amount of the proposed Borrowing is \$[\_\_\_\_\_].
- 3. The payment instructions with respect to the funds to be made available to Borrower are as follows:

Bank name:	[]
Bank Address: [	]
Routing Number:	[]
Account Number:	[]
Swift Code:	[ ]

Borrower hereby certifies that the following statements are true on the date hereof, and will be true on the date of the proposed borrowing of the Loan, before and after giving effect thereto and to the application of the proceeds therefrom:

a) the representations and warranties made by Borrower in **Section 7** of the Credit Agreement shall be true on and as of the Borrowing Date and immediately after giving effect to the application of the proceeds of the Borrowing with the same force and effect as if made on and as of such date except that the representation regarding representations and warranties that refer to a specific earlier date shall be that they were true on such earlier date;

Exhibit B-1

- b) on and as of the Borrowing Date, there shall have occurred no Material Adverse Change since [INSERT DATE OF LAST AUDITED FINANCIAL STATEMENTS]; and
- c) no Default exists or would result from such proposed borrowing.

[Signature Page Follows]

Exhibit B-2

IN WITNESS WHEREOF, Borrower has caused this Borrowing Notice to be duly executed and delivered as of the day and year first above written.

BORROWER:

## MONOSOL RX, LLC

By Name: Title:

Exhibit B-3

## FORM OF NOTE

## U.S. \$[\_\_\_\_]

[\_\_\_\_], 2016

FOR VALUE RECEIVED, the undersigned, MonoSol Rx, LLC, a Delaware limited liability company ("*Borrower*"), hereby promises to pay to Perceptive Credit Holdings, LP or its assigns (the "*Lender*"), in immediately available funds, the aggregate principal sum set forth above, or, if less, the aggregate unpaid principal amount of all Loans made by the Lender pursuant to **Section 2.01** of the Credit Agreement, dated as of August 16, 2016 (as the same may be amended or otherwise modified from time to time, the "*Credit Agreement*"), among Borrower, the Subsidiary Guarantors party thereto, the lenders party thereto and Perceptive Credit Holdings, LP, a Delaware limited partnership, as administrative agent and collateral agent for the lenders (in such capacity, together with its successors and assigns, "*Administrative Agent*"), on the date or dates specified in the Credit Agreement, together with interest on the principal amount of such Loans from time to time outstanding thereunder at the rates, and payable in the manner and on the dates, specified in the Credit Agreement.

This Note is a Note issued pursuant to the terms of **Section 2.04** of the Credit Agreement, and this Note and the holder hereof are entitled to all the benefits and security provided for thereby or referred to therein, to which Credit Agreement reference is hereby made for a statement thereof. All defined terms used in this Note, except terms otherwise defined herein, shall have the same meaning as in the Credit Agreement.

THIS NOTE AND THE RIGHTS AND OBLIGATIONS OF THE PARTIES HEREUNDER SHALL BE GOVERNED BY, AND CONSTRUED IN ACCORDANCE WITH, THE LAW OF THE STATE OF NEW YORK, WITHOUT REGARD TO PRINCIPLES OF CONFLICTS OF LAWS THAT WOULD RESULT IN THE APPLICATION OF THE LAWS OF ANY OTHER JURISDICTION; <u>PROVIDED</u> THAT SECTION 5-1401 OF THE NEW YORK GENERAL OBLIGATIONS LAW SHALL APPLY.

Borrower hereby waives demand, presentment, protest or notice of any kind hereunder, other than notices provided for in the Loan Documents. The non-exercise by the holder hereof of any of its rights hereunder in any particular instance shall not constitute a waiver thereof in such particular or any subsequent instance.

THIS NOTE MAY NOT BE TRANSFERRED EXCEPT IN COMPLIANCE WITH THE TERMS OF THE CREDIT AGREEMENT.

### MONOSOL RX, LLC

By

Name: Title:

Exhibit C-1

## FORM OF U.S. TAX COMPLIANCE CERTIFICATE

Reference is made to the Credit Agreement, dated as of August 16, 2016 (as the same may be amended or otherwise modified from time to time, the "*Credit Agreement*"), among MonoSol Rx, LLC, a Delaware limited liability company ("*Borrower*"), the Subsidiary Guarantors party thereto, the lenders party thereto and Perceptive Credit Holdings, LP, a Delaware limited partnership, as administrative agent and collateral agent for the lenders (in such capacity, together with its successors and assigns, "*Administrative Agent*"). [\_\_\_\_\_] (the "*Foreign Lender*") is providing this certificate pursuant to **Section 5.03(e)(ii)(B)** of the Credit Agreement. The Foreign Lender hereby represents and warrants that:

1. The Foreign Lender is the sole record owner of the Loans as well as any obligations evidenced by any Note(s) in respect of which it is providing this certificate;

2. The Foreign Lender's direct or indirect partners/members are the sole beneficial owners of the Loans as well as any obligations evidenced by any Note(s) in respect of which it is providing this certificate;

3. Neither the Foreign Lender nor its direct or indirect partners/members is a "bank" for purposes of Section 881(c)(3)(A) of the Internal Revenue Code of 1986, as amended (the "*Code*"). In this regard, the Foreign Lender further represents and warrants that:

(a) neither the Foreign Lender nor its direct or indirect partners/members is subject to regulatory or other legal requirements as a bank in any jurisdiction; and

(b) neither the Foreign Lender nor its direct or indirect partners/members has been treated as a bank for purposes of any tax, securities law or other filing or submission made to any Governmental Authority, any application made to a rating agency or qualification for any exemption from tax, securities law or other legal requirements;

4. Neither the Foreign Lender nor its direct or indirect partners/members is a 10-percent shareholder of Borrower within the meaning of Section 881(c)(3)(B) of the Code; and

5. Neither the Foreign Lender nor its direct or indirect partners/members is a controlled foreign corporation receiving interest from a related person within the meaning of Section 881(c)(3)(C) of the Code.

[Signature follows]

Exhibit D-1

IN WITNESS WHEREOF, the undersigned has caused this certificate to be duly executed and delivered as of the date indicated below.

[NAME OF NON-U.S. LENDER]

By

Name: Title:

Date:

Exhibit D-2

#### FORM OF COMPLIANCE CERTIFICATE

#### [DATE]

This certificate is delivered pursuant to **Section 8.01(d)** of, and in connection with the consummation of the transactions contemplated in, the Credit Agreement, dated as of August 16, 2016 (as the same may be amended or otherwise modified from time to time, the "*Credit Agreement*"), among MonoSol Rx, LLC, a Delaware limited liability company ("*Borrower*"), the Subsidiary Guarantors party thereto, the lenders party thereto and Perceptive Credit Holdings, LP, a Delaware limited partnership, as administrative agent and collateral agent for the lenders (in such capacity, together with its successors and assigns, "*Administrative Agent*"). Capitalized terms used herein and not otherwise defined herein are used herein as defined in the Credit Agreement.

The undersigned, a duly authorized Responsible Officer of Borrower having the name and title set forth below under his signature, hereby certifies, on behalf of Borrower for the benefit of the Secured Parties and pursuant to **Section 8.01(d)** of the Credit Agreement that such Responsible Officer of Borrower is familiar with the Credit Agreement and that, in accordance with each of the following sections of the Credit Agreement, each of the following is true on the date hereof, both before and after giving effect to any Loan to be made on or before the date hereof:

In accordance with Section **8.01**[(a)/(b)/(c)] of the Credit Agreement, attached hereto as **Annex A** are the financial statements for the [fiscal quarter/fiscal year/fiscal month] ended [\_\_\_\_\_] required to be delivered pursuant to **Section 8.01**[(a)/(b)/(c)] of the Credit Agreement. Such financial statements fairly present in all material respects the consolidated financial position, results of operations and cash flow of Borrower and its Subsidiaries as at the dates indicated therein and for the periods indicated therein in accordance with GAAP [(subject to the absence of footnote disclosure and normal year-end audit adjustments)]<sup>1</sup>

Attached hereto as **Annex B** are the calculations used to determine compliance with each financial covenant contained in **Section 10** of the Credit Agreement.

No Default or Event of Default is continuing as of the date hereof[, except as provided for on **Annex C** attached hereto, with respect to each of which Borrower proposes to take the actions set forth on **Annex C**].

The representations and warranties made by Borrower in **Section 7** of the Credit Agreement are true on and as of the date hereof, with the same force and effect as if made on and as of the date hereof (except that the representation regarding representations and warranties that refer to a specific earlier date shall be that they were true on such earlier date).

<sup>1</sup> Insert language in brackets only for quarterly and monthly certifications.

IN WITNESS WHEREOF, the undersigned has executed this certificate on the date first written above.

## MONOSOL RX, LLC

By

Name: Title:

## FINANCIAL STATEMENTS

[see attached]

## CALCULATIONS OF FINANCIAL COVENANT COMPLIANCE

	Section 10.01: Minimum Liquidity	
I.A	Balance of cash in the Controlled Account with account number	\$
I.B	Balance of cash in the Controlled Account with account number	
I.C	Balance of cash in the Controlled Account with account number2	
I.D	\$4,000,000	\$
	<i>Is the sum of Lines I.A</i> + <i>I.B</i> + <i>I.C equal to or greater than Line I.D?</i>	Yes: In compliance; No: Not in compliance
	Section 10.02: Minimum Revenue	
II.A	All revenue generated by Borrower and its Subsidiaries in the last twelve months as a result of the ordinary course manufacturing and sale of Products that, in accordance with GAAP, would be classified as net revenue, excluding upfront payments, milestones and royalties revenue generated by Borrower and its Subsidiaries that are not related to the sale of products or services.	\$
II.B	\$[]	
	Is line II.A equal to or greater than Line II.B?	Yes: In compliance; No: Not in compliance

<sup>2</sup> Add more lines, if necessary, to list all controlled accounts.

## DEFAULTS OR EVENTS OF DEFAULT

## [IF NEEDED]

#### FORM OF ASSIGNMENT AND ASSUMPTION

This Assignment and Assumption (this "Assignment and Assumption") is dated as of the Effective Date set forth below and is entered into by and between [\_\_\_\_\_] (the "Assignor") and [\_\_\_\_\_] (the "Assignee"). Capitalized terms used but not defined herein shall have the meanings given to them in the Credit Agreement, dated as of August 16, 2016 (as the same may be amended or otherwise modified from time to time, the "Credit Agreement"), among MonoSol Rx, LLC, a Delaware limited liability company, the Subsidiary Guarantors party thereto, the lenders party thereto and Perceptive Credit Holdings, LP, a Delaware limited partnership, as administrative agent and collateral agent for the lenders, receipt of a copy of which is hereby acknowledged by the Assignee. The Standard Terms and Conditions set forth in Annex 1 attached hereto are hereby agreed to and incorporated herein by reference and made a part of this Assignment and Assumption as if set forth herein in full.

For an agreed consideration, the Assignor hereby irrevocably sells and assigns to the Assignee, and the Assignee hereby irrevocably purchases and assumes from the Assignor, subject to and in accordance with the Standard Terms and Conditions and the Credit Agreement, as of the Effective Date inserted by the Agent as contemplated below (i) all of the Assignor's rights and obligations in its capacity as a Lender under the Credit Agreement and any other documents or instruments delivered pursuant thereto to the extent related to the amount and percentage interest identified below of all of such outstanding rights and obligations of the Assignor under the respective facilities identified below (including without limitation any letters of credit, any guarantees, and swingline loans included in such facilities) and (ii) to the extent permitted to be assigned under applicable law, all claims, suits, causes of action and any other right of the Assignor (in its capacity as a Lender) against any Person, whether known or unknown, arising under or in connection with the Credit Agreement, any other documents or instruments delivered pursuant thereto or the loan transactions governed thereby or in any way based on or related to any of the foregoing, including, but not limited to, contract claims, tort claims, malpractice claims, statutory claims and all other claims at law or in equity related to the rights and obligations sold and assigned pursuant to clause (i) above (the rights and obligations sold and assigned by the Assignor to the Assignor and, except as expressly provided in this Assignment and Assumption, without representation or warranty by the Assignor.

[Remainder of page intentionally left blank; signature page(s) follow]

Effective Date: \_\_\_\_\_\_\_\_\_, 20\_\_\_\_ [TO BE INSERTED BY ADMINISTRATIVE AGENT AND WHICH SHALL BE THE EFFECTIVE DATE OF RECORDATION OF TRANSFER IN THE REGISTER THEREFOR.]

The terms set forth in this Assignment and Assumption are hereby agreed to:

## ASSIGNOR

[NAME OF ASSIGNOR]

By:	
Name:	
Title:	

## ASSIGNEE

[NAME OF ASSIGNEE]

By: Name: Title:

Consented to and Accepted:

Title:

PERCEPTIVE CREDIT HOLDINGS, LP, as Administrative Agent

By: PERCEPTIVE CREDIT OPPORTUNITIES GP, LLC, its general partner

#### 1. **Representations and Warranties.**

1.1 <u>Assignor</u>. The Assignor (a) represents and warrants that (i) it is the legal and beneficial owner of the Assigned Interest, (ii) the Assigned Interest is free and clear of any lien, encumbrance or other adverse claim and (iii) it has full power and authority, and has taken all action necessary, to execute and deliver this Assignment and Assumption and to consummate the transactions contemplated hereby and (iv) it is [not] a Defaulting Lender; and (b) assumes no responsibility with respect to (i) any statements, warranties or representations made in or in connection with the Credit Agreement or any other Loan Document, (ii) the execution, legality, validity, enforceability, genuineness, sufficiency or value of the Loan Documents or any collateral thereunder, (iii) the financial condition of Borrower, any of its Subsidiaries or Affiliates or any other Person obligated in respect of any Loan Document or (iv) the performance or observance by Borrower, any of its Subsidiaries or Affiliates or any other Person of any of their respective obligations under any Loan Document.

1.2 Assignee. The Assignee (a) represents and warrants that (i) it has full power and authority, and has taken all action necessary, to execute and deliver this Assignment and Assumption and to consummate the transactions contemplated hereby and to become a Lender under the Credit Agreement, [(ii) it meets all requirements of an Eligible Transferee under the Credit Agreement]<sup>3</sup>, (iii) from and after the Effective Date, it shall be bound by the provisions of the Credit Agreement as a Lender thereunder and, to the extent of the Assigned Interest, shall have the obligations of a Lender thereunder, (iv) it is sophisticated with respect to decisions to acquire assets of the type represented by the Assigned Interest and is experienced in acquiring assets of such type, (v) it has received a copy of the Credit Agreement, and has received or has been accorded the opportunity to receive copies of the most recent financial statements delivered pursuant to Section 8.01(a), (b) and (c) thereof, as applicable, and such other documents and information as it has deemed appropriate to make its own credit analysis and decision to enter into this Assignment and Assumption and to purchase the Assigned Interest, (vi) it has, independently and without reliance upon the Administrative Agent or any other Lender and based on such documents and information as it has deemed appropriate, made its own credit analysis and decision to enter into this Assignment and Assumption and to purchase the Assigned Interest, and [(vii) attached to the Assignment and Assumption is any documentation required to be delivered by it pursuant to the terms of the Credit Agreement, duly completed and executed by the Assignee]<sup>4</sup>; and (b) agrees that (i) it will, independently and without reliance on the Administrative Agent, the Assignor or any other Lender, and based on such documents and information as it shall deem appropriate at the time, continue to make its own credit decisions in taking or not taking action under the Loan Documents, and (ii) it will perform in accordance with their terms all of the obligations which by the terms of the Loan Documents are required to be performed by it as a Lender.

 $<sup>\</sup>overline{\mathbf{3}}$  To be deleted if assignment occurs during an Event of Default

<sup>&</sup>lt;sup>4</sup> To be included only if Assignee is a Foreign Lender

2. **Payments.** From and after the Effective Date, the Administrative Agent shall make all payments in respect of the Assigned Interest (including payments of principal, interest, fees and other amounts) to the Assignor for amounts which have accrued to but excluding the Effective Date and to the Assignee for amounts which have accrued from and after the Effective Date. Notwithstanding the foregoing, the Administrative Agent shall make all payments of interest, fees or other amounts paid or payable in kind from and after the Effective Date to the Assignee.

3. **General Provisions.** This Assignment and Assumption shall be binding upon, and inure to the benefit of, the parties hereto and their respective successors and assigns. This Assignment and Assumption may be executed in any number of counterparts, which together shall constitute one instrument. Delivery of an executed counterpart of a signature page of this Assignment and Assumption by facsimile or in electronic (i.e., "pdf" or "tif") format shall be effective as delivery of a manually executed counterpart of this Assignment and Assumption. This Assignment and Assumption shall be governed by, and construed in accordance with, the law of the State of New York.

## FORM OF LANDLORD CONSENT

WHEREAS, MonoSol Rx, LLC, a Delaware limited liability company ("*Debtor*"), has entered into a Credit Agreement and a Security Agreement (collectively, the "*Agreements*"), each dated as of August 16, 2016, with certain subsidiary guarantors and lenders and Perceptive Credit Holdings, LP, a Delaware limited partnership, as administrative agent and collateral agent for the lenders (in such capacity, together with its successors and assigns, "*Administrative Agent*"), pursuant to which Secured Parties referred to in the Agreements have been granted a security interest in all of Debtor's personal property, including but not limited to inventory, equipment and trade fixtures (hereinafter "*Personal Property*"); and

WHEREAS, [\_\_\_\_\_] ("*Landlord*") is the owner of the real property located at [\_\_\_\_\_] (the "*Premises*"); and

WHEREAS, Landlord and Debtor have entered into that certain Lease dated [\_\_\_\_\_][, as amended by [\_\_\_\_] dated [\_\_\_]] ([collectively,] the "*Lease*"); and

WHEREAS, certain of the Personal Property has or may become affixed to or be located on, wholly or in part, the Premises.

NOW, THEREFORE, in consideration of any loans or other financial accommodation extended by Secured Parties to Debtor at any time, and other good and valuable consideration, the parties agree as follows:

1. Landlord subordinates to Secured Parties all security interests or other interests or rights Landlord may now or hereafter have in, or to any of the Personal Property, whether for rent or otherwise, while Debtor is indebted to Secured Parties.

2. The Personal Property may be installed in or located on the Premises and is not and shall not be deemed a fixture or part of the real estate and shall at all times be considered personal property.

3. Administrative Agent or its representatives may enter upon the Premises during normal business hours, and upon not less than 24 hours' advance notice, to inspect the Personal Property.

4. Upon and during the continuance of an Event of Default under the Agreements, Administrative Agent or its representatives, at Administrative Agent's option, upon written notice delivered to Landlord not less than ten Business Days in advance, may enter the Premises during normal business hours for the purpose of repossessing, removing or otherwise dealing with said Personal Property; <u>provided</u> that neither Administrative Agent nor any other Secured Party shall be permitted to operate the business of Debtor on the Premises or sell, auction or otherwise dispose of any Personal Property at the Premises or advertise any of the foregoing; and such license shall continue, from the date Administrative Agent enters the Premises for as long as Administrative Agent reasonably deems necessary but not to exceed a period of ten days. During the period Administrative Agent occupies the Premises, it shall pay to Landlord the rent provided under the Lease relating to the Premises, prorated on a per diem basis to be determined on a 30 day month, without incurring any other obligations of Debtor.

Exhibit G-1

5. Administrative Agent shall pay to Landlord any costs for damage to the Premises or the building in which the Premises is located in removing or otherwise dealing with said Personal Property pursuant to **Paragraph 4** above, and shall indemnify and hold harmless Landlord from and against (i) all claims, disputes and expenses, including reasonable attorneys' fees, suffered or incurred by Landlord arising from Administrative Agent's exercise of any of its rights hereunder, and (ii) any injury to third persons, caused by actions of Administrative Agent pursuant to this consent.

6. Landlord agrees to give notice to Administrative Agent in writing by certified mail or facsimile of Landlord's intent to exercise its remedies in response to any default by Debtor of any of the provisions of the Lease, to:

Perceptive Credit Holdings, LP c/o Perceptive Advisors LLC 51 Astor place, 10th floor New York, NY 10003 Attn: Sandeep Dixit Email: Sandeep@perceptivelife.com

7. Landlord shall have no obligation to preserve or protect the Personal Property or take any action in connection therewith, and Administrative Agent, on behalf of the Secured Parties, waives all claims Secured Parties may now or hereafter have against Landlord in connection with the Personal Property.

8. This consent shall terminate and be of no further force or effect upon the earlier of (i) the date on which all indebtedness secured by the Personal Property indefeasibly is paid in full in cash and (ii) the date on which the Lease is terminated or expires.

9. Nothing contained herein shall be construed to amend the Lease, and the Lease remains unchanged and in full force and effect.

This consent shall be construed and interpreted in accordance with and governed by the laws of the State of New York.

This consent may not be changed or terminated orally and is binding upon and shall inure to the benefit of Landlord, Administrative Agent and the other Secured Parties, and Debtor and the heirs, personal representatives, successors and assigns of Landlord, Administrative Agent and the other Secured Parties, and Debtor.

[Signature Page follows]

Exhibit G-2

Dated this \_\_\_\_\_, 20\_\_.

## LANDLORD:

[\_\_\_\_\_]

By

Name: Title:

ADMINISTRATIVE AGENT:

## PERCEPTIVE CREDIT HOLDINGS, LP

By: PERCEPTIVE CREDIT OPPORTUNITIES GP, LLC, its general partner

By

Name: Title:

By

Name: Title:

Acknowledged and Agreed:

BORROWER:

## MONOSOL RX, LLC

By

Name: Title:

Exhibit G-3

#### **OMNIBUS AMENDMENT NO. 1**

This **OMNIBUS AMENDMENT NO. 1**, dated as of January 1, 2018 (this "*Amendment*"), is among MonoSol Rx, LLC, a Delaware limited liability company (to be renamed Aquestive Therapeutics, Inc. and converted into a Delaware corporation upon consummation of the Conversion Transaction (as defined below)) (the "*Borrower*"), the Lenders party hereto (the "*Lenders*") and Perceptive Credit Holdings, LP, a Delaware limited partnership, as administrative agent and collateral agent for the Lenders (in such capacity, together with its successors and assigns, "*Administrative Agent*"). Reference is made to the Credit Agreement and Guaranty, dated as of August 16, 2016 (as amended, modified, restated and supplemented, the "*Credit Agreement*"), among the Borrower, the Subsidiary Guarantors party thereto, the Lenders parties thereto and the Administrative Agent. Capitalized terms used herein without definition shall have the same meanings as set forth in the Credit Agreement, as amended hereby.

#### RECITALS

WHEREAS, the Borrower, the Lenders and the Administrative Agent are party to the letter (the "Consent Letter") dated as of January 1, 2018;

WHEREAS, pursuant to the Consent Letter the parties thereto agreed to negotiate in good faith to enter into an amendment to the Loan Documents, and the Lender's and Administrative Agent's consent to the Conversion Transaction (as defined therein) is conditioned upon the effectiveness of such amendment; and

WHEREAS, the Borrower, the Lenders party hereto and the Administrative Agent wish to amend the Loan Documents pursuant to the terms hereof.

**NOW, THEREFORE**, in consideration of the premises and the agreements, provisions and covenants herein contained, the parties hereto agree as follows:

## SECTION 1. AMENDMENTS.

**A.** As of the Amendment Effective Date (as defined in Section 3), each reference in each Loan Document to "MonoSol Rx, LLC" shall be deemed to refer to "Aquestive Therapeutics, Inc." and each reference to "MonoSol Rx, LLC, a Delaware limited liability company" shall be deemed to refer to "Aquestive Therapeutics, Inc., a Delaware corporation".

B. Each of the following definitions in Section 1.01 of the Credit Agreement is hereby amended and restated in its entirety as follows:

"Change of Control" means (i) the acquisition of ownership, directly or indirectly, beneficially or of record, by any Person or group of Persons acting jointly or otherwise in concert of Equity Interests representing more than 40% of the aggregate ordinary voting power represented by the issued and outstanding Equity Interests of Aquestive Partners, (ii) during any period of 12 consecutive calendar months, the occupation of a majority of the seats (other than vacant seats) on the board of directors (or other managing body) of Borrower or Aquestive Partners by Persons who were neither (x) nominated by the board of directors of Borrower or Aquestive Partners, as applicable, nor (y) appointed by directors so nominated, (iii) the acquisition of direct or indirect Control of Aquestive Partners by any Person or group of Persons acting jointly or otherwise in concert; in each case whether as a result of a tender or exchange offer, open market purchases, privately negotiated purchases or otherwise, (iv) the sale, conveyance or disposal of all or substantially all of the property or business of (1) Borrower and its Subsidiaries, taken as a whole, or (2) Aquestive Partners, (v) Borrower shall cease to own, directly or indirectly, beneficially and of record, 100% of the issued and outstanding Equity Interests of Borrower issued pursuant to (x) a Qualified Private Placement of Borrower Equity Interests or (y) equity-based compensation plans, arrangements or agreements established by Borrower in order to replace or otherwise modify Borrower's existing phantom equity plans, Aquestive Partners shall cease to own directly, beneficially and outstanding Equity Interests of all Liens.

"Loan Documents" means, collectively, this Agreement, the Notes, the Security Documents, the Warrant Agreement, each Warrant, the Fee Letter, the Parent Guaranty, the Pledge Agreement and any subordination agreement, intercreditor agreement or other present or future document, instrument, agreement or certificate delivered to Administrative Agent or any Lender in connection with this Agreement or any of the other Loan Documents, in each case, as amended or otherwise modified.

"*Obligors*" means, collectively, Borrower, Aquestive Partners, the Subsidiary Guarantors and each of their respective successors and permitted assigns.

"*Public Offering*" means any sale of Equity Interests of a Person pursuant to an offering that is underwritten on a firm commitment basis by a nationally recognized investment banking firm, or a merger, reverse merger or similar transaction to which a Person is a party and, as a result of which, such Person becomes subject to the reporting requirements of Section 13 or Section 15 of the Securities Act immediately following such offering.

"*Qualified IPO*" means Borrower's initial Public Offering of its common Equity Interests following a Qualified IPO Restructuring, which offering results in gross proceeds to Borrower of not less than \$40,000,000, and as a result of which such Equity Interests are listed on either the New York Stock Exchange or the NASDAQ National Market.

"Senior Common Interests" has the meaning set forth in the Limited Liability Company Agreement (as in effect on January 1, 2018) of Aquestive Partners.

"*Warrant Agreement*" means that certain Warrant Certificate and Agreement by and between the Aquestive Partners and Perceptive Credit Holdings, LP delivered pursuant to the Amendment No. 1.

"*Warrant*" means one or more warrants, issued pursuant to the Warrant Agreement, exercisable into an aggregate number of Senior Common Interests equal to four and half percent (4.5%) of the aggregate issued and outstanding Equity Interests of Aquestive Partners, in each case determined on a fully-diluted basis. Each Warrant shall be exercisable at \$0.01 per unit of Senior Common Interests and shall be subject to the terms and conditions of the Warrant Agreement.

C. The following definitions are added to Section 1.01 of the Credit Agreement in appropriate alphabetical order:

"*Amendment No. 1*" means the Omnibus Amendment No. 1, dated as of January 1, 2018, among the Borrower, the Subsidiary Guarantors party thereto, the Lenders party thereto and the Administrative Agent.

"Aquestive Partners" means Aquestive Partners, LLC, a Delaware limited liability company.

"*Parent Guaranty*" means the Parent Guaranty, dated as of January 1, 2018, made by Aquestive Partners in favor of Administrative Agent, for the benefit of the Secured Parties.

"*Pledge Agreement*" means the Pledge Agreement, dated as of January 1, 2018, between Aquestive Partners and Administrative Agent (for the benefit of the Secured Parties).

"Qualified IPO Restructuring" means, in a single transaction or series of related transactions, a liquidation, merger, consolidation or other business combination involving Aquestive Partners and Borrower as constituent parties in each case consummated in anticipation of a Qualified IPO, pursuant to which the Equity Interests of Aquestive Partners and all Equity Interests of Aquestive Partners issuable upon exercise of any rights, options or warrants to subscribe for, purchase or otherwise acquire Equity Interests of Aquestive Partners, as applicable, outstanding immediately prior to such merger, consolidation or other business combination are converted or exchanged for Equity Interests of Borrower as the surviving or resulting entity in such transaction; <u>provided</u> that as part of a Qualified IPO Restructuring, equity-based compensation plans, arrangements or agreements may be established for or on behalf of such surviving or resulting entity in the event of termination or conversion of Borrower's existing performance equity plans.

"*Qualified Private Placement of Borrower Equity Interests*" means a private offering and sale of the Equity Interests of Borrower to recognized institutional investors prior to (but in anticipation of) a Qualified IPO.

**D.** The word "and" at the end of Section 9.03(d) of the Credit Agreement is deleted, the period at the end of Section 9.03(e) is replaced with "; and", and new clause (f) is added in Section 9.03 of the Credit Agreement immediately following clause (e):

(f) (x) subject to compliance with all anti-dilution and other protections pursuant to the Warrant and the Warrant Agreement and (y) so long as immediately prior to, and after giving effect thereto, no Default shall have occurred and be continuing or would result therefrom, Qualified IPO Restructuring.

E. The following Section 9.19 is added to Section 9 of the Credit Agreement immediately following Section 9.18:

**9.10 Passive Holding Company.** No Obligor will permit Aquestive Partners to conduct, transact or otherwise engage in any active trade or business or operations or incur any Indebtedness or other liability other than through Borrower, and no Obligor will permit Aquestive Partners to own any assets other than the Equity Interests of Borrower; <u>provided</u> that the foregoing will not prohibit Aquestive Partners from the following: (i) the maintenance of its legal existence and (including the ability to incur reasonable fees, costs, expenses and other liabilities relating to such maintenance), (ii) obligations incidental to its legal existence and other obligations that are limited to obligations under the Loan Documents to which it is a party, (iii) the making of contributions to (or other equity investments in) Borrower, which contributions shall be subordinated to the Obligations, (iv) participating in tax, accounting and other administrative and fiduciary matters as a direct owner of Borrower, in each case, in accordance with the terms of the Loan Documents, (v) holding any cash or Permitted Cash Equivalent Investments on a temporary basis (and in no event longer than three Business Days) that is in the process of being transferred through Aquestive Partners as part of a downstream contribution to Borrower and (vi) providing customary compensation, indemnification and insurance coverage to officers and directors.

#### SECTION 2. ACKNOWLEDGEMENT, AGREEMENT AND CONSENT AND REPRESENTATIONS AND WARRANTIES.

A. Each Subsidiary Guarantor has read this Amendment and consents to the terms hereof. Each Obligor confirms and agrees that, notwithstanding the effectiveness of this Amendment, the obligations of such Obligor under each Loan Documents to which such Obligor is a party shall not be impaired and each Loan Documents to which such Obligor is a party is, and shall continue to be, in full force and effect and is hereby confirmed and ratified in all respects.

**B.** Each Obligor hereby acknowledges and agrees that the Guaranteed Obligations will include all Obligations under, and as defined in, the Credit Agreement as amended by this Amendment.

**C.** Each Subsidiary Guarantor acknowledges and agrees that (i) notwithstanding the conditions to effectiveness set forth in this Amendment, such Subsidiary Guarantor is not required by the terms of the Credit Agreement or any other Loan Document to consent to the amendments to the Credit Agreement effected pursuant to this Amendment and (ii) nothing in the Credit Agreement, this Amendment or any other Loan Document shall be deemed to require the consent of such Subsidiary Guarantor to any future amendments to the Credit Agreement.

**D.** In order to induce the Administrative Agent and the Lenders party hereto to enter into this Amendment, each Obligor represents and warrants to the Administrative Agent and the Lenders that the following statements are true, correct and complete:

- (i) such Obligor has full power, authority and legal right to enter into each Amendment Document (as defined below) to which it is a party and perform its obligations under each Amendment Document to which it is a party and each Loan Document as amended hereby or thereby;
- (ii) the transactions contemplated by the Amendment Documents to which it is a party are within such Obligor's corporate powers and have been duly authorized by all necessary corporate and, if required, by all necessary shareholder action. This Amendment has been duly executed and delivered by such Obligor and constitutes, and each of the other Amendment Documents to which it is a party when executed and delivered by such Obligor will constitute, a legal, valid and binding obligation of such Obligor, enforceable against such Obligor in accordance with its terms, except as such enforceability may be limited by (i) bankruptcy, insolvency, reorganization, moratorium or similar laws of general applicability affecting the enforcement of creditors' rights and (ii) the application of general principles of equity (regardless of whether such enforceability is considered in a proceeding in equity or at law);
- (iii) the transactions contemplated by the Amendment Documents to which it is a party (1) do not require any Governmental Approval of, registration or filing with, or any other action by, any Governmental Authority or any third party, except for such as have been obtained or made and are in full force and effect, (2) will not violate (x) any Requirement of Law or any order of any Governmental Authority, other than any such violations that, individually or in the aggregate, could not reasonably be expected to have a Material Adverse Effect, or (y) the Organic Documents of such Obligor or its Subsidiaries, (3) will not violate or result in a default under any indenture, agreement or other instrument binding upon such Obligor or its Subsidiaries or assets, or give rise to a right thereunder to require any payment to be made by any such Person, and (4) will not result in the creation or imposition of any Lien (other than Permitted Liens) on any asset of such Obligor or its Subsidiaries; and

(iv) both immediately before and after giving effect to each Amendment Document and the Conversion Transaction, (x) the representations and warranties set forth in this Amendment and each other Loan Document shall, in each case, be true and correct and (y) no Default shall have then occurred and be continuing, or would result from the Amendment Documents and the Conversion Transaction.

**SECTION 3. CONDITIONS TO EFFECTIVENESS.** This Amendment shall become effective only upon the satisfaction of the following conditions precedent (the date of satisfaction of such conditions being referred to as the "*Amendment Effective Date*"):

A. The Obligors, the Administrative Agent and the Lenders shall have indicated their consent to this Amendment by the execution and delivery of the signature pages hereto to the Administrative Agent.

**B.** The Administrative Agent shall have received (i) an officer's certificate of Borrower, either confirming that there have been no changes to its organizational documents since August 16, 2016, or if there have been changes to its organizational documents since such date, certifying as to such changes, (ii) copies of resolutions of Borrower's board of directors (or other managing body) then in full force and effect authorizing (x) the execution, delivery and performance of each Amendment Document to which it is a party and, (y) the Conversion Transaction, each certified by a Responsible Officer of Borrower, (iii) a copy of a good standing certificate of Borrower dated a date reasonably close to the date hereof, and (iv) an incumbency certificate from Borrower.

**C.** The Administrative Agent shall have received (i) an officer's certificate of Aquestive Partners, certifying the full force and validity of each Organic Document of Aquestive Partners and attaching copies thereof, (ii) copies of resolutions of Aquestive Partners board of directors (or other managing body) then in full force and effect authorizing the execution, delivery and performance of the Amendment Documents to which it is a party, certified by a Responsible Officer of Aquestive Partners, (iii) a copy of a good standing certificate of Aquestive Partners dated a date reasonably close to the date hereof, and (iv) an incumbency certificate from Aquestive Partners.

**D.** The UCC-3 financing statement amendment suitable in form for filing with the Secretary of State of the State of Delaware naming the Borrower as a debtor and Administrative Agent as the secured party amending the name of the Borrower from "MonoSol Rx, LLC" to "Aquestive Therapeutics, Inc.".

E. The Administrative Agent shall have received an executed copy of (x) the Warrant Certificate and Agreement (the "*Replacement Warrant Agreement*") between Aquestive Partners and Perceptive Credit Holdings, LP, and (y) the corresponding Warrant Certificate (the "*Replacement Warrant*") by Aquestive Partners, each in form and substance reasonably satisfactory to the Administrative Agent, each to replace the Warrant Certificate and Agreement (the "*2016 Warrant Agreement*") and Warrant Certificate No. 18 (the "*2016 Warrant*") delivered to the Administrative Agent on August 16, 2016. By operation of the execution and delivery of the Replacement Warrant Agreement and the 2016 Warrant, shall be terminated and be of no further force and effect and the 2016 Warrant Certificate shall be tendered promptly by the Administrative Agent to the Borrower for cancellation.

**F.** The Administrative Agent shall have received an executed copy of the Parent Guaranty and the Pledge Agreement, each, in form and substance reasonably satisfactory to the Administrative Agent.

**G.** The Administrative Agent shall have received all reasonable and documented out of pocket expenses for which invoices have been presented (including the reasonable fees and expenses of legal counsel for which the Borrower agrees it is responsible pursuant to Section 14.03 of the Credit Agreement) that are due and payable in connection with this Amendment.

H. The Administrative Agent shall be satisfied with Lien searches regarding Aquestive Partners made reasonably close to the date hereof.

I. The Administrative Agent shall have received all certificates (in the case of Equity Interests that are securities (as defined in the NYUCC)) evidencing the issued and outstanding Equity Interests of Borrower owned by Aquestive Partners that are required to be pledged under the Pledge Agreement, which certificates in each case shall be accompanied by undated instruments of transfer duly executed in blank, or, in the case of Equity Interests that are uncertificated securities (as defined in the NYUCC), confirmation and evidence satisfactory to Administrative Agent that the security interest required to be pledged therein under the Pledge Agreement has been transferred to and perfected by the Administrative Agent in accordance with Articles 8 and 9 of the NYUCC and all laws otherwise applicable to the perfection of the pledge of such Equity Interests.

J. The Administrative Agent shall have financing statements suitable in form for naming Aquestive Partners as a debtor and the Administrative Agent as the secured party, or other similar instruments or documents to be filed under the UCC of all jurisdictions as may be necessary or, in the opinion of the Administrative Agent, desirable to perfect the security interests of the Administrative Agent pursuant to the Pledge Agreement.

**SECTION 4. CONDITIONS SUBSEQUENT.** The Borrower shall deliver, or shall cause to be delivered, the following items to the Administrative Agent within 30 days of the date hereof, or such later date set forth below:

**A.** Duly executed amendments (to reflect the change of the Borrower's name from "MonoSol Rx, LLC" to "Aquestive Therapeutics, Inc.") to the following agreements (collectively with this Amendment, the Parent Guaranty, the Pledge Agreement, the Replacement Warrant and the Replacement Warrant Agreement, the "*Amendment Documents*"):

- (i) the amendment to the Patent Security Agreement, dated as of August 16, 2016, among the Patent Grantors party thereto and the Administrative Agent;
- (ii) the amendment to the Trademark Security Agreement, dated as of August 16, 2016, among the Trademark Grantors party thereto and the Administrative Agent;
- (iii) within 60 days of the date hereof, the amendment to the Deposit Account Control Agreement, dated as of October 26, 2016, among the Borrower, the Administrative Agent and Bank of America, N.A.; and
- (iv) within 60 days of the date hereof, the amendment to the Pledged Collateral Account Control Agreement, dated as of October 26, 2016, among the Borrower, the Administrative Agent and Merrill Lynch, Pierce, Fenner & Smith Incorporated.



**B.** Duly executed copy of (i) an incumbency certificate of the Borrower (after giving effect to the Conversion Transaction) and (ii) an officer's certificate of the Borrower as to the full force and validity of each Organic Document of the Borrower (which shall be in form and substance reasonably satisfactory to the Administrative Agent), including, without limitation, any certificate of conversion, and copies thereof, in each case, that are in effect after giving effect to the Conversion Transaction.

**C.** Within 60 days of the date hereof, evidence (which shall be in form any substance reasonably satisfactory to the Administrative Agent) of the merger, amalgamation, consolidation, liquidation, winding up or dissolution of MonoSol Rx, Inc. and MSRX US, LLC in a transaction permitted by Section 9.03 of the Credit Agreement.

The parties hereto agree that, notwithstanding Section 11.01 of the Credit Agreement, the failure of the Borrower to comply with the terms of Section 4 hereof shall be deemed an immediate Event of Default.

**SECTION 5. RELEASE OF SUBSIDIARY GUARANTORS.** Effective as of the Amendment Effective Date, the Administrative Agent and the Lenders hereby irrevocably release MonoSol Rx, Inc. and MSRX US, LLC, as Subsidiary Guarantors, from all Guaranteed Obligations. Nothing in this in this Section 5 shall be construed as releasing the Borrower or any other Obligor (other than MonoSol Rx, Inc. and MSRX US, LLC) in respect of the Obligations.

## SECTION 6. MISCELLANEOUS

### A. Reference to and Effect on the Loan Documents.

- (i) On and after the Amendment Effective Date, each reference in any Loan Document to any Loan Document amended hereby shall mean and be a reference to such Loan Document as amended by this Amendment.
- (ii) Except as specifically amended by this Amendment, each Loan Documents shall remain in full force and effect and is hereby ratified and confirmed.
- (iii) The execution, delivery and performance of this Amendment shall not constitute a waiver of any provision of, or operate as a waiver of any right, power or remedy of the Administrative Agent or any Lender under any Loan Document or applicable Law.
- (iv) This Amendment shall constitute a Loan Document.

**B.** Captions. The captions and section headings appearing herein are included solely for convenience of reference and are not intended to affect the interpretation of any provision of this Amendment.

**C. Governing Law.** This Amendment and the rights and obligations of the parties hereunder shall be governed by, and construed in accordance with, the law of the State of New York, without regard to principles of conflicts of laws that would result in the application of the laws of any other jurisdiction; <u>provided</u> that Section 5-1401 of the New York General Obligations Law shall apply.

**D. Counterparts.** This Amendment may be executed in any number of counterparts, all of which taken together shall constitute one and the same instrument and any of the parties hereto may execute this Amendment by signing any such counterpart. Delivery of an executed signature page of this Amendment by facsimile transmission or electronic transmission (in PDF format) shall be effective as delivery of a manually executed counterpart hereof.

**IN WITNESS WHEREOF**, the parties hereto have caused this Amendment to be duly executed and delivered by their respective officers thereunto duly authorized as of the date first written above.

BORROWER:

**MONOSOL RX, LLC** (to be renamed Aquestive Therapeutics, Inc. upon consummation of the Conversion Transaction)

By: /s/ John Maxwell

Name: John Maxwell Title: CFO

[Signature Page- Omnibus Amendment No. 1]

## **PERCEPTIVE CREDIT HOLDINGS, LP, as**

Administrative Agent and Lender

## By Perceptive Credit Opportunities GP, LLC, its general partner

By: /s/ Sandeep Dixit Name: Sandeep Dixit Title: Chief Credit Officer

## By: /s/ Sam Chawla

Name: Sam Chawla Title: Portfolio Manager

[Signature Page- Omnibus Amendment No. 1]

## AMENDMENT NO. 2 TO CREDIT AGREEMENT AND GUARANTY AND CONSENT

This **AMENDMENT NO. 2 TO CREDIT AGREEMENT AND GUARANTY AND CONSENT**, dated as of May 21, 2018 (this "*Amendment*"), is among Aquestive Therapeutics, Inc., a Delaware corporation (the "*Borrower*"), the Lenders party hereto (the "*Lenders*") and Perceptive Credit Holdings, LP, a Delaware limited partnership, as administrative agent and collateral agent for the Lenders (in such capacity, together with its successors and assigns, "*Administrative Agent*"). Reference is made to the Credit Agreement and Guaranty, dated as of August 16, 2016 (as amended, modified, restated and supplemented, the "*Credit Agreement*"), among the Borrower, the Subsidiary Guarantors party thereto, the Lenders parties thereto and the Administrative Agent. Capitalized terms used herein without definition shall have the same meanings as set forth in the Credit Agreement, as amended hereby.

#### RECITALS

WHEREAS, the Borrower has requested that the Administrative Agent and the Lenders (i) consent to the assignment, sale, securitization or other monetization of the Apomorphine Royalty Income (as defined below) and (ii) agree to certain amendments and other modifications to the Credit Agreement; and

WHEREAS, subject to the terms and conditions hereof, the Lenders party hereto and the Administrative Agent are willing to grant such consent and agree to such amendments and other modifications.

**NOW, THEREFORE**, in consideration of the premises and the agreements, provisions and covenants herein contained, the parties hereto agree as follows:

#### SECTION 1. AMENDMENTS.

A. Each of the following definitions in Section 1.01 of the Credit Agreement is hereby amended and restated in its entirety as follows:

"*Maturity Date*" means August 16, 2020; <u>provided</u> that, so long as no Default has occurred and is continuing, if a Qualified IPO is consummated on or before December 31, 2018, then immediately prior to the consummation of such Public Offering, the Maturity Date shall automatically (and without need of notice or other action) be deemed to be extended to December 16, 2020.

"*Prepayment Premium*" means, as of any time of determination, the sum of (i) the Standard Prepayment Premium, <u>plus</u> (ii) if then in effect or otherwise applicable, the Supplemental Prepayment Premium.

**B.** The following definitions are added to Section 1.01 of the Credit Agreement in appropriate alphabetical order:

"*Amendment No. 2*" means the Amendment No. 2 to Credit Agreement and Guaranty and Consent, dated as of May \_\_\_\_\_, 2018, among the Borrower, the Lenders party thereto and the Administrative Agent.

"Amendment No. 2 Effective Date" means May \_\_\_\_\_, 2018.

"Apomorphine License Agreement" means the agreement between the Borrower and Cynapsus Therapeutics, Inc., dated as of April 1, 2016, with respect to the development and commercialization of the Apomorphine Product, as the same may be amended from time to time as permitted pursuant to this Agreement.

"Apomorphine Product" means a sublingual film product containing the active pharmaceutical ingredient Apomorphine.

"Apomorphine Royalty Income" means any royalty income or revenues payable to any Obligor or any Subsidiary thereof pursuant to the Apomorphine License Agreement to the extent related to the development and commercialization (and not manufacturing) of the Apomorphine Product.

"Apomorphine Royalty Monetization Agreement" means any agreement or arrangement pursuant to which any Obligor or any of its Subsidiaries sells, transfers or otherwise conveys, borrows against, securitizes or otherwise monetizes its right to receive the Apomorphine Royalty Income.

"Standard Prepayment Premium" means, (i) with respect to any prepayment pursuant to Section 3.03(a) or (b) occurring on or prior to the first anniversary of the Closing Date, an amount equal to 5.00% of the aggregate outstanding principal amount of the Loans being prepaid on such Redemption Date; (ii) with respect to any prepayment pursuant to Section 3.03(a) or (b) occurring after the first anniversary of the Closing Date, an amount equal to 3.00% of the aggregate outstanding principal amount of the Loans being prepaid on such Redemption Date; (iii) with respect to any prepayment pursuant to Section 3.03(a) or (b) occurring after the second anniversary of the Closing Date, an amount equal to 3.00% of the aggregate outstanding principal amount of the Loans being prepaid on such Redemption Date; (iii) with respect to any prepayment pursuant to Section 3.03(a) or (b) occurring after the second anniversary of the Closing Date and on or prior to the third anniversary of the Closing Date, an amount equal to 2.00% of the aggregate outstanding principal amount of the Loans being prepaid on such Redemption Date; and (iv) with respect to any prepayment pursuant to Section 3.03(a) or (b) occurring at any time after the third anniversary of the Closing Date, an amount equal to 1.00% of the aggregate outstanding principal amount of the Loans being prepaid on such Redemption Date; and (iv) with respect to any prepayment pursuant to Section 3.03(a) or (b) occurring at any time after the third anniversary of the Closing Date, an amount equal to 1.00% of the aggregate outstanding principal amount of the Loans being prepaid on such Redemption Date.

"*Supplemental Prepayment Premium*" means (i) with respect to any prepayment pursuant to **Section 3.03(a)** or (b) occurring on or after the Amendment No. 2 Effective Date and on or prior to the first anniversary of such date, an amount equal to 10.00% of the aggregate outstanding principal amount of the Loans being prepaid, and (ii) with respect to any prepayment pursuant to **Section 3.03(a)** or (b) occurring after the first anniversary of the Amendment No. 2 Effective Date and on or prior to the 180<sup>th</sup> day following such first anniversary date, an amount equal to 4.00% of the aggregate outstanding principal amount of the Loans being prepaid.

C. Clauses (b) and (c) of Section 3.01 of the Credit Agreement are hereby amended and restated in their entireties as follows:

## (b) Initial Amortization.

(i) if a Qualified IPO is consummated on or before December 31, 2018, during the period commencing on May 1, 2019 and ending on November 30, 2019, the Borrower shall make monthly scheduled repayments of the Loans in an amount equal to \$550,000, such repayments to be made on the Payment Date of each calendar month ending during such period.

(ii) if a Qualified IPO is not consummated on or before December 31, 2018, during the period commencing on January 1, 2019 and ending on July 31, 2019, the Borrower shall make monthly scheduled repayments of the Loans in an amount equal to \$550,000, such repayments to be made on the Payment Date of each calendar month ending during such period.

#### (c) Subsequent Amortization.

(i) if a Qualified IPO is consummated on or before December 31, 2018, during the period commencing on December 1, 2019 and ending on November 30, 2020, the Borrower shall make monthly scheduled repayments of the Loans in an amount equal to \$750,000, such repayments to be made on the Payment Date of each calendar month ending during such period.

(ii) if a Qualified IPO is not consummated on or before December 31, 2018, during the period commencing on August 1, 2019 and ending on July 31, 2020, the Borrower shall make monthly scheduled repayments of the Loans in an amount equal to \$750,000, such repayments to be made on the Payment Date of each calendar month ending during such period.

**D.** Section 3.03(b) of the Credit Agreement is hereby amended and restated in its entirety as follows:

(b) **Mandatory Prepayments**. Upon the occurrence of a Casualty Event or any Public Offering (other than a Qualified IPO), the Borrower shall make a mandatory prepayment of the Loans as set forth below:

(i) in the event of any Casualty Event, the Borrower shall mandatorily prepay the outstanding principal amount of the Loans in an amount equal to the sum of (i) 100% of the net insurance or other proceeds received by the Borrower with respect thereto, (ii) the applicable Prepayment Premium on the principal amount of the Loans being prepaid and (iii) any accrued but unpaid interest on any principal amount of the Loans being prepaid; <u>provided</u> that the Borrower may, upon notice to Administrative Agent, use such proceeds to acquire or repair fixed or capital assets useful in the Borrower's or its Subsidiaries' businesses, as long as such investment is made within six months of the Casualty Event; and

(ii) in the event of any Public Offering (other than a Qualified IPO), the Borrower shall mandatorily prepay the outstanding principal amount of the Loans in an amount equal to the sum of (i) 25% of the net cash proceeds thereof; (ii) the applicable Prepayment Premium on the principal amount of the Loans being prepaid and (iii) any accrued but unpaid interest on any principal amount of the Loans being prepaid.

**E.** If a Qualified IPO is consummated on or before December 31, 2018, the chart set forth in Section 10.02 of the Credit Agreement will be amended by adding the following at the end thereof:

September 30, 2020	\$40,000,000

#### SECTION 2. ACKNOWLEDGEMENT, AGREEMENT AND CONSENT AND REPRESENTATIONS AND WARRANTIES.

A. Aquestive Partners has read this Amendment and consents to the terms hereof. Each Obligor confirms and agrees that, notwithstanding the effectiveness of this Amendment, the obligations of such Obligor under each Loan Documents to which such Obligor is a party shall not be impaired and each Loan Documents to which such Obligor is a party is, and shall continue to be, in full force and effect and is hereby confirmed and ratified in all respects.

**B.** Each Obligor hereby acknowledges and agrees that the Guaranteed Obligations will include all Obligations under, and as defined in, the Credit Agreement as amended by this Amendment.

**C.** Aquestive Partners acknowledges and agrees that (i) notwithstanding the conditions to effectiveness set forth in this Amendment, Aquestive Partners is not required by the terms of the Credit Agreement or any other Loan Document to consent to the amendments to the Credit Agreement effected pursuant to this Amendment and (ii) nothing in the Credit Agreement, this Amendment or any other Loan Document shall be deemed to require the consent of Aquestive Partners to any future amendments to the Credit Agreement.

**D.** In order to induce the Administrative Agent and the Lenders party hereto to enter into this Amendment, each Obligor represents and warrants to the Administrative Agent and the Lenders that the following statements are true, correct and complete:

(i) such Obligor has full power, authority and legal right to enter into this Amendment and perform its obligations under this Amendment and each Loan Document as amended hereby or thereby;

(ii) the transactions contemplated by this Amendment are within such Obligor's corporate powers and have been duly authorized by all necessary corporate and, if required, by all necessary shareholder action. This Amendment has been duly executed and delivered by such Obligor and constitutes a legal, valid and binding obligation of such Obligor, enforceable against such Obligor in accordance with its terms, except as such enforceability may be limited by (i) bankruptcy, insolvency, reorganization, moratorium or similar laws of general applicability affecting the enforcement of creditors' rights and (ii) the application of general principles of equity (regardless of whether such enforceability is considered in a proceeding in equity or at law);

(iii) the transactions contemplated by this Amendment (1) do not require any Governmental Approval of, registration or filing with, or any other action by, any Governmental Authority or any third party, except for such as have been obtained or made and are in full force and effect, (2) will not violate (x) any Requirement of Law or any order of any Governmental Authority, other than any such violations that, individually or in the aggregate, could not reasonably be expected to have a Material Adverse Effect, or (y) the Organic Documents of such Obligor or its Subsidiaries, (3) will not violate or result in a default under any indenture, agreement or other instrument binding upon such Obligor or its Subsidiaries or assets, or give rise to a right thereunder to require any payment to be made by any such Person, and (4) will not result in the creation or imposition of any Lien (other than Permitted Liens) on any asset of such Obligor or its Subsidiaries; and

(iv) both immediately before and after giving effect to this Amendment, (x) the representations and warranties set forth in this Amendment and each other Loan Document shall, in each case, be true and correct and (y) no Default shall have then occurred and be continuing, or would result from this Amendment or the transaction contemplated hereby.

**SECTION 3. CONSENT.** Effective as of the date (i) the Administrative Agent and the Lenders have delivered to the Borrower their prior written consent to the terms and provisions of the Apomorphine Royalty Monetization Agreement and (ii) the applicable Obligor or the applicable Subsidiary thereof has entered into the Apomorphine Royalty Monetization Agreement with the other parties thereto:

A. the Administrative Agent and the Lenders shall amend or otherwise modify the Credit Agreement as follows:

(i) If the Apomorphine Royalty Monetization Agreement relates to incurrence of Indebtedness by any Obligor or its Subsidiaries, Section 9.01 of the Credit Agreement shall be amended by (1) deleting the word "and" at the end of clause (h) thereof, (2) replacing the period at the end of clause (i) thereof with "; and", and (3) adding the following new clause (j) immediately after the clause (i) thereof:

(j) Indebtedness incurred pursuant to the Apomorphine Royalty Monetization Agreement; <u>provided</u> that the sole recourse of the creditor under or pursuant to such arrangement shall be limited to the collateral described in **Section 9.02(j)**.

(ii) If the Apomorphine Royalty Monetization Agreement relates to incurrence of a Lien by any Obligor or its Subsidiaries, Section 9.02 of the Credit Agreement shall be amended by (1) deleting the word "and" at the end of clause (h) thereof, (2) replacing the period at the end of clause (i) thereof with "; and", (3) replacing "(i)" in the proviso at the end thereof with "(j)" and (4) adding the following new clause (j) immediately after the clause (i) thereof:

(j) Liens securing Indebtedness permitted under **Section 9.01(j**); <u>provided</u> that the collateral securing such Indebtedness shall be limited to the right to receive the Apomorphine Royalty Income;

(iii) If the Apomorphine Royalty Monetization Agreement relates to assignment or sale of the Apomorphine Royalty Income, Section 9.09 of the Credit Agreement shall be amended by (1) replacing the period at the end of clause (f) thereof with "; and", and (2) adding the following new clause (g) immediately after the clause (f) thereof:

(g) assignment or sale of the Apomorphine Royalty Income pursuant to the Apomorphine Royalty Monetization Agreement.

**B.** the Secured Parties' Lien on the Apomorphine Royalty Income (but solely on such income) shall be released and, at the expense of the Borrower, the Administrative Agent and the Lenders agree to deliver to the Borrower release documents as the Borrower may reasonably request to evidence such release.

**C.** the Apomorphine Royalty Monetization Agreement shall be deemed to be a Material Agreement under the Loan Documents unless otherwise consented to by the Administrative Agent and the Lenders.

**SECTION 4. CONDITIONS TO EFFECTIVENESS.** This Amendment shall become effective only upon the satisfaction of the following conditions precedent (the date of satisfaction of such conditions being referred to as the "*Amendment Effective Date*"):

A. The Obligors, the Administrative Agent and the Lenders shall have indicated their consent to this Amendment by the execution and delivery of the signature pages hereto to the Administrative Agent.

**B.** The Administrative Agent shall have received (i) an officer's certificate of each Obligor, either confirming that (x) there have been no changes to its organizational documents since January 1, 2018, or if there have been changes to its organizational documents since such date, certifying as to such changes and (y) (1) the representations and warranties set forth in this Amendment and each other Loan Document are, in each case, true and correct and (2) no Default has occurred and is continuing, or would result from this Amendment or the transaction contemplated hereby, (ii) copies of resolutions of each Obligor's board of directors (or other managing body) then in full force and effect authorizing the execution, delivery and performance of this Amendment certified by a Responsible Officer of such Obligor, (iii) a copy of a good standing certificate of each Obligor dated a date reasonably close to the date hereof, and (iv) an incumbency certificate from each Obligor.

**C.** The Administrative Agent shall have received all reasonable and documented out of pocket expenses for which invoices have been presented (including the reasonable fees and expenses of legal counsel for which the Borrower agrees it is responsible pursuant to Section 14.03 of the Credit Agreement) that are due and payable in connection with this Amendment.

## SECTION 5. MISCELLANEOUS

## A. Reference to and Effect on the Loan Documents.

(i) On and after the Amendment Effective Date, each reference in any Loan Document to the Credit Agreement shall mean and be a reference to the Credit Agreement as amended by this Amendment.

(ii) Except as expressly amended hereby, all of the representations, warranties, terms, covenants, conditions and other provisions of the Loan Documents shall remain unchanged and shall continue to be, and shall remain, in full force and effect in accordance with their respective terms. The amendments, consents and modifications set forth herein shall be limited precisely as provided for herein to the provisions expressly amended herein or otherwise modified or consented to hereby and shall not be deemed to be an amendment to, waiver of, consent to or modification of any other term or provision of the Credit Agreement or any other Loan Document or of any transaction or further or future action on the part of any Obligor which would require the consent of the Lenders or the Administrative Agent under the Credit Agreement or any other Loan Document.

(iii) The execution, delivery and performance of this Amendment shall not constitute a waiver of any provision of, or operate as a waiver of any right, power or remedy of the Administrative Agent or any Lender under any Loan Document or applicable Law.

(iv) This Amendment shall constitute a Loan Document.

**B. Captions**. The captions and section headings appearing herein are included solely for convenience of reference and are not intended to affect the interpretation of any provision of this Amendment.

**C. Governing Law**. This Amendment and the rights and obligations of the parties hereunder shall be governed by, and construed in accordance with, the law of the State of New York, without regard to principles of conflicts of laws that would result in the application of the laws of any other jurisdiction; provided that Section 5-1401 of the New York General Obligations Law shall apply.

**D. Counterparts**. This Amendment may be executed in any number of counterparts, all of which taken together shall constitute one and the same instrument and any of the parties hereto may execute this Amendment by signing any such counterpart. Delivery of an executed signature page of this Amendment by facsimile transmission or electronic transmission (in PDF format) shall be effective as delivery of a manually executed counterpart hereof.

[Signature Pages Follow]

**IN WITNESS WHEREOF**, the parties hereto have caused this Amendment to be duly executed and delivered by their respective officers thereunto duly authorized as of the date first written above.

## BORROWER:

## AQUESTIVE THERAPEUTICS, INC.

By /s/ John Maxwell Name: John Maxwell Title: Chief Financial Officer

# **PERCEPTIVE CREDIT HOLDINGS, LP**, as Administrative Agent and Lender

# By Perceptive Credit Opportunities GP, LLC, its general partner

By:	/s/ Sandeep Dixit
	Name: Sandeep Dixit
	Title: Chief Credit Officer

By: /s/ Sam Chawla

> Name: Sam Chawla Title: Portfolio Manager

The undersigned hereby acknowledges, agrees and consents to the foregoing Amendment.

## AQUESTIVE PARTNERS, LLC

By /s/ John Maxwell

Name: John Maxwell Title: Chief Financial Officer