As filed with the U.S. Securities and Exchange Commission on July 16, 2018

Registration No. 333-225924

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

Pre-Effective Amendment No. 1 to FORM S-1

REGISTRATION STATEMENT

UNDER

THE SECURITIES ACT OF 1933

Aquestive Therapeutics, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**2834**	**82-3827296**
(State or Other Jurisdiction of Incorporation or Organization)	(Primary Standard Industrial Classification Code Number)	(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.
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:

David S. Rosenthal
Dechert LLP
1095 Avenue of the Americas
New York, New York 10036
Telephone: (212) 698-3500
Facsimile: (212) 698-3599

Daniel I. Goldberg
Ryan Sansom
Divakar Gupta
Cooley LLP
1114 Avenue of the Americas
New York, New York 10036
Telephone: (212) 479-6000
Facsimile: (212) 479-6275

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	Non-accelerated filer ☒	Smaller reporting company o
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 Securities to be Registered	Proposed Maximum Aggregate Offering Price[1]	Amount of Registration Fee[2][3]
Common Stock, par value $0.001 per share	$ 73,600,000	$ 9,163.20

(1) 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 that the underwriters have the option to purchase to cover over-allotments.

(2) 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 price of shares that the underwriters have the option to purchase to cover over-allotments.

(3) $8,590.50 previously paid.

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 July 16, 2018*

4,000,000 Shares

Aquestive Therapeutics, Inc.

Common Stock

$ Per Share

This is the initial public offering of our common stock. We are offering 4,000,000 shares of our common stock. The initial public offering price of our common stock is expected to be between $14.00 and $16.00 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 12.

	Per Share	Total
Initial public offering price	$	$
Underwriting discount(1)	$	$
Proceeds, before expenses, to Aquestive Therapeutics, Inc.	$	$

(1) We refer you to “Underwriting” beginning on page 158 of this prospectus for additional information regarding underwriting compensation.

To the extent that the underwriters sell more than 4,000,000 shares of common stock, the underwriters have the option to purchase up to an additional 600,000 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.

Certain existing investors have indicated an interest in purchasing an aggregate of up to $20.0 million of shares of our common stock in this offering at the initial public offering price. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters may determine to sell more, less or no shares in this offering to any of these stockholders, and any of these stockholders may determine to purchase more, less or no shares in this offering. The underwriters will receive the same underwriting discount on any shares purchased by these stockholders as they will on any other shares sold to the public in this offering.

Joint Book-Running Managers

BMO Capital Markets **RBC Capital Markets**

Co-Lead Managers

Wedbush PacGrow **JMP Securities**

Prospectus dated , 2018.

TABLE OF CONTENTS

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 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 elsewhere in this prospectus are those of MonoSol Rx, LLC, our predecessor entity and its consolidated subsidiary.

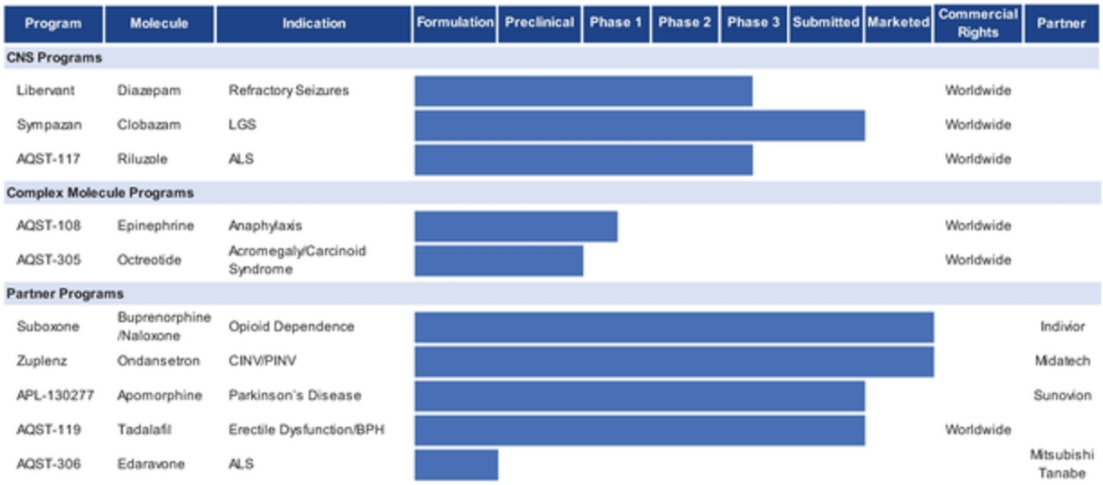
Overview

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 AQST-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 Amyotrophic Lateral Sclerosis, or ALS, for which we expect to submit an NDA in the first half of 2019. 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 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 1.1 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:



Program	Molecule	Indication	Formulation	Preclinical	Phase 1	Phase 2	Phase 3	Submitted	Marketed	Commercial Rights	Partner
CNS Programs											
Libervant	Diazepam	Refractory Seizures								Worldwide	
Sympazan	Clobazam	LGS								Worldwide	
AQST-117	Riluzole	ALS								Worldwide	
Complex Molecule Programs											
AQST-108	Epinephrine	Anaphylaxis								Worldwide	
AQST-305	Octreotide	Acromegaly/Carcinoid Syndrome								Worldwide	
Partner Programs											
Suboxone	Buprenorphine /Naloxone	Opioid Dependence									Indivior
Zuplenz	Ondansetron	CINV/PINV									Midatech
APL-130277	Apomorphine	Parkinson's Disease									Sunovion
AQST-119	Tadalafil	Erectile Dysfunction/BPH								Worldwide	
AQST-306	Edaravone	ALS									Mitsubishi Tanabe

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 during the first half of 2019.

In July 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 June 2018, 27 subjects had completed the study across the two treatment arms. This represents 90% 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=27 patients) provided appropriate maximal plasma concentrations of diazepam (Cmax) with comparable bioavailability to the referenced standard Diastat label. 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 around 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 dose levels of Libervant will be similar or somewhat less than dose levels of Diastat.

We have completed enrollment in our adult EMU study and expect final results in the third quarter of 2018.

Following a face-to-face meeting with the FDA held on June 14, 2018, where these data, along with other clinical data, were presented, we believe that, upon the completion of our clinical studies, we will have the necessary supporting data to submit a marketing application under the 505(b)(2) regulatory pathway to the FDA for Libervant in 2018.

Proprietary Complex Molecule Portfolio

We are utilizing our technology and know-how to target large market opportunities by developing orally-administered 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 soluble 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 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.
- **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 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 its NDA to the FDA and has PDUFA date of January 29, 2019. Sunovion has publicly disclosed topline results from their definitive efficacy study, CTH-300, during recent industry events. These results indicate that APL-130277 demonstrated a statistically significant improvement in the Movement Disorder Society Unified Parkinson's Disease Rating Scale Part III score at 30 minutes post-dosing when compared to placebo. Sunovion has also indicated that a statistically significant percentage of patients had a patient-rated full 'on' response within 30 minutes at week 12 when compared to placebo. We are currently exploring alternative royalty monetization opportunities for the expected royalty and milestone revenue streams from this product which could lead to additional non-dilutive capital for the Company.

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 statements and selected historical 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.

THE OFFERING	
Shares of common stock offered by us	4,000,000 shares
Shares of common stock to be outstanding after this offering	24,000,000 shares
Over-allotment option to purchase additional shares	600,000 shares
Use of proceeds	We estimate that the net proceeds from this offering will be $51.6 million, or approximately $60.0 million if the underwriters exercise their over-allotment option in full, assuming an initial public offering price of $15.00 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 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 CNS diseases and other indications and (iv) for general corporate purposes, including working capital and capital expenditures. See “Use of Proceeds” on page 55.
Indications of Interest	Certain existing investors have indicated an interest in purchasing an aggregate of up to $20.0 million of shares of our common stock in this offering at the initial public offering price. However, because indications of interest are not binding agreements or commitments to purchase, the underwriters may determine to sell more, less or no shares in this offering to any of these stockholders, and any of these stockholders may determine to purchase more, less or no shares in this offering. The underwriters will receive the same underwriting discount on any shares purchased by these stockholders as they will on any other shares sold to the public in this offering.
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 outstanding after this offering is based on 20,000,000 shares of common stock outstanding as of March 31, 2018 (on a pro forma basis), and includes:

- 863,400 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:
- 4,100,000 and 250,000 shares of common stock reserved for future issuance under our 2018 Equity Incentive Plan, or the 2018 Plan and our Employee Stock Purchase Plan, or ESPP, respectively.

Unless otherwise indicated, all information contained in this prospectus assumes:

- a 1 for 12.34 reverse stock split of our common stock effected on July 16, 2018;
- the distribution of shares of our common stock held by APL to its members in exchange for their interests in APL and the subsequent liquidation of APL upon consummation of this offering; and
- no exercise by the underwriters of their option to purchase an additional 600,000 shares of our common stock.

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. As a result of the conversion of MonoSol Rx, LLC into Aquestive Therapeutics, Inc. on January 1, 2018 (see "Prospectus Summary—Corporate Information"), the interests and per interests information included in the summary financial data below for and as of the years ended December 31, 2017 and 2016 and for and as of the three-months ended March 31, 2017 does not give effect for the 1 for 12.34 reverse stock split of our common stock effected on July 16, 2018. 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)			(unaudited)	
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)	$ 0.27	

(In thousands, except per membership interest and per share data)	Year Ended December 31, 2017	Year Ended December 31, 2016	Three Months Ended March 31, 2018	Three Months Ended March 31, 2017
			(unaudited)	
Weighted-average number of shares of common stock / membership interests outstanding—basic and diluted	121,228,353	118,785,104	15,077,924	
Unaudited pro forma net income (loss)[1]			$ (23,201)	
Unaudited pro forma net income (loss) per share of common stock			$ (1.16)	
Unaudited pro forma weighted-average number of shares of common stock outstanding used to compute net loss per share of common stock[1]			20,000,000	

	As of March 31, 2018		
	Actual	Pro Forma[1]	Pro Forma As Adjusted[2][3]
		(unaudited)	
Balance Sheet Data:			
Cash and cash equivalents	$ 16,488	$ 16,488	$ 68,088
Working capital[4]	14,349	6,949	58,549
Total assets	46,082	46,082	97,682
Total debt	45,965	45,965	45,965
Accumulated deficit	(115,994)	(143,294)	(143,294)
Total stockholders' (deficit)/equity	(22,396)	(22,820)	28,780

(1) The pro forma column reflects the charge of $27.3 million for the termination of the Performance Unit Plan, effective January 1, 2018. Also included is the conversion of the warrant liability of $7.0 million 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 4.0 million shares of our common stock in this offering at an assumed initial public offering price of $15.00 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 $15.00 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 $3.7 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 $14.0 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 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 acquire or license intellectual property rights and other operating restrictions that could adversely impact 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 year-to-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.

We are currently involved in antitrust litigation in connection with the launch of Suboxone Sublingual Film and any adverse decisions in such litigation could significantly harm our business.

We are currently named as a defendant in antitrust 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. We deny any wrongdoing and are vigorously defending such litigation. However, 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 and significantly harm our business. Moreover, regardless of the merits of any claim, the continued maintenance of these legal and administrative proceedings may result in substantial legal expenses and divert our management's time and attention away from our other business operations, which could also significantly harm our business. For more information, please see the section titled “Business – Legal Proceedings – Antitrust Litigation.”

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 any clinical trial for any product candidates that we develop, the commercial prospects of such product candidates will be harmed 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 products or 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 products or product candidates or negatively impact our ability to gain market acceptance and market share. For example, Suboxone, which treats opioid addiction, has as one of its active ingredients an opioid, buprenorphine. Revisions to regulations or guidelines suggesting the reduced use of opioid drugs such as buprenorphine could result in decreased use of Suboxone.

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 hole." 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. Further, the Trump administration released a "Blueprint", or plan, to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. The Department of Health and Human Services, or HHS, has already started the process of soliciting feedback on some of these measures and, at the same, is immediately implementing others under its existing authority. While some 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 qualified 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 and, if approved, product candidates, may give rise to potential product liability claims or false marketing claims, 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. 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 and false marketing claims relating to the commercialization of such products or product candidates. Product liability or false marketing claims might be brought against us by consumers, healthcare providers, pharmaceutical companies, others selling or otherwise coming into contact with our product candidates, or governmental agencies. Suboxone, which treats opioid addiction, has as one of its active ingredients an opioid, buprenorphine. There can be no assurance that we will not become the target of claims relating to opioid addiction as have companies that market opioids. Any product liability claims or false marketing 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 or false marketing

claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims or false marketing 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 non-compliance 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 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 off-label 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. For more information, please see section titled “Business − Legal Proceedings − Patent Related Litigation.”

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 license 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 July 16, 2018, our executive officers, directors, 5% or greater stockholders and their affiliates beneficially owned approximately 79.5% 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, including the assumed

exercise of the underwriters' overallotment option, upon the closing of this offering, that same group will beneficially own approximately 64.6% of our outstanding voting stock. Bratton Capital Management L.P., which controls certain of our major stockholders, has beneficial ownership of approximately 56.7% of our common stock as of July 16, 2018. 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 Section 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). In addition to providing Mr. Kendall or Mr. Schobel with a tax gross-up payment, 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 may 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 $13.79 per share, based on an assumed initial public offering price of $15.00 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 granted to our employees. The exercise of any of these options 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.

As of July 12, 2018, we had options to purchase 81,068 shares of our common stock outstanding pursuant to grants made to certain of our employees, consultants and directors. Additionally, we have adopted 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. Investors will be relying on our judgment regarding the application of the net proceeds from this offering. 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.

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. Such determining factors include 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. In addition, as part of our strategic plan, 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.

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 $51.6 million (or approximately $60.0 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 $15.00 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 $15.00 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 $3.7 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 1.0 million 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 approximately $14.0 million, assuming the assumed initial public offering price of $15.00 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 $28.0 million to fund commercialization investments for our late-stage epilepsy products, Libervant and Sympazan, as well as our ALS product candidate, AQST-117;
- approximately $13.0 million to fund the commencement of our clinical trials for our complex molecules AQST-108 and AQST-305;
- approximately $2.0 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. For example, we may change our priorities due to the success or failure of certain of our clinical trials or what we perceive the market for our product candidates to be and as such may reallocate resources to other product candidates in our pipeline ahead of those we currently intend to prioritize with the use of proceeds from this offering. 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, interest-bearing 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) granting of 4,922,353 non-voting common shares with a valuation thereof of $27.3 million, all related to terminating of the PUP plans; and (ii) conversion of Perceptive Warrants outstanding into 863,400 shares of common stock; and
- on a pro forma as adjusted basis to give further effect to our issuance and sale of 4,000,000 shares of our common stock offered in the offering, assuming an initial public offering price of $15.00 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		
	Actual	Pro Forma	Pro Forma As Adjusted[1]
(In thousands, except share and per share data)		(unaudited)	
Cash and cash equivalents	$ 16,488	$ 16,488	$ 68,088
Long-term debt	45,965	45,965	45,965
Stockholders’ equity:			
Common stock, $0.001 par value per share: Authorized 350,000,000 shares; 15,077,647 shares issued and outstanding at March 31, 2018; authorized 350,000,000 shares; 20,000,000 issued and outstanding, pro forma; authorized 250,000,000 shares; and 24,000,000 shares issued and outstanding, pro forma as adjusted	15	20	24
Additional paid-in capital	93,412	111,827	
Accumulated deficit	(115,994)	(143,294)	(143,294)
Total stockholders’ (deficit)/equity	(22,396)	(22,820)	28,780
Total capitalization	$ 23,569	$ 23,145	$ 74,745

(1) A $1.00 increase (decrease) in the assumed initial public offering price of $15.00 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 $3.7 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 1.0 million share 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 $14.0 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:

- 863,400 shares of common stock issuable immediately prior to the consummation of this offering pursuant to the automatic exercise of the Perceptive Warrants; but excludes
- 4,000,000 and 250,000 shares of common stock reserved for future issuance under the 2018 Plan and ESPP, respectively.

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 $(1.50) 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 $(22.6) million, or $(1.13) per share of common stock. Pro forma net tangible book value (deficit) gives effect to the conversion of the previously outstanding PUP plan performance units into an aggregate of 4,922,353 shares of our common stock.

Pro forma as adjusted net tangible book value is our pro forma net tangible book value (deficit), plus the effect of the sale of 4,000,000 shares of our common stock in this offering at an assumed initial public offering price of $15.00 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 $2.34 per share to our existing stockholders, and an immediate dilution of $13.79 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		$ 15.00
Historical net tangible book value (deficit) per share as of March 31, 2018	$ (1.50)	
Pro forma increase in net tangible book value per share as of March 31, 2018, attributable to pro forma transactions and other adjustments described above	0.37	
Pro forma net tangible book value per share as of March 31, 2018	(1.13)	
Increase in pro forma net tangible book value per share attributable to new investors participating in this offering	2.34	
Pro forma as adjusted net tangible book value per share after this offering	1.21	
Dilution in net tangible book value per share to new investors participating in this offering		$ 13.79

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 $15.00 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 approximately $0.16 per share and the pro forma dilution per share to investors participating in this offering would be approximately $13.95 per share (or $13.64 for a decrease in share price), 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. A 1.0 million 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 $0.51 and the pro forma dilution per share to investors participating in this offering would be approximately $14.30, assuming the assumed initial public offering price of $15.00 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 1.0 million 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 $0.55 and the pro forma dilution per share to investors participating in this offering would be approximately $13.24, assuming the assumed initial public offering price of $15.00 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 600,000 additional shares of our common stock in this offering, the pro forma as adjusted net tangible book value will increase to $1.52 per share, representing an immediate increase to existing stockholders of $2.65 per share and an immediate dilution of $13.48 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 $15.00 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.

	Shares purchased		Total consideration		
	Number (in thousands)	Percent	Amount (in thousands)	Percent	Average price per share
Existing stockholders before this offering	20,000	83.3%	$ 75,739	55.5%	$ 3.77
Investors participating in this offering	4,000	16.7	60,000	44.5	
Total	24,000	100%	$ 135,739	100%	

Each $1.00 increase (decrease) in the assumed initial public offering price of $15.00 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 $4.0 million and, in the case of an increase, would increase the percentage of total consideration paid by new investors by 1.4 percentage points and, in the case of a decrease, would decrease the percentage of total consideration paid by new investors by 2.0 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 1,000,000 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 $15.0 million, and, in the case of an increase, would increase the percentage of total consideration paid by new investors by 5.4 percentage points and, in the case of a decrease, would decrease the percentage of total consideration paid by new investors by 7.2 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 81.3% 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 4,600,000, or 18.7% of the total number of shares of common stock to be outstanding after this offering.

The foregoing discussion is based on 20,000,000 shares of common stock outstanding as of March 31, 2018, including shares issued in April for terminating the PUP plans, and assumes an initial public offering price of $15.00 (the mid-point of the range set forth on the cover of this prospectus) and includes:

- 863,400 shares of common stock issuable immediately prior to the consummation of this offering pursuant to the automatic exercise of the Perceptive Warrants; but excludes
- 4,100,000 and 250,000 shares of common stock reserved for future issuance under our 2018 Plan and ESPP, respectively.

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. As a result of the conversion of MonoSol Rx, LLC into Aquestive Therapeutics, Inc. on January 1, 2018 (see "Prospectus Summary—Corporate Information"), the interests and per interests information included in the selected financial data below for and as of the years ended December 31, 2017 and 2016 and for and as of the three months ended March 31, 2017 does not give effect to the 1 for 12.34 reverse stock split of our common stock on July 16, 2018. 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 Ended December 31,		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)	$ 0.27	
Weighted-average number of shares of common stock / membership interests outstanding — basic and diluted	121,228,353	118,785,104	15,077,647	
Unaudited pro forma net loss[1]			$ (23,201)	
Unaudited pro forma net loss per share of common stock[1]			$ (1.16)	
Unaudited pro forma weighted-average number of shares of common stock outstanding used to compute net loss per share of common stock[1]			20,000,000	

(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

(In thousands)	As of December 31, 2017	As of December 31, 2016	As of March 31, 2018 Actual	As of March 31, 2018 Pro Forma[1] (unaudited)	As of March 31, 2018 Pro Forma As Adjusted[2][3]
Balance Sheet Data:					
Cash and cash equivalents	$ 17,379	$ 9,209	$ 16,488	$ 16,488	$ 68,088
Working capital[4]	12,813	12,526	14,349	6,949	58,549
Total assets	43,116	39,389	46,082	46,082	97,682
Total debt	45,507	38,650	45,965	45,965	45,965
Accumulated deficit	(120,093)	(108,670)	(115,994)	(143,294)	(143,294)
Total members' / stockholders' (deficit)/equity	(68,596)	(57,197)	(22,396)	(22,820)	28,780

(1) The pro forma column reflects the charge of $27.3 million for the termination of the Performance Unit Plan, effective January, 2018. Also included is the conversion of the warrant liability of $7.0 million 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 $15.00 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 $15.00 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 $3.7 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 $14.0 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 treatments 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 soluble 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 soluble 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 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. In July 2018, our board of directors approved a Certificate of Amendment to the Certificate of Incorporation in order to effect a reverse stock split of shares of our common stock at a ratio of 1 for 12.34. For purposes of our unaudited interim consolidated financial statements, the stock splits have been presented as if each had 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

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.

(In thousands, except %)	Three Months Ended March 31, 2018	2017	Change $	%
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:

(In thousands, except %)	Three Months Ended March 31, 2018	2017	Change $	%
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:

in 000's	Three Months Ended March 31, 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.

			Change	
	2017	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:

	2017	2016	Change $	Change %
(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:

	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, 2018, 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 4.3% 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 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 2 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,* long-lived 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 863,400 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 4.3% 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 Rx, 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 equity-based awards is determined based on FASB ASC Topic 718, *Compensation – Stock Compensation* using the grant-date 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 4.9 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 $4.04 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 $19.9 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 $27.3 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

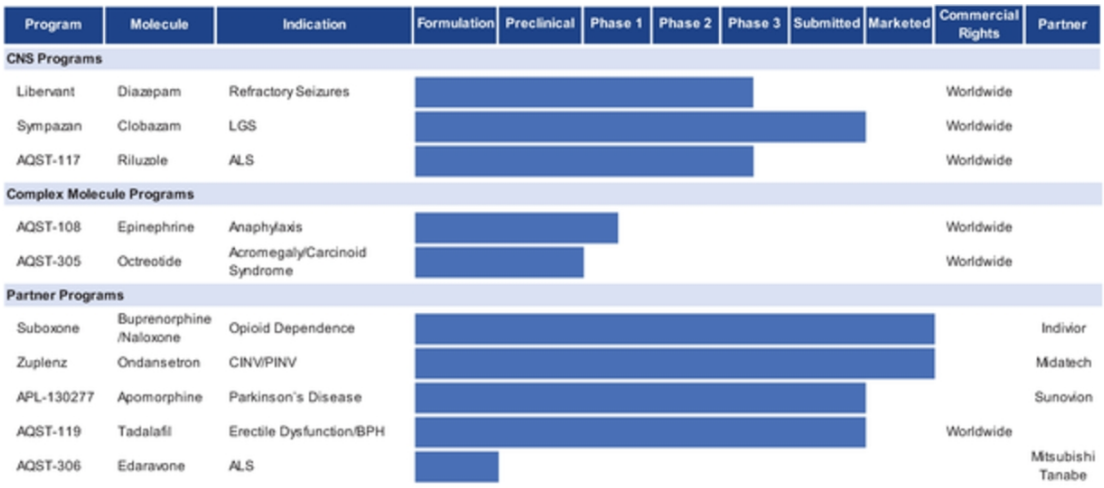
Overview

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) 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 during the first half of 2019. 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 1.1 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 administration. 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 during the first half of 2019.

Proprietary Complex Molecule Portfolio

We are utilizing our technology and know-how to target large market opportunities by developing orally-administered 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:

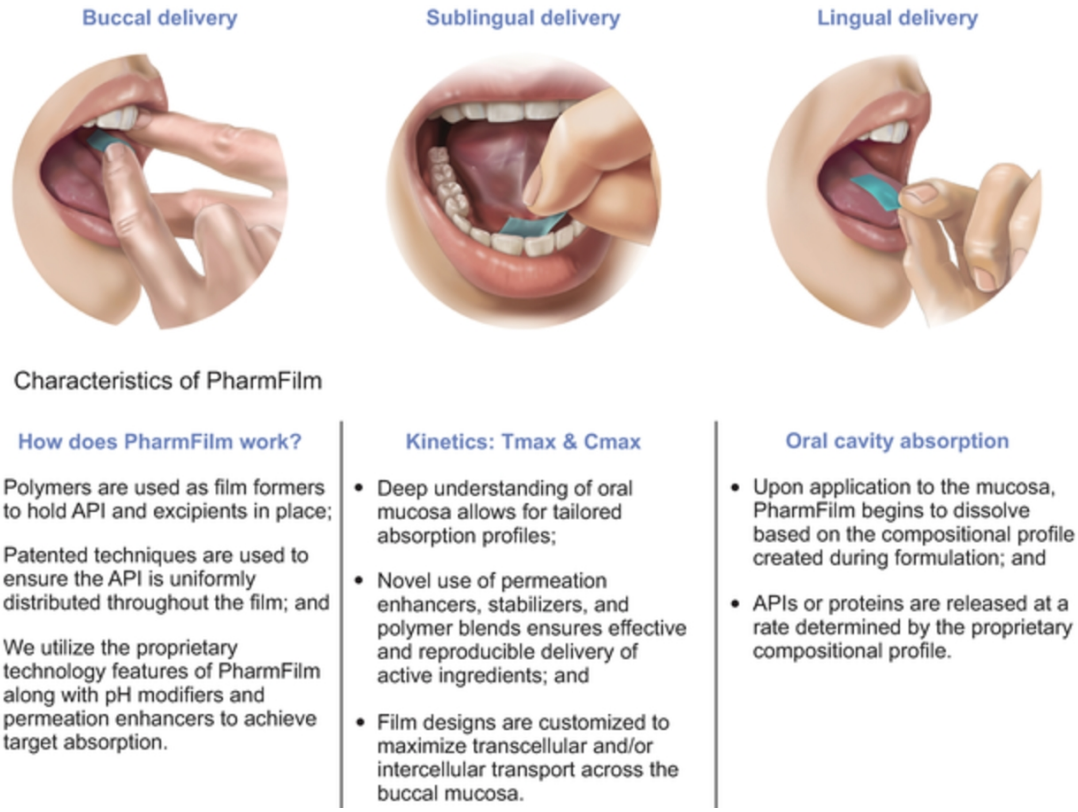
- **Suboxone** – a sublingual film formulation of buprenorphine and naloxone that is marketed in the United States and internationally for the treatment of opioid dependence. Suboxone Sublingual Film was launched in partnership with Indivior Inc., or Indivior, in 2010. Suboxone Sublingual Film is the 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, has submitted its NDA and has a PDUFA date of January 29, 2019. Sunovion has publicly disclosed topline results from their definitive efficacy study, CTH-300, during recent industry events. These results indicate that APL-130277 demonstrated a statistically significant improvement in the Movement Disorder Society Unified Parkinson's Disease Rating Scale Part III score at 30 minutes post-dosing when compared to placebo. Sunovion has also indicated that a statistically significant percentage of patients had a patient-rated full 'on' response within 30 minutes at week 12 when compared to placebo. We are currently exploring alternative royalty monetization opportunities for the expected royalty and milestone revenue streams from this product which could lead to additional non-dilutive capital for the Company.

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;
- 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 in 2018 and AQST-117 during the first half of 2019.
- ***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, 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, 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, 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.

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, 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, 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 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 July 2018, we received interim data from our adult EMU clinical study for Libervant. Through June 2018, 27 subjects had completed the study across the two treatment arms. This represents 90% 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=27 patients) provided appropriate maximal plasma concentrations of diazepam (Cmax) with comparable bioavailability to the referenced standard Diastat label. 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 around 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 dose levels of Libervant will be similar or somewhat less than dose levels of Diastat.

We have completed enrollment in our adult EMU study and expect final results in the third quarter of 2018.

Following a face-to-face meeting with the FDA held on June 14, 2018, where these data, along with other clinical data, were presented, we believe that, upon the completion of our clinical studies, we will have the necessary supporting data to submit a marketing application under the 505(b)(2) regulatory pathway to the FDA for Libervant in 2018.

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 during the first half of 2019.

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 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 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 1.1 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_3 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, 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 and/or patients who have discontinued or avoided use of the existing injectable product due to site irritation. 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, has submitted its NDA and has a PDUFA date of January 29, 2019. 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." We are currently exploring alternative royalty monetization opportunities for the expected royalty and milestone revenue streams from this product which could lead to additional non-dilutive capital for the Company.

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 were given a PDUFA date of November 18, 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 out-licensed 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.

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 1.1 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 long-acting 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 (which was recently granted FDA approval) 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 to pay royalties on Suboxone sold in the United States will terminate. Except as set forth in the prior sentence, 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 the Indivior Supplemental 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 the Indivior Supplemental 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 (i) up to $42.0 million in the aggregate from any combination of (a) performance or event-based milestone payments and (b) single digit percentage royalties on net revenue earned by Indivior on sales of Suboxone and (ii) an additional $2.5 million that may be earned through the issuance of additional process patent rights to us. The aggregate payments under the Indivior Supplemental Agreement are capped at $75.0 million. Accordingly, the Indivior Supplemental 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.

Indivior is our largest customer and the combined revenue received from Indivior pursuant to the Indivior License Agreement and the Indivior Supplemental Agreement represented 97% of our total revenue for the three-month period ended March 31, 2018 and 88% of the total revenue in 2017.

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 low teens 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 dosaqe 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 is coverage 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 dosaqe 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 to develop and maintain our competitive position. Our trademarks or registered trademarks are filed in the United States and other select geographical.

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, or more 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. Orphan 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 prohibit 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 entry in connection with the delivery of or payment for healthcare benefits, items 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. Further, the Trump administration released a “Blueprint”, or plan, to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. The Department of Health and Human Services, or HHS, has already started the process of soliciting feedback on some of these measures and, at the same, is immediately implementing others under its existing authority. While some 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 stand-alone 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 in Warren, New Jersey. Pursuant to various amendments in February 2011, June 2012 and May 2013, we have secured additional space to provide growth of its laboratory facilities and corporate and administrative requirements. In June 2018, we entered into an Amended and Restated Lease Agreement. This extends our lease to February 2020 and increases the space to 23,589 square feet from 16,554. Our monthly rent for the facility is currently $34,115.

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 the above-mentioned ANDA patent litigation 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 that the cases between Indivior and us and Par and certain affiliates have been resolved by a settlement agreement.

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 or '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. On June 19, 2018, BDSI filed a motion to terminate and remand the appeal, which the Company opposes.

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, and they have each been consolidated with the actions asserting infringement of the ’454 and ’221 patents. 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.

All 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. As required by law, the parties submitted the settlement agreement to the U.S. Federal Trade Commission and the U.S. Department of Justice for review.

On June 14, 2018, Dr. Reddy’s notified the U.S. District Court for the District of New Jersey that the FDA had granted final approval of its ANDAs and that it had launched generic versions of Suboxone Sublingual Film. The Company and Indivior filed a motion for a preliminary injunction and request for a

temporary restraining order, and the Court granted the temporary restraining order on June 15, 2018 enjoining and restraining Dr. Reddy's from offering for sale, selling, or importing its generic versions of Suboxone Sublingual Film. On July 13, 2018, the Court granted the preliminary injunction, which enjoins Dr. Reddy's from launching a generic version of Suboxone during the pendency of the litigation and until further order from the Court. Dr. Reddy's filed a motion to stay the preliminary injunction pending appeal of the Court's decision. Dr. Reddy's also filed a notice of appeal of the Court's decision on the preliminary injunction.

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.

MANAGEMENT

Executive Officers, Directors and Key Employees

The following table sets forth certain information regarding our executive officers, directors and key employees and consultants as of June 30, 2018:

Name	Age	Position(s)
Executive Officers and Key Employees		
Keith J. Kendall	61	President, Chief Executive Officer and Director
Daniel Barber	42	Senior Vice President – Chief Strategy and Development Officer
Peter Boyd	52	Senior Vice President – Operations and Value Delivery
Ken Marshall	58	Commercial Leader
John T. Maxwell	53	Senior Vice President – Chief Financial Officer
A. Mark Schobel	62	Chief Innovation and Technology Officer and Director
Theresa Wood	55	Senior Vice President – Human Resources and Organizational Development
Non-Employee Directors		
Douglas Bratton(2)(3)	59	Chairman of the Board of Directors
Gregory Brown, M.D.(1)(3)	64	Director
John Cochran(2)(3)	52	Director
Santo Costa(2)	73	Director
Nancy Lurker (1)(2)	60	Director
James S. Scibetta(1)	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 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, our Senior Vice President – Chief Strategy and Development Officer, joined our team in July 2007 and has led our Strategy and 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, our Senior Vice President – Operations and Value Delivery, joined our company in August 2013 and has led our Operations and Value Delivery functions 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 our Commercial Leader. 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 Senior Vice President – 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 the effective date of this offering. 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, our Senior Vice President – Human Resources and Organizational Development, 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). 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. (Nasdaq: 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 Quintiles, 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 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 and a director of Maverick Therapeutics. 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 $66^{2/3}\%$ 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 Keith J. Kendall, Nancy Lurker and James S. Scibetta;
- Class II, which will consist of John Cochran and Gregory Brown, M.D.; and
- Class III, which will consist of Douglas Bratton and Santo Costa.

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 Chief Strategy and Development Officer;

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 ($)[1]	Bonus ($)	Stock Awards ($)[2]	Non-Equity Incentive Plan Compensation ($)[3]	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 *Chief Strategy and Development Officer*	2017	300,000	—	378,652	201,390	18,858[5]	898,901
John T. Maxwell[8] *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 18 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.

Employment Agreements with Our Named Executive Officers

In June and July 2018, we entered into amended and restated employment agreements with each of Mr. Kendall, our President and Chief Executive Officer, Mr. Schobel, our Chief Innovation and Technology Officer, and Mr. Maxwell, our Chief Financial Officer and an employment agreement with Mr. Barber, our Chief Strategy and Development Officer. 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 and are qualified in all respects by the full terms of such agreements. The terms "cause," "good reason," "permanent disability" and "change in control" referred to below are defined in each named executive officer's employment agreement.

Keith J. Kendall

The initial term of employment for Mr. Kendall under his employment agreement is for three years ending June 30, 2021, and thereafter his employment term renews annually, unless either party gives written notice of non-renewal at least 90 days prior to the end of the then-current term or until his employment with us terminates for any reason. Mr. Kendall's initial base salary is $500,000, 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 is subject to annual review and adjustment may be increased but not decreased. His bonus award will be based upon the achievement of performance targets established by our board of directors or 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.

Mr. Kendall has previously been awarded shares of our non-voting common stock in connection with our PUP Plans equal to 5% of the issued and outstanding capital securities of the Company as of the time of such grant. Mr. Kendall's employment agreement provides that upon the completion of this offering, each share of non-voting common stock shall become one share of voting common stock. Pursuant to his employment agreement, upon the effectiveness of this offering, Mr. Kendall is entitled to receive stock appreciation rights covering a number of shares equal to the difference between 5% of the total number of shares of our common stock outstanding following the consummation of this offering on a fully diluted basis, less the aggregate number of any shares of non-voting common stock and shares covered by stock appreciation rights that Mr. Kendall holds immediately prior to the completion of this offering, such that the total number of all of the shares of common stock and shares subject to stock appreciation rights held by Mr. Kendall immediately following the completion of this offering represent 5% of our shares of common stock, on a fully diluted basis. In addition to the foregoing, upon the completion of this offering, Mr. Kendall will receive a grant of restricted stock equal to 0.24% of our common stock outstanding following the consummation of this offering on a fully diluted basis or 57,600 shares of restricted stock. Each of these equity grants 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 each case, subject to Mr. Kendall's continued employment with us on the applicable vesting date and subject to accelerated vesting if his employment terminates for any reason other than as a result of a termination by the Company for "cause" or a resignation by Mr. Kendall without "good reason."

In the event Mr. Kendall's employment is terminated by the Company for "cause", or if he voluntarily resigns from his employment (without "good reason"), he will be entitled to receive his salary that had accrued but had remained unpaid through the date of termination, any unpaid annual bonus earned with respect to the year prior to such termination of employment and any benefits under any plans in which Mr. Kendall participates consistent with his rights under such plans, or his Accrued Payments.

In the event that Mr. Kendall's employment is terminated by reason of death or permanent disability, in addition to the Accrued Payments, he will be entitled to a cash payment within five business days following such termination consisting of an amount equal to (i) any accrued and unused vacation pay for the year in which his employment terminated, (ii) 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 (iii) accelerated vesting of his outstanding unvested stock options,

restricted stock units, stock appreciation rights, restricted stock and other 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. With respect to the vesting of unvested equity awards in connection with such termination, if any such equity awards are subject to a performance condition or a performance period that ends after the date of termination, the performance goals will be assumed to have been achieved at “target” levels. 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 or, if earlier, until the expiration of the stated term of the award.

In the event that Mr. Kendall’s employment is terminated by us without “cause” or he terminates his employment for “good reason”, (other than in connection with a change in control, as described below), in addition to the Accrued Payments, he will be entitled to receive, subject to the delivery of a fully effective release of claims and continued compliance with his restrictive covenant obligations, (i) a cash payment of an amount equal to any accrued and unused vacation pay for the year in which his employment terminated, (ii) 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, (iii) 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, (iv) 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 (v) full and immediate vesting of all outstanding unvested stock options, restricted stock units, stock appreciation rights, restricted stock and other equity-based compensation awards, and any equity compensation awards that are or become vested upon such termination of his employment will 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 18 monthly of the payments described in section (iii) 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 (iv) 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 the excise tax imposed by Section 4999 of the Code, Mr. Kendall will receive an additional payment in such amount 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.

Daniel Barber

The term of employment for Mr. Barber under his employment agreement continues until Mr. Barber’s employment with us terminates for any reason. Under his employment agreement, Mr. Barber’s initial base salary is $320,000, he will be eligible for a target annual performance bonus of at least 35% of his base salary, and he is eligible to participate in such benefit plans as are generally available to our other senior executives. Following the consummation of this offering, Mr. Barber’s annual base salary and target bonus opportunity shall be increased to $340,000 and 50% of his base salary, respectively. His base salary is subject to annual review and may be increased (but not decreased) as determined by our board of directors or our Compensation Committee. His bonus award each year will be determined by our

board of directors or our Compensation Committee and, except in connection with certain terminations of employment (as described below), any annual bonus will only be paid if he is employed by us on the date of payment of such bonus. Mr. Barber's 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.

Mr. Barber has previously been awarded shares of our non-voting common stock equal to 0.49% of the issued and outstanding capital securities of the Company as of the time of such grant. Mr. Barber's employment agreement provides that upon the completion of this offering, each share of non-voting common stock shall become one share of voting common stock. In addition, Mr. Barber shall be eligible to receive awards of additional shares of non-voting common stock and to participate in other employee incentive plans and equity-based compensation awards at the times and in the amounts as our board of directors determines in its sole discretion.

In the event Mr. Barber's employment is terminated by the Company for "cause," he will be entitled to receive his salary through the effective date of such termination, any unpaid annual performance bonus relating for the year prior to the year of such termination, and any benefits under any employee benefit plans of the Company in which Mr. Barber is a participant, consistent with his rights under such plans, or his Accrued Payments.

In the event that Mr. Barber's employment is terminated by reason of death or permanent disability, in addition to his Accrued Payments, he will be entitled to (i) a cash payment consisting of the target performance bonus for the year of such termination, pro-rated for the number of days he was employed during such year, and (ii) accelerated vesting of all outstanding stock options, restricted stock units, stock appreciation rights, restricted stock and other equity awards as if his employment had continued through the end of the year of such termination or, in the case of any award subject to cliff vesting, on a pro-rated basis determined by the number of days during the vesting period that have lapsed during the applicable vesting period. With respect to the vesting of equity awards in connection with such termination, if any such equity awards are performance-based and the relevant performance period ends after the date of termination, the performance goals will be assumed to have been achieved at "target" levels.

In the event that Mr. Barber's employment is terminated by us without "cause" or he terminates his employment for "good reason," in either case, during the period beginning 180 days prior to a change in control and ending 12 months following the change in control, in addition to the Accrued Payments, he will be entitled to receive, subject to the delivery of a fully effective release of claims and continued compliance with his restrictive covenant obligations, (i) a cash payment consisting of the target performance bonus corresponding to the year of such termination, pro-rated for the number of days he was employed during such year, (ii) an immediate cash payment equal to 12 months of his base salary and one times his target performance bonus, and (iii) 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 and (iv) full vesting of all outstanding unvested stock options, restricted stock units, stock appreciation rights, restricted stock and other equity awards and his stock options will remain outstanding and exercisable for 12 months following termination or, if earlier, until the expiration date of the options. With respect to the vesting of unvested equity awards in connection with such termination, if any such equity awards are subject to a performance condition or a performance period that ends after the date of termination, the performance goals will be assumed to have been achieved at "target" levels.

In the event that Mr. Barber's employment is terminated by us without "cause" or he terminates his employment for "good reason" other than in connection with a change in control (as described above), in addition to the Accrued Payments, he will be entitled to receive, subject to the delivery of a fully effective release of claims and continued compliance with his restrictive covenant obligations, the same benefits as those provided as if his employment had been terminated in connection with a change in control, except

that the payment of base salary and bonus severance described in clause (ii) of the immediately preceding paragraph will be made in monthly payments for a period of 12 months following such termination in equal monthly installments with each installment to be equal to 1/12 of the sum of his base salary and target annual bonus.

To the extent that any medical or dental benefits covering any post-employment period constitute a “self-insured medical reimbursement plan” and such coverage would be deemed to be discriminatory, then the value of the insurance coverage provided will be reportable as taxable income to Mr. Barber and the Company shall pay him, no later than January 15 of the year of such coverage, such additional cash payments as are necessary for him to receive the same net after-tax benefit he would have received as if he were still employed by the Company.

If any of the payments or benefits provided to Mr. Barber by the Company or its affiliates would constitute parachute payments within the meaning of Section 280G of the Code and would otherwise be subject to the excise tax under Section 4999 of the Code, then a comparison will be made of the present value of all payments to Mr. Barber net of all federal, state, local, foreign, employment and excise taxes, or the Net Benefit, as if the payments were subject to the excise tax under Section 4999 of the Code and the Net Benefit as if such payments were reduced to avoid being subject to such excise tax. If the Net Benefit as calculated to avoid being subject to such excise taxes is greater, then such payments will be reduced or cut back by the minimum extent necessary to ensure that no portion of the payments due to Mr. Barber are subject to the excise tax under Section 4999 of the Code.

John T. Maxwell

The term of employment for Mr. Maxwell under his employment agreement continues until Mr. Maxwell’s employment with us terminates for any reason. Under his employment agreement, Mr. Maxwell’s initial base salary is $350,000, he will be eligible for a target annual performance bonus of at least 50% of his base salary, and he is eligible to participate in such benefit plans as are generally available to our other senior executives. Following the consummation of this offering, Mr. Maxwell’s annual base salary shall be increased to $375,000. His base salary is subject to annual review and may be increased (but not decreased) as determined by our board of directors or our Compensation Committee. His bonus award each year will be determined by our board of directors or our Compensation Committee and, except in connection with certain terminations of employment (as described below), any annual bonus will only be paid if he is employed by us on the date of payment of such bonus. Mr. Maxwell’s 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.

Mr. Maxwell has previously been awarded shares of our non-voting common stock equal to 0.69% of the issued and outstanding capital securities of the Company as of the time of such grant. Mr. Maxwell’s employment agreement provides that upon the completion of this offering, each share of non-voting common stock shall become one share of voting common stock. In addition, Mr. Maxwell shall be eligible to receive awards of additional shares of non-voting common stock and to participate in other employee incentive plans and equity-based compensation awards at the times and in the amounts as our board of directors determines in its sole discretion.

In the event Mr. Maxwell’s employment is terminated by the Company for “cause,” he will be entitled to receive his salary through the effective date of such termination, any unpaid annual performance bonus relating for the year prior to the year of such termination, and any benefits under any employee benefit plans of the Company in which Mr. Maxwell is a participant, consistent with his rights under such plans, or his Accrued Payments.

In the event that Mr. Maxwell’s employment is terminated by reason of death or permanent disability, in addition to his Accrued Payments, he will be entitled to (i) a cash payment consisting of the target performance bonus for the year of such termination, pro-rated for the number of days he was employed during such year, and (ii) accelerated vesting of all outstanding stock options, restricted stock units, stock

appreciation rights, restricted stock and other equity awards as if his employment had continued through the end of the year of such termination or, in the case of any award subject to cliff vesting, on a pro-rated basis determined by the number of days during the vesting period that have lapsed during the applicable vesting period. With respect to the vesting of equity awards in connection with such termination, if any such equity awards are performance-based and the relevant performance period ends after the date of termination, the performance goals will be assumed to have been achieved at "target" levels.

In the event that Mr. Maxwell's employment is terminated by us without "cause" or he terminates his employment for "good reason," in either case, during the period beginning 180 days prior to a change in control and ending 12 months following the change in control, in addition to the Accrued Payments, he will be entitled to receive, subject to the delivery of a fully effective release of claims and continued compliance with his restrictive covenant obligations, (i) a cash payment consisting of the target performance bonus corresponding to the year of such termination, pro-rated for the number of days he was employed during such year, (ii) an immediate cash payment equal to 12 months of his base salary and one times his target performance bonus, and (iii) 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 and (iv) full vesting of all outstanding unvested stock options, restricted stock units, stock appreciation rights, restricted stock and other equity awards and his stock options will remain outstanding and exercisable for 12 months following termination or, if earlier, until the expiration date of the options. With respect to the vesting of unvested equity awards in connection with such termination, if any such equity awards are subject to a performance condition or a performance period that ends after the date of termination, the performance goals will be assumed to have been achieved at "target" levels.

In the event that Mr. Maxwell's employment is terminated by us without "cause" or he terminates his employment for "good reason" other than in connection with a change in control (as described above), in addition to the Accrued Payments, he will be entitled to receive, subject to the delivery of a fully effective release of claims and continued compliance with his restrictive covenant obligations, the same benefits as those provided as if his employment had been terminated in connection with a change in control, except that the payment of base salary and bonus severance described in clause (ii) of the immediately preceding paragraph will be made in monthly payments for a period of 12 months following such termination in equal monthly installments with each installment to be equal to 1/12 of the sum of his base salary and target annual bonus.

To the extent that any medical or dental benefits covering any post-employment period constitute a "self-insured medical reimbursement plan" and such coverage would be deemed to be discriminatory, then the value of the insurance coverage provided will be reportable as taxable income to Mr. Maxwell and the Company shall pay him, no later than January 15 of the year of such coverage, such additional cash payments as are necessary for him to receive the same net after-tax benefit he would have received as if he were still employed by the Company.

If any of the payments or benefits provided to Mr. Maxwell by the Company or its affiliates would constitute parachute payments within the meaning of Section 280G of the Code and would otherwise be subject to the excise tax under Section 4999 of the Code, then a comparison will be made of the present value of all payments to Mr. Maxwell net of all federal, state, local, foreign, employment and excise taxes, or the Net Benefit, as if the payments were subject to the excise tax under Section 4999 of the Code and the Net Benefit as if such payments were reduced to avoid being subject to such excise tax. If the Net Benefit as calculated to avoid being subject to such excise taxes is greater, then such payments will be reduced or cut back by the minimum extent necessary to ensure that no portion of the payments due to Mr. Maxwell are subject to the excise tax under Section 4999 of the Code.

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 initial term of employment for Mr. Schobel under his employment agreement is for approximately two and a half years ending December 31, 2020, and thereafter his employment term renews annually, unless either party gives written notice of non-renewal at least 90 days prior to the end of the then-current

term or until his employment with us terminates for any reason. Mr. Schobel's initial base salary is $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 is subject to annual review and may be increased but not decreased. His bonus award will based upon the achievement of performance targets established by our board of directors with recommendations from our chief executive officer. 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.

Mr. Schobel has previously been awarded shares of our non-voting common stock in connection with our PUP Plans equal to 5% of the issued and outstanding capital securities of the Company as of the time of such grant. Mr. Schobel's employment agreement provides that upon the completion of this offering, each share of non-voting common stock shall become one share of voting common stock. Pursuant to his employment agreement, upon the effectiveness of this offering, Mr. Schobel is entitled to receive stock appreciation rights covering a number of shares equal to the difference between 5% of the total number of shares of our common stock outstanding following the consummation of this offering on a fully diluted basis less the aggregate number of shares of common and shares covered by stock appreciation rights that Mr. Schobel holds immediately prior to the completion of this offering, such that the total number of all of the shares of common stock and shares subject to stock appreciation rights held by Mr. Schobel immediately following the completion of this offering represent 5% of our shares of common stock, on a fully diluted basis. In addition to the foregoing, upon the completion of this offering, Mr. Schobel will receive a grant of restricted stock equal to 0.47% of our common stock outstanding following the consummation of this offering on a fully diluted basis, or 112,800 shares of restricted stock. Each of these equity grants 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 each case, subject to Mr. Schobel's continued employment with us on the applicable vesting date and subject to accelerated vesting if his employment terminates for any reason other than as a result of a termination by the Company for "cause" or a resignation by Mr. Schobel without "good reason."

In the event Mr. Schobel's employment is terminated by the Company for "cause" or if he voluntarily resigns from his employment (without "good reason"), he will be entitled to receive his salary that had accrued but had remained unpaid through the date of termination, any unpaid annual bonus earned with respect to the year prior to such termination of employment and any benefits under any plans in which Mr. Schobel participates consistent with his rights under such plans, or his Accrued Payments.

In the event that Mr. Schobel's employment is terminated by reason of death or permanent disability, in addition to the Accrued Payments, he will be entitled to a cash payment within five business days following such termination consisting of an amount equal to (i) any accrued and unused vacation pay for the year in which his employment terminated, (ii) 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 (iii) accelerated vesting of his outstanding unvested stock options, restricted stock units, stock appreciation rights, restricted stock and other 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. With respect to the vesting of unvested equity awards in connection with such termination, if any such equity awards are subject to a performance condition or a performance period that ends after the date of termination, the performance goals will be assumed to have been achieved at "target" levels. 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 or, if earlier, until the expiration of the stated term of the award.

In the event that Mr. Schobel's employment is terminated by us without "cause" or he terminates his employment for "good reason" (other than in connection with a change in control, as described below), in addition to his Accrued Payments, he will be entitled to receive, subject to the delivery of a fully effective release of claims and continued compliance with his restrictive covenant obligations, (i) a cash payment of an amount equal to any accrued and unused vacation pay for the year in which his employment terminated, (ii) 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, (iii) 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, (iv) 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 (v) full and immediate vesting of all outstanding unvested stock options, restricted stock units, stock appreciation rights, restricted stock and other equity-based compensation awards, and any equity compensation awards that are or become vested upon such termination of his employment will 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 18 monthly payments described in section (iii) 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 (iv) 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 the excise tax imposed by Section 4999 of the Internal Revenue Code, Mr. Schobel will receive an additional payment in such amount 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.

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 (#)[1]	Equity Incentive Plan Awards: Market Value of Unearned Shares, Units or Other Rights That Have Not Vested ($)[2]
Keith J. Kendall	January 13, 2017	9,900	35,857
	January 1, 2017	197,994	717,377
	December 18, 2015	16,386	66,453
	August 1, 2010	193,898	1,000,217
	October 21, 2008	199,525	1,275,257
	June 16, 2006	382,169	1,934,023
Daniel Barber	January 2, 2017	66,786	241,981
	December 1, 2011	10,130	49,188
	October 1, 2010	8,104	41,803
	October 1, 2008	13,927	97,458
John T. Maxwell	January 9, 2017	138,614	589,837
A. Mark Schobel	January 13, 2017	9,900	35,857
	December 18, 2015	20,482	83,066
	August 1, 2010	193,898	1,000,217
	October 21, 2008	266,033	1,700,342
	September 21, 2006	198,855	882,036
	June 16, 2006	9,299	47,061
	March 22, 2006	7,389	55,135
	February 13, 2006	118,982	887,877
	November 17, 2005	175,033	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, 2018, 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").

Named Executive Officer	Number of Units Granted	Base Value 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	1,000,000	1,642,241
Mr. Barber	98,959	94,660
Mr. Maxwell	138,614	135,823
Mr. Schobel	1,000,000	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 Equity Incentive 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 adopted 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 4,100,000 shares, or the Plan Limit; provided, however, that on January 1, 2019 and each January 1st 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 31st and (y) such lesser number as the board of directors may determine in its discretion. Up to 4,100,000 shares available for Awards under the 2018 Plan may be issued pursuant to incentive stock options, or the ISO Limit (the ISO Limit will equal the Plan Limit on the effective date of the 2018 Plan), provided that on January 1, 2019 and each January 1st thereafter prior to the termination of the 2018 Plan, the ISO 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 31st, (y) 4,100,000 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 non-employee 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 "non-qualified 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 and to partnerships in which 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 adopted the Aquestive Therapeutics, Inc. Employee Stock Purchase Plan. 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 sub-plans 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 have initially reserved 250,000 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 the lesser of (x) 1.0% of the number of shares of common stock outstanding as of the immediately preceding December 31st and (y) such lesser number of shares as the board of directors may determine in its discretion. 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 25% 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 5,000 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	Annual Service Retainer	Chairperson Additional 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, we intend to grant to each of our existing non-employee directors options to purchase shares of our common stock pursuant to the 2018 Plan. Additionally, we intend make annual grants of options to purchase shares of our common stock to each of our non-employee directors. The amount, terms of and timing surrounding the grant of such options will be determined by our board of directors at a later date and will remain subject to the sole discretion of our board of directors on an ongoing basis.

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 ($)[1]	Stock Awards[2] ($)	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	926,426
Gregory Brown, M.D.	926,426
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	75,085	103,377
Gregory Brown, M.D.	75,085	103,377
John Cochran	75,085	103,377
Nancy Lurker(1)	—	—
Santo Costa	17,327	23,856
James S. Scibetta	8,664	11,928

(1) 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	1,000,000
Daniel Barber	98,959
Peter Boyd	49,439
John T. Maxwell	138,614
A. Mark Schobel	1,000,000
Theresa Wood	79,265
Douglas Bratton	75,085
Gregory Brown, M.D.	75,085
John Cochran	75,085
Santo Costa	17,327
James S. Scibetta	8,664

See "Executive and Director Compensation — Narrative to the Summary Compensation Table — Equity Incentive Plans — PUP Plans" for more information about the PUP Plans.

Stock Option Grants

In April 2018, we granted stock options to purchase an aggregate of 81,068 shares of our common stock each with an exercise price $6.54 per share, to certain of our employees, consultants and directors in connection with services provided by such parties to us in the following amounts:

Nancy Lurker	5,078
Kenneth Marshall	19,997
Daniel Barber	25,997
Peter Boyd	29,996

Registration Rights to Directors and Officers

We have granted certain registration rights to certain of our officers and directors. If, following the completion of this offering, we register any of our securities for public sale in another offering, such directors and officers will have the right to include their shares in the registration statement, subject to reduction provisions whereby, 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 such a case the number of shares to be registered will be apportioned pro rata among these holders, according to the total amount of Registrable Securities entitled to be included by each holder.

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 or as a director or executive officer 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 June 30, 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 20,000,000 shares of our common stock outstanding as of June 30, 2018. The percentage of shares beneficially owned after the offering is computed on the basis of 24,000,000 shares of our common stock outstanding including 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:

- 863,400 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.

Certain existing investors have indicated an interest in purchasing $20.0 million of shares of our common stock in this offering at the initial public offering price. Assuming an initial public offering price of $15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, these entities would purchase an aggregate of up to approximately 1,333,333 of the 4,000,000 shares in this offering based on these indications of interest. However, because indications of interest are not binding agreements or commitments to purchase, these stockholders may determine to purchase fewer shares than they indicate an interest in purchasing or not to purchase any shares in this offering. It is also possible that these stockholders could indicate an interest in purchasing more shares of our common stock. In addition, the underwriters could determine to sell fewer shares to any of these stockholders than the stockholders indicate an interest in purchasing or not to sell any shares to these stockholders. The following table does not reflect any potential purchases by these investors or their affiliated entities.

	Shares Beneficially Owned			
	Prior to the Offering		After the Offering	
	Number	%	Number	%
Five percent stockholders:				
MRX Partners, LLC[1]	2,249,077	11.2%	2,249,077	9.4%
MonoLine RX, L.P.[1]	2,213,314	11.1%	2,213,314	9.2%
MonoLine RX II, L.P.[1]	4,032,907	20.2%	4,032,907	16.8%
MonoLine RX III, L.P.[1]	2,755,541	13.8%	2,755,541	11.5%
Monosol Investors, L.P.[2]	1,944,628	9.7%	1,944,628	8.1%

	Shares Beneficially Owned			
	Prior to the Offering		After the Offering	
	Number	%	Number	%
Directors, executive officers and key employees:				
Keith J. Kendall(3)	1,000,000	5.0%	1,000,000	4.2%
Daniel Barber	98,959	*	98,959	*
Peter Boyd	49,439	*	49,439	*
John T. Maxwell	138,614	*	138,614	*
A. Mark Schobel	1,000,000	5.0%	1,000,000	4.2%
Theresa Wood	79,265	*	79,265	*
Douglas Bratton	75,085	*	75,085	*
Gregory Brown, M.D.	75,085	*	75,085	*
John Cochran	75,085	*	75,085	*
Santo Costa	17,327	*	17,327	*
Nancy Lurker	—	*	—	*
James S. Scibetta	8,664	*	8,664	*
All directors executive officers and key employees as a group (11 persons)	2,617,521	13.1%	2,617,521	10.9%

* *Represents beneficial ownership of less than 1%.*

(1) Bratton Capital Management L.P., or Bratton Capital Management, is the general partner of each of MRX Partners, LLC, or MRX Partners, Monoline R.X., L.P. or Monoline, Monoline II R.X., L.P. or Monoline II, and Monoline III R.X., L.P. or Monolineor III. MRX Partners, Monoline, Monoline II and Monoline III are collectively know as the Monosol Entities. Bratton Capital Inc., or Bratton, is the general partner of Bratton Capital Management. Douglas K. Bratton is the sole director of Bratton. The Monosol Entities are each ultimately controlled by Mr. Bratton and Mr. Bratton has voting and investment power over all shares held by the Monosol Entities, Bratton Capital Management, Bratton, and Mr. Bratton may each be deemed to beneficially own all shares held of record by the Monosol Entities. Each such entity and Mr. Bratton disclaims beneficial ownership of the reported securities except to the extent of its or his respective pecuniary interest therein. The percentage of shares beneficially owned after this offering would be 48.6%, assuming the purchase of all of the shares that the entities affiliated with this stockholder have indicated an interest in purchasing in this offering.

(2) Genpar MonoSol, LLC is the general partner of MonoSol Investors, L.P. Genpar MonoSol, LLC is ultimately controlled by David Dupree and Michael Marshall, who together have voting and investment power over all shares held by MonoSol Investors, L.P. Genpar MonoSol, LLC, David Dupree and Michael Marshall may each be deemed to beneficially own all shares held of record by MonoSol Investors, L.P. Each such entity, David Dupree and Michael Marshall disclaims beneficial ownership of the reported securities except to the extent of its or his respective pecuniary interest therein.

(3) Includes 396,053 shares of our common stock currently issued and outstanding, which are held by Mr. Kendall in constructive trust for his former spouse pursuant to a divorce settlement agreement reached in November 2016 and which will be transferred and come under the control of Mr. Kendall's former spouse shortly after this offering.

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 $66^{2/3}\%$ 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 $66^{2/3}\%$ 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 July 12, 2018, we had no shares of preferred stock outstanding. 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. In April 2018, we granted stock options to purchase 81,068 shares of our common stock to certain of our employees, consultants and directors, each at an exercise price of $6.54 per share.

We may in the future grant options or other forms of equity compensation to our employees, consultants and directors pursuant to our equity incentive plan(s). 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 863,400 warrants to purchase shares of our common stock representing 4.3% 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 Agreement

We have entered into a Registration Rights Agreement dated June 26, 2018 with Aquestive Partners, LLC, or APL, the members of the board of directors of APL and certain holders of membership interests of APL (“collectively, the “Holders”), or the Registration Rights Agreement, which covers shares of our common stock to be issued to the Holders. The registration rights granted under the Registration Rights Agreement, as described below, supersede any prior registration rights we have granted to such holders.

Series A-3 Registration Rights

Pursuant to the Registration Rights Agreement, we granted certain demand registration rights to holders of registerable securities to be issued to holders in respect of their Series A-3 Preferred Interests in APL upon consummation of this offering, or the Series A-3 Registrable Securities. The holders of a majority of the Series A-3 Preferred Interests have waived all registration rights with respect to the registrable securities to be issued to holders in respect of Series A-3 Preferred Interests in connection with this offering.

Beginning upon the earlier of (i) August 16, 2021 and (ii) 180 days after the consummation of this offering, holders of at least 40% of the Registrable Securities into which the Series A-3 Preferred Interests in APL have been converted can request that we register all or part of their securities on Form S-1 and holders of at least 50% of the Registrable Securities into which the Series A-3 Preferred Interests in APL have been converted 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, or a Demand Registration. 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 Registrable Securities entitled to be included by each holder, provided that the requesting Holders will be reduced last.

Series A-2 Registration Rights

Pursuant to the Registration Rights Agreement, we granted certain demand registration rights to holders of Registerable Securities into which the Series A-2 Preferred Interests in APL will have been converted upon consummation of this offering, or the Series A-2 Registrable Securities. These demand registration rights will terminate on July 31, 2018.

The holders of a majority of the Series A-2 Preferred Interests have waived all registration rights with respect to the registrable securities to be issued to holders in respect of Series A-2 Preferred Interests in connection with this offering.

“Piggyback” Registration Rights

Pursuant to the Registration Rights Agreement, we have granted “piggyback” registration rights to holders of our Registrable Securities, all of which have been effectively waived with respect to this offering.

If (i) a Demand Registration is made or (ii) we propose to register any of our securities for public sale in another offering and the Holders of at least a majority of either (a) the Registrable Securities into which the Series A-3 Registrable Securities have been converted or (b) the Registrable Securities into which the Series A-3 Registrable Securities have been converted, request in writing then holders of all Registrable Securities will have the right to include their Registrable Securities in such registration statement. 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 among these holders, (w) first to all of the securities we propose to sell (if the registration is an underwritten offering for our own account); (x) second the holders of Series A-3 Registrable Securities and Series A-2 Registrable Securities; (y) third to shares held by certain of our executives and (z) finally to all other holders of Registrable Securities; and in the cases of clauses (x), (y) and (z), each pro rate according to the total percentage of the Registrable Securities requested to be included by each holder.

Expenses of Registration

We and APL 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.

Indemnification

Pursuant to the Registration Rights Agreement, we have agreed to indemnify the holders of Registerable Securities against all losses, claims, damages, liabilities, and expenses (or actions or proceedings, whether commenced or threatened, in respect thereof), resulting from or arising out of (i) any untrue or alleged untrue statement of material fact or material omission contained in or omitted from (A) any registration statement, prospectus or preliminary prospectus, free writing prospectus, or any amendment thereof or supplement thereto (other than for such statements or omissions prepared by the

holder of Registrable Securities for use in a registration statement) or (B) any documents filed by us in order to qualify any securities covered by a registration under the “blue sky” laws; and (ii) any Securities Act violations committed by us in registering the Registerable Securities pursuant to the Registration Rights Agreement.

Termination of Registration Rights

Shares of common stock will cease to be considered Registerable Securities when they have been (x) effectively registered under the Securities Act and disposed of in accordance with the registration statement covering them pursuant to the Registration Rights Agreement or (y) eligible to be sold to the public through a broker, dealer or market maker pursuant to Rule 144-13-(or by any similar provision then in force) under the Securities Act without volume or manner-of sale restrictions and without the requirement for us to be in compliance with the current public information requirement under Rule 144(c)(1), in each case in compliance with the terms and conditions of the Registration Rights Agreement.

The Registration Rights Agreement will automatically terminate when there are no Registerable Securities outstanding.

Registration Rights to Directors and Officers

We have granted certain registration rights to certain of our officers and directors. If, following the completion of this offering, we register any of our securities for public sale in another offering, such officers and directors will have the right to include their shares in the registration statement, subject to reduction provisions whereby, 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 such a case the number of shares to be registered will be apportioned pro rata among these holders, according to the total amount of Registrable Securities entitled to be included by each holder.

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 $66^{2/3}\%$ 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 $66^{2/3}\%$ 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 $66^{2/3}\%$ 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, the 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 after the restrictions lapse could adversely affect the prevailing 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, 24,000,000 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
19,397,402 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 15,939,557 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 and the ESPP, as well as certain other non-plan based equity awards. 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 on a net income basis at regular 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 equal 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 non-compliant 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	4,000,000

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 600,000 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. in an amount not to exceed $35,000 in the aggregate.

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, 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 Nasdaq 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, except under circumstances that will result in compliance with the applicable rules and regulations of that 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 in which such an offer or a solicitation 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(l) 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. 1197l, 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.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

MonoSol Rx, LLC

Aquestive Therapeutics, Inc. (formerly known as MonoSol Rx, LLC)

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, 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. 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	4,402	3,366
Deferred revenue	1,347	802
Total current liabilities	15,350	10,806
Noncurrent liabilities:		
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):		
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 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)
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 capital	Accumulated deficit	Total members' deficit
	Units	Amount	Units	Amount	Units	Amount			
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	$ —	$ (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
Cash flows from operating activities:		
Net loss	$ (8,943)	$ (9,602)
Adjustments to reconcile net loss to net cash provided by (used for) operating activities:		
Depreciation and amortization	3,750	3,840
Loss on impairment of investment	—	1,006
Change in fair value of warrant	1,123	750
Asset retirement obligation accretion	122	107
Amortization of intangible	51	51
Amortization of debt issuance costs and discounts	1,860	857
Loss on extinguishment of debt	—	757
Equity in milestone revenue of affiliate	—	254
Loss on sale of investment	—	95
Non-cash interest expense	33	(13)
Bad debt (recovery) provision	(53)	16
Changes in operating assets and liabilities:		
Trade receivables and other receivables	4,691	(6,508)
Inventories	(1,128)	(1,587)
Prepaid expenses	(171)	(82)
Accounts payable	2,943	1,650
Accrued expenses	1,001	452
Deferred revenue	545	(218)
Net cash provided by (used for) operating activities	5,824	(8,175)
Cash flows from investing activities:		
Capital expenditures	(2,068)	(976)
Proceeds from sale of investment	—	1,166
Net cash (used for) provided by investing activities	(2,068)	190
Cash flows from financing activities:		
Proceeds from warrant exercise	24	—
Proceeds from issuance of debt	5,000	45,000
Debt repayment	—	(37,500)
Payments for debt issuance costs	(610)	(1,248)
Payment of premium on early extinguishment of debt	—	(563)
Net cash provided by financing activities	4,414	5,689
Net increase (decrease) in cash and cash equivalents	8,170	(2,296)
Cash and cash equivalents:		
Beginning of period	9,209	11,505
End of period	$ 17,379	$ 9,209
Supplemental disclosures of cash flow information:		
Cash payments for interest	$ 5,814	$ 5,047
Capital expenditures included in accounts payable	20	192
Accrued Series A-2 and A-3 preferred dividends	2,480	2,342

See accompanying notes to the consolidated financial statements

MonoSol Rx, LLC

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 late-stage 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.

(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 participates in any dividends declared by the Company and are therefore considered to be participating securities. 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

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

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*, long-lived 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.

(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

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 Company's license revenues most commonly are non-refundable once collected, and are typically recognized as revenue at the time that the transferred licensed rights can be utilized for the benefit of the licensee, subject to determinable pricing, performance contingencies and collectability assessments. In the event that a licensing agreement requires the Company to meet ongoing or future performance objectives that are other than inconsequential or perfunctory, licensing revenue may be recognized ratably, or in conjunction with its performance obligations, during the initial term of the license agreement. If a performance obligation, milestone, or contingency exists, revenue is deferred until such time that the contingencies are satisfied or obligations are met. 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 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.

(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-for-sale 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

(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	$ 40,092	$ 37,324
License and royalty revenue	23,133	11,320
Co-development and research fees	3,693	3,141
Revenues	$ 66,918	$ 51,785

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.

(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 to pay royalties on Suboxone sold in the United States will terminate. Except as set forth in the prior sentence, 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 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 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 the Indivior Supplemental 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 the Indivior Supplemental Agreement are non-refundable. 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 has also received $9,250 in February 2018 as a part of this agreement. In addition to amounts received, the Company may receive up to an additional $48,750, consisting of (i) up to $45,000 in the aggregate from any combination of (a) performance or event-based milestone payments and (b) single digit percentage royalties on net revenue earned by Indivior on sales of Suboxone and (ii) an additional $3,750 that may be earned through the issuance of additional process patent rights to us with the aggregate payment amounts under the Indivior Supplemental Agreement capped at $75,000. Accordingly, the Indivior Supplemental 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 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

(In thousands, except unit and per unit information)

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 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

(In thousands, except unit and per unit information)

8. Property and Equipment, Net

	Useful Lives	December 31, 2017	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.

(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:

	December 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).

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.

(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*:

	Amount
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

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

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.

(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

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

(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[2]
Outstanding at December 31, 2015	55,773	$ 64,562	$ 0.26	$ 9,823
Granted[1]	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[1]	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.

(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[1]	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.

MonoSol Rx, LLC

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:

	December 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%

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 (Unaudited)	December 31, 2017	Pro Forma March 31, 2018 (Note 2(D)) (Unaudited)
Assets			
Current assets:			
Cash and cash equivalents	$ 16,488	17,379	$ 16,488
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:			
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	—
Preferred A-1 interests, no par value. Authorized 100,000,000 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	—	12,727	—
Common stock, $0.001 par value. Authorized 350,000,000 shares, 15,077,647 issued and outstanding at March 31, 2018; 20,000,000 issued and outstanding at March 31, 2018 (pro forma)	15	—	20
Additional paid-in capital	93,583	—	120,454
Accumulated deficit	(115,994)	(120,093)	(143,294)
Total shareholders' / members' deficit	(22,396)	(68,596)	(22,820)
Total liabilities and shareholders'/members' equity	$ 46,082	43,116	$ 46,082

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)

	Three Months Ended March 31, 2018	*Three 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 per share - basic and diluted	$ 0.027	
Weighted-average number of common shares / membership interests outstanding - basic and diluted	15,077,647	
Unaudited pro forma net loss (Note 2(D))	$ (23,201)	
Unaudited pro forma net loss per share (Note 2(D))	$ (1.16)	
Unaudited pro forma basic and diluted weighted-average shares of common stock outstanding (Note 2(D))	20,000,000	

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)

	Preferred A interests		Preferred A-1 interests		Common interests		Common stock		Additional paid-in capital	Accumulated deficit	Total members'/ shareholders' deficit
	Units	Amount	Units	Amount	Units	Amount	Shares	Amount			
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)	—	—	—	—	—	—	15,072,647	15	(15)	—	—
Net income (unaudited)	—	—	—	—	—	—	—	—	—	4,099	4,099
Balance at March 31, 2018 (unaudited)	—	$ —	—	$ —	—	$ —	15,077,647	$ 15	$ 93,583	$ (115,994)	$ (22,396)
Termination and conversion of performance unit plans (unaudited) (Note 2(D) and Note 20(C))	—	—	—	—	—	—	4,922,353	5	19,985	(27,300)	(7,400)
Conversion of warrants (unaudited) (Note 2(D))	—	—	—	—	—	—	—	—	6,976	—	6,976
Pro Forma Balance at March 31, 2018 (unaudited)	—	$ —	—	$ —	—	$ —	20,000,000	$ 20	$ 120,454	$ (144,294)	$ (22,820)

See accompanying notes to the consolidated financial statements

Aquestive Therapeutics, Inc. (formerly known as MonoSol Rx, LLC)
Consolidated Statements of Cash Flows
(In thousands)
(Unaudited)

	For the Three Months March 31,	
	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
Supplemental disclosures of cash flow information:		
Cash payments for interest	$ 1,485	$ 1,359
Capital expenditures included in accounts payable	15	212
Accrued Series A-2 and A-3 preferred dividends	—	613

See accompanying notes to the consolidated financial statements

Aquestive Therapeutics, Inc. (formerly known as MonoSol Rx, LLC)

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.

(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 Splits

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.

In June 2018, the board approved an additional amendment to the Certificates of Incorporation of the Company to effect a reverse stock split of the Company's common stock, par value $0.001 per share, such that each 12.34 shares outstanding converted into one share of common stock, par value $0.001 per share.

For purposes of these financial statements, the net effect of these stock splits have been presented as if they 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 should be read in conjunction with MonoSol Rx, LLC's 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 of operations for the three months ended March 31, 2018 and 2017 are not necessarily indicative of 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").

(In thousands, except share and per share information)

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 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 4,922,353 shares of non-voting common stock granted in connection with the termination of the Performance Unit Plans (see Note 20(C)).

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 $27,300 to general and administrative expense in May 2018 (see Note 20(C)).

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.

	For the Three Months Ended March 31, 2018 (unaudited)
Numerator:	
Net income attributable to common shares - basic and diluted	$ 4,099
Add: Charge for termination of PUP Plans	(27,300)
Net loss attributable to common shares - basic and diluted	$ (23,201)
Denominator:	
Weighted-average number of common shares outstanding	15,077,647
Effect of pro forma adjustments:	
Issuance of common stock for performance units	4,922,353
Pro forma weighted average shares outstanding	20,000,000
Unaudited pro forma net loss per share - basic and diluted	$ (1.16)

(E) Net Income Per Share

Basic net income per share is calculated by dividing net income by the weighted-average number of common shares.

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, 2018
Numerator:	
Net income	$ 4,099
Denominator:	
Weighted-average number of common shares – basic and diluted	15,077,647
Income per common share – basic and diluted	$ 0.27

The LLC interests, prior to the corporate conversion and reorganization of the Company described in Note 1(B), were complex and varied across several series of LLC equity interest conveying different economics and rights. As such, income per share information prior to the reorganization under the prior equity structure is not comparable to earnings per share for periods presented after the reorganization.

(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.

(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 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*, long-lived 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.

(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 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 Company's license revenues most commonly are non-refundable once collected and are typically recognized as revenue at the time that the transferred licensed rights can be utilized for the benefit of the licensee, subject to determinable pricing, performance contingencies and collectability assessments. In the event that a licensing agreement requires the Company to meet ongoing or future performance objectives that are other than inconsequential or perfunctory, licensing revenue may be recognized ratably, or in conjunction with its performance obligations, during the initial term of the license agreement. If a performance obligation, milestone, or contingency, such as a specified level of cumulative product sales or the approval of a regulatory agency, exists, revenue is deferred until such time that the

contingencies are satisfied or obligations are met. 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.

(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-for-sale 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 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 thousands, except share and per share information)

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 Three Months Ended March 31,	
	2018	2017
	(unaudited)	
Manufacture and supply revenue	$ 11,560	$ 10,155
License and royalty revenue	9,500	5,223
Co-development and research fees	2,351	1,058
Revenues	$ 23,411	$ 16,436

Trade receivables, net consist of the following:

	March 31, 2018	December 31, 2017
	(Unaudited)	
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.

The following table presents the changes in the allowance for bad debts account:

	March 31, 2018	December 31, 2017
	(Unaudited)	
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 to pay royalties on Suboxone sold in the United States will terminate. Except as set forth in the prior sentence, 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 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 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 (i) up to $42,000 in the aggregate from any combination of (a) performance or event-based milestone payments and (b) single digit percentage royalties on net revenue earned by Indivior on sales of Suboxone and (ii) an additional $2,500 that may be earned through the issuance of additional process patent rights to us 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 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.

(In thousands, except share and per share information)

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, 2018 (Unaudited)	December 31, 2017
Raw material	$ 754	$ 725
Packaging material	2,147	2,225
Finished goods	949	1,064
Total inventory	$ 3,850	$ 4,014

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.

	March 31, 2018 (Unaudited)	December 31, 2017
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

(In thousands, except share and per share information)

8. Property and Equipment, Net

	Useful Lives	March 31, 2018 (Unaudited)	December 31, 2017
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:

	March 31, 2018 (Unaudited)	December 31, 2017
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

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

(In thousands, except share and per share information)

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:

	March 31, 2018 (Unaudited)	December 31, 2017
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.

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, 2016 to March 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 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. ("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 that the cases between the Company and Indivior on the one hand and Par and certain affiliates on the other hand. The trial against Alvogen occurred in September 2017, and on March 22, 2018 the Court issued its Trial Opinion finding the '514 and '497 patents valid but not infringed by Alvogen's ANDA Products. This case is also on appeal to the Federal Circuit.

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. On June 19, 2018, BDSI filed a motion to terminate and remand the appeal, which the Company opposes.

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

(In thousands, except share and per share information)

New Jersey, and by agreement of the parties, each of the individual cases against each defendant have been consolidated with the cases asserting infringement of the ’454 and ’221 patent. 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® (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 submitted 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 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:

	For the Three Months Ended March 31,	
	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.

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.

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 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 Events

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 July 15, 2018. The Company has concluded that the following events require 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.

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.

(B) Patent Infringement Actions

On June 14, 2018, Dr. Reddy's notified the U.S. District Court for the District of New Jersey that the FDA had granted final approval of its ANDAs and that it had launched generic versions of Suboxone Sublingual Film. The Company and Indivior filed a motion for a preliminary injunction and a request for a temporary restraining order, and the Court granted the request on June 15, 2018 enjoining and restraining Dr. Reddy's from offering for sale, selling, or importing its generic versions of Suboxone Sublingual Film. On July 13, 2018, the Court granted the preliminary injunction, which enjoins Dr. Reddy's from launching a generic version of Suboxone during the pendency of the litigation and until further order from the Court. On July 13, 2018, Dr. Reddy's filed a motion to stay the preliminary injunction pending appeal of the Court's decision. Dr. Reddy's also filed a notice of appeal of the Court's decision on the preliminary injunction.

(C) Termination of Performance Unit Plans

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 $27,300 in the second quarter of 2018 to reflect the compensation cost associated with the issuance of the non-voting common shares and related withholding taxes, which the Company has elected to pay on behalf of the performance unit holders. 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.

4,000,000 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	$	9,163
FINRA filing fee		11,540
Nasdaq listing fee		125,000
Printing and engraving expenses		129,850
Legal fees and expenses		1,642,296
Accounting fees and expenses		1,035,142
Transfer agent and registrar fees and expenses		3,500
Miscellaneous expenses		1,243,509
Total	$	4,200,000

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;
- 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 Partners, 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 863,400 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 4.3% 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.

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 paid the equivalent value in shares of our common stock. Shares of common stock were issued to directors, officers and key employees in the following amounts:

Keith J. Kendall	1,000,000
Daniel Barber	98,959
Peter Boyd	49,439
John T. Maxwell	138,614
A. Mark Schobel	1,000,000
Theresa Wood	79,265
Douglas Bratton	75,085
Gregory Brown, M.D.	75,085
John Cochran	75,085
Santo Costa	17,327
James S. Scibetta	8,664

Stock Option Grants

In April 2018, we granted stock options to purchase an aggregate of 81,068 shares of our common stock each with an exercise price $6.54 per share, to certain of our employees, consultants and directors in connection with services provided by such parties to us in the following amounts:

Nancy Lurker	5,078
Kenneth Marshal	19,997
Daniel Barber	25,997
Peter Boyd	29,996

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 setting forth that the applicable securities have not been registered and reciting the applicable restrictions on transfer. All of the foregoing securities are deemed restricted securities for purposes of the Securities Act. There were no underwriters employed in connection with any of the transactions set forth in this Item 15. 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.

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.

EXHIBIT INDEX

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 of Incorporation, as currently in effect.
3.3	Certificate of Amendment No. 2 to the Certificate of Incorporation, as currently in effect.
3.4*	Form of Amended and Restated Certificate of Incorporation, to be in effect upon consummation of this offering.
3.5*	Bylaws, as currently in effect.
3.6*	First Amendment to Bylaws, as currently in effect.
3.7*	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, dated June 24, 2016, by and between Aquestive Partners, LLC and certain of the holders of its membership interests.
5.1	Opinion of Dechert LLP.
10.1*	Form of Indemnity Agreement by and between 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 January 1, 2018, by and between Monosol Rx, LLC, the Lenders party thereto and Perceptive Credit Holdings, LP.
10.4*	Amendment No. 2 to Credit Agreement and Guaranty dated May 21, 2018, by and between Aquestive Therapeutics, Inc. and Perceptive Credit Opportunities Fund, LP.
10.5	Employment Agreement dated June 30, 2018, by and between Aquestive Therapeutics, Inc., LLC and Keith J. Kendall.
10.6*	Employment Agreement dated June 26, 2018, by and between Aquestive Therapeutics, Inc., LLC and Daniel Barber.
10.7*	Employment Agreement dated June 26, 2018, by and between Aquestive Therapeutics, Inc., LLC and John T. Maxwell.
10.8	Employment Agreement dated July 9, 2018, by and between Aquestive Therapeutics, Inc., LLC and A. Mark Schobel.
10.9†	Commercial Exploitation Agreement by and between MonoSol Rx, LLC and Reckitt Benckiser Pharmaceuticals Inc., dated August 15, 2008 (as amended on August 19, 2009, November 13, 2009, March 30, 2010, October 13, 2010, December 15, 2010, December 9, 2011, December 1, 2012, October 14, 2013 (by Addendum A), July 30, 2014 (by Addendum 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 between MonoSol Rx, LLC and KemPharm, Inc., dated as of March 20, 2012.
10.12†*	License Agreement by and between MonoSol Rx, LLC and Cynapsus Therapeutics Inc., dated as of April 1, 2016.
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.
10.15	Aquestive Therapeutics, Inc. Employee Stock Purchase Plan.
10.16*	Form of Stock Option Agreement dated April 2018.
10.17	Form of Stock Option Agreement for the Aquestive Therapeutics, Inc., 2018 Equity Incentive Plan.
10.18	Form of Restricted Stock Unit Agreement.
23.1	Consent of KPMG LLP, Independent Registered Public Accounting Firm.
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).

† 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.

* Previously filed.

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 16th day of July, 2018.

Aquestive Therapeutics, Inc.

By: /s/ Keith J. Kendall
Keith J. Kendall
President and Chief Executive Officer

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

Signature	Title	Date
/s/ Keith J. Kendall Keith J. Kendall	President, Chief Executive Officer and Member of the Board of Directors (Principal Executive Officer)	July 16, 2018
/s/ John T. Maxwell John T. Maxwell	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	July 16, 2018
/s/ Douglas Bratton Douglas Bratton	Chairman of the Board of Directors	July 16, 2018
/s/ Gregory Brown Gregory Brown, M.D.	Member of the Board of Directors	July 16, 2018
/s/ John Cochran John Cochran	Member of the Board of Directors	July 16, 2018
/s/ Santo Costa Santo Costa	Member of the Board of Directors	July 16, 2018
/s/ Nancy Lurker Nancy Lurker	Member of the Board of Directors	July 16, 2018
/s/ James S. Scibetta James S. Scibetta	Member of the Board of Directors	July 16, 2018
/s/ A. Mark Schobel A. Mark Schobel	Member of the Board of Directors	July 16, 2018

Exhibit 1.1

[●] Shares

AQUESTIVE THERAPEUTICS, INC.

Common Stock, $0.001 par value per share

UNDERWRITING AGREEMENT

July [•], 2018

BMO Capital Markets Corp.
RBC Capital Markets, LLC
As Representatives of the Several Underwriters

c/o BMO Capital Markets Corp.
3 Times Square
New York, New York 10036

and

c/o RBC Capital Markets, LLC
200 Vesey Street
Three World Financial Center
New York, New York 10281

Ladies and Gentlemen:

AQUESTIVE THERAPEUTICS, INC., a Delaware corporation (the "Company"), proposes, subject to the terms and conditions stated herein, to issue and sell an aggregate of [●] shares (the "Firm Shares") of the Company's common stock, $0.001 par value per share (the "Common Stock"), to the several underwriters (collectively, the "Underwriters") named in Schedule I to this agreement (this "Agreement"), for whom BMO Capital Markets Corp. ("BMOCM") and RBC Capital Markets, LLC are acting as representatives (the "Representatives"). The Company has also agreed to grant to the Underwriters an option (the "Option") to purchase an aggregate of up to [●] additional shares of Common Stock (the "Option Shares") on the terms set forth in Section 1(b) hereof. The Firm Shares and the Option Shares are hereinafter collectively referred to as the "Shares."

The Company confirms as follows its agreement with the Representatives and the several other Underwriters:

1. Agreement to Sell and Purchase.

(a) *Purchase of Firm Shares.* On the basis of the representations, warranties and agreements of the Company contained herein and subject to all the terms and conditions of this Agreement, the Company agrees to sell to the several Underwriters and each of the several Underwriters, severally and not jointly, agrees to purchase from the Company, at a purchase price per share of $[●] (the "Purchase Price"), the number of Firm Shares set forth opposite the name of such Underwriter in Schedule I, plus such additional number of Firm Shares which such Underwriter may become obligated to purchase pursuant to Section 8 hereof.

(b) *Purchase of Option Shares.* Subject to all the terms and conditions of this Agreement, the Company grants the Option to the several Underwriters to purchase, severally and not jointly, all or less than all of the Option Shares at the Purchase Price less an amount per share equal to any dividends or distributions declared by the Company and payable on the Firm Shares but not payable on the Option Shares. The Option may be exercised in whole or in part at any time on or before the 30th day after the date of this Agreement, upon written notice (the "Option Shares Notice") by the Representatives to the Company no later than 12:00 noon, New York City time, at least two and no more than five business days before the date specified for closing in the Option Shares Notice (the "Option Closing Date") setting forth the aggregate number of Option Shares to be purchased and the time and date for such purchase. On any Option Closing Date, the Company shall issue and sell to the Underwriters the number of Option Shares set forth in the Option Shares Notice and each Underwriter shall purchase from the Company such percentage of the Option Shares as is equal to the percentage of Firm Shares that such Underwriter is purchasing, as adjusted by the Representatives in such manner as they deem advisable to avoid fractional shares.

2. Delivery and Payment.

(a) *Closing.* Delivery of the Firm Shares shall be made to the Representatives through the facilities of the Depository Trust Company ("DTC") for the respective accounts of the Underwriters against payment of the Purchase Price by wire transfer of immediately available funds to the Company. Such payment shall be made at 10:00 a.m., New York City time, on the second business day (the third business day, should the offering be priced after 4:00 p.m., Eastern Time) after the date on which the first *bona fide* offering of the Firm Shares to the public is made by the Underwriters or at such time on such other date, not later than ten business days after such date, as may be agreed upon by the Company and the Representatives (such date is hereinafter referred to as the "Closing Date").

(b) *Option Closing.* To the extent the Option is exercised, delivery of the Option Shares against payment by the Representatives (in the manner and at the location specified above) shall take place at the time and date (which may be the Closing Date, but not earlier than the Closing Date) specified in the Option Shares Notice.

(c) *Electronic Transfer.* Electronic transfer of Shares shall be made at the time of purchase in such names and in such denominations as the Representatives shall specify.

(d) *Stamp Tax.* The Company shall pay, bear and hold the Underwriters harmless against any stamp duty, stamp duty reserve tax, and any other issue, transfer, registration, documentary or sales tax or duty in any jurisdiction ("Stamp Tax") which is payable in connection with: (i) the execution, delivery, consummation or enforcement of this Agreement; (ii) the grant, exercise or lapsing of the Option; (iii) the creation, allotment, or issue of any Shares; (iv) the initial entry of the Shares into the facilities of DTC; (v) the acquisition of the Shares by, or crediting or delivery of the Shares to or for the account of, the Underwriters (or any purchasers or subscribers procured by the Underwriters); or (vi) the sale and/or delivery of any Shares by any Underwriter to any initial purchaser in the manner contemplated in this Agreement.

3. Representations and Warranties of the Company. The Company represents and warrants to, and covenants with, each Underwriter as follows:

(a) *Compliance with Registration Requirements.* A registration statement on Form S-1 (Registration No. 333-225924) relating to the Shares, including a preliminary prospectus and such amendments to such registration statement as may have been required to the date of this Agreement, has been prepared by the Company under the provisions of the Securities Act of 1933, as amended (the "Act"), and the rules and regulations (collectively referred to as the "Rules and Regulations") of the Securities and Exchange Commission (the "Commission") thereunder, and has been filed with the Commission. Copies of such registration statement and of each amendment thereto, if any, including the related preliminary prospectuses, heretofore filed by the Company with the Commission have been delivered or made available to the Representatives. The term "Registration Statement" means the registration statement as amended at the time it becomes or became effective, including financial statements and all exhibits and any information deemed to be included therein by Rule 430A, Rule 430B or Rule 430C of the Rules and Regulations, as applicable. If the Company files a registration statement to register a portion of the Shares and relies on Rule 462(b) of the Rules and Regulations for such registration statement to become effective upon filing with the Commission (the "Rule 462 Registration Statement"), then any reference to the "Registration Statement" shall be deemed to include the Rule 462 Registration Statement, as amended from time to time. The term "preliminary prospectus" as used herein means a preliminary prospectus as contemplated by Rule 430, Rule 430A or Rule 430B of the Rules and Regulations included at any time as part of, or deemed to be part of or included in, the registration statement. The term "Prospectus" means the final prospectus in connection with this offering as first filed with the Commission pursuant to Rule 424(b) of the Rules and Regulations or, if no such filing is required, the form of final prospectus included in the Registration Statement at the effective date. The term "Testing-the-Waters Communication" means any oral or written communication with potential investors in reliance on Section 5(d) of the Act. The term "Written Testing-the-Waters Communication" means any Testing-the-Waters Communication that is a written communication within the meaning of Rule 405 of the Rules and Regulations.

(b) *Effectiveness of Registration.* The Registration Statement and any post-effective amendment thereto have been declared effective by the Commission under the Act or have become effective pursuant to Rule 462 of the Rules and Regulations. The Company has responded to all requests, if any, of the Commission for additional or supplemental information. No stop order suspending the effectiveness of the Registration Statement or any Rule 462 Registration Statement is in effect and no proceedings for such purpose have been instituted or are pending or, to the knowledge of the Company, are threatened by the Commission.

(c) *Accuracy of Registration Statement.* Each of the Registration Statement, and any post-effective amendment thereto, at the time it became effective and at all subsequent times, complied and will comply in all material respects with the Act and the Rules and Regulations, and did not and will not contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary in order to make the statements therein not misleading. The Prospectus, as amended or supplemented, as of its date and at all subsequent times, complied and will comply in all material respects with the Act and the Rules and Regulations, and did not or will not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements therein not misleading, in the light of the circumstances under which they were made. Each preliminary prospectus (including the preliminary prospectus or prospectuses filed as part of the Registration Statement or any amendment thereto) complied when so filed in all material respects with the Rules and Regulations, and each preliminary prospectus and the Prospectus delivered or made available to the Underwriters for use in connection with this offering is identical to the electronically transmitted copies thereof filed with the Commission on EDGAR, except to the extent permitted by Regulation S-T. The foregoing representations and warranties in this Section 3(c) do not apply to any statements or omissions made in reliance on and in conformity with information relating to any Underwriter furnished in writing to the Company by the Representatives specifically for inclusion in the Registration Statement or Prospectus or any amendment or supplement thereto. For all purposes of this Agreement the only information (the "Underwriters' Information") relating to any Underwriter furnished in writing to the Company by the Representatives specifically for inclusion in the preliminary prospectus, the Registration Statement or the Prospectus is the following information contained under the caption "Underwriting": the amounts of the selling concession set forth in the Prospectus in the first sentence of the fourth paragraph and information regarding stabilization, syndicate covering transactions, penalty bids and passive market making in paragraphs 11, 12, 13 and 14.

(d) *Company Not Ineligible Issuer*. (i) At the time of filing the Registration Statement relating to the Shares and (ii) as of the date of the execution and delivery of this Agreement (with such date being used as the determination date for purposes of this clause (ii)), the Company was not and is not an "ineligible issuer" (as defined in Rule 405 of the Rules and Regulations).

(e) *Disclosure at the Time of Sale.* As of the Applicable Time (as defined below), neither (i) the Issuer General Use Free Writing Prospectus(es) (as defined below) issued at or prior to the Applicable Time, the Pricing Prospectus (as defined below), and the information included on Schedule IV hereto, all considered together (collectively, the "General Disclosure Package"), nor (ii) any individual Issuer Limited Use Free Writing Prospectus (as defined below), when considered together with the General Disclosure Package, nor (iii) any Written Testing-the-Waters Communication, when considered together with the General Disclosure Package, included any untrue statement of a material fact or omitted to state any material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading. The preceding sentence does not apply to statements in or omissions from the General Disclosure Package based upon and in conformity with written information furnished to the Company by or on behalf of any Underwriter through the Representatives specifically for use therein, it being understood and agreed that the only such information furnished by or on behalf of any Underwriter consists of the Underwriters' Information.

As used in this subsection and elsewhere in this Agreement:

"Applicable Time" means __:__ [a.m.][p.m.] (New York City Time) on _____, 2018 or such other time as agreed by the Company and the Representative(s).

"Issuer Free Writing Prospectus" means any "issuer free writing prospectus," as defined in Rule 433 of the Rules and Regulations, relating to the Shares that (i) is required to be filed with the Commission by the Company, (ii) is a "written communication that is a road show" within the meaning of Rule 433(d)(8)(i), whether or not required to be filed with the Commission or (iii) is exempt from filing pursuant to Rule 433(d)(5)(i) because it contains a description of the Shares or of the offering that does not reflect the final terms, in each case in the form filed or required to be filed with the Commission or, if not required to be filed, in the form retained in the Company's records pursuant to Rule 433(g); *provided*, *however*, that a Written Testing-the-Waters Communication shall be deemed not to be an Issuer Free Writing Prospectus.

"Issuer General Use Free Writing Prospectus" means any Issuer Free Writing Prospectus that is intended for general distribution to prospective investors, as evidenced by its being specified in Schedule II hereto.

"Issuer Limited Use Free Writing Prospectus" means any Issuer Free Writing Prospectus that is not an Issuer General Use Free Writing Prospectus.

"Pricing Prospectus" means, as of any time, the preliminary prospectus relating to the Shares that is included in the Registration Statement immediately prior to such time, including any document incorporated by reference therein.

(f) *Issuer Free Writing Prospectuses.* Each Issuer Free Writing Prospectus, as of its issue date and at all subsequent times through the Prospectus Delivery Period (as defined below), does not include any information that conflicts with the information contained in the Registration Statement. The foregoing sentence does not apply to statements in or omissions from any Issuer Free Writing Prospectus based upon and in conformity with the Underwriters' Information. If at any time following the issuance of an Issuer Free Writing Prospectus there occurred or occurs an event or development as a result of which such Issuer Free Writing Prospectus conflicted or would conflict with the information contained in the Registration Statement relating to the Shares or included or would include an untrue statement of a material fact or omitted or would omit to state a material fact necessary in order to make the statements therein, in light of such circumstances, not misleading, the Company has promptly notified or will promptly notify the Representatives and has promptly amended or will promptly amend or supplement, at its own expense, such Issuer Free Writing Prospectus to eliminate or correct such conflict, untrue statement, or omission. This subsection (f) does not apply to statements in or omissions from any Issuer Free Writing Prospectus in reliance upon and in conformity with written information furnished to the Company by any Underwriter through the Representatives specifically for use therein, it being understood and agreed that the only such information furnished by or on behalf of any Underwriter consists of the Underwriters' Information.

(g) *Distribution of Offering Material by the Company.* The Company has not distributed and will not distribute, prior to the later of the Closing Date, any Option Closing Date and the completion of the Underwriters' distribution of the Shares, any offering material in connection with the offering or sale of the Shares other than any Testing-the-Waters Communication made in compliance with Section 3(xx) hereof, the Registration Statement, any preliminary prospectus, the Permitted Free Writing Prospectuses reviewed and reasonably and timely consented to by the Representatives and included in Schedule II hereto, and the Prospectus.

(h) *Due Incorporation; Subsidiaries*.

(i) The Company is, and at the Closing Date will be, a corporation duly organized, validly existing and in good standing under the laws of its jurisdiction of incorporation. The Company has, and at the Closing Date will have, full power and authority to conduct all the activities conducted by it, to own or lease all the assets owned or leased by it and to conduct its business as described in the Registration Statement, the General Disclosure Package and the Prospectus. The Company is, and at the Closing Date will be, duly licensed or qualified to do business in and in good standing as a foreign corporation in all jurisdictions in which the nature of the activities conducted by it or the character of the assets owned or leased by it makes such licensing or qualification necessary, except where the failure to be so qualified or in such good standing would not, individually or in the aggregate, (i) have a material adverse effect on the business, properties, assets, management, business prospects, condition (financial or otherwise), results of operations or capitalization of the Company, or (ii) prevent or materially interfere with the consummation of the transactions contemplated hereby or the performance by the Company of its obligations hereunder (any such effect, prevention or interference, a "Material Adverse Effect").

(ii) The Company does not have any subsidiaries.

(i) *Capitalization.* The authorized, issued and outstanding capital stock of the Company is as set forth in the Registration Statement, the General Disclosure Package and the Prospectus under the caption "Capitalization." The outstanding shares of Common Stock and any other outstanding capital stock of the Company have been, and the Shares will be, duly authorized, validly issued, fully paid and non-assessable and will not be subject to any preemptive, first refusal, or similar right. The description of the Common Stock included in the Registration Statement, the General Disclosure Package and the Prospectus is now, and at the Closing Date will be, complete and accurate in all material respects. Except as set forth in the Registration Statement, the General Disclosure Package and the Prospectus, the Company does not have outstanding, and at the Closing Date and any Option Closing Date will not have outstanding, any options to purchase, or any rights or warrants to subscribe for, or any securities or obligations convertible into, or any contracts or commitments to issue or sell, any shares of capital stock of the Company or any such warrants, convertible securities or obligations. There are no stockholder agreements, voting agreements or other similar agreements with respect to the Company's capital stock to which the Company is a party or to or between or among any of the Company's stockholders. Upon the issuance and delivery pursuant to the terms of this Agreement, the Underwriters will acquire good and marketable title to the Shares, free and clear of any lien, charge, claim, encumbrance, pledge, security interest, defect or other restriction or equity of any kind whatsoever.

(j) *Financial Statements.* The financial statements of the Company (including the related notes thereto) and schedules included in the Registration Statement, the General Disclosure Package and the Prospectus present fairly in all material respects the financial condition of the Company as of the respective dates thereof and their results of operations and cash flows for the respective periods covered thereby, all in conformity with generally accepted accounting principles applied in the United States on a consistent basis throughout the entire period involved. The selected financial data and the summary financial information included in the Registration Statement, the General Disclosure Package and the Prospectus present fairly in all material respects the information shown therein and have been compiled on a basis consistent with that of the financial statements included therein and the books and records of the Company. The pro forma financial statements, if any, and the other pro forma financial information included in the Registration Statement, the General Disclosure Package and the Prospectus present fairly in all material respects the information shown therein, have been prepared in accordance with the Commission's rules and guidelines with respect to pro forma financial statements and have been properly computed on the bases described therein. The assumptions used in the preparation of the pro forma financial statements, if any, and other pro forma financial information included in the Registration Statement, the General Disclosure Package and the Prospectus are reasonable and the adjustments used therein are appropriate to give effect to the transactions or circumstances referred to therein. No other financial statements, schedules or reconciliations of "non-GAAP financial measures" (as such term is defined by the rules and regulations of the Commission) of the Company are required by the Act or the Rules and Regulations to be included in the Registration Statement, the General Disclosure Package and the Prospectus.

(k) *Independent Accountants*. KPMG LLP (the "Accountants"), who certified the financial statements and supporting schedules of the Company included in the Registration Statement, the General Disclosure Package and the Prospectus, are (i) independent accountants as required by the Act and the Rules and Regulations and by the rules of the Public Company Accounting Oversight Board (United States) (the "PCAOB"), (ii) in compliance with the applicable requirements relating to the qualification of accountants under Rule 2-01 of Regulation S-X under the Act, and (iii) a registered public accounting firm as defined by the PCAOB whose registration has not been suspended or revoked and who has not requested such registration to be withdrawn.

(l) *No Material Adverse Changes.* Since the respective dates as of which information is given in the Registration Statement and the Prospectus and prior to the Closing Date and any Option Closing Date, except as set forth in the Registration Statement, the General Disclosure Package and the Prospectus, (i) there has not been any change in the capital stock or long-term debt of the Company or any material adverse change, or any development that would be expected to result in a material adverse change, in or affecting the business, properties, assets, management, business prospects, condition (financial or otherwise), earnings, rights, results of operations or capitalization of the Company arising for any reason whatsoever (a "Material Adverse Change"), (ii) the Company has not incurred, nor will it incur, any material liabilities or obligations, direct or contingent, nor has it entered into, nor will it enter into, any material transactions not in the ordinary course of business, other than pursuant to this Agreement and the transactions referred to herein, (iii) the Company has not and will not have paid or declared any dividends or other distributions of any kind on any class of its capital stock, (iv) the Company has not sustained any material loss or interference with its business from fire, explosion, flood or other calamity, whether or not covered by insurance, or from any labor disturbance or dispute or any action, order or decree of any court or arbitrator or governmental or regulatory authority, except in each case as otherwise disclosed in each of the Registration Statement, the General Disclosure Package and the Prospectus, and (v) the Company has not altered its method of accounting.

(m) *Investment Company*. The Company is not and, after giving effect to the issuance and sale of the Shares and the use of the proceeds therefrom as described in the General Disclosure Package and the Prospectus, will not be, an "investment company" or an entity "controlled" by an "investment company," as such terms are defined in the Investment Company Act of 1940, as amended, and the rules and regulations of the Commission promulgated thereunder.

(n) *Litigation.* Except as set forth in the Registration Statement, the General Disclosure Package and the Prospectus, there are no actions, suits or proceedings pending, or to the Company's knowledge, threatened against or affecting, the Company or any of its officers in their capacity as such, before or by any foreign, federal or state court, commission, regulatory body, including the Financial Industry Regulatory Authority, Inc. ("FINRA") and the Nasdaq Stock Market LLC, administrative agency or other governmental body, domestic or foreign, wherein an unfavorable ruling, decision or finding could reasonably be expected to result in a Material Adverse Effect. Except as set forth in the Registration Statement, the General Disclosure Package and the Prospectus, the Company has not received any written notice of proceedings relating to the revocation or modification of any authorization, approval, order, license, certificate, franchise or permit, where such revocation or modification would reasonably be expected to result in a Material Adverse Effect. There are no pending investigations known to the Company involving the Company by any governmental agency having jurisdiction over the Company or its business or operations that would reasonably be expected to result in a Material Adverse Effect.

(o) *Compliance with Laws and Regulations and Performance of Obligations and Contracts.* The Company has, and at the Closing Date and any Option Closing Date will have, (i) complied in all material respects with all laws, regulations and orders applicable to it or its business and (ii) performed all obligations required to be performed by it, and is not, and at the Closing Date will not be, in default under any indenture, mortgage, deed of trust, voting trust agreement, loan agreement, bond, debenture, note agreement, lease or other agreement or instrument (individually, a "Contract" and collectively, "Contracts") to which it is a party or by which its property is bound or affected, except, with respect to this clause (ii), where any non-performance or default would not reasonably be expected to result in a Material Adverse Effect. To the knowledge of the Company, no other party under any Contract to which it is a party is in default in any respect thereunder or has given written or oral notice to the Company or any of its officers or directors of such other party's intention to terminate, cancel or refuse to renew any Contract. The Company is not now, and at the Closing Date will not be, in violation of any provision of its certificate of incorporation or by-laws. The disclosures included in the Registration Statement, the General Disclosure Package and the Prospectus concerning the effects of federal, state, local and foreign laws, rules and regulations on the business of the Company as currently conducted and as proposed to be conducted are correct in all material respects.

(p) *No Consent of Governmental Body Needed.* No consent, approval, authorization, license, registration, qualification or order of, or any filing or declaration with, any court or arbitrator or governmental or regulatory authority, agency or body is required in connection with the authorization, issuance, transfer, sale or delivery of the Shares by the Company, in connection with the execution, delivery and performance of this Agreement by the Company or in connection with the taking by the Company of any action contemplated hereby, except as have been obtained under the Act and such as may be required under state securities or Blue Sky laws or the by-laws and rules of FINRA, or the Nasdaq Stock Market LLC in connection with the purchase and distribution by the Underwriters of the Shares to be sold by the Company.

(q) *Agreement Duly Authorized.* The Company has full corporate power and authority to enter into this Agreement. This Agreement has been duly authorized, executed and delivered by the Company.

(r) *No Conflicts.* The execution and delivery by the Company of this Agreement and the performance of this Agreement, the consummation of the transactions contemplated hereby, and the application of the net proceeds from the offering and sale of the Shares to be sold in the manner set forth in the General Disclosure Package and the Prospectus under "Use of Proceeds" do not and will not (i) violate the certificate of incorporation or by-laws of the Company or (ii) result in the creation or imposition of any lien, charge or encumbrance upon any of the assets of the Company pursuant to the terms or provisions of, or result in a breach or violation of any of the terms or provisions of, or constitute a default under, or give any other party a right to terminate any of its obligations under, or result in the acceleration of any obligation under any Contract to which the Company is a party or by which the Company or any of its properties is bound or affected, or violate or conflict with any judgment, ruling, decree, order, law, statute, rule or regulation of any court or other governmental agency or body applicable to the business or properties of the Company, except, in the case of clause (ii), as would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect.

(s) *Title to Real and Personal Property.* The Company has good and marketable title to all properties and assets described in the Registration Statement, the General Disclosure Package and the Prospectus as being owned by it, free and clear of all liens, charges, encumbrances or restrictions, except as set forth in the Registration Statement, the General Disclosure Package and the Prospectus or those where the failure to have such title would not have, individually or in the aggregate, have a Material Adverse Effect. The Company has valid, subsisting and enforceable leases for the properties described in the General Disclosure Package and the Prospectus as leased by it, with such exceptions as are not material and do not materially interfere with the use made and proposed to be made of such properties by the Company.

(t) *Documents Described in Registration Statement.* There is no document or Contract of a character required to be described in the Registration Statement, the General Disclosure Package and the Prospectus or to be filed as an exhibit to the Registration Statement that is not described or filed as required. All such documents and Contracts described in the Registration Statement, General Disclosure Package and the Prospectus or filed as an exhibit to the Registration Statement were duly authorized, executed and delivered by the Company, constitute valid and binding agreements of the Company and are enforceable against the Company in accordance with the terms thereof.

(u) *No Untrue Statement; Statistical and Market Data.* No statement, representation, warranty or covenant made by the Company in this Agreement or made in any certificate or document required by this Agreement to be delivered to Representatives was or will be, when made, inaccurate, untrue or incorrect. All statistical or market-related data included in the Registration Statement, the General Disclosure Package and the Prospectus are based on or derived from sources that the Company believes to be reliable and accurate in all material respects, and the Company has obtained the written consent to the use of such data from such sources to the extent required.

(v) *No Price Stabilization or Manipulation.* Neither the Company nor any of its directors, officers or controlling persons has taken, directly or indirectly, any action intended to cause or result in, or which might reasonably be expected to cause or result in, or which has constituted, stabilization or manipulation, under the Act or otherwise, of the price of any security of the Company to facilitate the sale or resale of the Shares.

(w) *No Registration Rights.* Except as disclosed in the Registration Statement, the General Disclosure Package and the Prospectus, no holder of securities of the Company has rights to register any securities of the Company because of the filing of the Registration Statement, the Prospectus or the offering of the Shares, except for rights that have been duly waived by such holder, have expired or have been fulfilled by registration prior to the date of this Agreement.

(x) *Stock Exchange Listing.* The Shares have been approved for listing on the the Nasdaq Global Market, subject only to official notice of issuance.

(y) *Labor Matters.* The Company is not involved in any labor dispute except, where the dispute would not, individually or in the aggregate, have a Material Adverse Effect, nor, to the knowledge of the Company, is any such dispute threatened.

(z) *No Unlawful Payments*. Neither the Company, nor any of its directors or officers, nor, to the Company's knowledge, any agent, employee or representative of the Company or its affiliates or other person associated with or acting on behalf of the Company, has (i) used any corporate funds for any unlawful contribution, gift, entertainment or other unlawful expense relating to political activity; (ii) made or taken an act in furtherance of an offer, promise or authorization of any direct or indirect unlawful payment of corporate funds or benefit to any foreign or domestic government or regulatory official or employee, including, without limitation, of any government-owned or controlled entity or of a public international organization, or any person acting in an official capacity for or on behalf of any of the foregoing, or any political party or party official or candidate for political office; (iii) taken any action, directly or indirectly, that would result in a violation of any provision of the U.S. Foreign Corrupt Practices Act of 1977, as amended, (the "FCPA), the U.K. Bribery Act 2010, or any applicable law or regulation implementing the OECD Convention on Combating Bribery of Foreign Public Officials in International Business Transactions, or committed an offense under any other applicable anti-bribery or anti-corruption laws; or (iv) made, offered, agreed, requested or taken an act in furtherance of any unlawful bribe or other unlawful benefit, including, without limitation, any rebate, payoff, influence payment, kickback or other unlawful or improper payment or benefit. The Company and, to the knowledge of the Company, its affiliates have conducted their businesses in compliance with the FCPA and have instituted, maintained and enforced, and will continue to maintain and enforce policies and procedures designed to promote and ensure compliance with all applicable anti-bribery and anti-corruption laws.

(aa) *Compliance with Anti-Money Laundering Laws*. The operations of the Company are and have been conducted at all times in compliance with applicable financial recordkeeping and reporting requirements, including those of the Currency and Foreign Transactions Reporting Act of 1970, as amended, those of the Bank Secrecy Act, as amended by Title III of the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001 (USA PATRIOT Act), and the applicable anti-money laundering statutes of all jurisdictions in which the Company conducts business, the rules and regulations thereunder and any related or similar rules, regulations or guidelines, issued, administered or enforced by any governmental or regulatory agency (collectively, the "Anti-Money Laundering Laws"), and no action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company with respect to the Anti-Money Laundering Laws is pending or, to the knowledge of the Company, threatened.

(bb) *No Conflicts with Sanctions Laws*. Neither the Company nor any director or officer of the Company, nor, to the knowledge of the Company, any agent, employee or representative of the Company, affiliate or other person associated with or acting on behalf of the Company is currently the subject or target of any sanctions administered or enforced by the U.S. government (including, without limitation, the Office of Foreign Assets Control of the U.S. Treasury Department ("OFAC") or the U.S. Department of State and including, without limitation, the designation as a "specially designated national" or "blocked person"), the United Nations Security Council, the European Union, Her Majesty's Treasury or other relevant sanctions authority (collectively, "Sanctions"), nor is the Company located, organized or resident in a country or territory that is the subject or the target of Sanctions, including, without limitation, Cuba, Iran, North Korea, the Crimean region and Syria (each, a "Sanctioned Country"); and the Company will not directly or indirectly use the proceeds of the offering of the Shares hereunder, or lend, contribute or otherwise make available such proceeds to any subsidiary, joint venture partner or other person or entity (i) to fund or facilitate any activities of or business with any person that, at the time of such funding or facilitation, is the subject or the target of Sanctions, (ii) to fund or facilitate any activities of or business in any Sanctioned Country or (iii) in any other manner that will result in a violation by any person (including any person participating in the transaction, whether as underwriter, advisor, investor or otherwise) of Sanctions. For the past five years, the Company has not knowingly engaged in, is not now knowingly engaged in, and will not engage in, any dealings or transactions with any person that at the time of the dealing or transaction is or was the subject or the target of Sanctions or with any Sanctioned Country.

(cc) *Taxes.* The Company has filed all federal, state and foreign income and franchise tax returns and has paid all taxes required to be filed or paid by it and, if due and payable, any related or similar assessment, fine or penalty levied against them (except for any such taxes, assessments fines or penalties currently being contested in good faith or in any case in which the failure to file or pay would not have a Material Adverse Effect). The Company has made adequate charges, accruals and reserves in the applicable financial statements referred to in Section 3(j) hereof in respect of all material federal, state and foreign income and franchise taxes for all periods as to which the tax liability of the Company has not been finally determined. The Company is not aware of any material claims against them by any taxing authority in relation to the filing of tax returns or the payment of required taxes.

(dd) *Insurance.* The Company carries, or is covered by, insurance in such amounts and covering such risks as the Company believes are adequate for the conduct of its business and the value of its properties and is customary for companies engaged in similar industries, and all such insurance is in full force and effect. The Company has no reason to believe that it will not be able to (i) renew their existing insurance coverage as and when such policies expire or (ii) obtain comparable coverage from similar institutions as may be necessary or appropriate to conduct their business as currently conducted or proposed to be conducted and at a cost that would not, individually or in the aggregate, result in a Material Adverse Effect. The Company has not been denied any insurance coverage which it has sought or for which it has applied.

(ee) *Defined Benefit Plans.* The Company has not maintained or contributed to a defined benefit plan as defined in Section 3(35) of the Employee Retirement Income Security Act of 1974, as amended ("ERISA"). No plan maintained or contributed to by the Company that is subject to ERISA (an "ERISA Plan") (or any trust created thereunder) has engaged in a "prohibited transaction" within the meaning of Section 406 of ERISA or Section 4975 of the Internal Revenue Code of 1986, as amended (the "Code") that could subject the Company to any material tax penalty on prohibited transactions and that has not adequately been corrected. Each ERISA Plan is in compliance in all material respects with all reporting, disclosure and other requirements of the Code and ERISA as they relate to such ERISA Plan, except for any noncompliance which would not result in the imposition of a material tax or monetary penalty. With respect to each ERISA Plan that is intended to be "qualified" within the meaning of Section 401(a) of the Code, either (i) a determination letter has been issued by the Internal Revenue Service stating that such ERISA Plan and the attendant trust are qualified thereunder, or (ii) the remedial amendment period under Section 401(b) of the Code with respect to the establishment of such ERISA Plan has not ended and a determination letter application will be filed with respect to such ERISA Plan prior to the end of such remedial amendment period. The Company has never completely or partially withdrawn from a "multiemployer plan," as defined in Section 3(37) of ERISA.

(ff) *Title to Intellectual Property*. Except as set forth in the Registration Statement, the General Disclosure Package and the Prospectus, the Company owns, has valid and enforceable licenses for or otherwise has adequate rights to use all technology (including but not limited to patented, patentable and unpatented inventions and unpatentable proprietary or confidential information, systems or procedures), designs, processes, patents, trademarks, service marks, trade secrets, trade names, know how, copyrights and other works of authorship, computer programs, technical data and information and all similar intellectual property or proprietary rights (including all registrations and applications for registration of, and all goodwill associated with, any of the foregoing, as applicable) (collectively, "Intellectual Property") that are or could reasonably be expected to be material to their business as currently conducted or as proposed to be conducted, including the development, manufacture, operation and sale of any of the Company's products or product candidates, as described in the Registration Statement, the General Disclosure Package or the Prospectus, except where the failure to own, license or otherwise have rights to such Intellectual Property would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect. Except as disclosed in the Registration Statement, the General Disclosure Package and the Prospectus, the Intellectual Property of the Company has not been adjudged by a court or other administrative body of competent jurisdiction invalid or unenforceable in whole or in part, except as would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect. Except as disclosed in the Registration Statement, the General Disclosure Package and the Prospectus, (i) to the knowledge of the Company, there are no third parties who have, or will be able to establish, rights to any Intellectual Property owned by or licensed to the Company, except for, and to the extent of, the rights of any third parties that are licensees of such Intellectual Property; (ii) to the Company's knowledge, there is no infringement, misappropriation or other violation by third parties of any Intellectual Property owned by, or licensed to, the Company; (iii) there is no pending or, to the knowledge of the Company, threatened action, suit, proceeding or claim by others against the Company challenging the Company's rights in or to any Intellectual Property owned by, or licensed to, the Company, and the Company is unaware of any facts which could form a reasonable basis for any such action, suit, proceeding or claim; (iv) there is no pending or, to the knowledge of the Company, threatened action, suit, proceeding or claim by others against the Company challenging the validity, enforceability or scope of any Intellectual Property owned by, or licensed to, the Company, and the Company is unaware of any facts which could form a reasonable basis for any such action, suit, proceeding or claim; (v) there is no pending or, to the knowledge of the Company, threatened action, suit, proceeding or claim by others against the Company that (nor has the Company received any written claim from a third party that) the Company infringed, misappropriated or otherwise violated, or is infringing, misappropriating or otherwise violating, any intellectual property rights of others, and the Company is unaware of any facts which could form a reasonable basis for any such action, suit, proceeding or claim; (vi) the Company has complied with and there has been no breach or default by the Company under the terms of each agreement pursuant to which Intellectual Property has been licensed to the Company, and all such agreements are in full force and effect; and (vii) all of the Company's products or product candidates as described in the Registration Statement, the General Disclosure Package or the Prospectus are covered by one or more claims of at least one issued patent or pending patent application owned by, or exclusively licensed to, the Company, except, in each case of (i) through (vii), as would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect. Except as set forth in the Registration Statement, the General Disclosure Package and the Prospectus, the Company is not obligated or under any liability whatsoever to make any material payment by way of royalties, fees or otherwise to any owner or licensee of, or other claimant to, any Intellectual Property, with respect to the use thereof or in connection with the conduct of its businesses or otherwise.

(gg) *Trademarks.* The Company owns, licenses or otherwise has the full exclusive right to use, all material trademarks and trade names that are used in or reasonably necessary for the conduct of its business as described in the Registration Statement, the General Disclosure Package and the Prospectus, except where the failure to own, license or otherwise have rights to such trademarks and tradenames would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect. The Company has not received any written notice of infringement of or conflict with asserted rights of others with respect to any such trademarks or trade names, or challenging or questioning the validity or effectiveness of any such trademark or trade name. To the Company's knowledge, the use of such trademarks and trade names in connection with the business and operations of the Company does not infringe on the rights of any person. Except as set forth in the Registration Statement, the General Disclosure Package and the Prospectus, the Company is not obligated or under any liability whatsoever to make any material payment by way of royalties, fees or otherwise to any owner or licensee of, or other claimant to, any trademark, service mark or trade name with respect to the use thereof or in connection with the conduct of its business or otherwise.

(hh) *Protection of Intellectual Property.* The Company has taken reasonable security measures to protect the secrecy, confidentiality and value of all its Intellectual Property in all material aspects, including, but not limited to complying with all duty of disclosure requirements before the U.S. Patent and Trademark Office and any other non-U.S. Patent Offices as appropriate.

(ii) *Related Party Transactions.* There are no business relationships or related party transactions involving the Company or any other person required to be described in the General Disclosure Package and the Prospectus that have not been described. Without limiting the generality of the immediately preceding sentence, no relationship, direct or indirect, exists between or among the Company on the one hand, and the directors, officers, stockholders, customers or suppliers of the Company on the other hand, that is required to be described in the General Disclosure Package and the Prospectus and that is not so described. Since inception, the Company has not, directly or indirectly, extended or maintained credit, arranged to extend credit, or renewed any extension of credit, in the form of a personal loan, to or for any director or executive officer of the Company, or to or for any family member or affiliate of any director or executive officer of the Company in violation of applicable laws, including Section 13(k) of the Securities Exchange Act of 1934, as amended (the "Exchange Act").

(jj) *Environmental Matters.* (a) (i) The Company is and has been in compliance with, and is not subject to any pending, or to the knowledge of the Company, threatened costs or liability under, any and all applicable federal, state, local and non-U.S. statutes, laws, rules, regulations, ordinances, codes, other requirements or rules of law (including common law) and applicable and binding judicial or administrative decisions or orders, relating to pollution, the generation, use, handling, transportation, treatment, storage, discharge, disposal or release of hazardous substances, the protection or restoration of the environment, human health and safety, noise or the protection of natural resources, including wildlife, migratory birds, eagles or endangered or threatened species or habitats (collectively, "Environmental Laws") and to the knowledge of the Company, no facts or circumstances currently exist that would reasonably be expected to result in such non-compliance, cost or liability, (ii) the Company does not own or, to the knowledge of the Company, occupy, operate, lease or use any real property contaminated with Hazardous Substances in violation of Environmental Laws, (iii) the Company is not conducting or funding any investigation, remediation, remedial action or monitoring of actual or suspected Hazardous Substances in the environment, (iv) to the knowledge of the Company, the Company is not subject to any pending or threatened liability for any release or threatened release of Hazardous Substances, including at any off-site treatment, storage or disposal site, (v) the Company is not subject to any written claim, action, suit, order, demand or notice by any governmental agency or governmental body or person alleging liability or violation relating to Environmental Laws or Hazardous Substances, (vi) the Company has received and is in compliance with all, and has received no written claim of liability under any, permits, licenses, authorizations, identification numbers or other approvals required under applicable Environmental Laws to conduct its business, as currently conducted, and (vii) to the knowledge of the Company, there are no new requirements applicable to the conduct of the Company's business, as currently conducted, proposed for adoption or implementation under any Environmental Law, except in each case covered by clauses (i) – (vii) such as would not individually or in the aggregate reasonably be expected to result in a Material Adverse Effect; (b) except as set forth in the Registration Statement, the General Disclosure Package and the Prospectus, there are no judicial or administrative proceedings that are pending, or known to be contemplated, against the Company pursuant to any Environmental Laws by a governmental authority, other than such proceedings for which it is reasonably believed no monetary sanctions of $100,000 or more will be imposed; and (c) except as set forth in the Registration Statement, the General Disclosure Package and the Prospectus, the Company has not incurred, and does not currently anticipate incurring, any costs or expenditures (including capital expenditures) required under or pursuant to Environmental Laws that would reasonably be expected to have a material effect on the capital expenditures, earnings or competitive position of the Company. For purposes of this subsection, "Hazardous Substances" means (A) petroleum and petroleum products, by-products or breakdown products, radioactive materials, asbestos-containing materials, polychlorinated biphenyls and mold, and (B) any other chemical, material or substance defined as toxic or hazardous or as a pollutant, contaminant or waste or words of similar import, or regulated or that can form the basis for liability, under Environmental Laws.

(kk) [Reserved.]

(ll) [Reserved.]

(mm) *Controls and Procedures.*

(i) *Disclosure Controls and Procedures.* The Company has established and maintains disclosure controls and procedures (as such term is defined in Rules 13a-15 and 15d-15 under the Exchange Act) that (A) are designed to ensure that material information relating to the Company is made known to the Company's principal executive officer and its principal financial officer by others within those entities, particularly during the periods in which the periodic reports required under the Exchange Act are being prepared; (B) provide for the periodic evaluation of the effectiveness of such disclosure controls and procedures as of the end of the period covered by the Company's most recent annual or quarterly report filed with the Commission; and (C) are effective in all material respects to perform the functions for which they were established.

(ii) *Internal Accounting Controls*. The Company maintains a system of internal accounting controls sufficient to provide reasonable assurance that (A) transactions are executed in accordance with management's general or specific authorizations; (B) transactions are recorded as necessary to permit preparation of financial statements in conformity with generally accepted accounting principles and to maintain asset accountability; (C) access to assets is permitted only in accordance with management's general or specific authorization; and (D) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences.

(iii) *No Material Weakness in Internal Controls*. Since the end of the Company's most recent audited fiscal year, there has been (A) no material weakness (as defined in Rule 1-02 of Regulation S-X of the Commission) in the Company's internal control over financial reporting (whether or not remediated) and (B) no change in the Company's internal control over financial reporting that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting. The Company is not aware of (x) any significant deficiency in the design or operation of its internal control over financial reporting which is reasonably likely to adversely affect the Company's ability to record, process, summarize and report financial data or any material weaknesses in its internal controls, except as disclosed in the Registration Statement, the General Disclosure Package and the Prospectus, since the end of the Company's most recent audited fiscal year; or (y) any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's internal controls.

(nn) *Off-Balance Sheet Transactions.* Except as described in the Registration Statement, the General Disclosure Package and the Prospectus, there are no off-balance sheet transactions (including, without limitation, transactions related to, and the existence of, "variable interest entities" within the meaning of Financial Accounting Standards Board Accounting Standards Codification Topic 810), arrangements, obligations (including contingent obligations), or any other relationships with unconsolidated entities or other persons, that may have a material current or future effect on the Company's financial condition, changes in financial condition, results of operations, liquidity, capital expenditures, capital resources, or significant components of revenues or expenses.

(oo) *Audit Committee.* The Company's Board of Directors has validly appointed an audit committee whose composition satisfies the requirements of Section 10A of, and Rule 10A-3 under, the Exchange Act and the Board of Directors and/or the audit committee has adopted a charter that satisfies the requirements of Section 10A of, and Rule 10A-3 under, the Exchange Act. The audit committee has reviewed the adequacy of its charter within the past twelve months. Neither the Board of Directors nor the audit committee has been informed, nor is any director of the Company aware, of (i) any significant deficiency in the design or operation of the Company's internal control over financial reporting which is reasonably likely to adversely affect the Company's ability to record, process, summarize and report financial data or any material weakness in the Company's internal controls; or (ii) any fraud, whether or not material, that involves management or other employees of the Company who have a significant role in the Company's internal controls.

(pp) *Sarbanes-Oxley.* The Company is, and after giving effect to the offering and sale of the Shares will be, in compliance in all material respects with all applicable effective provisions of the Sarbanes-Oxley Act of 2002 and the rules and regulations of the Commission promulgated thereunder.

(qq) *Accurate Disclosure*. The statements included in the Registration Statement, the General Disclosure Package and the Prospectus under the captions "Business – Legal Proceedings," "Business – Intellectual Property," "Business – Government Regulation," "Risk Factors – Risk Related to Regulatory Approval," "Risk Factors – Risks Related to Our Intellectual Property," "Material United States Federal Income Tax Considerations for Non-U.S. Holders," "Description of Capital Stock," "Shares Eligible for Future Sale" and "Underwriting" (other than, in each case, the Underwriter Information) and the statements in the Registration Statement under Items 14 and 15 thereof, insofar as such statements contain descriptions of the terms of statutes, rules, regulations or legal or governmental proceedings, or contracts or other documents, are fair and accurate in all material respects.

(rr) *Clinical Trials*. The pre-clinical studies and clinical trials conducted by or, to the knowledge of the Company, on behalf of or sponsored by the Company, or in which the Company has participated, that are described in, or the results of which are referred to in, the Registration Statement, the General Disclosure Package, the Prospectus or any Written Testing-the-Waters Communication were and, if still pending, are being conducted in accordance with protocols filed with the appropriate regulatory authorities for each such study or trial, as the case may be, and with standard medical and scientific research standards and procedures, all applicable statutes, all applicable rules and regulations of the United States Food and Drug Administration (the "FDA") and comparable regulatory agencies outside of the United States to which they are subject and Good Clinical Practices and Good Laboratory Practices, except to the extent where failure to conduct in such manner would not have a Material Adverse Effect. Each description of the results of such studies and trials contained in the Registration Statement, the General Disclosure Package, the Prospectus or any Written Testing-the-Waters Communication is accurate and complete in all material respects and fairly presents the data derived from such studies and trials, and the Company has no knowledge of any other studies or trials the results of which are inconsistent with, or otherwise call into question, the results described or referred to in the Registration Statement, the General Disclosure Package, the Prospectus or any Written Testing-the-Waters Communication. The Company has not received any written notices, correspondence or other written communications from the FDA or any committee thereof or from any other U.S. or foreign government or drug or medical device regulatory agency (collectively, the "Regulatory Agencies") requiring or, to the Company's knowledge, threatening the termination, suspension or modification of any clinical trials that are described or referred to in the Registration Statement, the General Disclosure Package, the Prospectus or any Written Testing-the-Waters Communication. The Company has operated at all times and currently is in compliance with all applicable statutes, rules and regulations of the Regulatory Agencies except where such failure to operate or non-compliance would not reasonably be expected, individually or in the aggregate, to result in a Material Adverse Effect.

(ss) *Regulatory Filings*. The Company has not failed to file with the Regulatory Agencies any required material filing, declaration, listing, registration, report or submission with respect to any products or product candidates that are described or referred to in the Registration Statement, the General Disclosure Package, the Prospectus or any Written Testing-the-Waters Communication or any other material filing required by any other applicable Regulatory Agency or governmental authority; all such filings, declarations, listings, registrations, reports or submissions were in material compliance with applicable laws when filed; all such filings, declarations, listings, registrations, reports or submissions were timely, complete, accurate and not misleading on the date filed in all material respects (or were corrected or supplemented by subsequent submission); and no material deficiencies regarding compliance with applicable law have been asserted in writing by any applicable regulatory authority with respect to any such filings, declarations, listings, registrations, reports or submissions.

(tt) *Licenses and Permits*. Except as would not, individually or in the aggregate, have a Material Adverse Effect, (i) the Company holds, and is operating in compliance with, such permits, licenses, franchises, registrations, exemptions, approvals, authorizations and clearances of any other governmental authorities (including, without limitation, the FDA) required for the conduct of its business as currently conducted (collectively, the "Permits"), and all such Permits are in full force and effect; and (ii) the Company has fulfilled and performed all of its obligations with respect to the Permits, and, to the Company's knowledge, no event has occurred which allows, or after notice or lapse of time would allow, revocation or termination thereof or results in any other impairment of the rights of the holder of any Permit. All applications, notifications, submissions, information, claims, reports and statistics, and other data and conclusions derived therefrom, utilized as the basis for any and all requests for a Permit from the FDA or other governmental authority relating to the Company, its business and its products, when submitted to the FDA or other governmental authority by or on behalf of the Company, were true, complete and correct in all material respects. Any necessary or required updates, changes, corrections or modification to such applications, notifications, submissions, information, claims, reports and statistics and other data have been submitted to the FDA or other governmental authority, except as would not, individually or in the aggregate, have a Material Adverse Effect. The Company has not received any notification, correspondence or any other written communication, including notification of any pending or, to the Company's knowledge, threatened claim, suit, proceeding, hearing, enforcement, investigation, arbitration or other action from any governmental authority, including, without limitation, the FDA or the United States Drug Enforcement Administration ("DEA"), of potential or actual non-compliance by, or liability of, the Company under any Permits except as would not, individually or in the aggregate, have a Material Adverse Effect. To the Company's knowledge, there are no facts or circumstances that would reasonably be expected to give rise to any liability of the Company under any Permits except as would not, individually or in the aggregate, have a Material Adverse Effect.

(uu) *Compliance with Certain Regulatory Matters*. The Company, its directors and officers, and to the Company's knowledge, its employees and agents have operated and currently are in compliance in all material respects with applicable statutes and implementing regulations administered or enforced by the FDA, the United States Drug Enforcement Administration ("DEA") or any other federal, state, local, or foreign governmental authority, including, without limitation, the federal Food, Drug and Cosmetic Act (21 U.S.C. § 301 et seq.), the federal Anti-kickback Statute (42 U.S.C. § 1320a-7b(b)), the civil False Claims Act (31 U.S.C. §3729 et seq.), the federal False Statements Law (42 U.S.C. § 1320a-7b(a)), the Civil Monetary Penalties Law (42 U.S.C. §1320a-7a), all criminal laws relating to health care fraud and abuse, including, but not limited, to 18 U.S.C. §§ 286 and 287, the exclusions law (42 U.S.C. § 1320a-7), the statutes and regulations of Medicare (Title XVIII of the Social Security Act), Medicaid (Title XIX of the Social Security Act) and all other government funded or sponsored healthcare programs, the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. § 1320d et seq.), as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (42 U.S.C. §17921 et seq.), and all other regulations promulgated pursuant to such laws; and any other similar local, state, federal or foreign law or regulation. The Company is not a party to, and does not have any ongoing reporting obligations pursuant to, any corporate integrity agreement, deferred prosecution agreement, monitoring agreement, consent decree, settlement order, plan of correction or similar agreement imposed by any governmental authority. Neither the Company, nor, to the knowledge of the Company, any of its directors, officers, employees or agents has been debarred, excluded or suspended from participation in or receiving payment from any federal, state or local government health care program or is subject to an audit, investigation, proceeding or other similar action by any governmental authority that could reasonably be expected to result in debarment, suspension or exclusion.

(vv) *Absence of Certain Regulatory Actions*. Except as described in the Registration Statement, the General Disclosure Package and the Prospectus, or as would not, individually or in the aggregate, have a Material Adverse Effect, the Company has not had any product or manufacturing site (whether Company-owned or that of a contract manufacturer for Company products or product candidates) subject to a governmental authority (including, without limitation, the FDA) shutdown or import or export prohibition, nor received any FDA Form 483 or other governmental authority notice of inspectional observations, "warning letters," "untitled letters," requests to make changes to the Company products, processes or operations, or similar written correspondence or notice from the FDA or other governmental authority alleging or asserting material noncompliance with any applicable laws. To the Company's knowledge, neither the FDA nor any other governmental authority has threatened such action. The Company has not received written notice of any claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action from any court, arbitrator, Regulatory Agency or other governmental authority alleging that any product operation or activity is in violation of any health care laws, nor to the Company's knowledge, is any such claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action threatened.

(ww) *Emerging Growth Company Status*. From the time of initial confidential submission of the Registration Statement to the Commission (or, if earlier, the first date on which the Company engaged directly or through any Person authorized to act on its behalf in any Testing-the-Waters Communication) through the date hereof, the Company has been and is an "emerging growth company," as defined in Section 2(a) of the Act (an "Emerging Growth Company").

(xx) *Testing-the-Waters Communications*. The Company (i) has not engaged in any Testing-the-Waters Communication other than Testing-the-Waters Communications with the consent of the Representatives with entities that are qualified institutional buyers within the meaning of Rule 144A under the Act or institutions that are accredited investors within the meaning of Rule 501 under the Act and (ii) has not authorized anyone other than the Representatives to engage in Testing-the-Waters Communications. The Company reconfirms that the Representatives have been authorized to act on its behalf in undertaking Testing-the-Waters Communications. The Company has not distributed or approved for distribution any Written Testing-the-Waters Communications other than those listed on Schedule III hereto. Each Written Testing-the-Waters Communication listed on Schedule III hereto did not, as of the Applicable Time, and at all times through the completion of the public offer and sale of the Shares will not, include any information that conflicted, conflicts or will conflict with the information contained in the Registration Statement, the General Disclosure Package or the Prospectus.

(yy) *Confidential Submission of Registration Statement*. The Company has filed publicly on EDGAR at least 15 calendar days prior to any "road show" (as defined in Rule 433 under the Act), any confidentially submitted registration statement and registration statement amendments relating to the offer and sale of the Shares.

(zz) *No Rating*. The Company has no debt securities or preferred stock that is rated by any "nationally recognized statistical rating organization" (as such term is defined in Section 3(a)(62) of the Exchange Act).

(aaa) *No Broker's Fees*. The Company is not a party to any contract, agreement or understanding with any person (other than (a) fees payable to Brookline Capital Market, a division of CIM Securities, LLC, Lakestreet Capital Markets, LLC and (b) this Agreement) that would give rise to a valid claim against the Company or any Underwriter for a brokerage commission, finder's fee or like payment in connection with the offering and sale of the Shares.

(bbb) *Insolvency*. No event of insolvency has occurred in relation to the Company, nor is there, nor will there be at the Closing Date, any act which has occurred or, to the best of the Company's knowledge, is anticipated to occur which is likely to result in an event of insolvency in relation to the Company.

4. Agreements of the Company. The Company agrees with each Underwriter as follows:

(a) *Amendments and Supplements to Registration Statement.* The Company shall not, either prior to any effective date of the Registration Statement or thereafter during such period as the Prospectus is required under the Act to be delivered (whether physically or through compliance with Rule 172 of the Rules and Regulations or any similar rule) in connection with sales of the Shares by an Underwriter or dealer (the "Prospectus Delivery Period"), amend or supplement the Registration Statement, the General Disclosure Package, the Prospectus or any Written Testing-the-Waters Communications, unless a copy of such amendment or supplement thereof shall first have been submitted to the Representatives within a reasonable period of time prior to the filing or, if no filing is required, the use thereof, and the Representatives shall not have reasonably objected thereto.

(b) *Amendments and Supplements to the Registration Statement, the General Disclosure Package, and the Prospectus and Other Securities Act Matters.* If, during the Prospectus Delivery Period, any event or development shall occur or condition exist as a result of which the General Disclosure Package, the Prospectus or any Written Testing-the-Waters Communication as then amended or supplemented would include any untrue statement of a material fact or omit to state any material fact necessary in order to make the statements therein, in the light of the circumstances then prevailing or under which they were made, as the case may be, not misleading, or if it shall be necessary to, in the judgment of the Company or in the reasonable opinion of the Representatives, amend or supplement the General Disclosure Package, the Prospectus or any Written Testing-the-Waters Communication in order to make the statements therein, in the light of the circumstances then prevailing or under which they were made, as the case may be, not misleading, or if in the opinion of the Representative(s) it is otherwise necessary to amend or supplement the Registration Statement, the General Disclosure Package, the Prospectus or any Written Testing-the-Waters Communication, or to file a new registration statement containing the Prospectus, in order to comply with the Act, the Rules and Regulations, the Exchange Act or the Exchange Act Rules, including in connection with the delivery of the Prospectus, the Company agrees to (i) if applicable, promptly notify the Representatives of any such event or condition and (ii) promptly prepare (subject to Section 4(a) and 4(f) hereof), file with the Commission (and use its reasonable best efforts to have any amendment to the Registration Statement or any new registration statement to be declared effective) and furnish at its own expense to the Underwriters (and, if applicable, to dealers), amendments or supplements to the Registration Statement, the General Disclosure Package, the Prospectus or any Written Testing-the-Waters Communication, or any new registration statement, reasonably necessary in order to make the statements in the General Disclosure Package, the Prospectus or the applicable Written Testing-the-Waters Communication as so amended or supplemented, in the light of the circumstances then prevailing or under which they were made, as the case may be, not misleading or so that the Registration Statement, the General Disclosure Package, the Prospectus or the applicable Written Testing-the-Waters Communication, as amended or supplemented, will comply with the Act, the Rules and Regulations, the Exchange Act or the Exchange Act Rules or any other applicable law.

(c) *Notifications to the Representatives.* The Company shall use its best efforts to cause the Registration Statement to become effective, and shall notify the Representatives promptly, and shall confirm such advice in writing, (i) when the Registration Statement has become effective and when any post-effective amendment thereto becomes effective, (ii) of any request by the Commission for amendments or supplements to the Registration Statement or the Prospectus or for additional information, (iii) of the commencement by the Commission or by any state securities commission of any proceedings for the suspension of the qualification of any of the Shares for offering or sale in any jurisdiction or of the initiation, or the threatening, of any proceeding for that purpose, including, without limitation, the issuance by the Commission of any stop order suspending the effectiveness of the Registration Statement or the initiation of any proceedings for that purpose or the threat thereof, (iv) of the happening of any event during the Prospectus Delivery Period that in the judgment of the Company makes any statement made in the Registration Statement, the Prospectus or any Written Testing-the-Waters Communication misleading (including by omission) or untrue or that requires the making of any changes in the Registration Statement, the Prospectus or any Written Testing-the-Waters Communication in order to make the statements therein, in light of the circumstances in which they are made, not misleading, (v) of receipt by the Company or any representative of the Company of any other communication from the Commission relating to the Company, the Registration Statement, any preliminary prospectus, the Prospectus or any Written Testing-the-Waters Communication and (vi) of any distribution of Written Testing-the-Waters Communication by or on behalf of the Company (other than through any Underwriter). If at any time the Commission shall issue any order suspending the effectiveness of the Registration Statement, the Company shall use best efforts to obtain the withdrawal of such order as soon as possible. The Company shall comply with the provisions of and make all requisite filings with the Commission pursuant to Rules 424(b), 430A, 430B, 430C and 462(b) of the Rules and Regulations and notify the Representatives promptly of all such filings.

(d) *Executed Registration Statement.* The Company shall furnish to the Representatives, without charge, for transmittal to each of the other Underwriters, two signed copies of the Registration Statement and of any post-effective amendment thereto, including financial statements and schedules, and all exhibits thereto, and shall furnish to the Representatives, without charge, for transmittal to each of the other Underwriters, a copy of the Registration Statement and any post-effective amendment thereto, including financial statements and schedules but without exhibits.

(e) *Undertakings.* The Company shall comply with all the provisions of any undertakings contained and required to be contained in the Registration Statement.

(f) *Prospectus.* The Company shall prepare the Prospectus in a form approved by the Representatives and shall file with the Commission such Prospectus pursuant to Rule 424(b) of the Rules and Regulations with a filing date not later than the second business day following the execution and delivery of this Agreement. Promptly after the effective date of the Registration Statement, and thereafter from time to time, the Company shall deliver to each of the Underwriters, without charge, as many copies of the Prospectus and any amendment or supplement thereto as the Representatives may reasonably request. The Company consents to the use of the Prospectus and any amendment or supplement thereto by the Underwriters and by all dealers to whom the Shares may be sold, both in connection with the offering or sale of the Shares and for any period of time thereafter during the Prospectus Delivery Period. If, during the Prospectus Delivery Period any event shall occur that in the judgment of the Company or counsel to the Underwriters should be set forth in the Prospectus in order to make any statement therein, in the light of the circumstances under which it was made, not misleading (including by omission), or if it is necessary to supplement or amend the Prospectus to comply with law, the Company shall forthwith prepare and duly file with the Commission an appropriate supplement or amendment thereto, and shall deliver to each of the Underwriters, without charge, such number of copies thereof as the Representatives may reasonably request.

(g) *Permitted Free Writing Prospectuses.* The Company represents and agrees that it has not made and, unless it obtains the prior consent of the Representatives, will not make, any offer relating to the Shares that would constitute a "free writing prospectus" as defined in Rule 405 of the Rules and Regulations, required to be filed with the Commission or retained by the Company under Rule 433 of the Rules and Regulations; *provided* that the prior written consent of the Representatives hereto shall be deemed to have been given in respect of the Issuer Free Writing Prospectuses included in Schedule II hereto. Any such free writing prospectus consented to by the Representatives is herein referred to as a "Permitted Free Writing Prospectus." The Company agrees that (i) it has treated and will treat, as the case may be, each Permitted Free Writing Prospectus as an Issuer Free Writing Prospectus, and (ii) has complied and will comply, as the case may be, with the requirements of Rules 164 and 433 of the Act applicable to any Permitted Free Writing Prospectus, including in respect of timely filing with the Commission, legending and record keeping. If at any time following the issuance of an Issuer Free Writing Prospectus there occurs an event or development as a result of which such Issuer Free Writing Prospectus would conflict with the information contained in the Registration Statement relating to the Shares or would include an untrue statement of a material fact or would omit to state a material fact necessary in order to make the statements therein, in light of the circumstances prevailing at that subsequent time under which they were made, not misleading, the Company will promptly notify the Representative and will promptly amend or supplement, at its own expense, such Issuer Free Writing Prospectus to eliminate or correct such conflict, untrue statement, or omission. The Company represents that it has satisfied and agrees that it will satisfy the conditions in Rule 433 to avoid a requirement to file with the Commission any electronic road show.

(h) *Compliance with Blue Sky Laws.* Prior to any public offering of the Shares by the Underwriters, the Company shall cooperate with the Representatives and counsel to the Underwriters in connection with the registration or qualification (or the obtaining of exemptions from the application thereof) of the Shares for offer and sale under the securities or Blue Sky laws of such jurisdictions as the Representatives may request, including, without limitation, the provinces and territories of Canada and other jurisdictions outside the United States; *provided*, *however*, that in no event shall the Company be obligated to qualify to do business in any jurisdiction where it is not now so qualified or to take any action which would subject it to general service of process in any jurisdiction where it is not now so subject.

(i) *Delivery of Financial Statements.* Upon request, during the period of two years commencing on the effective date of the Registration Statement applicable to the Underwriters, the Company shall furnish to the Representatives and each other Underwriter who may so request copies of such financial statements and other periodic and special reports as the Company may from time to time distribute generally to the holders of any class of its capital stock, and will furnish to the Representatives and each other Underwriter who may so request a copy of each annual or other report it shall be required to file with the Commission; provided, however, that electronically transmitted copies filed with the Commission pursuant to EDGAR shall satisfy the Company's obligation to furnish copies hereunder.

(j) *Availability of Earnings Statements.* The Company shall make generally available to holders of its securities as soon as may be practicable but in no event later than the last day of the fifteenth full calendar month following the calendar quarter in which the most recent effective date occurs in accordance with Rule 158 of the Rules and Regulations, an earnings statement (which need not be audited but shall be in reasonable detail) for a period of 12 months ended commencing after the effective date of the Registration Statement, and satisfying the provisions of Section 11(a) of the Act (including Rule 158 of the Rules and Regulations).

(k) *Payment of Expenses.* Whether or not any of the transactions contemplated by this Agreement are consummated or this Agreement is terminated, the Company will pay or cause to be paid, or reimburse if paid by the Representatives, all reasonable costs and expenses incident to the performance of the obligations of the Company under this Agreement, including but not limited to: (i) the costs incident to the authorization, issuance, sale, preparation and delivery of the Shares and any Stamp Tax or other taxes payable in connection therewith, (ii) the costs incident to the preparation, printing and filing under the Act of the Registration Statement and exhibits to it, each preliminary prospectus, each Permitted Free Writing Prospectus, the Prospectus, each Written Testing-the-Waters Communications, if any, and any amendment or supplement to the Registration Statement, the Prospectus or any Written Testing-the-Waters Communication, and the distribution thereof, (iii) the costs of preparing, printing and delivering certificates representing the Shares, (iv) the costs of producing and delivering this Agreement, the Agreement Among Underwriters and any other related documents in connection with the offering, purchase, sale and delivery of the Shares, (v) the costs of furnishing (including costs of shipping, mailing and courier) such copies of the Registration Statement, the Prospectus, any preliminary prospectus, any Permitted Free Writing Prospectus and any Written Testing-the-Waters Communication, and all amendments and supplements thereto, as may be reasonably requested for use in connection with the offering and sale of the Shares by the Underwriters or by dealers to whom Shares may be sold, (vi) the costs, fees and expenses of listing the Shares on the Nasdaq Global Market, (vii) the filing fees incident to, and the reasonable and documented the fees and disbursements of counsel to the Underwriters in connection with, the review by FINRA of the terms of the sale of the Shares, (viii) the fees and expenses incident to the registration or qualification of the Shares for offer and sale under the securities or Blue Sky laws of such jurisdictions designated pursuant to Section 4(g) hereof and the securities laws of Canada, including the fees, disbursements and other charges of counsel to the Underwriters in connection therewith, and, if requested by the Representatives, the preparation and printing of preliminary, supplemental and final Blue Sky memoranda and a "Canadian wrapper;" provided, however, that the Company shall not be required to pay or reimburse the Underwriters for fees and disbursements of counsel to the Underwriters in excess of $35,000 in connection with Sections 4(k)(vii) and 4(k)(viii), (ix) the fees and expenses of counsel to the Company, (x) the costs and charges of DTC and the transfer agent for the Shares, (xi) the fees and expenses of the Accountants, (xii) the costs and expenses of the Company relating to investor presentations on any "road show" or any Testing-the-Waters Communication, undertaken in connection with the marketing of the Shares, including, without limitation, all costs and expenses associated with any electronic road show, travel and lodging expenses of the officers, employees, agents and other representatives of the Company and consultants engaged in connection with investor presentations, and the cost of any aircraft and other transportation chartered in connection with the road show provided, however, that the Company shall only be responsible for one-half of the cost and expenses of any aircraft or other transportation chartered in connection with the "road show" for the Securities and the Underwriters shall be responsible for the remaining one-half, and (xiii) all fees, costs and expenses for consultants used by the Company in connection with the offering. Except as provided in this Section 4(k), Section 4(l) and in Section 11, the Underwriters shall pay their own costs and expenses, including the costs and expenses of their counsel.

(l) *Reimbursement of Expenses upon Termination of Agreement.* If for any reason the Company shall be unable to perform its obligations or to fulfill any conditions hereunder or if the Underwriters shall terminate this Agreement pursuant to Section 7 hereof, the Company shall reimburse the Underwriters for all out-of-pocket expenses (including the fees, disbursements and other charges of counsel to the Underwriters) reasonably incurred by them in connection herewith; *provided*, *however*, that the Company shall not be obligated to reimburse the expenses of any defaulting Underwriter under Section 8 hereof.

(m) *No Stabilization or Manipulation.* The Company shall not at any time, directly or indirectly, take any action intended to cause or result in, or which might reasonably be expected to cause or result in, or which will constitute, stabilization or manipulation, under the Act or otherwise, of the price of the shares of Common Stock to facilitate the sale or resale of any of the Shares.

(n) *Use of Proceeds.* The Company shall apply the net proceeds from the offering and sale of the Shares to be sold by the Company in the manner set forth in the General Disclosure Package and the Prospectus under "Use of Proceeds" and shall file such reports with the Commission with respect to the sale of the Shares and the application of the proceeds therefrom as may be required in accordance with Rule 463 under the Act.

(o) *Lock-Up Agreements of Company, Management, Affiliates and Equityholders.* The Company shall not, for a period of 180 days after the date of the Prospectus (the "Lock-Up Period"), without the prior written consent of the Representatives (which consent may be withheld in their sole discretion), (1) 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, or file with the Commission a registration statement under the Act to register, any shares of Common Stock or any securities convertible into or exercisable or exchangeable for Common Stock or warrants or other rights to acquire shares of Common Stock or (2) enter into any swap or other derivatives transaction that transfers to another, in whole or in part, directly or indirectly, any of the economic benefits or risks of ownership of such shares of Common Stock, securities, warrants or other rights to acquire Common Stock, whether any such transaction described in clause (1) or (2) above is to be settled by delivery of Common Stock or other securities, in cash or otherwise, or publicly disclose the intention to enter into any transaction described in clause (1) or (2) above. The foregoing sentence shall not apply to (A) the Shares to be sold hereunder, (B) any shares of Common Stock issued by the Company upon the exercise of an option or warrant or the conversion of a security outstanding on the date hereof and referred to in the Registration Statement, General Disclosure Package and the Prospectus, (C) any shares of Common Stock issued or options to purchase Common Stock granted pursuant to existing employee benefit plans of the Company referred to in the Registration Statement, General Disclosure Package and the Prospectus; (D) the filing of a registration statement on Form S-8 relating to shares of Common Stock granted pursuant to the Company's equity incentive plans existing as of the Closing Date and disclosed in the General Disclosure Package, and (e) shares of Common Stock or any securities convertible into, or exercisable, or exchangeable for, shares of Common Stock issued, sold or delivered in connection with any acquisition or strategic investment (including any joint venture, strategic alliance or partnership) as long as (x) the aggregate number of shares of Common Stock issued or issuable does not exceed 5% of the number of shares of Common Stock outstanding immediately after the completion of the offering of the Shares contemplated herein, and (y) each recipient of any such shares or other securities executes a lock-up agreement restricting the resale of such securities in the form executed by each of the executive officers and directors of the Company for the remainder of the 180-day restricted period. The Company has caused substantially all of its officers, directors and beneficial owners of its capital stock (including stockholders, option holders and other equityholders) to enter into agreements with the Representatives in the form set forth in Exhibit A.

(p) *Lock-Up Releases*. If the Representatives, in their sole discretion, agree to release or waive the restrictions set forth in a lock-up letter described in Section 5(j) hereof for an officer or director of the Company and provides the Company with notice of the impending release or waiver at least three business days before the effective date of the release or waiver, the Company agrees to announce the impending release or waiver by a press release substantially in the form of Exhibit B hereto through a major news service at least two business days before the effective date of such release or waiver.

(q) [Reserved.]

(r) *Emerging Growth Company Status*. The Company shall promptly notify the Representatives if the Company ceases to be an Emerging Growth Company at any time prior to the later of (i) the time when a prospectus relating to the offering or sale of the Shares is not required by the Act to be delivered (whether physically or through compliance with Rule 172 of the Rules and Regulations or any similar rule) and (ii) completion of the Lock-Up Period.

(s) *Transfer Agent*. The Company shall engage and maintain, at its expense, a registrar and transfer agent for the Shares.

5. Conditions of the Obligations of the Underwriters. The obligation of each Underwriter to purchase the Firm Shares on the Closing Date or any Option Shares on the Option Closing Date, as the case may be, as provided herein is subject to the accuracy of the representations and warranties of the Company, the performance by the Company of its covenants and other obligations hereunder and to the following additional conditions:

(a) *Post Effective Amendments and Prospectus Filings.* Notification that the Registration Statement has become effective shall be received by the Representatives not later than 6:00 p.m., New York City time, on the date of this Agreement or at such later date and time as shall be consented to in writing by the Representatives and all filings made pursuant to Rules 424, 430A, 430B or 430C of the Rules and Regulations, as applicable, shall have been made or will be made prior to the Closing Date in accordance with all such applicable rules.

(b) *No Stop Orders, Requests for Information and No Amendments.* (i) No stop order suspending the effectiveness of the Registration Statement shall have been issued and no proceedings for that purpose shall be pending or are, to the knowledge of the Company, threatened by the Commission, (ii) no order suspending the qualification or registration of the Shares under the securities or Blue Sky laws of any jurisdiction shall be in effect and no proceeding for such purpose shall be pending before or threatened or contemplated by the authorities of any such jurisdiction, (iii) any request for additional information on the part of the staff of the Commission or any such authorities shall have been complied with to the satisfaction of the staff of the Commission or such authorities and (iv) after the date hereof no amendment or supplement to the Registration Statement or the Prospectus shall have been filed unless a copy thereof was first submitted to the Representatives and the Representatives did not object thereto in good faith, and the Representatives shall have received certificates, dated the Closing Date and any Option Closing Date and signed by the Chief Executive Officer or the Chairman of the Board of Directors and the Chief Financial Officer of the Company (who may, as to proceedings threatened, rely upon the best of their information and belief), to the effect of clauses (i), (ii) and (iii).

(c) *No Material Adverse Changes.* Since the respective dates as of which information is given in the Registration Statement and the Prospectus, except as set forth in the Registration Statement, the General Disclosure Package and the Prospectus (i) there shall not have been a Material Adverse Change, (ii) the Company shall not have incurred any material liabilities or obligations, direct or contingent, (iii) the Company shall not have entered into any material transactions not in the ordinary course of business other than pursuant to this Agreement and the transactions referred to herein, (iv) the Company shall not have issued any securities (other than the Shares) or declared or paid any dividend or made any distribution in respect of its capital stock of any class or debt (long-term or short-term), and (v) no material amount of the assets of the Company shall have been pledged, mortgaged or otherwise encumbered.

(d) *No Actions, Suits or Proceedings.* Since the respective dates as of which information is given in the Registration Statement, the General Disclosure Package and the Prospectus, there shall have been no actions, suits or proceedings instituted, or to the Company's knowledge, threatened against or affecting, the Company or any of its officers in their capacity as such, before or by any federal, state or local court, commission, regulatory body, administrative agency or other governmental body, domestic or foreign except, where the actions, suits or proceedings would not, individually or in the aggregate, have a Material Adverse Effect.

(e) *All Representations True and Correct and All Conditions Fulfilled.* Each of the representations and warranties of the Company contained herein shall be true and correct at the Closing Date as if made at the Closing Date and any Option Closing Date as if made on such Option Closing Date, as the case may be, and all covenants and agreements contained herein to be performed by the Company and all conditions contained herein to be fulfilled or complied with by the Company at or prior to the Closing Date and any Option Closing Date, shall have been duly performed, fulfilled or complied with.

(f) *Opinions of Counsel to the Company.* The Representatives shall have received the opinions and letters, each dated the Closing Date and any Option Closing Date, as the case may be, from Dechert LLP, counsel to the Company, Hoffmann & Baron, LLP, intellectual property counsel to the Company, Steptoe & Johnson LLP, intellectual property counsel to the Company, and Hyman, Phelps & McNamara, P.C., regulatory counsel to the Company, each in the form and substance satisfactory to the Representatives.

(g) *Opinion of Counsel to the Underwriters.* The Representatives shall have received an opinion, dated the Closing Date and any Option Closing Date, from Cooley LLP, counsel to the Underwriters, with respect to the Registration Statement, the Prospectus and this Agreement, which opinion shall be satisfactory in all respects to the Representatives.

(h) *Accountants' Comfort Letter.* On the date hereof, the Representatives shall have received from the Accountants a letter dated the date of its delivery, addressed to the Representatives, in form and substance reasonably satisfactory to the Representatives, containing statements and information of the type ordinarily included in accountant's "comfort letters" to underwriters, delivered according to Statement of Auditing Standards No. 72 (or any successor bulletin), with respect to the audited and unaudited financial statements and certain financial information contained in the Registration Statement and the Prospectus. At the Closing Date and any Option Closing Date, as the case may be, the Representatives shall have received from the Accountants a letter dated such date, in form and substance reasonably satisfactory to the Representatives, to the effect that they reaffirm the statements made in the letter furnished by them pursuant to the preceding sentence and have conducted additional procedures with respect to certain financial figures included in the Prospectus, except that the specified date referred to therein for the carrying out of procedures shall be no more than three business days prior to the Closing Date or any Option Closing Date, as the case may be.

(i) *Officers' Certificates.* At the Closing Date and any Option Closing Date, as the case may be, there shall be furnished to the Representatives an accurate certificate, dated the date of its delivery, signed by each of the Chief Executive Officer and the Chief Financial Officer of the Company, in form and substance satisfactory to the Representatives, to the effect that:

(i) each signer of such certificate has carefully examined the Registration Statement and the Prospectus;

(ii) there has not been a Material Adverse Change;

(iii) each of the representations and warranties of the Company contained in this Agreement are, at the time such certificate is delivered, true and correct; and

(iv) each of the covenants required herein to be performed by the Company on or prior to the date of such certificate has been duly, timely and fully performed and each condition herein required to be complied with by the Company on or prior to the delivery of such certificate has been duly, timely and fully complied with.

(j) *Lock-Up Agreements.* At the date of this Agreement, the Representatives shall have received the executed "lock-up" agreements referred to in Section 4(o) hereof from the Company's officers, directors and beneficial owners (including stockholders, option holders and other equityholders) owning in the aggregate substantially all of the Company's fully diluted capital stock.

(k) *Compliance with Blue Sky Laws.* The Shares shall be qualified for sale in such states and jurisdictions as the Representatives may reasonably request, and each such qualification shall be in effect and not subject to any stop order or other proceeding on the Closing Date and any Option Closing Date.

(l) *Stock Exchange Listing.* The Shares shall have been duly authorized for listing or quotation on the Nasdaq Global Market, subject only to notice of issuance.

(m) *Good Standing.* At the Closing Date and any Option Closing Date, the Company shall have furnished to the Representatives satisfactory evidence of the good standing of the Company in its jurisdiction of organization and its good standing as a foreign entity in such other jurisdictions as the Representatives may reasonably request, in each case in writing or any standard form of telecommunication from the appropriate governmental authorities of such jurisdictions, except for jurisdictions in which the failure by the Company to be in good standing as a foreign entity would not have a Material Adverse Effect.

(n) *Company Certificates.* The Company shall have furnished to the Representatives such certificates, in addition to those specifically mentioned herein, as the Representatives may have reasonably requested as to the accuracy and completeness at the Closing Date and any Option Closing Date of any statement in the Registration Statement, the Prospectus or any Written Testing-the-Waters Communication, as to the accuracy at the Closing Date and any Option Closing Date of the representations and warranties of the Company herein, as to the performance by the Company of its obligations hereunder, or as to the fulfillment of the conditions concurrent and precedent to the obligations hereunder of the Underwriters.

(n) *No Objection*. FINRA has confirmed that it has not raised any objection with respect to the fairness and reasonableness of the underwriting terms and arrangements relating to the offering of the Shares.

If any of the conditions hereinabove provided for in this Section 5 shall not have been fulfilled when and as required by this Agreement to be fulfilled, the obligations of the Underwriters hereunder may be terminated by the Representatives by notifying the Company of such termination in writing at or prior to the Closing Date or any Option Closing Date, as the case may be.

6. Indemnification.

(a) *Indemnification of the Underwriters.* The Company shall indemnify and hold harmless each Underwriter, its affiliates, the directors, officers, employees, counsel and agents of each Underwriter and each person, if any, who controls each Underwriter within the meaning of Section 15 of the Act or Section 20 of the Exchange Act from and against any and all losses, claims, liabilities, expenses and damages (including any and all investigative, legal and other expenses reasonably incurred in connection with, and any amount paid in settlement of, any action, suit or proceeding between any of the indemnified parties and any indemnifying parties or between any indemnified party and any third party, or otherwise, or any claim asserted), to which they, or any of them, may become subject under the Act, the Exchange Act or other Federal or state statutory law or regulation, at common law or otherwise, insofar as such losses, claims, liabilities, expenses or damages arise out of or are based on (i) any untrue statement or alleged untrue statement of a material fact contained in the Registration Statement (or any amendment thereto), including any information deemed to be a part thereof pursuant to Rules 430A, 430B or 430C, as applicable or the omission or alleged omission therefrom of a material fact required to be stated therein or necessary to make the statements therein not misleading or (ii) any untrue statement or alleged untrue statement of a material fact contained in any preliminary prospectus, any preliminary prospectus supplement, any Issuer Free Writing Prospectus, the Prospectus or any Written Testing-the-Waters Communication (or any amendment or supplement to any of the foregoing) or the omission or alleged omission therefrom of a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading or (iii) any untrue statement or alleged untrue statement of a material fact contained in any materials or information provided to investors by, or with the approval of, the Company in connection with the marketing of the offering of the Shares, including any roadshow or investor presentations made to investors by the Company (whether in person or electronically) or the omission or alleged omission therefrom of a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading; *provided, however*, that the Company shall not be liable to the extent that such loss, claim, liability, expense or damage arises from the sale of the Shares in the public offering to any person by an Underwriter and is based on an untrue statement or omission or alleged untrue statement or omission made in reliance on and in conformity with Underwriters' Information. This indemnity agreement will be in addition to any liability that the Company might otherwise have.

(b) *Indemnification of the Company.* Each Underwriter shall severally and not jointly, indemnify and hold harmless the Company, each person, if any, who controls the Company within the meaning of Section 15 of the Act or Section 20 of the Exchange Act, each director of the Company and each officer of the Company who signs the Registration Statement to the same extent as the foregoing indemnity from the Company to each Underwriter, but only insofar as losses, claims, liabilities, expenses or damages arise out of or are based on any untrue statement or omission or alleged untrue statement or omission made in reliance on and in conformity with Underwriters' Information. This indemnity will be in addition to any liability that each Underwriter might otherwise have.

(c) *Indemnification Procedures.* Any party that proposes to assert the right to be indemnified under this Section 6 shall, promptly after receipt of notice of commencement of any action against such party in respect of which a claim is to be made against an indemnifying party or parties under this Section 6, notify each such indemnifying party of the commencement of such action, enclosing a copy of all papers served, but the omission so to notify such indemnifying party shall not relieve the indemnifying party from any liability that it may have to any indemnified party under the foregoing provisions of this Section 6 unless, and only to the extent that the indemnifying party is materially prejudiced through the forfeiture of substantive rights or defenses by the indemnifying party resulting from such omission. If any such action is brought against any indemnified party and it notifies the indemnifying party of its commencement, the indemnifying party will be entitled to participate in and, to the extent that it elects by delivering written notice to the indemnified party promptly after receiving notice of the commencement of the action from the indemnified party, jointly with any other indemnifying party similarly notified, to assume the defense of the action, with counsel reasonably satisfactory to the indemnified party, and after notice from the indemnifying party to the indemnified party of its election to assume the defense, the indemnifying party will not be liable to the indemnified party for any legal or other expenses except as provided below and except for the reasonable costs of investigation subsequently incurred by the indemnified party in connection with the defense. The indemnified party will have the right to employ its own counsel in any such action, but the fees, expenses and other charges of such counsel will be at the expense of such indemnified party unless (i) the employment of counsel by the indemnified party has been authorized in writing by the indemnifying party, (ii) the indemnified party has reasonably concluded (based on advice of counsel) that there may be legal defenses available to it or other indemnified parties that are different from or in addition to those available to the indemnifying party, (iii) the indemnified party has reasonably concluded that a conflict or potential conflict exists (based on advice of counsel to the indemnified party) between the indemnified party and the indemnifying party (in which case the indemnifying party shall not have the right to direct the defense of such action on behalf of the indemnified party) or (iv) the indemnifying party has not in fact employed counsel satisfactory to the indemnified party to assume the defense of such action within a reasonable time after receiving notice of the commencement of the action, in each of which cases the reasonable fees, disbursements and other charges of counsel shall be at the expense of the indemnifying party or parties. It is understood that the indemnifying party or parties shall not, in connection with any proceeding or related proceedings in the same jurisdiction, be liable for the reasonable fees, disbursements and other charges of more than one separate firm admitted to practice in such jurisdiction at any one time for all such indemnified party or parties. All such fees, disbursements and other charges shall be reimbursed by the indemnifying party promptly as they are incurred. An indemnifying party shall not be liable for any settlement of any action or claim effected without its written consent (which consent will not be unreasonably withheld or delayed). No indemnifying party shall, without the prior written consent of each indemnified party, settle or compromise or consent to the entry of any judgment in any pending or threatened claim, action or proceeding relating to the matters contemplated by this Section 6 (whether or not any indemnified party is a party thereto), unless such settlement, compromise or consent (i) includes an unconditional release of each indemnified party from all liability arising or that may arise out of such claim, action or proceeding and (ii) does not include a statement as to or an admission of fault, culpability or failure to act by or on behalf of any indemnified party. Notwithstanding the foregoing, if at any time an indemnified party shall have requested an indemnifying party to reimburse the indemnified party for fees and expenses of counsel, such indemnifying party agrees that it shall be liable for any settlement of the nature contemplated by Section 6(a) effected without its written consent if (i) such settlement is entered into more than 45 days after receipt by such indemnifying party of the aforesaid request, (ii) such indemnifying party shall have received notice of the terms of such settlement at least 30 days prior to such settlement being entered into and (iii) such indemnifying party shall not have reimbursed such indemnified party in accordance with such request prior to the date of such settlement.

(d) *Contribution.* In order to provide for just and equitable contribution in circumstances in which the indemnification provided for in the foregoing paragraphs of this Section 6 is applicable in accordance with its terms but for any reason is held to be unavailable from the Company or the Underwriters, the Company and the Underwriters shall contribute to the total losses, claims, liabilities, expenses and damages (including any investigative, legal and other expenses reasonably incurred in connection with, and any amount paid in settlement of, any action, suit or proceeding or any claim asserted, but after deducting any contribution received by the Company from persons other than the Underwriters, such as persons who control the Company within the meaning of the Act, officers of the Company who signed the Registration Statement and directors of the Company, who also may be liable for contribution) to which the Company and the Underwriters may be subject in such proportion as shall be appropriate to reflect the relative benefits received by the Company on the one hand and the Underwriters on the other. The relative benefits received by the Company on the one hand and the Underwriters on the other shall be deemed to be in the same proportion as the total net proceeds from the offering (before deducting expenses) received by the Company bear to the total underwriting discounts and commissions received by the Underwriters, in each case as set forth in the table on the cover page of the Prospectus. If, but only if, the allocation provided by the foregoing sentence is not permitted by applicable law, the allocation of contribution shall be made in such proportion as is appropriate to reflect not only the relative benefits referred to in the foregoing sentence but also the relative fault of the Company, on the one hand, and the Underwriters, on the other, with respect to the statements or omissions which resulted in such loss, claim, liability, expense or damage, or action in respect thereof, as well as any other relevant equitable considerations with respect to such offering. Such relative fault shall be determined by reference to whether the untrue or alleged untrue statement of a material fact or omission or alleged omission to state a material fact relates to information supplied by the Company or Representatives on behalf of the Underwriters, the intent of the parties and their relative knowledge, access to information and opportunity to correct or prevent such statement or omission. The Company and the Underwriters agree that it would not be just and equitable if contributions pursuant to this Section 6(d) were to be determined by pro rata allocation or by any other method of allocation (even if the Underwriters were treated as one entity for such purpose) which does not take into account the equitable considerations referred to herein. The amount paid or payable by an indemnified party as a result of the loss, claim, liability, expense or damage, or action in respect thereof, referred to above in this Section 6(d) shall be deemed to include, for purpose of this Section 6(d), any legal or other expenses reasonably incurred by such indemnified party in connection with investigating or defending any such action or claim. Notwithstanding the provisions of this Section 6(d), no Underwriter shall be required to contribute any amount in excess of the underwriting discounts and commissions received by it, and no person found guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Act) shall be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation. The Underwriters' obligation to contribute as provided in this Section 6(d) are several in proportion to their respective underwriting obligations and not joint. For purposes of this Section 6(d), any person who controls a party to this Agreement within the meaning of the Act will have the same rights to contribution as that party, and each director of the Company and each officer of the Company who signed the Registration Statement will have the same rights to contribution as the Company, and each affiliate, director, officer, employee, counsel or agent of any Underwriter will have the same rights to contribution as such Underwriter, subject in each case to the provisions hereof. Any party entitled to contribution, promptly after receipt of notice of commencement of any action against such party in respect of which a claim for contribution may be made under this Section 6(d), will notify any such party or parties from whom contribution may be sought, but the omission so to notify will not relieve the party or parties from whom contribution may be sought from any other obligation it or they may have under this Section 6(d). No party will be liable for contribution with respect to any action or claim settled without its written consent (which consent will not be unreasonably withheld).

(e) *Survival.* The indemnity and contribution agreements contained in this Section 6 and the representations and warranties of the Company contained in this Agreement shall remain operative and in full force and effect regardless of (i) any investigation made by or on behalf of the Underwriters, (ii) acceptance of any of the Shares and payment therefor or (iii) any termination of this Agreement.

7. Termination. The obligations of the several Underwriters under this Agreement may be terminated at any time prior to the Closing Date (or, with respect to the Option Shares, on or prior to any Option Closing Date), by notice to the Company from the Representatives, without liability on the part of any Underwriter to the Company, if, prior to delivery and payment for the Firm Shares (or the Option Shares, as the case may be), any of the following shall occur:

(a) trading or quotation in any of the equity securities of the Company shall have been suspended or limited by the Commission or by an exchange or otherwise;

(b) trading in securities generally on the New York Stock Exchange, the Nasdaq Global Market or the Nasdaq Global Select Market shall have been suspended or limited or minimum or maximum prices shall have been generally established on such exchange, or additional material governmental restrictions, not in force on the date of this Agreement, shall have been imposed upon trading in securities generally by such exchange or by order of the Commission or any court or other governmental authority;

(c) a general banking moratorium shall have been declared by any of federal, New York or Delaware authorities;

(d) the United States shall have become engaged in new hostilities, there shall have been an escalation in hostilities involving the United States or there shall have been a declaration of a national emergency or war by the United States or there shall have occurred such a material adverse change in general economic, political or financial conditions, including, without limitation, as a result of terrorist activities after the date hereof (or the effect of international conditions on the financial markets in the United States shall be such), or any other calamity or crisis shall have occurred, the effect of any of which is, in the sole judgment of the Representatives, such as to make it impracticable or inadvisable to market the Shares on the terms and in the manner contemplated by the Prospectus;

(e) the Company shall have sustained a loss material or substantial to the Company by reason of flood, fire, accident, hurricane, earthquake, theft, sabotage, or other calamity or malicious act, whether or not such loss shall have been insured, the effect of any of which is, in the sole judgment of the Representatives, such as to make it impracticable or inadvisable to market the Shares on the terms and in the manner contemplated by the Prospectus; or

(f) there shall have been a Material Adverse Change that is, in the sole judgment of the Representatives, so material and adverse as to make it impractical or inadvisable to proceed with the offer, sale or delivery of the Shares on the terms and in the manner contemplated by the Prospectus.

8. Substitution of Underwriters. If any one or more of the Underwriters shall fail or refuse to purchase any of the Firm Shares which it or they have agreed to purchase hereunder, and the aggregate number of Firm Shares which such defaulting Underwriter or Underwriters agreed but failed or refused to purchase is not more than one-tenth of the aggregate number of Firm Shares, the other Underwriters shall be obligated, severally, to purchase the Firm Shares which such defaulting Underwriter or Underwriters agreed but failed or refused to purchase, in the proportions which the number of Firm Shares which they have respectively agreed to purchase pursuant to Section 1 hereof bears to the aggregate number of Firm Shares which all such non-defaulting Underwriters have so agreed to purchase, or in such other proportions as the Representatives may specify; *provided* that in no event shall the maximum number of Firm Shares which any Underwriter has become obligated to purchase pursuant to Section 1 hereof be increased pursuant to this Section 8 by more than one-ninth of the number of Firm Shares agreed to be purchased by such Underwriter without the prior written consent of such Underwriter. If any Underwriter or Underwriters shall fail or refuse to purchase any Firm Shares and the aggregate number of Firm Shares which such defaulting Underwriter or Underwriters agreed but failed or refused to purchase exceeds one-tenth of the aggregate number of the Firm Shares and arrangements satisfactory to the Company and the Representatives for the purchase of such Firm Shares are not made within 48 hours after such default, this Agreement will terminate without liability on the part of any non-defaulting Underwriter, or the Company (except as provided in Section 4(l) hereof) for the purchase or sale of any Shares under this Agreement. In any such case either the Representatives or the Company shall have the right to postpone the Closing Date, but in no event for longer than seven days, in order that the required changes, if any, in the Registration Statement and in the Prospectus or in any other documents or arrangements may be effected. Any action taken pursuant to this Section 8 shall not relieve any defaulting Underwriter from liability in respect of any default of such Underwriter under this Agreement.

9. Miscellaneous.

(a) *Notices.* Notice given pursuant to any of the provisions of this Agreement shall be in writing and, unless otherwise specified, shall be mailed, hand delivered or telecopied (a) if to the Company, at the office of the Company, 30 Technology Drive, Warren, NJ 07059, Attention: Keith Kendall (Fax: (908) 561-1209) or (b) if to the Underwriters, c/o BMO Capital Markets Corp., 3 Times Square, New York, New York 10036, Attention: Legal Department (Fax: (212) 702-1205) and RBC Capital Markets, LLC, 200 Vesey Street, 10th Floor, New York, New York 1028; Attention: Equity Capital Markets (Fax: (212) 428-6260). Any such notice shall be effective only upon receipt. Any notice under Section 6 hereof may be made by telecopy or telephone, but if so made shall be subsequently confirmed in writing.

(b) *No Third Party Beneficiaries.* This Agreement has been and is made solely for the benefit of the several Underwriters, the Company and the controlling persons, affiliates, directors, officers, employees, counsel and agents referred to in Section 6 hereof, and their respective successors and assigns, and no other person shall acquire or have any right under or by virtue of this Agreement. The term “successors and assigns” as used in this Agreement shall not include a purchaser of Shares from the Underwriters in his, her or its capacity as such a purchaser.

(c) *Survival of Representations and Warranties.* All representations, warranties and agreements of the Company contained herein or in certificates or other instruments delivered pursuant hereto shall remain operative and in full force and effect regardless of any investigation made by or on behalf of any Underwriter or any of their controlling persons and shall survive delivery of and payment for the Shares hereunder.

(d) *Disclaimer of Fiduciary Relationship*. The Company acknowledges and agrees that (i) the purchase and sale of the Shares pursuant to this Agreement, including the determination of the public offering price of the Shares and any related discounts and commissions, is an arm's-length commercial transaction between the Company, on the one hand, and the Underwriters, on the other hand, (ii) in connection with the offering contemplated by this Agreement and the process leading to such transaction, each of the Underwriters is and has been acting solely as a principal and is not the agent or fiduciary of the Company or its securityholders, creditors, employees or any other party, (iii) none of the Underwriters has assumed nor will it assume any advisory or fiduciary responsibility in favor of the Company with respect to the offering of the Shares contemplated by this Agreement or the process leading thereto (irrespective of whether any Underwriter or its affiliates has advised or is currently advising the Company on other matters) and the Underwriters have no obligation to the Company with respect to the offering of the Shares contemplated by this Agreement except the obligations expressly set forth in this Agreement, (iv) each of the Underwriters and their respective affiliates may be engaged in a broad range of transactions that involve interests that differ from those of the Company, and (v) the Underwriters have not provided any legal, accounting, regulatory or tax advice with respect to the offering contemplated by this Agreement and the Company has consulted its own legal, accounting, regulatory and tax advisors to the extent it deemed appropriate.

(e) *Actions of the Representatives.* Any action by the Underwriters hereunder may be taken by the Representatives on behalf of the Underwriters, and any such action taken by the Representatives shall be binding upon the Underwriters.

(f) *Governing Law.* THIS AGREEMENT SHALL BE GOVERNED BY AND CONSTRUED IN ACCORDANCE WITH THE LAWS OF THE STATE OF NEW YORK APPLICABLE TO AGREEMENTS MADE AND TO BE PERFORMED ENTIRELY WITHIN SUCH STATE. Each party hereto hereby irrevocably submits for purposes of any action arising from this Agreement brought by the other party hereto to the jurisdiction of the courts of New York State located in the Borough of Manhattan and the U.S. District Court for the Southern District of New York.

(g) *Counterparts.* This Agreement may be signed in two or more counterparts with the same effect as if the signatures thereto and hereto were upon the same instrument.

(h) *Survival of Provisions Upon Invalidity of Any Single Provision.* In case any provision in this Agreement shall be invalid, illegal or unenforceable, the validity, legality and enforceability of the remaining provisions shall not in any way be affected or impaired thereby.

(i) *Waiver of Jury Trial.* The Company and the Underwriters each hereby irrevocably waive any right they may have to a trial by jury in respect of any claim based upon or arising out of this Agreement or the transactions contemplated hereby.

(j) *Titles and Subtitles.* The titles of the sections and subsections of this Agreement are for convenience and reference only and are not to be considered in construing this Agreement.

(k) *Entire Agreement.* This Agreement embodies the entire agreement and understanding between the parties hereto and supersedes all prior agreements and understandings relating to the subject matter hereof. This Agreement may not be amended or otherwise modified or any provision hereof waived except by an instrument in writing signed by the Representatives and the Company.

[Signature page follows]

Please confirm that the foregoing correctly sets forth the agreement between the Company and the several Underwriters.

Very truly yours,

AQUESTIVE THERAPEUTICS, INC.

By: _____

Name:
Title:

Confirmed as of the date first above mentioned:

BMO Capital Markets Corp.
RBC Capital Markets, LLC

Acting on behalf of themselves and as Representatives of the several Underwriters named in Schedule I hereof

BMO Capital Markets Corp.

By: _____
Name:
Title:

RBC Capital Markets, LLC

By: _____
Name:
Title:

Underwriter	Number of Firm Shares
BMO Capital Markets Corp.	[●]
RBC Capital Markets, LLC	[●]
JMP Securities LLC	[●]
Wedbush Securities Inc.	[●]
Total	[●]

ISSUER FREE WRITING PROSPECTUSES:

[None]

WRITTEN TESTING-THE-WATERS COMMUNICATIONS:

[●]

1. The initial public offering price per share of Common Stock shall be $[●].

[2. The Company is selling [●] shares of Common Stock.][1]

[3. The Company has granted an option to the Underwriters, severally and not jointly, to purchase up to an additional [●] shares of Common Stock.]

[1] Include to the extent the number of shares has changed from that set forth in the preliminary prospectus.

[*Circulated under separate cover*]

Form of Press Release

Aquestive Therapeutics, Inc.
_____, 2018

Aquestive Therapeutics, Inc. (the "Company") announced today that BMO Capital Markets Corp. and RBC Capital Markets, LLC, the book-running managers in the Company's recent public sale of shares of common stock, is [waiving][releasing] a lock-up restriction with respect to [●] shares of the Company's common stock held by [certain officers or directors][an officer or director] of the Company. The [waiver][release] will take effect on [●], and the shares may be sold on or after such date.

This press release is not an offer for sale of the securities in the United States or in any other jurisdiction where such offer is prohibited, and such securities may not be offered or sold in the United States absent registration or an exemption from registration under the United States Securities Act of 1933, as amended.

Exhibit 3.3

CERTIFICATE OF AMENDMENT NO. 2
OF THE
CERTIFICATE OF INCORPORATION
OF
AQUESTIVE THERAPEUTICS, INC.

JULY 16, 2018

Pursuant to the provisions of Section 242 of the General Corporation Law of the State of Delaware, Aquestive Therapeutics, Inc., a Delaware corporation (the "Corporation"), hereby certifies as follows:

1. That the name of this corporation is Aquestive Therapeutics, Inc., and that this corporation was originally incorporated pursuant to the General Corporation Law effective January 1, 2018 under the name Aquestive Therapeutics, Inc. (the "Original Certificate"). The Original Certificate was amended on April 30, 2018 by the Certificate of Amendment of the Original Certificate (the "First Amendment," and the Original Certificate as amended by the First Amendment, the "Amended Certificate").

2. This Certificate of Amendment No. 2 of the Amended Certificate (this "Second Amendment") amends provisions of the Amended Certificate and has been duly adopted by the Board of Directors of the Corporation and by written consent of the requisite holders of the outstanding stock of the Corporation entitled to vote thereon in accordance with the provisions of Sections 228 and 242 and all other applicable provisions of the General Corporation Law of the State of Delaware.

3. This Second Amendment amends the Amended Certificate by inserting the following paragraph after Section (b) of Article V of the Amended Certificate:

"Effective upon the effective time of this Certificate of Amendment No. 2 of the Certificate of Incorporation, as amended, with the Secretary of State of the State of Delaware (the "Effective Time"), each 12.34 shares of Common Stock issued and outstanding immediately prior to the Effective Time shall, automatically and without the necessity of any further action, be changed, reclassified and combined into one (1) share of Common Stock (the "Reverse Stock Split"). No fractional shares shall be issued in connection with the Reverse Stock Split. Stockholders who otherwise would be entitled to receive fractional shares of Common Stock shall be entitled to receive cash (without interest or deduction) in an amount equal to the product obtained by multiplying (a) the fair value (as determined by the Board of Directors) of one whole share of Common Stock (after the effect of Reverse Stock Split) by (b) the fraction of one share owned by the stockholder. Each certificate that immediately prior to the Effective Time represented shares of Common Stock ("Old Certificates"), shall thereafter represent that number of shares of Common Stock into which the shares of Common Stock represented by the Old Certificate shall have been combined, subject to the elimination of fractional shares as described above."

4. All other provisions of the Amended Certificate shall remain in effect.

[*signature page follows*]

IN WITNESS WHEREOF, this Certificate of Amendment No. 2 has been executed by a duly authorized officer of this Corporation on this 16th day of July, 2018.

AQUESTIVE THERAPEUTICS, INC.

By: /s/ John T. Maxwell
Name: John T. Maxwell
Title: Chief Financial Officer

Exhibit 5.1

Dechert LLP

1095 Avenue of the Americas
New York, NY 10036-6797
+1 212 698 3500 Main
+1 212 698 3599 Fax
www.dechert.com

July 16, 2018

Aquestive Therapeutics, Inc.
30 Technology Drive
Warren, NJ 07922

Re: REGISTRATION STATEMENT ON FORM S-1
REGISTRATION NO. 333-225924

Ladies and Gentlemen:

We have acted as counsel to Aquestive Therapeutics, Inc. a Delaware corporation (the "Company"), in connection with the filing with the Securities and Exchange Commission (the "Commission") of a Registration Statement on Form S-1 (File No. 333-225924) (the "Registration Statement") for the purpose of registering under the Securities Act of 1933, as amended (the "Securities Act"), 4,600,000 shares of its common stock, par value $0.001 per share (the "Shares"), all of which will be sold by the Company (the "Securities"), and which includes 600,000 shares subject to an over-allotment option granted by the Company to the underwriters. The term "Securities" shall include any additional Securities registered by the Company pursuant to Rule 462(b) under the Securities Act in connection with the offering contemplated by the Registration Statement.

This opinion (the "Opinion") is being furnished to the Company in connection with the requirements of Item 601(b)(5) of Regulation S-K under the Securities Act, and no opinion is expressed herein as to any matter pertaining to the contents of the Registration Statement other than as expressly stated herein with respect to the Securities.

As your counsel, we have examined such documents and such matters of fact and law that we have deemed necessary for the purpose of rendering the Opinion expressed herein. In our examination, we have assumed the genuineness of all signatures, the authenticity of all documents submitted to us as original documents, and the conformity to original documents of all documents submitted to us as copies, the legal capacity of natural persons who are signatories to the documents examined by us, and the legal power and authority of all persons signing on behalf of parties (other than the Company) to all documents.

Based on the foregoing, we advise you that, in our opinion, when the price at which the Securities are to be sold has been approved by or on behalf of the Board of Directors of the Company, when the Registration Statement has been declared effective by the Commission and when the Securities have been duly issued and delivered against payment therefor in accordance with the terms of the Underwriting Agreement referred to in the prospectus that is a part of the Registration Statement, the Securities will be validly issued, fully paid and non-assessable.

We are members of the Bar of the State of New York and the foregoing Opinion is limited to the General Corporation Law of the State of Delaware.

We hereby consent to the filing of this opinion as an exhibit to the Registration Statement and further consent to the reference to our name under the caption "Legal Matters" in the prospectus that is a part of the Registration Statement. We further consent to the incorporation by reference of this letter and consent into any registration statement filed pursuant to Rule 462(b) with respect to the Securities. In giving this consent, we do not admit that we are in the category of persons whose consent is required under Section 7 of the Securities Act or the rules and regulations of the Commission thereunder.

Very truly yours,

/s/ Dechert LLP

Exhibit 10.5

EXECUTIVE EMPLOYMENT AGREEMENT

This Executive Employment Agreement (the "Agreement") is made and entered into as of June 30, 2018 by and between Aquestive Therapeutics, Inc. (the "Company") and Keith J. Kendall (the "Executive").

WITNESSETH:

WHEREAS, the Executive is currently employed by the Company as its Chief Executive Officer under an Executive Employment Agreement dated November 17, 2008, as amended, between the Executive and MonoSol Rx, LLC, the predecessor of the Company, as amended (the "2008 Employment Agreement"); and

WHEREAS, the parties desire that the Executive continue to be employed by the Company as its Chief Executive Officer upon the terms and conditions of this Agreement and that this Agreement will supersede the 2008 Employment Agreement;

NOW, THEREFORE, in consideration of the premises and the mutual covenants herein set forth, and for other good and valuable consideration (the receipt and sufficiency of which are hereby acknowledged), the parties hereto, intending to be legally bound, hereby agree as follows:

1. Employment. During the Employment Term (as hereinafter defined) of this Agreement, the Executive agrees to be employed by and to serve the Company as its Chief Executive Officer, and the Company agrees to employ and retain Executive in such capacity. The Executive shall report directly to the Board of Directors of the Company (the "Board"). The Executive shall: (i) devote his entire business time, energy and skill to the affairs of the Company; (ii) faithfully, loyally, and industriously perform all duties incident to the position of Chief Executive Officer, as well as any other duties consistent with the stature and responsibility of the Executive's position as may from time to time be assigned by the Board; and (iii) comply with the Company's policies in effect from time to time. Notwithstanding any provision herein to the contrary, Executive shall not be precluded from devoting reasonable periods of time required for serving as a member of one or more advisory boards or boards of directors of companies or organizations or engaging in other minor business activities, so long as such memberships or activities do not interfere with the performance of Executive's duties hereunder and are not directly or indirectly competitive with, nor contrary to, the business or other interests of the Company, subject to prior approval by the Board, which approval shall not be unreasonably withheld.

2. Employment Term. The term of this Agreement (the "Employment Term") shall begin as of June 26, 2018 and continue through June 30, 2021. Thereafter, the Employment Term will automatically renew for successive one-year periods unless either party gives written notice of non-renewal to the other at least ninety (90) days before the end of the initial term or then current renewal term, as the case may be.

3. Compensation.

A. Base Salary. The Company shall pay Executive a base salary (the "Base Salary") at a rate of $500,000.00 per annum, payable in accordance with the standard payroll practices of the Company. The Board and/or Compensation Committee of the Board ("Compensation Committee") will review Executive's Base Salary at least annually and may increase but not decrease the then current annual rate.

B. Annual Bonus. Executive shall be eligible for a target annual performance bonus ("Annual Bonus") of at least seventy-five percent (75%) of Executive's Base Salary for each calendar year, provided the Company achieves performance targets established by the Board and/or the Compensation Committee. The Annual Bonus amount, if any, for a calendar year will be determined by the Board and/or the Compensation Committee and paid by the Company by March 15th of the following calendar year, unless it is administratively impracticable to determine and/or make the payment by such date. Except as otherwise provided by this Agreement, the Executive must be employed by the Company on the day any Annual Bonus payment is due and payable in order to receive said bonus payment. If the Company exceeds established performance targets, the Board and/or the Compensation Committee may, in its sole discretion, increase the amount of the Annual Bonus.

C. Award of Non-Voting Common Stock. Executive has previously been awarded Non-Voting Common Stock, par value $.001 per share, of the Company (the "Non-Voting Common Stock") equal to five percent (5%) of the issued and outstanding capital securities of the Company as of the time of grant of the Non-Voting Common Stock to the Executive. Each share of Non-Voting Common Stock awarded to the Executive will become one share of voting common stock, par value $.001 per share, of the Company (the "Common Stock") upon completion of an initial public offering and sale of the capital stock of the Company (an "IPO"). The Executive shall be eligible for awards of additional shares of Non-Voting Common Stock and to participate in other employee incentive plans and equity-based compensation awards of the Company during the Employment Term at the times and in the amounts as the Board and/or Compensation Committee in its sole discretion shall determine. The award of the shares of Non-Voting Common Stock is governed by the Shareholders Agreement dated as of April 19, 2018 by and among the Company, the Executive and other parties who are signatories thereto (the "Shareholders Agreement"). Notwithstanding anything to the contrary in this Agreement or the Shareholders Agreement, if during the Employment Term the Company or any successor thereto (with any such successor being referred to in this Agreement as the "Company") issues or grants additional equity interests, options, or warrants of the capital stock of the Company during the Employment Term (a "Dilution Event"), other than upon or after an IPO of the Company (which event is addressed in Section 3(D) below), the Company shall award to Executive, prior to or simultaneously with the effective date of the Dilution Event, stock appreciation rights covering shares of Common Stock ("SARs") equal to the difference between:

(1) the number of shares of Common Stock representing five percent (5%) of the total outstanding shares of the Common Stock upon completion of such Dilution Event determined on a fully diluted basis (including, after giving effect to such Dilution Event, any exercise or conversion of all then outstanding options, warrants or all other derivative securities convertible into or exchangeable for Common Stock, whether or not such options, warrants or other derivative securities are then in-the-money); and

(2) the number of shares of Non-Voting Common Stock and the number of SARs, if any, held by Executive immediately prior to the effective date of the Dilution Event, such that the total of all the shares of Non-Voting Common Stock and SARs held by Executive immediately following such Dilution Event represents in the aggregate five percent (5%) of the total outstanding Common Stock (determined on a fully diluted basis, including, after converting shares of Non-Voting Common Stock into shares of Common Stock and, after giving effect to such Dilution Event, any exercise or conversion of all then outstanding options, warrants or all other derivative securities convertible into or exchangeable for Common Stock, whether or not such options, warrants, or other derivative securities are then in-the-money).

D. Equity Participation Awards upon IPO. At the time of any IPO, the Company will make the following additional awards to the Executive:

(1) SARs equal to the difference between:

(a) the number of shares of Common Stock representing five percent (5%) of the total outstanding shares of Common Stock upon completion of the IPO (determined on a fully diluted basis, including giving effect to (i) conversion of any and all Non-Voting Common Stock to Common Stock upon completion of the IPO, (ii) the exercise of options, warrants or other rights to purchase Common Stock and/or the conversion or exchange of securities or evidences of indebtedness convertible into or exchangeable for shares of Common Stock issued by the Company under any equity plan or agreement, all on an equivalent IPO converted basis, and (iii) the exercise of any overallotment option (if exercised) and the exercise or exchange of all then outstanding options, warrants or all other derivative securities convertible or exchangeable for Common Stock, whether or not such options, warrants or other derivative securities are then in-the-money); and

(b) the number of shares of Non-Voting Common Stock and the number of SARs, if any, held by Executive immediately prior to the completion of the IPO, such that the total number of all of the shares of Non-Voting Common Stock and SARs held by Executive immediately following the IPO represents in the aggregate five percent (5%) of the Common Stock of the Company (determined on a fully diluted basis, including giving effect to (i) the conversion of any and all Non-Voting Common Stock to Common Stock upon completion of the IPO, (ii) the exercise of options, warrants or other rights to purchase shares of Common Stock and/or the conversion or exchange of securities or evidences of indebtedness convertible into or exchangeable for shares of Common Stock issued by the Company under any equity plan or agreement, all on an equivalent IPO converted basis, and (iii) the exercise of any overallotment option (if exercised) and the exercise or exchange of all then outstanding options, warrants or all other derivative securities convertible or exchangeable for Common Stock, whether or not such options, warrants or other derivative securities are then in-the-money), and

(2) an additional award of a number of shares of restricted stock ("Restricted Stock") equal to .24% of the aggregate number of outstanding shares of Common Stock upon completion of such IPO (determined on the same fully diluted basis as in subsection (1)(a) in this Section 3(D)).

E. Vesting. The SARs awarded in Section 3(C) and 3(D)(1), as applicable, shall vest in thirty-six (36) equal monthly installments beginning on the last day of the month next following the month in which the Dilution Event or IPO, as the case may be, is completed, and the additional shares of Restricted Stock awarded in Section 3(D)(2) shall vest in eight (8) equal quarterly installments beginning on the last day of the month next following the month in which the IPO is completed, in each case subject to Executive's continued employment on the applicable vesting date, and all subject to any earlier or accelerated vesting as provided in this Agreement below or in any applicable award agreement or employee incentive compensation or similar plan of the Company so long as the early or accelerated vesting provisions of such award agreements or plans are not inconsistent with the terms of this Agreement. Vesting of the SARs and shares of Restricted Stock will accelerate and become nonforfeitable if Executive's employment terminates for any reason other than by the Company for "Cause" (as defined below) or by the Executive without "Good Reason" (as defined below). The Company shall withhold from the issuance of any Company shares, on each vesting date of such SARs and/or Restricted Stock, that number of shares of Common Stock (using the fair market value of the shares at the particular vesting date) as is necessary to satisfy Executive's minimum federal, state and local income and employment tax withholding obligations on such vesting or delivery event.

4. Additional Benefits.

A. Executive Benefits. During the Employment Term, Executive shall be eligible to participate in such employee benefit plans as are generally available to other senior executives of the Company.

B. Paid Time Off. The Executive will be allowed to take up to six weeks of vacation each year, and shall be eligible for such sick leave and other paid time off in accordance with the Company' policies applicable to other executives generally.

C. Expense Reimbursement. The Company will pay or reimburse Executive for reasonable expenses incurred by Executive in connection with the performance of his duties and responsibilities under this Agreement, subject to presentation of vouchers and compliance with generally applicable business expense reimbursement policies of the Company.

5. Termination.

A. Termination for Cause. The Company may terminate Executive's employment for "Cause" if Executive:

(i) is convicted of or pleads nolo contendre to a felony (or its equivalent under applicable state law);

(ii) commits fraud or a material act or omission involving dishonesty with respect to the Company or any of its respective employees, customers or affiliates;

(iii) willfully and repeatedly fails or refuses to carry out the material responsibilities of Executive's employment by the Company (except where due to physical or mental incapacity);

(iv) engages in willful misconduct or a pattern of behavior which in either case has had or is reasonably likely to have a significant adverse effect on the Company;

(v) willfully engages in any act or omission which is in material violation of the Company's policy, including but not limited to engaging in insider trading transactions or disseminating inside information; or

(vi) commits a material breach of Executive's material obligations under this Agreement, including but not limited to Section 8.

A decision to terminate the Executive's employment for Cause must be made, if at all, by the Board, after reasonable notice to Executive and an opportunity for Executive, together with counsel, to be heard by the Board, and the Board finding that, in its good faith opinion, Executive engaged in conduct set forth above and specifying the particulars thereof in reasonable detail. If the act or omission giving rise to the termination for Cause is curable by Executive, the Board will provide thirty (30) days' written notice to Executive of its intent to terminate Executive for Cause, with an explanation of the reason(s) for the termination for Cause and, if Executive cures the act or omission within the 30-day notice period, the Board will rescind the notice of termination and Executive's employment will not be terminated for Cause at the end of the 30-day notice period. If Executive has previously been afforded the opportunity to cure particular behavior and successfully cured under this provision, the Board will have no obligation to provide Executive with notice and an opportunity to cure a recurrence of that behavior prior to a termination for Cause. For purposes of this Section 5(A), an action or inaction shall not be treated as "willful misconduct" if authorized by the Board, or taken by Executive in the good faith belief that it was in, or not opposed to, the best interests of the Company.

B. Termination by Reason of Permanent Disability. In a manner consistent with the Americans with Disabilities Act and the Family and Medical Leave Act, this Agreement may be terminated at the Company's option immediately upon notice to Executive if Executive shall suffer a Permanent Disability. For purposes of this Agreement, the term "Permanent Disability" shall mean the Executive's inability to perform the essential functions of his job under this Agreement, with or without reasonable accommodation, for a period of 150 consecutive days or for an aggregate of 180 days, whether or not consecutive, in any twelve (12) month period, due to illness, accident or other physical or mental incapacity, as determined by a duly licensed physician mutually agreed to by both the Executive and the Company.

C. Termination by Reason of Death. In the event of the Executive's death, the Executive's employment shall be deemed to have terminated on the date of Executive's death.

D. Voluntary Resignation. Executive may terminate this Agreement at any time, subject to providing ninety (90) days' written notice to the Company. The Company may waive such notice and/or set an earlier termination date, without pay in lieu of notice.

E. Termination without Cause. The Company may terminate Executive's employment under this Agreement at any time without Cause upon ninety (90) days' prior written notice to Executive. The Company, at its sole discretion, may relieve Executive of his active duties during the notice period. Executive's termination without Cause will be effective upon the expiration of the 90-day notice period. For purposes of this Agreement, (1) a termination of employment by the Company that purports to be for Cause, but is not in full compliance with all of the substantive and procedural requirements relating to a termination for Cause under this Agreement, shall be treated as a termination of employment without Cause; and (2) the Executive will be deemed to have been terminated by the Company without Cause if the term of this Agreement expires by reason of non-renewal by the Company pursuant to Section 2.

F. Termination for Good Reason. The Executive may terminate his employment under this Agreement at any time for Good Reason upon the occurrence (or within 180 days following the occurrence, provided that the Executive furnishes the Company with written notice of his belief that grounds for a Good Reason termination by the Executive exists no later than sixty (60) days after becoming aware of the occurrence) of any one or more of the following acts or omissions which, if curable, is not cured within thirty (30) days after notice of the occurrence is provided by Executive: (1) any action by the Company which results in a material diminution in Executive's position, authority, duties or responsibilities as Chief Executive Officer of the Company (including status, offices, titles and reporting requirements contemplated by this Agreement); (2) a material breach by the Company of its obligations under this Agreement, including, without limitation, a reduction of Executive's Base Salary or target bonus opportunity in violation of this Agreement; or (3) the Company requiring the Executive to be based at any office location that is more than fifty (50) miles from its current headquarters in Warren, New Jersey, except for travel reasonably required in connection with the performance of the Executive's responsibilities hereunder.

6. Obligations of the Company Upon Termination.

A. Termination for Cause. In the event that the Executive's employment under this Agreement is terminated for Cause, the Company shall have no obligation to pay the Base Salary or any other compensation provided under this Agreement, to or for the benefit of the Executive for any period after the effective date of such termination, or to pay the Target Annual Bonus or any other bonus or incentive compensation for the fiscal year in which such termination occurs; provided, however, that the Company shall promptly provide: (i) all Base Salary earned by the Executive through the effective date of such termination; (ii) any unpaid Annual Bonus earned by the Executive for the year preceding the year in which his employment terminates; and (iii) any benefits under any plans of the Company in which the Executive is a participant, consistent with the Executive's (or his beneficiaries') rights under such plans.

B. Termination by Reason of Death or Permanent Disability. In the event that the Executive's employment under this Agreement terminates due to his death or is terminated by the Company due to the Executive's Permanent Disability, the Company shall, within five (5) business days following such termination, provide to the Executive (or his estate or other beneficiaries, as the case may be): (i) a cash payment consisting of the sum of any previously unpaid Base Salary earned by the Executive through the date on which his employment terminates, any unpaid Annual Bonus earned by the Executive for the year preceding the year in which his employment terminates, and any accrued and unused vacation pay for the year in which his employment terminates; (ii) any benefits under any plans of the Company in which the Executive is a participant, to the full extent of the Executive's (or his beneficiaries') rights under such plans; (iii) a cash payment consisting of the Executive's Target Annual Bonus for the year of termination, pro-rated for the number of days Executive is employed during the calendar year in which his employment terminates ("Pro Rata Bonus"); and (iv) accelerated vesting of all outstanding stock options, restricted stock units ("RSUs"), SARs, Restricted Stock and other equity-based compensation awards as if the Executive's employment had continued through the end of the year in which his employment terminates or, in the case of any such award that is subject to "cliff vesting," on a pro rata basis, determined by a fraction the numerator of which is the number of days during such vesting period, and the denominator of which is the total number of days in the vesting period that have elapsed as of the date his employment terminates. Notwithstanding the immediately preceding sentence, with respect to any unvested stock options, RSUs, SARs, Restricted Stock and other equity-based compensation that are unvested at the time of termination of employment under this Section 6(B), and which are subject to a performance condition or performance period that ends at or after the date of employment termination, such awards will be assumed to have been achieved at "target", and the Executive will be entitled to receive a pro rata share of such awards, determined by a fraction the numerator of which is the number of days during the performance period in which Executive was employed, and the denominator of which is the total number of days in the performance period. Stock options, SARs and other equity-based compensation awards that are or become vested upon termination of the Executive's employment due to death or Permanent Disability will be exercisable (if applicable) for at least one year after the date of such termination or, if earlier, until the expiration of the stated term of the award.

C. Voluntary Resignation. In the event that the Executive voluntarily resigns from his employment with the Company, the Company may, at its discretion, continue the Executive's employment with the Company for any part or the full duration of the 90-day notice period. In the event of said termination, the Company shall have no obligation to pay the Base Salary or any other compensation provided under this Agreement to or for the benefit of the Executive for any period after such termination; provided, however, that the Company shall promptly provide: (i) all Base Salary earned by the Executive through the date of such termination; (ii) any unpaid Annual Bonus earned by the Executive for the year preceding the year in which his employment terminates; and (iii) any benefits under any plans of the Company in which Executive is a participant, to the full extent of the Executive's (or his beneficiaries') rights under such plans.

D. Termination by the Company Without Cause or by Executive for Good Reason--Unrelated to Change in Control. In the event that the Executive's employment under this Agreement is terminated by the Company without Cause (pursuant to Section 5(E)) or by the Executive for Good Reason (pursuant to Section 5(F)), the Company shall provide to the Executive: (i) a cash payment consisting of the sum of any previously unpaid Base Salary earned by the Executive through the date on which his employment terminates, any unpaid Annual Bonus earned by the Executive for the year preceding the year in which his employment terminates, and any accrued and unused vacation pay for the year in which his employment terminates; (ii) any benefits under any plans of the Company in which the Executive is a participant, to the full extent of the Executive's (or his beneficiaries') rights under such plans; (iii) a cash payment consisting of the Executive's Pro Rata Bonus for the year of termination; (iv) monthly payments for a period of eighteen 18 months (the "Severance Period") following the termination of Executive's employment or, if longer, until the expiration of the Employment Term, equal to 1/12 of the sum of Executive's Base Salary and Target Annual Bonus (in each case determined without regard to any reduction prior to the termination of Executive's employment); (v) continuing coverage under the Company's group health and life insurance plans in which the Executive is a participant immediately before the termination of his employment (or any successor plans), at the same levels and on the same terms and conditions as are provided to similarly situated executives during the Severance Period (or, if such coverage is not permitted by law or the applicable plan, the cash equivalent of such coverage, grossed up if and to the extent necessary to negate the tax impact of such payment and to negate the tax impact of the gross-up payment); and (vi) full and immediate vesting of outstanding unvested stock options, RSUs, SARs, Restricted Stock and other equity-based compensation awards with any such stock options, SARs and other equity-based compensation awards that are or become vested upon termination of the Executive's employment by the Company without Cause or by the Executive for Good Reason remaining exercisable, as applicable, for at least one year after the date the Executive's employment terminates or, if earlier, until the expiration of the stated term of the award. Notwithstanding the immediately preceding sentence, with respect to any unvested stock options, RSUs, SARs, Restricted Stock and other equity-based compensation that are unvested at the time of termination of employment under this Section 6(D), and which are subject to a performance condition or performance period that ends at or after the date of employment termination, such awards will be assumed to have been achieved at "target." The payments and benefits described in parts (iv) - (vi) of this subsection shall be conditioned upon and subject to the Executive's continuing compliance with his obligations under Section 8 of this Agreement, and the Executive's execution and delivery of a general release substantially in the form annexed hereto as Exhibit A.

E. Termination in Conjunction with a Change in Control.

(1) Severance Protection Upon Involuntary Termination. In the event that, during the period beginning one hundred and eighty (180) days before the effective date of a Change in Control (as defined below) and ending twenty four (24) months following the effective date of a Change in Control, the Executive's employment is terminated by the Company without Cause (pursuant to Section 5(E)) or by the Executive for Good Reason (pursuant to Section 5(F)), the Executive shall be entitled to the payments and benefits described in the preceding Section 6(D) except (i) in lieu of the severance payments described in Section 6(D)(iv), Executive will be entitled to receive an immediate cash payment of an amount consisting of 2.75 times the sum of the Executive's Base Salary and Target Annual Bonus (in each case determined without regard to any reduction prior to the termination of Executive's employment); and (ii) the benefit continuation period described in Section 6(D)(v) shall commence on the date the Executive's employment terminates and expire 33 months from such date of termination. The payments and benefits described in the preceding sentence and in Sections 6(D)(iv) and 6(D)(v) and the single sum severance payment described in the preceding sentence shall be conditioned upon and subject to the Executive's continuing compliance with his obligations under Section 8 of this Agreement, and the Executive's execution and delivery of a general release substantially in the form annexed hereto as Exhibit A.

(2) Definition of Change in Control. For the purposes of this Agreement, a "Change in Control" shall be deemed to have occurred if (a) any person (within the meaning of Section 13(d)(3) or 14(d)(2) of the Securities Exchange Act of 1934, as amended ("Exchange Act")), or group (within the meaning of Section 409A of the Internal Revenue Code of 1986, as amended (the "Code")), becomes, in any 12-month period ending on the date of the most recent acquisition of the voting securities of the Company or any successor entity by such person, persons, or group, directly or indirectly, the beneficial owner (within the meaning of Rule 13d-3 promulgated under the Exchange Act) of 40% or more of the outstanding voting securities of the Company or successor entity; (b) there shall have been consummated a consolidation, merger or reorganization of the Company or any successor entity, unless the holders of the equity interests of the Company or successor entity, immediately before such consolidation, merger or reorganization own, directly or indirectly, at least a majority of the outstanding voting securities or at least a majority of the aggregate fair market value of the corporation or other entity resulting from such consolidation, merger or reorganization; (c) during any 12-month period prior to an IPO (i) Bratton Capital Management L.P. ("Bratton"), or affiliates thereof, cease to beneficially own, directly or indirectly, at least a majority of the outstanding voting securities of, or cease to maintain the right to direct the management of, MonoSolRx Genpar, L.P. (the sole manager of Aquestive Partners, LLC ("APL"), the parent company of the Company as of the Effective Date), or any successor or other or additional manager or managers (or their equivalent) of APL or any successor entity and (ii) if satisfaction of a "change in effective control" is necessary in order to avoid noncompliance with the requirements of Section 409A of the Code, individuals who, as of the Effective Date, constitute the entire Board of the Company (the "Incumbent Board") cease to constitute a majority of the Board or equivalent governing body; provided that (A) any individual becoming a member of the Board or equivalent governing body subsequent to the Effective Date whose appointment was made by a Bratton entity or an affiliate thereof referred to in subclause (i) above or was otherwise approved by at least a majority of the individuals then comprising the Incumbent Board or equivalent governing body shall be considered as though such individual were a member of the Incumbent Board or equivalent governing body as of the Effective Date, and (B) the voluntary resignation of the Executive from the Board, if a member thereof, shall not be considered for purposes of this subclause (ii); or (d) a sale, transfer, liquidation or other disposition of the Company or successor entity's assets and properties representing all or substantially all of the aggregate fair market value of such assets and properties is consummated during any 12-month period; provided, however, that no "Change in Control" shall be deemed to have occurred under this Section 6(E)(2) unless such occurrence, event or condition shall constitute a change in the ownership or effective control of the Company or any successor entity or a change in the ownership of a substantial portion of the Company or successor entity's assets, each as determined under Section 409A(a)(2)(A)(v) of the Code.

F. 409A Compliance. The Company shall take all reasonable actions to ensure that none of the amounts earned or payable under this Agreement or under any Company stock purchase, compensation or other equity incentive plan will violate Section 409A of the Code. To the extent necessary to comply with the restriction in Section 409A(a)(2)(B) of the Code concerning payments to "specified employees," any amounts payable on account of the Executive's separation from service shall be paid (or commence to be paid in the case of any payments to be made in installments) on the first business day of the seventh month following the Executive's date of termination (or death, if earlier) and the first such payment shall include the cumulative amount of any payments that would have been made prior to such date if not for such restriction, together with interest at an annual rate equal to the minimum rate required by the Code in order to avoid the imputation of interest on short-term loans between employers and employees. The date of the Executive's termination of employment shall be determined in accordance with Treasury Regulation Section 1.409A-1(h). Except as otherwise provide herein, any payment required as a result of a termination of employment will be made (or, with respect to any payments to be made in installments under this Agreement, commenced) within 45 days following such event. Notwithstanding anything else herein to the contrary, to the extent that any payments due under the terms of this Agreement are conditioned upon the delivery and non-revocation of a release, and if any of those payments are determined to be nonqualified deferred compensation that is subject to the requirements of Section 409A of the Code, and if the period for consideration and revocation of such release spans two calendar years, then any such payment shall not be made until the later of (i) the end of the revocation period following delivery of the release, or (ii) the first business day of the second calendar year.

G. Value of Insurance Coverage During Severance Period. To the extent any medical or dental plan covering any post-employment period is a "self-insured medical reimbursement plan" under Section 105(h) of the Code, and such coverage would be discriminatory thereunder, the value of the insurance coverage during the post-termination coverage period (based upon premium value) shall be reported as taxable income to the Executive, and the Company shall pay the Executive promptly no later than January 15th of the year of coverage, such additional cash payments as are necessary for the Executive to receive the same net after-tax benefits (taking into account all federal, state and local income, excise and employment taxes) that the Executive would have received under such plans if the Executive had continued to receive such plan benefits while employed with the Company; provided that any such additional cash payment that would be so immediately paid shall be subject to the provisions of Section 6(F) in connection with compliance with Section 409A of the Code.

7. Excise Tax Gross Up. If Executive becomes entitled to one or more payments (with a "payment" including, without limitation, payments in connection with a Change in Control or the vesting of a SAR, stock option or other equity award or other non-cash benefit or property), whether pursuant to the terms of this Agreement or any other plan, arrangement, or agreement with the Company or any affiliated company (the "Total Payments"), which are or become subject to the tax imposed by Section 4999 of the Code or a successor provision of the Code (the "Excise Tax"), the Company shall pay to Executive at the time specified below an additional amount (the "Gross-up Payment") (which shall include, without limitation, reimbursement for any penalties and interest that may accrue in respect of such Excise Tax) such that the net amount retained by Executive, after reduction for any Excise Tax (including any penalties or interest thereon) on the Total Payments and any federal, state and local income or employment tax and Excise Tax on the Gross-up Payment provided for by this Section, but before reduction for any federal, state, or local income or employment tax on the Total Payments, shall be equal to the sum of (a) the Total Payments, and (b) an amount equal to the product of any deductions by the Executive disallowed for federal, state, or local income tax purposes because of the inclusion of the Gross-up Payment in Executive's adjusted gross income multiplied by the highest applicable marginal rate of federal, state, or local income taxation, respectively, for the calendar year in which the Gross-up Payment is to be made. For purposes of determining whether any of the Total Payments will be subject to the Excise Tax and the amount of such Excise Tax:

(i) The Total Payments shall be treated as "parachute payments" within the meaning of Section 280G(b)(2) of the Code, and all "excess parachute payments" within the meaning of Section 280G(b)(1) of the Code shall be treated as subject to the Excise Tax, unless, and except to the extent that, in the written opinion of independent compensation consultants, counsel or auditors of nationally recognized standing ("Independent Advisors") selected by the Company and reasonably acceptable to Executive, the Total Payments (in whole or in part) do not constitute parachute payments, or such excess parachute payments (in whole or in part) represent reasonable compensation for services actually rendered within the meaning of Section 280G(b)(4) of the Code in excess of the base amount within the meaning of Section 280G(b)(3) of the Code or are otherwise not subject to the Excise Tax;

(ii) The amount of the Total Payments which shall be treated as subject to the Excise Tax shall be equal to the lesser of (A) the total amount of the Total Payments or (B) the total amount of excess parachute payments within the meaning of Section 280G(b)(1) of the Code (after applying clause (i) above); and

(iii) The value of any non-cash benefits or any deferred payment or benefit shall be determined by the Independent Advisors in accordance with the principles of Sections 280G(d)(3) and (4) of the Code.

For purposes of determining the amount of the Gross-up Payment, Executive shall be deemed (A) to pay federal income taxes at the highest marginal rate of federal income taxation for the calendar year in which the Gross-up Payment is to be made; (B) to pay any applicable state and local income taxes at the highest marginal rate of taxation for the calendar year in which the Gross-up Payment is to be made, net of the maximum reduction in federal income taxes which could be obtained from deduction of such state and local taxes if paid in such year (determined without regard to limitations on deductions based upon the amount of Executive's adjusted gross income); and (C) to have otherwise allowable deductions for federal, state, and local income tax purposes at least equal to those disallowed because of the inclusion of the Gross-up Payment in Executive's adjusted gross income. In the event that the Excise Tax is subsequently determined to be less than the amount taken into account hereunder at the time the Gross-up Payment is made, Executive shall repay to the Company at the time that the amount of such reduction in Excise Tax is finally determined (but, if previously paid to the taxing authorities, not prior to the time the amount of such reduction is refunded to Executive or otherwise realized as a benefit by Executive) (the "Repayment Date") the portion of the Gross-up Payment that would not have been paid if such Excise Tax had been applied in initially calculating the Gross-up Payment, plus interest on the amount of such repayment at the rate provided in Section 1274(b)(2)(B) of the Code from the Repayment Date until paid. In the event that the Excise Tax is determined to exceed the amount taken into account hereunder at the time the Gross-up Payment is made (including by reason of any payment the existence or amount of which cannot be determined at the time of the Gross-up Payment), the Company shall make an additional Gross-up Payment in respect of such excess (plus any interest and penalties payable with respect to such excess) at the time that the amount of such excess is finally determined. The Gross-up Payment provided for above shall be paid to the Executive (or to the IRS on behalf of the Executive) on the 30th day (or such earlier date as the Excise Tax becomes due and payable to the taxing authorities) after it has been determined that the Total Payments (or any portion thereof) are subject to the Excise Tax; provided, however, that if the amount of such Gross-up Payment or portion thereof cannot be finally determined on or before such day, the Company shall pay to Executive on such day an estimate, as determined by the Independent Advisors, of the minimum amount of such payments and shall pay the remainder of such payments (together with interest at the rate provided in Section 1274(b)(2)(B) of the Code), as soon as the amount thereof can be determined. In the event that the amount of the estimated payments exceeds the amount subsequently determined to have been due, such excess shall constitute a loan by the Company to Executive, payable on the fifth day after demand by the Company (together with interest at the rate provided in Section 1274(b)(2)(B) of the Code). If more than one Gross-up Payment is made, the amount of each Gross-up Payment shall be computed so as not to duplicate any prior Gross-up Payment subject to the Company compliance with the provisions of this Section. The Company shall have the right to control all proceedings with the Internal Revenue Service that may arise in connection with the determination and assessment of any Excise Tax and, at its sole option, the Company may pursue or forego any and all administrative appeals, proceedings, hearings, and conferences with any taxing authority in respect of such Excise Tax (including any interest or penalties thereon); provided, however, that the Company's control over any such proceedings shall be limited to issues with respect to which a Gross-up Payment would be payable hereunder, and Executive shall be entitled to settle or contest any other issue raised by the Internal Revenue Service or any other taxing authority. Executive shall cooperate with the Company in any proceedings relating to the determination and assessment of any Excise Tax and shall not take any position or action that would materially increase the amount of any Gross-up Payment hereunder. Prior to the third anniversary of the date of this Agreement, the Board (and/or the Compensation Committee) and Executive agree to discuss a provision to replace this Section 7, on terms and conditions mutually satisfactory to the Board and Executive, which takes into account the then current public market conditions. In the event that the Board (and/or the Compensation Committee) and Executive mutually agree to a replacement of this Section 7, the parties shall set forth the terms and conditions of such modification in a written amendment to this Agreement.

8. Covenants of the Executive. In order to induce the Company to enter into this Agreement and continue to employ the Executive hereunder, the Executive hereby covenants and agrees as follows. For all purposes under this Section 8 herein, references to "Company" shall be deemed to include the Company's wholly-owned subsidiaries, if any, and the Company's "business" shall mean film based delivery systems to deliver drug actives, nutraceuticals, cosmaceuticals or flavors, and soluble film based packaging systems and such other lines of business in which the Company or its wholly-owned subsidiaries, if any, is actively engaged or actively pursuing and with respect to which Executive has oversight responsibility or is otherwise substantively involved.

A. Non-Competition. During the Employment Term, including any extensions thereof, and for a period of 18 months immediately following the termination of Executive's employment under this Agreement for any reason other than death (the "Restrictive Period"), except as provided herein, Executive shall not directly or indirectly: (a) engage in or in any manner be connected or concerned, whether as an officer, director, stockholder, partner, owner, employee, advisor, creditor, or otherwise with the development, operation, management, or conduct of any business in the United States that competes with the business of the Company being conducted at the time of such termination; (b) solicit or otherwise attempt to divert business from or interfere in the Company relationship with any supplier of the Company or any customer served by the Company or and potential customer identified by the Company during the period of Executive's employment hereunder; or (c) solicit, hire or otherwise interfere with the Company relationship with any person then or previously employed by the Company; provided, however, that, after the termination of Executive's employment, Executive shall not be bound by the Covenant set forth in this subparagraph following a material breach by the Company of any of its obligations to the Executive hereunder or in the event of the cessation or dissolution of the Company business. As used herein, "cessation or dissolution" means total liquidation of the Company and does not include a cessation of business due to any Change in Control. Nothing contained herein shall prohibit Executive from owning up to 3% of the stock of a publicly traded company that competes with the business of the Company or, following the termination of his employment with the Company, prevent the Executive from being employed by or otherwise affiliated with a line of business of another company that engages in multiple lines of business so long as the Executive is not employed by, does not provide services with respect to and is not otherwise involved in the line or lines of business of such other company that compete with the Company.

B. Confidentiality. During the Employment Term, and following the termination of this Agreement for any reason for as long as the information remains confidential, Executive shall not make any use, for his own benefit or for the benefit of a business or entity other than the Company, of any verbal or written secret or confidential information. Such confidential information shall include, but not be limited to, customer lists, trade secrets, sales, marketing or consignment information, vendor lists or operational resource information, forms, processes or procedures, budget and financial statements or information, files, records, documents, compilation of data, engineering drawings, computer print-outs, or any other data of or pertaining to the Company, its business, customers and financial affairs, or its services not generally known within the Company's trade and which was acquired by him during his affiliation with the Company. Executive shall not remove from the Company premises or retain without the Company's written consent any of the Company's confidential information as defined herein, or copies thereof or extracts therefrom. Executive shall hold in a fiduciary capacity for the benefit of the Company all secret or confidential information, knowledge, or data of the Company or its business or production operations obtained by Executive during his employment by the Company, which shall not be generally known to the public or recognized as standard practice (whether or not developed by Executive) and shall not, during his employment hereunder or after the termination of such employment, communicate or divulge any such information, knowledge or data to any person, firm or corporation other than the Company or persons, firms or corporations designated by the Company. Executive acknowledges that this information is treated as confidential by the Company, that the Company takes meaningful steps to protect the confidentiality of this information, and that the Company has at all times directed Executive to maintain the confidentiality of this information. Immediately upon termination of this Agreement, Executive shall return all of the Company's property to it, including any and all copies of said property. Notwithstanding this provision or any provision in this Agreement to the contrary, nothing contained in this Agreement is intended to nor shall it limit or prohibit the Executive, or waive any right on his part, to make any good faith reports to, initiate or engage in communication with, respond to any inquiry from, otherwise provide information to, participate in any investigation or proceeding that may be conducted by, or obtain any monetary recovery from, any federal or state regulatory, self-regulatory, or enforcement agency or authority, as provided for, protected under or warranted by applicable law, in all events without notice to or consent of the Company.

C. Ownership of Work Product. Executive agrees that the Company shall own all intellectual property including trade secrets, patents, patentable inventions, discoveries and improvements that relate to the Company's business that Executive conceives, develops during the period of his employment with the Company or delivers to the Company while performing services pursuant to this Agreement ("Work Product"). Executive further agrees to deliver to the Company, and that the Company shall thereafter own for all purposes, all Work Product conceived or developed by the Executive relating to the business of the Company which does not otherwise belong to Employee's former employer or to which the former employer has no legal right or claim. Executive hereby irrevocably extinguishes for the benefit of the Company and its assigns any moral right to the Work Product recognized by applicable law. All Work Product shall be considered a work made for hire by Executive and owned by the Company. If any of the Work Product may not, by operation of law, be considered work made for hire by Executive for the Company, or if ownership of all right, title and interest of the intellectual property rights therein shall not otherwise vest exclusively in the Company, Executive agrees to assign, and upon creation thereof automatically assign, without further consideration, the ownership of all trade secrets, copyrights, patentable inventions, and other intellectual property rights therein to the Company, its successors and assigns. The Company, its successors, and assigns, shall have the right to obtain and hold in its or their own name copyrights, patents, registrations and any other protection available in the foregoing. For purposes hereof, a "trade secret" shall mean any information, including, but not limited to, technical or nontechnical data, formulae, patterns, compilations, programs, devices, methods, techniques, drawings. processes, financial data, financial plans, product plans or lists of actual or potential customers or suppliers that derive economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from their disclosure or use and are the subject of efforts that are reasonable under the circumstances to maintain their secrecy. Executive agrees to perform, upon the reasonable request of the Company and at no cost to the Company (other than travel out of pocket costs where applicable), during or after the period(s) that this Agreement remains in effect, such further acts as may be necessary or desirable to transfer, perfect and defend the Company's ownership of Work Product, or to enforce the Company's Work Product against third parties. When requested, Executive shall promptly and at no cost to the Company (other than travel out of pocket costs, where applicable): (a) execute, acknowledge and deliver any requested affidavits and documents of assignment and conveyance; (b) obtain and aid in the enforcement of copyright and, if applicable, patents with respect to the Work Product in any countries; (c) provide testimony in connection with any enforcement proceeding or any proceeding affecting the right, title or interest of the Company in any Work Product; and (d) perform any other acts deemed necessary or desirable to carry out the purposes of this Agreement.

D. Inventions. All discoveries, designs, improvements, ideas and inventions, whether patentable or not, relating to (or suggested by or resulting from) products, services, or other technology of the Company or relating to (or suggested by or resulting from) methods or processes used or usable in connection with the business of the Company that have been, or may be, conceived, developed or made by Executive during the Employment Term (hereinafter "Inventions"), either solely or jointly with others, shall automatically become the sole property of the Company. Executive shall immediately disclose to the Company all such Inventions and shall, without additional compensation, execute all assignments and other documents deemed necessary by the Company to perfect the Company's title thereto, or to the patents issued thereon, or to otherwise secure and protect the Company's property rights therein. These obligations shall continue beyond the termination of Executive's employment with respect to Inventions conceived, developed or made by Executive during employment with the Company. The Company acknowledges and agrees that the provisions of this paragraph shall not apply to any invention for which no equipment, supplies, facilities or trade secret (or proprietary) information of the Company is used by Executive and which is developed entirely on Executive's own time, unless (a) such invention related to the business of the Company or to the Company's actual or demonstrably anticipated research or development; or (b) such invention results from any work performed by Executive for the Company.

E. Acknowledgment. Executive acknowledges that all of the restrictions set forth in this Section entitled "Covenants of the Executive" are reasonable in scope, both individually and in the aggregate, and essential to the preservation of the Company's business and proprietary interests and that the enforcement thereof will not in any manner preclude Executive, in the event of Executive's termination of employment with the Company for any reason, from becoming gainfully employed in such manner and to such extent as to provide a standard of living for himself, the members of his family, and those dependent upon him of at least the sort and fashion to which he and they have become accustomed and may expect. The Company and the Executive further agree that if any particular provision or portion of this Section 8 shall be adjudicated to be invalid or unenforceable, such adjudication shall apply only with respect to the operation of such provision in the particular jurisdiction in which such adjudication is made. The Company and Executive also agree that in the event that any restriction herein shall be found to be void or unenforceable if some part or parts thereof were deleted or the period or area of application reduced, such restriction shall apply with such modification as may be necessary to make it valid and enforceable to the fullest extent possible consonant with applicable law. In addition, pursuant to the Defend Trade Secrets Act of 2016, the parties acknowledge that (a) an individual may not be held criminally or civilly liable under any federal or state trade secret law for the disclosure of a trade secret that: (i) is made in confidence to a federal, state or local government official, either directly or indirectly, or to an attorney and solely for the purpose of reporting or investigating a suspected violation of law; or (ii) is made in a complaint or other document that is filed under seal in a lawsuit or other proceeding; and (b) an individual who files a lawsuit for retaliation by an employer for reporting a suspected violation of law may disclose the employer's trade secrets to the attorney and use the trade secret information in the court proceeding if the individual: (i) files any document containing the trade secret under seal; and (ii) does not disclose the trade secret, except pursuant to court order.

F. Representations and Warranties. Executive represents and warrants to the Company as follows: (a) Executive is under no contractual or other restriction or obligation which may conflict with or be inconsistent with the execution of this Agreement or with the performing of any duties for the Company, or any other rights of the Company; and (b) neither the Company nor any of its affiliates nor any of their respective officers, directors, employees, agents or employees has requested that Executive communicate or otherwise make available to any such parties at any time any proprietary information, data, trade secrets, or other confidential information belonging to Executive's former employers or others.

G. Severability. All of the covenants of Executive contained in this Section entitled "Covenants of the Executive" shall each be construed as an agreement independent of any other provision in this Agreement, and the existence of any claim or cause of action of Executive against the Company, whether predicated on this Agreement or otherwise, shall not constitute a defense to the enforcement by the Company of such covenants. Both parties hereby expressly agree that it is not the intention of either party to violate any public policy, statutory or common law. If any sentence, paragraph, clause or combination of the same of this Agreement is in violation of the law of any state where applicable, such sentence, paragraph, clause or combination of the same shall be void in the jurisdictions where it is unlawful, and the remainder of such paragraph and this Agreement shall remain binding on the parties to the extent that it may be lawfully done under existing applicable laws. In the event that any part of any covenant of this Agreement is determined by a court of law to be overly broad thereby making the covenant unenforceable, the parties hereto agree, and it is their desire, that such court shall substitute a judicially enforceable limitation in its place, and that as so modified the covenant shall be binding upon the parties as if originally set forth herein.

H. Remedies. The Executive agrees that irreparable harm would result from any breach by Executive of the covenants of this Section 8 in particular, and this Agreement in general, and that monetary damages alone would not provide the Company adequate relief for any such breach. Accordingly, if Executive breaches any covenant in this Section 8, the parties acknowledge that equitable or injunctive relief in favor of the Company is a proper remedy, and nothing in this Agreement shall be construed as precluding the Company from seeking such equitable or injunctive relief in a court of competent jurisdiction for Executive's violations of Section 8. Any award of equitable or injunctive relief shall not preclude the Company from seeking or recovering any lawful compensatory damages that may have resulted from a breach of the covenants of this Agreement. Any waiver or failure to seek enforcement or remedy for any breach or suspected breach of any covenant of Executive in this Agreement shall not be deemed a waiver of such provision in the future. Furthermore, the existence of any claim of Executive against the Company, whether based upon this Agreement or otherwise, shall not operate as a defense to the Company enforcement of any provision of this Agreement. Proceedings seeking equitable and injunctive relief to enforce the terms of this Section 8 may be brought in any court of competent jurisdiction.

9. Indemnification. Subject to the Company by-laws, to the fullest extent allowed or permitted under any provision of applicable law, the Company shall indemnify Executive against any losses, claims, damages or liabilities, or expenses (including reasonable attorneys' fees) incurred by Executive arising out of any claim based upon acts performed or omitted to be performed by Executive in connection with his employment with the Company.

10. Attorneys' Fees. In any action brought by any party under this Agreement to enforce any of its terms, or any appeal therefrom, each party shall bear its own costs and expenses, including its own attorneys' fees; provided, however, that the Executive (or his estate or other beneficiaries, as the case may be) will be entitled to reimbursement for reasonable costs and expenses, including reasonable attorneys' fees, with respect to such action if and to the extent that the Executive (or his estate or other beneficiaries, as the case may be) is the prevailing party.

11. Cooperation. Executive agrees that, after the termination of his employment, he shall cooperate on a reasonable basis in the truthful and honest prosecution and/or defense of any claim in which the Company, its affiliates and/or its subsidiaries may have an interest (subject to reasonable limitations and the Executive's other commitments concerning time and place), which may include, without limitation, making himself available on a reasonable basis to participate in any proceeding involving the Company, its affiliates and/or its subsidiaries, appearing for depositions and testimony without requiring a subpoena, and producing and/or providing any documents or names of other persons with relevant information. The Company agrees to reimburse Executive for all expenses reasonably incurred by him and to pay reasonable compensation to Executive for and in connection with services provided by him pursuant to this Section.

12. Travel Restrictions. As is reasonable, Executive has the right to refuse travel to destinations deemed politically unstable or otherwise hostile and/or those that may represent a danger to the Executive's health and well-being.

13. Notices. Any notices permitted or required under this Agreement shall be deemed given upon the date of personal delivery or forty-eight (48) hours after deposit in the United States mail, postage fully paid, certified mail, return receipt requested, addressed to the Company at its principal headquarters address and to the Executive at his last address on record with the Company. Either party may change the address to which notices to such party shall be delivered personally or mailed by giving notice thereof to the other party hereto in accordance with the terms of this Section 13.

14. Venue; Jurisdiction. The validity, construction, interpretation, and enforceability of this Agreement shall be determined and governed by the laws (procedural and substantive) of the State of New Jersey without giving effect to the principles of conflicts of law. For the purpose of litigating any dispute that arises under this Agreement, the parties hereby consent to exclusive jurisdiction of, and agree that such litigation shall be conducted in, any state or federal court located in the State of New Jersey.

15. Binding Effect; Assignment. Executive shall not, without the prior written consent of the Company, assign, transfer, or otherwise convey this Agreement, or any right or interest herein. This Agreement, and all rights and obligations of the Company or any of its successors, may be assigned or otherwise transferred to any of its successors and shall be binding upon and inure to the benefit of its successors. As used herein, the term "successor" shall mean any person, corporation or other entity that, by merger, consolidation, purchase of stock, assets, liquidation, voluntary or involuntary assignment, or otherwise, acquires all or a substantial part of the assets of the Company or succeeds to one or more lines of business of the Company.

16. Entire Agreement. This Agreement constitutes the entire agreement between the parties hereto with respect to the subject matter hereof and supersedes all prior agreements, understandings and arrangements, both oral and written, between the parties hereto with respect to such subject matter, it being understood that this Agreement shall expressly supersede the Executive's 2008 Employment Agreement with the Company and all amendments thereto. This Agreement may not be modified, amended, altered or rescinded in any manner, except by written instrument signed by all of the parties hereto; provided, however, that any waiver by either party with respect to any provision hereof, or the breach of any provision hereof by the other party, need be signed only by the party waiving such provision or breach; and provided, further, that the waiver by either party hereto of a breach or compliance with any provision of this Agreement shall not operate nor be construed as a waiver of any subsequent breach or compliance.

17. Severability. In case any one or more of the provisions of this Agreement shall be held by any court of competent jurisdiction to be illegal, invalid or unenforceable in any respect, the remainder of this Agreement, or the application of such provision to persons or circumstances other than those to which it is held to be illegal, invalid, or unenforceable, shall not be affected thereby.

18. Section Headings. The section headings contained in this Agreement are for reference purposes only and shall not affect in any manner the meaning or interpretation of this Agreement.

19. Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be deemed an original, but all of which taken together shall constitute one and the same instrument.

20. Survival. The provisions of Sections 6-11 and 13-20 of this Agreement shall survive any termination of this Agreement and the termination of Executive's employment by either party for any reason.

IN WITNESS WHEREOF, the parties hereto have executed and delivered this Agreement as of the day and year first above written.

AQUESTIVE THERAPEUTICS, INC.	EXECUTIVE
By: /s/ John Cochran Name: John Cochran Title: Vice President	/s/ Keith J. Kendall KEITH J. KENDALL

EXHIBIT A
GENERAL RELEASE

In exchange for certain payments and benefits to be provided to me by Aquestive Therapeutics, Inc. pursuant to the Employment Agreement dated as of June 26, 2018, between the undersigned executive (the "Executive") and Aquestive Therapeutics, Inc., the Executive hereby knowingly and voluntarily waives, releases and discharges Aquestive Therapeutics, Inc., its predecessors, successors, parent corporations, subsidiaries, affiliates and each of their employees, officers and directors, agents, trustees, and fiduciaries (the "Company") from any and all claims, liabilities, demands, and causes of action, which he may have or claim to have against the Company, including any and all claims arising out of or relating in any way to the Executive's employment and/or separation of employment from the Company. This General Release specifically waives and releases all rights, claims, causes of action, demands, and liabilities which may arise up to and including the date the Executive signs this General Release. This General Release does not, however, waive or release any rights or claims which may arise after the date the Executive signs this General Release. This General Release of claims includes, but is not limited to:

a. all State and Federal statutory claims including, but not limited to, claims arising under Title VII of the Civil Rights Act of 1964, the Age Discrimination in Employment Act, the Older Worker Benefit Protection Act, the Americans with Disabilities Act, the Family and Medical Leave Act, the Sarbanes-Oxley Act, the Employee Retirement Income Security Act, the Fair Labor Standards Act, the Worker Adjustment and Retraining Notification Act, the New Jersey Law Against Discrimination, the New Jersey Civil Rights Act, the New Jersey Civil Union Act, the New Jersey Wage and Hour Law, the New Jersey Conscientious Employee Protection Act, the New Jersey Domestic Partnership Act, and the New Jersey Family Leave Act;

b. All claims arising under the United States and New Jersey Constitutions;

c. All claims arising under any Executive Order or derived from or based upon any State or Federal regulations;

d. All common law claims including, but not limited to, claims for wrongful or constructive discharge, public policy claims, retaliation claims, claims for breach of an express or implied contract, claims for breach of an implied covenant of good faith and fair dealing, intentional infliction of emotional distress, defamation, fraud, conspiracy, loss of consortium, tortious interference with contract or prospective economic advantage, promissory estoppel and negligence;

e. All claims for any compensation including, but not limited to, back wages, front pay, overtime pay, bonuses or awards, fringe benefits, reinstatement, retroactive seniority, pension benefits, or any other form of economic loss;

f. All claims for personal injury including, but not limited to, physical injury, mental anguish, emotional distress, pain and suffering, embarrassment, humiliation, damage to name or reputation, liquidated damages, and punitive damages; and

g. All claims for costs and attorneys' fees.

The Executive hereby acknowledges that the Company is advising him in writing that he should consult with an attorney prior to executing this General Release. The Executive hereby states that he has had the opportunity to discuss this General Release with whomever the Executive wished, including an attorney of his own choosing. The Executive further states that he has had the opportunity to read, review, and consider all of the provisions of this General Release; that the Executive understands its provisions and its binding effect on him; and that the Executive is entering into this General Release freely, voluntarily, and without duress or coercion. The Executive acknowledges that he has not relied upon the Company employees, officers or directors, counsel, agents or accountants for any legal, tax or other advice, and the Executive has, to the extent the Executive deems necessary, consulted with his own advisors as to these matters. The Executive represents that he has not filed any grievance, charge, claim, or complaint of any kind seeking personal recovery or personal injunctive relief against the Company or any of its owners, officers, directors, employees or agents, with respect to any matter, including but not limited to, his employment with the Company and/or the separation of that employment. Nothing contained in this paragraph shall prohibit the Executive from (a) bringing any action to enforce the terms of this Agreement and General Release; (b) filing a timely charge or complaint with the Equal Employment Opportunity Commission ("EEOC") regarding the validity of this Agreement and General Release; (c) filing a timely charge or complaint with the EEOC or participating in any investigation or proceeding conducted by the EEOC regarding any claim of employment discrimination (although the Executive has waived any right to personal recovery or personal injunctive relief in connection with any such charge or complaint); (d) initiating or engaging in communication with, responding to any inquiry from, or otherwise providing information to, any other federal or state regulatory, self-regulatory or enforcement agency or authority; or (e) seeking or obtaining an award under the whistleblower provisions of the federal securities laws.

The Executive understands that he has twenty-one (21) calendar days within which to consider this General Release before signing it. The Executive also understands that he is free to use as much of the twenty-one (21) calendar day period as he wishes or considers necessary before deciding to sign this General Release. The Executive may revoke his signature of this General Release within seven (7) calendar days of signing it by delivering written notice of revocation to the Director of Human Resources of the Company, 30 Technology Drive South, Warren, New Jersey 07059. If Executive has not revoked his signature of this General Release by written notice delivered within the seven (7) calendar day period, it becomes effective immediately thereafter.

The Executive understands that his failure or refusal to execute this General Release or his timely revocation of this General Release will result in forfeiture of any severance payments and benefits.

BY SIGNING THIS GENERAL RELEASE, EXECUTIVE ACKNOWLEDGES THAT:

HE HAS READ IT;

HE UNDERSTANDS IT AND KNOWS HE IS GIVING UP IMPORTANT RIGHTS;

HE AGREES WITH EVERYTHING IN IT;

HE HAS BEEN ADVISED TO CONSULT WITH AN ATTORNEY PRIOR TO EXECUTING THIS GENERAL RELEASE; AND

HE HAS SIGNED THIS GENERAL RELEASE KNOWINGLY AND VOLUNTARILY.

EXECUTIVE

KEITH J. KENDALL

AQUESTIVE THERAPEUTICS, INC.

By:

Name:

Title:

Exhibit 10.8

EXECUTIVE EMPLOYMENT AGREEMENT

This Executive Employment Agreement (the "Agreement") is made and entered into as of July 9, 2018 (the "Effective Date") by and between Aquestive Therapeutics, Inc. (the "Company") and Alexander Mark Schobel (the "Executive").

WITNESSETH:

WHEREAS, the Executive is currently employed by the Company as its Chief Innovation and Technology Officer under an Executive Employment Agreement dated November 17, 2008, as amended, between the Executive and MonoSol Rx, LLC, the predecessor of the Company, as amended (the "2008 Employment Agreement"); and

WHEREAS, the parties desire that the Executive continue to be employed by the Company as its Chief Innovation and Technology Officer upon the terms and conditions of this Agreement and that this Agreement will supersede the 2008 Employment Agreement;

NOW, THEREFORE, in consideration of the premises and the mutual covenants herein set forth, and for other good and valuable consideration (the receipt and sufficiency of which are hereby acknowledged), the parties hereto, intending to be legally bound, hereby agree as follows:

1. Employment.

A. Position. During the Employment Term (as hereinafter defined) of this Agreement, the Executive agrees to be employed by and to serve the Company as its Chief Innovation and Technology Officer, and the Company agrees to employ and retain Executive in such capacity. The Executive shall report directly to the Chief Executive Officer Board of the Company (the "CEO").

B. Employment Obligations. The Executive shall: (i) devote his entire business time, energy and skill to the affairs of the Company; (ii) faithfully, loyally, and industriously perform all duties incident to the position of Chief Innovation and Technology Officer, as well as any other duties consistent with the stature and responsibility of the Executive's position as may from time to time be assigned by the CEO; and (iii) comply with the Company's policies in effect from time to time.

C. Succession Responsibilities. A critical responsibility of Executive is to ensure that the intellectual property assets of the Company are protected, preserved and always available to carry out the strategy and objectives of the Company and for the transfer of institutional and tacit knowledge upon the retirement or withdrawal of Executive from the Company. Accordingly, as Chief Innovation and Technology Officer of the Company, Executive shall be responsible for preparing during the Employment Term for an orderly, well-executed handover of the Company's intellectual property and knowledge transfer that proceeds from a robust management development process including, but not limited to (i) developing programs and procedures to codify and manage institutional and historical information in accessible places, (ii) developing a training program on available knowledge transfer tools documenting, where appropriate, content for each knowledge item; (iii) establishing the mechanisms to make succession planning for Executive's position and responsibilities an ongoing and real-time process, (iv) assessing potential internal and external candidates based on defined profile and selection criteria, and (vi) apprising the CEO and chief human resources officer of the results of Executive's handover and succession program.

D. External Activities. Notwithstanding any provision in this Section 1 to the contrary, Executive shall not be precluded from devoting reasonable periods of time required for serving as a member of one or more advisory boards or boards of directors of companies or organizations or engaging in other minor business activities, so long as such memberships or activities do not interfere with the performance of Executive's duties hereunder and are not directly or indirectly competitive with, nor contrary to, the business or other interests of the Company, subject to prior approval by the CEO.

2. Employment Term. The term of this Agreement (the "Employment Term") shall begin on the Effective Date and, unless earlier terminated in accordance with this Agreement, shall continue through December 31, 2020. Thereafter, the Employment Term will automatically renew for successive one-year periods unless either party gives notice of non-renewal to the other at least 90 days before the end of the initial term or then current renewal term, as the case may be.

3. Compensation.

A. Base Salary. The Company shall pay Executive a base salary (the "Base Salary") at a rate of $350,000.00 per annum, payable in accordance with the standard payroll practices of the Company. The Board of Directors of the Company (the "Board") will review Executive's Base Salary at least annually and, with recommendations from the CEO, may increase but not decrease the then current annual rate.

B. Annual Bonus. Executive shall be eligible for a target annual performance bonus ("Annual Bonus") of at least seventy-five percent (75%) of Executive's Base Salary for each calendar year, provided the Company and Executive each achieves performance targets established by the Board, with recommendations from the CEO for the Company and Executive. The Annual Bonus amount, if any, for a calendar year will be determined by the Board, with recommendations from the CEO, and paid by the Company by March 15th of the following calendar year, unless it is administratively impracticable to determine and/or make the payment by such date. Except as otherwise provided by this Agreement, the Executive must be employed by the Company on the day any Annual Bonus payment is due and payable in order to receive said bonus payment. If the Company exceeds established performance targets, the Board and/or the Compensation Committee may, in its sole discretion, with recommendations from the CEO, increase the amount of the Annual Bonus.

C. Award of Non-Voting Common Stock. Executive has previously been awarded Non-Voting Common Stock, par value $.001 per share, of the Company (the "Non-Voting Common Stock") equal to five percent (5%) of the issued and outstanding capital securities of the Company as of the time of grant of the Non-Voting Common Stock to the Executive. Each share of Non-Voting Common Stock awarded to the Executive will become one share of voting common stock, par value $.001 per share, of the Company (the "Common Stock") upon completion of an initial public offering and sale of the capital stock of the Company (an "IPO"). The Executive shall be eligible for awards of additional shares of Non-Voting Common Stock and to participate in other employee incentive plans and equity-based compensation awards of the Company during the Employment Term at the times and in the amounts as the Board and/or Compensation Committee in its sole discretion shall determine. The award of the shares of Non-Voting Common Stock is governed by the Shareholders Agreement dated as of April 19, 2018 by and among the Company, the Executive and other parties who are signatories thereto (the "Shareholders Agreement"). Notwithstanding anything to the contrary in this Agreement or the Shareholders Agreement, if during the Employment Term the Company or any successor thereto (with any such successor being referred to in this Agreement as the "Company") issues or grants additional equity interests, options, or warrants of the capital stock of the Company during the Employment Term (a "Dilution Event"), other than upon or after an IPO of the Company (which event is addressed in Section 3(D) below), the Company shall award to Executive, prior to or simultaneously with the effective date of the Dilution Event, stock appreciation rights covering shares of Common Stock ("SARs") equal to the difference between:

(1) the number of shares of Common Stock representing five percent (5%) of the total outstanding shares of the Common Stock upon completion of such Dilution Event determined on a fully diluted basis (including, after giving effect to such Dilution Event, any exercise or conversion of all then outstanding options, warrants or all other derivative securities convertible into or exchangeable for Common Stock, whether or not such options, warrants or other derivative securities are then in-the-money); and

(2) the number of shares of Non-Voting Common Stock and the number of SARs, if any, held by Executive immediately prior to the effective date of the Dilution Event, such that the total of all the shares of Non-Voting Common Stock and SARs held by Executive immediately following such Dilution Event represents in the aggregate five percent (5%) of the total outstanding Common Stock (determined on a fully diluted basis, including, after converting shares of Non-Voting Common Stock into shares of Common Stock and, after giving effect to such Dilution Event, any exercise or conversion of all then outstanding options, warrants or all other derivative securities convertible into or exchangeable for Common Stock, whether or not such options, warrants, or other derivative securities are then in-the-money).

D. Equity Participation Awards upon IPO. At the time of any IPO, the Company will make the following additional awards to the Executive:

(1) SARs equal to the difference between:

(a) the number of shares of Common Stock representing five percent (5%) of the total outstanding shares of Common Stock upon completion of the IPO (determined on a fully diluted basis, including giving effect to (i) conversion of any and all Non-Voting Common Stock to Common Stock upon completion of the IPO, (ii) the exercise of options, warrants or other rights to purchase Common Stock and/or the conversion or exchange of securities or evidences of indebtedness convertible into or exchangeable for shares of Common Stock issued by the Company under any equity plan or agreement, all on an equivalent IPO converted basis, and (iii) the exercise of any overallotment option (if exercised) and the exercise or exchange of all then outstanding options, warrants or all other derivative securities convertible or exchangeable for Common Stock, whether or not such options, warrants or other derivative securities are then in-the-money); and

(b) the number of shares of Non-Voting Common Stock and the number of SARs, if any, held by Executive immediately prior to the completion of the IPO, such that the total number of all of the shares of Non-Voting Common Stock and SARs held by Executive immediately following the IPO represents in the aggregate five percent (5%) of the Common Stock of the Company (determined on a fully diluted basis, including giving effect to (i) the conversion of any and all Non-Voting Common Stock to Common Stock upon completion of the IPO, (ii) the exercise of options, warrants or other rights to purchase shares of Common Stock and/or the conversion or exchange of securities or evidences of indebtedness convertible into or exchangeable for shares of Common Stock issued by the Company under any equity plan or agreement, all on an equivalent IPO converted basis, and (iii) the exercise of any overallotment option (if exercised) and the exercise or exchange of all then outstanding options, warrants or all other derivative securities convertible or exchangeable for Common Stock, whether or not such options, warrants or other derivative securities are then in-the-money), and

(2) an additional award of a number of shares of restricted stock ("Restricted Stock") equal to .47% of the aggregate number of outstanding shares of Common Stock upon completion of such IPO (determined on the same fully diluted basis as in subsection (1)(a) in this Section 3(D)).

E. Vesting. The SARs awarded in Section 3(C) and 3(D)(1), as applicable, shall vest in thirty-six (36) equal monthly installments beginning on the last day of the month next following the month in which the Dilution Event or IPO, as the case may be, is completed, and the additional shares of Restricted Stock awarded in Section 3(D)(2) shall vest in eight (8) equal quarterly installments beginning on the last day of the month next following the month in which the IPO is completed, in each case subject to Executive's continued employment on the applicable vesting date, and all subject to any earlier or accelerated vesting as provided in this Agreement below or in any applicable award agreement or employee incentive compensation or similar plan of the Company so long as the early or accelerated vesting provisions of such award agreements or plans are not inconsistent with the terms of this Agreement. Vesting of the SARs and shares of Restricted Stock will accelerate and become nonforfeitable if Executive's employment terminates for any reason other than by the Company for "Cause" (as defined below) or by the Executive without "Good Reason" (as defined below). The Company shall withhold from the issuance of any Company shares, on each vesting date of such SARs and/or Restricted Stock, that number of shares of Common Stock (using the fair market value of the shares at the particular vesting date) as is necessary to satisfy Executive's minimum federal, state and local income and employment tax withholding obligations on such vesting or delivery event.

4. Additional Benefits.

A. Executive Benefits. During the Employment Term, Executive shall be eligible to participate in such employee benefit plans as are generally available to other senior executives of the Company.

B. Paid Time Off. The Executive will be allowed to take up to four weeks of vacation each year, and shall be eligible for such sick leave and other paid time off in accordance with the Company' policies applicable to other executives generally.

C. Expense Reimbursement. The Company will pay or reimburse Executive for reasonable expenses incurred by Executive in connection with the performance of his duties and responsibilities under this Agreement, subject to presentation of vouchers and compliance with generally applicable business expense reimbursement policies of the Company.

5. Termination.

A. Termination for Cause. The Company may terminate Executive's employment for "Cause" if Executive:

(i) is convicted of or pleads nolo contendre to a felony (or its equivalent under applicable state law);

(ii) commits fraud or a material act or omission involving dishonesty with respect to the Company or any of its respective employees, customers or affiliates;

(iii) willfully and repeatedly fails or refuses to carry out the material responsibilities of Executive's employment by the Company (except where due to physical or mental incapacity);

(iv) engages in willful misconduct or a pattern of behavior which in either case has had or is reasonably likely to have a significant adverse effect on the Company;

(v) willfully engages in any act or omission which is in material violation of the Company's policy, including but not limited to engaging in insider trading transactions or disseminating inside information; or

(vi) commits a material breach of Executive's material obligations under this Agreement, including but not limited to Section 8.

A decision to terminate the Executive's employment for Cause must be made, if at all, by the CEO, after consultation with the Board, after reasonable notice to Executive and an opportunity for Executive, together with counsel, to be heard by the CEO, and the CEO finding that, in his good faith opinion, Executive engaged in conduct set forth above and specifying the particulars thereof in reasonable detail. If the act or omission giving rise to the termination for Cause is curable by Executive, the Company will provide thirty (30) days' written notice to Executive of the Company's intent to terminate Executive for Cause, with an explanation of the reason(s) for the termination for Cause and, if Executive cures the act or omission within the 30-day notice period, the CEO will rescind the notice of termination and Executive's employment will not be terminated for Cause at the end of the 30-day notice period. If Executive has previously been afforded the opportunity to cure particular behavior and successfully cured under this provision, the Company will have no obligation to provide Executive with notice and an opportunity to cure a recurrence of that behavior prior to a termination for Cause. For purposes of this Section 5(A), an action or inaction shall not be treated as "willful misconduct" if authorized by the CEO or the Board, or taken by Executive in the good faith belief that it was in, or not opposed to, the best interests of the Company.

B. Termination by Reason of Permanent Disability. In a manner consistent with the Americans with Disabilities Act and the Family and Medical Leave Act, this Agreement may be terminated at the Company's option immediately upon notice to Executive if Executive shall suffer a Permanent Disability. For purposes of this Agreement, the term "Permanent Disability" shall mean the Executive's inability to perform the essential functions of his job under this Agreement, with or without reasonable accommodation, for a period of 150 consecutive days or for an aggregate of 180 days, whether or not consecutive, in any twelve (12) month period, due to illness, accident or other physical or mental incapacity, as determined by a duly licensed physician mutually agreed to by both the Executive and the Company.

C. Termination by Reason of Death. In the event of the Executive's death, the Executive's employment shall be deemed to have terminated on the date of Executive's death.

D. Voluntary Resignation. Executive may terminate this Agreement at any time, subject to providing thirty (30) days' written notice to the Company. The Company may waive such notice and/or set an earlier termination date, without pay in lieu of notice.

E. Termination without Cause. The Company may terminate Executive's employment under this Agreement at any time without Cause upon thirty (30) days' prior written notice to Executive. The Company, at its sole discretion, may relieve Executive of his active duties during the notice period. Executive's termination without Cause will be effective upon the expiration of the 30-day notice period. For purposes of this Agreement, a termination of employment by the Company that purports to be for Cause, but is not in full compliance with all of the substantive and procedural requirements relating to a termination for Cause under this Agreement, shall be treated as a termination of employment without Cause.

F. Termination for Good Reason. The Executive may terminate his employment under this Agreement at any time for Good Reason upon the occurrence (or within 180 days following the occurrence, provided that the Executive furnishes the Company with written notice of his belief that grounds for a Good Reason termination by the Executive exists no later than sixty (60) days after becoming aware of the occurrence) of any one or more of the following acts or omissions which, if curable, is not cured within thirty (30) days after notice of the occurrence is provided by Executive: (1) any action by the Company which results in a material diminution in Executive's position, authority, duties or responsibilities as Chief Innovation and Technology Officer of the Company (including status, offices, titles and reporting requirements contemplated by this Agreement); (2) a material breach by the Company of its obligations under this Agreement, including, without limitation, a reduction of Executive's Base Salary or target bonus opportunity in violation of this Agreement; or (3) the Company requiring the Executive to be based at any office location that is more than fifty (50) miles from its current headquarters in Warren, New Jersey, except for travel reasonably required in connection with the performance of the Executive's responsibilities hereunder. Notwithstanding the foregoing, if a "Change in Control" (as hereinafter defined) occurs, the Executive will not have "Good Reason" to terminate the Executive's employment under this Agreement merely because the Executive reports to a senior executive officer of a company that acquires the Company.

6. Obligations of the Company Upon Termination.

A. Termination for Cause. In the event that the Executive's employment under this Agreement is terminated for Cause, the Company shall have no obligation to pay the Base Salary or any other compensation provided under this Agreement, to or for the benefit of the Executive for any period after the effective date of such termination, or to pay the Target Annual Bonus or any other bonus or incentive compensation for the fiscal year in which such termination occurs; provided, however, that the Company shall promptly provide: (i) all Base Salary earned by the Executive through the effective date of such termination; (ii) any unpaid Annual Bonus earned by the Executive for the year preceding the year in which his employment terminates; and (iii) any benefits under any plans of the Company in which the Executive is a participant, consistent with the Executive's (or his beneficiaries') rights under such plans.

B. Termination by Reason of Death or Permanent Disability. In the event that the Executive's employment under this Agreement terminates due to his death or is terminated by the Company due to the Executive's Permanent Disability, the Company shall, within five (5) business days following such termination, provide to the Executive (or his estate or other beneficiaries, as the case may be): (i) a cash payment consisting of the sum of any previously unpaid Base Salary earned by the Executive through the date on which his employment terminates, any unpaid Annual Bonus earned by the Executive for the year preceding the year in which his employment terminates, and any accrued and unused vacation pay for the year in which his employment terminates; (ii) any benefits under any plans of the Company in which the Executive is a participant, to the full extent of the Executive's (or his beneficiaries') rights under such plans; (iii) a cash payment consisting of the Executive's Target Annual Bonus for the year of termination, pro-rated for the number of days Executive is employed during the calendar year in which his employment terminates ("Pro Rata Bonus"); and (iv) accelerated vesting of all outstanding stock options, restricted stock units ("RSUs"), SARs, Restricted Stock and other equity-based compensation awards as if the Executive's employment had continued through the end of the year in which his employment terminates or, in the case of any such award that is subject to "cliff vesting," on a pro rata basis, determined by a fraction the numerator of which is the number of days during such vesting period, and the denominator of which is the total number of days in the vesting period that have elapsed as of the date his employment terminates. Notwithstanding the immediately preceding sentence, with respect to any unvested stock options, RSUs, SARs, Restricted Stock and other equity-based compensation that are unvested at the time of termination of employment under this Section 6(B), and which are subject to a performance condition or performance period that ends at or after the date of employment termination, such awards will be assumed to have been achieved at "target", and the Executive will be entitled to receive a pro rata share of such awards, determined by a fraction the numerator of which is the number of days during the performance period in which Executive was employed, and the denominator of which is the total number of days in the performance period. Stock options, SARs and other equity-based compensation awards that are or become vested upon termination of the Executive's employment due to death or Permanent Disability will be exercisable (if applicable) for at least one year after the date of such termination or, if earlier, until the expiration of the stated term of the award.

C. Voluntary Resignation. In the event that the Executive voluntarily resigns from his employment with the Company, the Company may, at its discretion, continue the Executive's employment with the Company for any part or the full duration of the 30-day notice period required under Section 5(D). In the event of said termination, the Company shall have no obligation to pay the Base Salary or any other compensation provided under this Agreement to or for the benefit of the Executive for any period after such termination; provided, however, that the Company shall promptly provide: (i) all Base Salary earned by the Executive through the date of such termination; (iii) any unpaid Annual Bonus earned by the Executive for the year preceding the year in which his employment terminates; and (iii) any benefits under any plans of the Company in which Executive is a participant, to the full extent of the Executive's (or his beneficiaries') rights under such plans.

D. Termination by the Company Without Cause or by Executive for Good Reason--Unrelated to Change in Control. In the event that the Executive's employment under this Agreement is terminated by the Company without Cause (pursuant to Section 5(E)) or by the Executive for Good Reason (pursuant to Section 5(F)), the Company shall provide to the Executive: (i) a cash payment consisting of the sum of any previously unpaid Base Salary earned by the Executive through the date on which his employment terminates, any unpaid Annual Bonus earned by the Executive for the year preceding the year in which his employment terminates, and any accrued and unused vacation pay for the year in which his employment terminates; (ii) any benefits under any plans of the Company in which the Executive is a participant, to the full extent of the Executive's (or his beneficiaries') rights under such plans; (iii) a cash payment consisting of the Executive's Pro Rata Bonus for the year of termination; (iv) monthly payments for a period of eighteen 18 months (the "Severance Period") following the termination of Executive's employment or, if longer, until the expiration of the Employment Term, equal to 1/12 of the sum of Executive's Base Salary and Target Annual Bonus (in each case determined without regard to any reduction prior to the termination of Executive's employment); (v) continuing coverage under the Company's group health and life insurance plans in which the Executive is a participant immediately before the termination of his employment (or any successor plans), at the same levels and on the same terms and conditions as are provided to similarly situated executives during the Severance Period (or, if such coverage is not permitted by law or the applicable plan, the cash equivalent of such coverage, grossed up if and to the extent necessary to negate the tax impact of such payment and to negate the tax impact of the gross-up payment); and (vi) full and immediate vesting of outstanding unvested stock options, RSUs, SARs, Restricted Stock and other equity-based compensation awards with any such stock options, SARs and other equity-based compensation awards that are or become vested upon termination of the Executive's employment by the Company without Cause or by the Executive for Good Reason remaining exercisable, as applicable, for at least one year after the date the Executive's employment terminates or, if earlier, until the expiration of the stated term of the award. Notwithstanding the immediately preceding sentence, with respect to any unvested stock options, RSUs, SARs, Restricted Stock and other equity-based compensation that are unvested at the time of termination of employment under this Section 6(D), and which are subject to a performance condition or performance period that ends at or after the date of employment termination, such awards will be assumed to have been achieved at "target." The payments and benefits described in parts (iv) - (vi) of this subsection shall be conditioned upon and subject to the Executive's continuing compliance with his obligations under Section 8 of this Agreement, and the Executive's execution and delivery of a general release substantially in the form annexed hereto as Exhibit A.

E. Termination in Conjunction with a Change in Control.

(1) Severance Protection Upon Involuntary Termination. In the event that, during the period beginning one hundred and eighty (180) days before the effective date of a Change in Control and ending twenty four (24) months following the effective date of a Change in Control, the Executive's employment is terminated by the Company without Cause (pursuant to Section 5(E)) or by the Executive for Good Reason (pursuant to Section 5(F)), the Executive shall be entitled to the payments and benefits described in the preceding Section 6(D) except (i) in lieu of the severance payments described in Section 6(D)(iv), Executive will be entitled to receive an immediate cash payment of an amount consisting of 2.75 times the sum of the Executive's Base Salary and Target Annual Bonus (in each case determined without regard to any reduction prior to the termination of Executive's employment); and (ii) the benefit continuation period described in Section 6(D)(v) shall commence on the date the Executive's employment terminates and expire 36 months from such date of termination. The payments and benefits described in the preceding sentence and in Sections 6(D)(iv) and 6(D)(v) and the single sum severance payment described in the preceding sentence shall be conditioned upon and subject to the Executive's continuing compliance with his obligations under Section 8 of this Agreement, and the Executive's execution and delivery of a general release substantially in the form annexed hereto as Exhibit A.

(2) Definition of Change in Control. For the purposes of this Agreement, a "Change in Control" shall be deemed to have occurred if (a) any person (within the meaning of Section 13(d)(3) or 14(d)(2) of the Securities Exchange Act of 1934, as amended ("Exchange Act")), or group (within the meaning of Section 409A of the Internal Revenue Code of 1986, as amended (the "Code")), becomes, in any 12-month period ending on the date of the most recent acquisition of the voting securities of the Company or any successor entity by such person, persons, or group, directly or indirectly, the beneficial owner (within the meaning of Rule 13d-3 promulgated under the Exchange Act) of 40% or more of the outstanding voting securities of the Company or successor entity; (b) there shall have been consummated a consolidation, merger or reorganization of the Company or any successor entity, unless the holders of the equity interests of the Company or successor entity, immediately before such consolidation, merger or reorganization own, directly or indirectly, at least a majority of the outstanding voting securities or at least a majority of the aggregate fair market value of the corporation or other entity resulting from such consolidation, merger or reorganization; (c) during any 12-month period prior to an IPO (i) Bratton Capital Management L.P. ("Bratton"), or affiliates thereof, cease to beneficially own, directly or indirectly, at least a majority of the outstanding voting securities of, or cease to maintain the right to direct the management of, MonoSolRx Genpar, L.P. (the sole manager of Aquestive Partners, LLC ("APL"), the parent company of the Company as of the Effective Date), or any successor or other or additional manager or managers (or their equivalent) of APL or any successor entity and (ii) if satisfaction of a "change in effective control" is necessary in order to avoid noncompliance with the requirements of Section 409A of the Code, individuals who, as of the Effective Date, constitute the entire Board of the Company (the "Incumbent Board") cease to constitute a majority of the Board or equivalent governing body; provided that (A) any individual becoming a member of the Board or equivalent governing body subsequent to the Effective Date whose appointment was made by a Bratton entity or an affiliate thereof referred to in subclause (i) above or was otherwise approved by at least a majority of the individuals then comprising the Incumbent Board or equivalent governing body shall be considered as though such individual were a member of the Incumbent Board or equivalent governing body as of the Effective Date, and (B) the voluntary resignation of the Executive from the Board, if a member thereof, shall not be considered for purposes of this subclause (ii); or (d) a sale, transfer, liquidation or other disposition of the Company or successor entity's assets and properties representing all or substantially all of the aggregate fair market value of such assets and properties is consummated during any 12-month period; provided, however, that no "Change in Control" shall be deemed to have occurred under this Section 6(E)(2) unless such occurrence, event or condition shall constitute a change in the ownership or effective control of the Company or any successor entity or a change in the ownership of a substantial portion of the Company or successor entity's assets, each as determined under Section 409A(a)(2)(A)(v) of the Code.

F. 409A Compliance. The Company shall take all reasonable actions to ensure that none of the amounts earned or payable under this Agreement or under any Company stock purchase, compensation or other equity incentive plan will violate Section 409A of the Code. To the extent necessary to comply with the restriction in Section 409A(a)(2)(B) of the Code concerning payments to "specified employees," any amounts payable on account of the Executive's separation from service shall be paid (or commence to be paid in the case of any payments to be made in installments) on the first business day of the seventh month following the Executive's date of termination (or death, if earlier) and the first such payment shall include the cumulative amount of any payments that would have been made prior to such date if not for such restriction, together with interest at an annual rate equal to the minimum rate required by the Code in order to avoid the imputation of interest on short-term loans between employers and employees. The date of the Executive's termination of employment shall be determined in accordance with Treasury Regulation Section 1.409A-1(h). Except as otherwise provide herein, any payment required as a result of a termination of employment will be made (or, with respect to any payments to be made in installments under this Agreement, commenced) within 45 days following such event. Notwithstanding anything else herein to the contrary, to the extent that any payments due under the terms of this Agreement are conditioned upon the delivery and non-revocation of a release, and if any of those payments are determined to be nonqualified deferred compensation that is subject to the requirements of Section 409A of the Code, and if the period for consideration and revocation of such release spans two calendar years, then any such payment shall not be made until the later of (i) the end of the revocation period following delivery of the release, or (ii) the first business day of the second calendar year.

G. Value of Insurance Coverage During Severance Period. To the extent any medical or dental plan covering any post-employment period is a "self-insured medical reimbursement plan" under Section 105(h) of the Code, and such coverage would be discriminatory thereunder, the value of the insurance coverage during the post-termination coverage period (based upon premium value) shall be reported as taxable income to the Executive, and the Company shall pay the Executive promptly no later than January 15th of the year of coverage, such additional cash payments as are necessary for the Executive to receive the same net after-tax benefits (taking into account all federal, state and local income, excise and employment taxes) that the Executive would have received under such plans if the Executive had continued to receive such plan benefits while employed with the Company; provided that any such additional cash payment that would be so immediately paid shall be subject to the provisions of Section 6(F) in connection with compliance with Section 409A of the Code.

7. Excise Tax Gross Up. If Executive becomes entitled to one or more payments (with a "payment" including, without limitation, payments in connection with a Change in Control or the vesting of a SAR, stock option or other equity award or other non-cash benefit or property), whether pursuant to the terms of this Agreement or any other plan, arrangement, or agreement with the Company or any affiliated company (the "Total Payments"), which are or become subject to the tax imposed by Section 4999 of the Code or a successor provision of the Code (the "Excise Tax"), the Company shall pay to Executive at the time specified below an additional amount (the "Gross-up Payment") (which shall include, without limitation, reimbursement for any penalties and interest that may accrue in respect of such Excise Tax) such that the net amount retained by Executive, after reduction for any Excise Tax (including any penalties or interest thereon) on the Total Payments and any federal, state and local income or employment tax and Excise Tax on the Gross-up Payment provided for by this Section, but before reduction for any federal, state, or local income or employment tax on the Total Payments, shall be equal to the sum of (a) the Total Payments, and (b) an amount equal to the product of any deductions by the Executive disallowed for federal, state, or local income tax purposes because of the inclusion of the Gross-up Payment in Executive's adjusted gross income multiplied by the highest applicable marginal rate of federal, state, or local income taxation, respectively, for the calendar year in which the Gross-up Payment is to be made. For purposes of determining whether any of the Total Payments will be subject to the Excise Tax and the amount of such Excise Tax:

(i) The Total Payments shall be treated as "parachute payments" within the meaning of Section 280G(b)(2) of the Code, and all "excess parachute payments" within the meaning of Section 280G(b)(1) of the Code shall be treated as subject to the Excise Tax, unless, and except to the extent that, in the written opinion of independent compensation consultants, counsel or auditors of nationally recognized standing ("Independent Advisors") selected by the Company and reasonably acceptable to Executive, the Total Payments (in whole or in part) do not constitute parachute payments, or such excess parachute payments (in whole or in part) represent reasonable compensation for services actually rendered within the meaning of Section 280G(b)(4) of the Code in excess of the base amount within the meaning of Section 280G(b)(3) of the Code or are otherwise not subject to the Excise Tax;

(ii) The amount of the Total Payments which shall be treated as subject to the Excise Tax shall be equal to the lesser of (A) the total amount of the Total Payments or (B) the total amount of excess parachute payments within the meaning of Section 280G(b)(1) of the Code (after applying clause (i) above); and

(iii) The value of any non-cash benefits or any deferred payment or benefit shall be determined by the Independent Advisors in accordance with the principles of Sections 280G(d)(3) and (4) of the Code.

For purposes of determining the amount of the Gross-up Payment, Executive shall be deemed (A) to pay federal income taxes at the highest marginal rate of federal income taxation for the calendar year in which the Gross-up Payment is to be made; (B) to pay any applicable state and local income taxes at the highest marginal rate of taxation for the calendar year in which the Gross-up Payment is to be made, net of the maximum reduction in federal income taxes which could be obtained from deduction of such state and local taxes if paid in such year (determined without regard to limitations on deductions based upon the amount of Executive's adjusted gross income); and (C) to have otherwise allowable deductions for federal, state, and local income tax purposes at least equal to those disallowed because of the inclusion of the Gross-up Payment in Executive's adjusted gross income. In the event that the Excise Tax is subsequently determined to be less than the amount taken into account hereunder at the time the Gross-up Payment is made, Executive shall repay to the Company at the time that the amount of such reduction in Excise Tax is finally determined (but, if previously paid to the taxing authorities, not prior to the time the amount of such reduction is refunded to Executive or otherwise realized as a benefit by Executive) (the "Repayment Date") the portion of the Gross-up Payment that would not have been paid if such Excise Tax had been applied in initially calculating the Gross-up Payment, plus interest on the amount of such repayment at the rate provided in Section 1274(b)(2)(B) of the Code from the Repayment Date until paid. In the event that the Excise Tax is determined to exceed the amount taken into account hereunder at the time the Gross-up Payment is made (including by reason of any payment the existence or amount of which cannot be determined at the time of the Gross-up Payment), the Company shall make an additional Gross-up Payment in respect of such excess (plus any interest and penalties payable with respect to such excess) at the time that the amount of such excess is finally determined. The Gross-up Payment provided for above shall be paid to the Executive (or to the IRS on behalf of the Executive) on the 30th day (or such earlier date as the Excise Tax becomes due and payable to the taxing authorities) after it has been determined that the Total Payments (or any portion thereof) are subject to the Excise Tax; provided, however, that if the amount of such Gross-up Payment or portion thereof cannot be finally determined on or before such day, the Company shall pay to Executive on such day an estimate, as determined by the Independent Advisors, of the minimum amount of such payments and shall pay the remainder of such payments (together with interest at the rate provided in Section 1274(b)(2)(B) of the Code), as soon as the amount thereof can be determined. In the event that the amount of the estimated payments exceeds the amount subsequently determined to have been due, such excess shall constitute a loan by the Company to Executive, payable on the fifth day after demand by the Company (together with interest at the rate provided in Section 1274(b)(2)(B) of the Code). If more than one Gross-up Payment is made, the amount of each Gross-up Payment shall be computed so as not to duplicate any prior Gross-up Payment subject to the Company compliance with the provisions of this Section. The Company shall have the right to control all proceedings with the Internal Revenue Service that may arise in connection with the determination and assessment of any Excise Tax and, at its sole option, the Company may pursue or forego any and all administrative appeals, proceedings, hearings, and conferences with any taxing authority in respect of such Excise Tax (including any interest or penalties thereon); provided, however, that the Company's control over any such proceedings shall be limited to issues with respect to which a Gross-up Payment would be payable hereunder, and Executive shall be entitled to settle or contest any other issue raised by the Internal Revenue Service or any other taxing authority. Executive shall cooperate with the Company in any proceedings relating to the determination and assessment of any Excise Tax and shall not take any position or action that would materially increase the amount of any Gross-up Payment hereunder. After the Effective Date, the Board (and/or the Compensation Committee) and Executive agree to discuss a provision to replace this Section 7, on terms and conditions mutually satisfactory to the Board and Executive, which takes into account the then current public market conditions. In the event that the Board (and/or the Compensation Committee) and Executive mutually agree to a replacement of this Section 7, the parties shall set forth the terms and conditions of such modification in a written amendment to this Agreement.

8. Covenants of the Executive. In order to induce the Company to enter into this Agreement and continue to employ the Executive hereunder, the Executive hereby covenants and agrees as follows. For all purposes under this Section 8 herein, references to "Company" shall be deemed to include the Company's wholly-owned subsidiaries, if any, and the Company's "business" shall mean film based delivery systems to deliver drug actives, nutraceuticals, cosmaceuticals or flavors, and soluble film based packaging systems and such other lines of business in which the Company or its wholly-owned subsidiaries, if any, is actively engaged or actively pursuing and with respect to which Executive has oversight responsibility or is otherwise substantively involved.

A. Non-Competition. During the Employment Term, including any extensions thereof, and for a period of 18 months immediately following the termination of Executive's employment under this Agreement for any reason other than death (the "Restrictive Period"), except as provided herein, Executive shall not directly or indirectly: (a) engage in or in any manner be connected or concerned, whether as an officer, director, stockholder, partner, owner, employee, advisor, creditor, or otherwise with the development, operation, management, or conduct of any business in the United States that competes with the business of the Company being conducted at the time of such termination; (b) solicit or otherwise attempt to divert business from or interfere in the Company relationship with any supplier of the Company or any customer served by the Company or and potential customer identified by the Company during the period of Executive's employment hereunder; or (c) solicit, hire or otherwise interfere with the Company relationship with any person then or previously employed by the Company; provided, however, that, after the termination of Executive's employment, Executive shall not be bound by the Covenant set forth in this subparagraph following a material breach by the Company of any of its obligations to the Executive hereunder or in the event of the cessation or dissolution of the Company business. As used herein, "cessation or dissolution" means total liquidation of the Company and does not include a cessation of business due to any Change in Control. Nothing contained herein shall prohibit Executive from owning up to 3% of the stock of a publicly traded company that competes with the business of the Company or, following the termination of his employment with the Company, prevent the Executive from being employed by or otherwise affiliated with a line of business of another company that engages in multiple lines of business so long as the Executive is not employed by, does not provide services with respect to and is not otherwise involved in the line or lines of business of such other company that compete with the Company.

B. Confidentiality. During the Employment Term, and following the termination of this Agreement for any reason for as long as the information remains confidential, Executive shall not make any use, for his own benefit or for the benefit of a business or entity other than the Company, of any verbal or written secret or confidential information. Such confidential information shall include, but not be limited to, customer lists, trade secrets, sales, marketing or consignment information, vendor lists or operational resource information, forms, processes or procedures, budget and financial statements or information, files, records, documents, compilation of data, engineering drawings, computer print-outs, or any other data of or pertaining to the Company, its business, customers and financial affairs, or its services not generally known within the Company's trade and which was acquired by him during his affiliation with the Company. Executive shall not remove from the Company premises or retain without the Company's written consent any of the Company's confidential information as defined herein, or copies thereof or extracts therefrom. Executive shall hold in a fiduciary capacity for the benefit of the Company all secret or confidential information, knowledge, or data of the Company or its business or production operations obtained by Executive during his employment by the Company, which shall not be generally known to the public or recognized as standard practice (whether or not developed by Executive) and shall not, during his employment hereunder or after the termination of such employment, communicate or divulge any such information, knowledge or data to any person, firm or corporation other than the Company or persons, firms or corporations designated by the Company. Executive acknowledges that this information is treated as confidential by the Company, that the Company takes meaningful steps to protect the confidentiality of this information, and that the Company has at all times directed Executive to maintain the confidentiality of this information. Immediately upon termination of this Agreement, Executive shall return all of the Company's property to it, including any and all copies of said property. Notwithstanding this provision or any provision in this Agreement to the contrary, nothing contained in this Agreement is intended to nor shall it limit or prohibit the Executive, or waive any right on his part, to make any good faith reports to, initiate or engage in communication with, respond to any inquiry from, otherwise provide information to, participate in any investigation or proceeding that may be conducted by, or obtain any monetary recovery from, any federal or state regulatory, self-regulatory, or enforcement agency or authority, as provided for, protected under or warranted by applicable law, in all events without notice to or consent of the Company.

C. Ownership of Work Product. Executive agrees that the Company shall own all intellectual property including trade secrets, patents, patentable inventions, discoveries and improvements that relate to the Company's business that Executive conceives, develops during the period of his employment with the Company or delivers to the Company while performing services pursuant to this Agreement ("Work Product"). Executive further agrees to deliver to the Company, and that the Company shall thereafter own for all purposes, all Work Product conceived or developed by the Executive relating to the business of the Company which does not otherwise belong to Employee's former employer or to which the former employer has no legal right or claim. Executive hereby irrevocably extinguishes for the benefit of the Company and its assigns any moral right to the Work Product recognized by applicable law. All Work Product shall be considered a work made for hire by Executive and owned by the Company. If any of the Work Product may not, by operation of law, be considered work made for hire by Executive for the Company, or if ownership of all right, title and interest of the intellectual property rights therein shall not otherwise vest exclusively in the Company, Executive agrees to assign, and upon creation thereof automatically assign, without further consideration, the ownership of all trade secrets, copyrights, patentable inventions, and other intellectual property rights therein to the Company, its successors and assigns. The Company, its successors, and assigns, shall have the right to obtain and hold in its or their own name copyrights, patents, registrations and any other protection available in the foregoing. For purposes hereof, a "trade secret" shall mean any information, including, but not limited to, technical or nontechnical data, formulae, patterns, compilations, programs, devices, methods, techniques, drawings. processes, financial data, financial plans, product plans or lists of actual or potential customers or suppliers that derive economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from their disclosure or use and are the subject of efforts that are reasonable under the circumstances to maintain their secrecy. Executive agrees to perform, upon the reasonable request of the Company and at no cost to the Company (other than travel out of pocket costs where applicable), during or after the period(s) that this Agreement remains in effect, such further acts as may be necessary or desirable to transfer, perfect and defend the Company's ownership of Work Product, or to enforce the Company's Work Product against third parties. When requested, Executive shall promptly and at no cost to the Company (other than travel out of pocket costs, where applicable): (a) execute, acknowledge and deliver any requested affidavits and documents of assignment and conveyance; (b) obtain and aid in the enforcement of copyright and, if applicable, patents with respect to the Work Product in any countries; (c) provide testimony in connection with any enforcement proceeding or any proceeding affecting the right, title or interest of the Company in any Work Product; and (d) perform any other acts deemed necessary or desirable to carry out the purposes of this Agreement.

D. Inventions. All discoveries, designs, improvements, ideas and inventions, whether patentable or not, relating to (or suggested by or resulting from) products, services, or other technology of the Company or relating to (or suggested by or resulting from) methods or processes used or usable in connection with the business of the Company that have been, or may be, conceived, developed or made by Executive during the Employment Term (hereinafter "Inventions"), either solely or jointly with others, shall automatically become the sole property of the Company. Executive shall immediately disclose to the Company all such Inventions and shall, without additional compensation, execute all assignments and other documents deemed necessary by the Company to perfect the Company's title thereto, or to the patents issued thereon, or to otherwise secure and protect the Company's property rights therein. These obligations shall continue beyond the termination of Executive's employment with respect to Inventions conceived, developed or made by Executive during employment with the Company. The Company acknowledges and agrees that the provisions of this paragraph shall not apply to any invention for which no equipment, supplies, facilities or trade secret (or proprietary) information of the Company is used by Executive and which is developed entirely on Executive's own time, unless (a) such invention related to the business of the Company or to the Company's actual or demonstrably anticipated research or development; or (b) such invention results from any work performed by Executive for the Company.

E. Acknowledgment. Executive acknowledges that all of the restrictions set forth in this Section entitled "Covenants of the Executive" are reasonable in scope, both individually and in the aggregate, and essential to the preservation of the Company's business and proprietary interests and that the enforcement thereof will not in any manner preclude Executive, in the event of Executive's termination of employment with the Company for any reason, from becoming gainfully employed in such manner and to such extent as to provide a standard of living for himself, the members of his family, and those dependent upon him of at least the sort and fashion to which he and they have become accustomed and may expect. The Company and the Executive further agree that if any particular provision or portion of this Section 8 shall be adjudicated to be invalid or unenforceable, such adjudication shall apply only with respect to the operation of such provision in the particular jurisdiction in which such adjudication is made. The Company and Executive also agree that in the event that any restriction herein shall be found to be void or unenforceable if some part or parts thereof were deleted or the period or area of application reduced, such restriction shall apply with such modification as may be necessary to make it valid and enforceable to the fullest extent possible consonant with applicable law. In addition, pursuant to the Defend Trade Secrets Act of 2016, the parties acknowledge that (a) an individual may not be held criminally or civilly liable under any federal or state trade secret law for the disclosure of a trade secret that: (i) is made in confidence to a federal, state or local government official, either directly or indirectly, or to an attorney and solely for the purpose of reporting or investigating a suspected violation of law; or (ii) is made in a complaint or other document that is filed under seal in a lawsuit or other proceeding; and (b) an individual who files a lawsuit for retaliation by an employer for reporting a suspected violation of law may disclose the employer's trade secrets to the attorney and use the trade secret information in the court proceeding if the individual: (i) files any document containing the trade secret under seal; and (ii) does not disclose the trade secret, except pursuant to court order.

F. Representations and Warranties. Executive represents and warrants to the Company as follows: (a) Executive is under no contractual or other restriction or obligation which may conflict with or be inconsistent with the execution of this Agreement or with the performing of any duties for the Company, or any other rights of the Company; and (b) neither the Company nor any of its affiliates nor any of their respective officers, directors, employees, agents or employees has requested that Executive communicate or otherwise make available to any such parties at any time any proprietary information, data, trade secrets, or other confidential information belonging to Executive's former employers or others.

G. Severability. All of the covenants of Executive contained in this Section entitled "Covenants of the Executive" shall each be construed as an agreement independent of any other provision in this Agreement, and the existence of any claim or cause of action of Executive against the Company, whether predicated on this Agreement or otherwise, shall not constitute a defense to the enforcement by the Company of such covenants. Both parties hereby expressly agree that it is not the intention of either party to violate any public policy, statutory or common law. If any sentence, paragraph, clause or combination of the same of this Agreement is in violation of the law of any state where applicable, such sentence, paragraph, clause or combination of the same shall be void in the jurisdictions where it is unlawful, and the remainder of such paragraph and this Agreement shall remain binding on the parties to the extent that it may be lawfully done under existing applicable laws. In the event that any part of any covenant of this Agreement is determined by a court of law to be overly broad thereby making the covenant unenforceable, the parties hereto agree, and it is their desire, that such court shall substitute a judicially enforceable limitation in its place, and that as so modified the covenant shall be binding upon the parties as if originally set forth herein.

H. Remedies. The Executive agrees that irreparable harm would result from any breach by Executive of the covenants of this Section 8 in particular, and this Agreement in general, and that monetary damages alone would not provide the Company adequate relief for any such breach. Accordingly, if Executive breaches any covenant in this Section 8, the parties acknowledge that equitable or injunctive relief in favor of the Company is a proper remedy, and nothing in this Agreement shall be construed as precluding the Company from seeking such equitable or injunctive relief in a court of competent jurisdiction for Executive's violations of Section 8. Any award of equitable or injunctive relief shall not preclude the Company from seeking or recovering any lawful compensatory damages that may have resulted from a breach of the covenants of this Agreement. Any waiver or failure to seek enforcement or remedy for any breach or suspected breach of any covenant of Executive in this Agreement shall not be deemed a waiver of such provision in the future. Furthermore, the existence of any claim of Executive against the Company, whether based upon this Agreement or otherwise, shall not operate as a defense to the Company enforcement of any provision of this Agreement. Proceedings seeking equitable and injunctive relief to enforce the terms of this Section 8 may be brought in any court of competent jurisdiction.

9. Indemnification. Subject to the Company by-laws, to the fullest extent allowed or permitted under any provision of applicable law, the Company shall indemnify Executive against any losses, claims, damages or liabilities, or expenses (including reasonable attorneys' fees) incurred by Executive arising out of any claim based upon acts performed or omitted to be performed by Executive in connection with his employment with the Company.

10. Attorneys' Fees. In any action brought by any party under this Agreement to enforce any of its terms, or any appeal therefrom, each party shall bear its own costs and expenses, including its own attorneys' fees; provided, however, that the Executive (or his estate or other beneficiaries, as the case may be) will be entitled to reimbursement for reasonable costs and expenses, including reasonable attorneys' fees, with respect to such action if and to the extent that the Executive (or his estate or other beneficiaries, as the case may be) is the prevailing party.

11. Cooperation. Executive agrees that, after the termination of his employment, he shall cooperate on a reasonable basis in the truthful and honest prosecution and/or defense of any claim in which the Company, its affiliates and/or its subsidiaries may have an interest (subject to reasonable limitations and the Executive's other commitments concerning time and place), which may include, without limitation, making himself available on a reasonable basis to participate in any proceeding involving the Company, its affiliates and/or its subsidiaries, appearing for depositions and testimony without requiring a subpoena, and producing and/or providing any documents or names of other persons with relevant information. The Company agrees to reimburse Executive for all expenses reasonably incurred by him and to pay reasonable compensation to Executive for and in connection with services provided by him pursuant to this Section.

12. Travel Restrictions. As is reasonable, Executive has the right to refuse travel to destinations deemed politically unstable or otherwise hostile and/or those that may represent a danger to the Executive's health and well-being.

13. Notices. Any notices permitted or required under this Agreement shall be deemed given upon the date of personal delivery or forty-eight (48) hours after deposit in the United States mail, postage fully paid, certified mail, return receipt requested, addressed to the Company at its principal headquarters address and to the Executive at his last address on record with the Company. Either party may change the address to which notices to such party shall be delivered personally or mailed by giving notice thereof to the other party hereto in accordance with the terms of this Section 13.

14. Venue; Jurisdiction. The validity, construction, interpretation, and enforceability of this Agreement shall be determined and governed by the laws (procedural and substantive) of the State of New Jersey without giving effect to the principles of conflicts of law. For the purpose of litigating any dispute that arises under this Agreement, the parties hereby consent to exclusive jurisdiction of, and agree that such litigation shall be conducted in, any state or federal court located in the State of New Jersey.

15. Binding Effect; Assignment. Executive shall not, without the prior written consent of the Company, assign, transfer, or otherwise convey this Agreement, or any right or interest herein. This Agreement, and all rights and obligations of the Company or any of its successors, may be assigned or otherwise transferred to any of its successors and shall be binding upon and inure to the benefit of its successors. As used herein, the term "successor" shall mean any person, corporation or other entity that, by merger, consolidation, purchase of stock, assets, liquidation, voluntary or involuntary assignment, or otherwise, acquires all or a substantial part of the assets of the Company or succeeds to one or more lines of business of the Company.

16. Entire Agreement. This Agreement constitutes the entire agreement between the parties hereto with respect to the subject matter hereof and supersedes all prior agreements, understandings and arrangements, both oral and written, between the parties hereto with respect to such subject matter, it being understood that this Agreement shall expressly supersede the Executive's 2008 Employment Agreement with the Company and all amendments thereto. This Agreement may not be modified, amended, altered or rescinded in any manner, except by written instrument signed by all of the parties hereto; provided, however, that any waiver by either party with respect to any provision hereof, or the breach of any provision hereof by the other party, need be signed only by the party waiving such provision or breach; and provided, further, that the waiver by either party hereto of a breach or compliance with any provision of this Agreement shall not operate nor be construed as a waiver of any subsequent breach or compliance.

17. Severability. In case any one or more of the provisions of this Agreement shall be held by any court of competent jurisdiction to be illegal, invalid or unenforceable in any respect, the remainder of this Agreement, or the application of such provision to persons or circumstances other than those to which it is held to be illegal, invalid, or unenforceable, shall not be affected thereby.

18. Section Headings. The section headings contained in this Agreement are for reference purposes only and shall not affect in any manner the meaning or interpretation of this Agreement.

19. Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be deemed an original, but all of which taken together shall constitute one and the same instrument.

20. Survival. The provisions of Sections 6-11 and 13-20 of this Agreement shall survive any termination of this Agreement and the termination of Executive's employment by either party for any reason.

IN WITNESS WHEREOF, the parties hereto have executed and delivered this Agreement as of the day and year first above written.

AQUESTIVE THERAPEUTICS, INC.	EXECUTIVE
By: /s/ Keith J. Kendall	/s/ Alexander Mark Schobel
Name: Keith J. Kendall	ALEXANDER MARK SCHOBEL
Title: President and Chief Executive Officer	

EXHIBIT A

GENERAL RELEASE

In exchange for certain payments and benefits to be provided to me by Aquestive Therapeutics, Inc. pursuant to the Employment Agreement dated as of _____, 2018, between the undersigned executive (the "Executive") and Aquestive Therapeutics, Inc., the Executive hereby knowingly and voluntarily waives, releases and discharges Aquestive Therapeutics, Inc., its predecessors, successors, parent corporations, subsidiaries, affiliates and each of their employees, officers and directors, agents, trustees, and fiduciaries (the "Company") from any and all claims, liabilities, demands, and causes of action, which he may have or claim to have against the Company, including any and all claims arising out of or relating in any way to the Executive's employment and/or separation of employment from the Company. This General Release specifically waives and releases all rights, claims, causes of action, demands, and liabilities which may arise up to and including the date the Executive signs this General Release. This General Release does not, however, waive or release any rights or claims which may arise after the date the Executive signs this General Release. This General Release of claims includes, but is not limited to:

a. all State and Federal statutory claims including, but not limited to, claims arising under Title VII of the Civil Rights Act of 1964, the Age Discrimination in Employment Act, the Older Worker Benefit Protection Act, the Americans with Disabilities Act, the Family and Medical Leave Act, the Sarbanes-Oxley Act, the Employee Retirement Income Security Act, the Fair Labor Standards Act, the Worker Adjustment and Retraining Notification Act, the New Jersey Law Against Discrimination, the New Jersey Civil Rights Act, the New Jersey Civil Union Act, the New Jersey Wage and Hour Law, the New Jersey Conscientious Employee Protection Act, the New Jersey Domestic Partnership Act, and the New Jersey Family Leave Act;

b. All claims arising under the United States and New Jersey Constitutions;

c. All claims arising under any Executive Order or derived from or based upon any State or Federal regulations;

d. All common law claims including, but not limited to, claims for wrongful or constructive discharge, public policy claims, retaliation claims, claims for breach of an express or implied contract, claims for breach of an implied covenant of good faith and fair dealing, intentional infliction of emotional distress, defamation, fraud, conspiracy, loss of consortium, tortious interference with contract or prospective economic advantage, promissory estoppel and negligence;

e. All claims for any compensation including, but not limited to, back wages, front pay, overtime pay, bonuses or awards, fringe benefits, reinstatement, retroactive seniority, pension benefits, or any other form of economic loss;

f. All claims for personal injury including, but not limited to, physical injury, mental anguish, emotional distress, pain and suffering, embarrassment, humiliation, damage to name or reputation, liquidated damages, and punitive damages; and

g. All claims for costs and attorneys' fees.

The Executive hereby acknowledges that the Company is advising him in writing that he should consult with an attorney prior to executing this General Release. The Executive hereby states that he has had the opportunity to discuss this General Release with whomever the Executive wished, including an attorney of his own choosing. The Executive further states that he has had the opportunity to read, review, and consider all of the provisions of this General Release; that the Executive understands its provisions and its binding effect on him; and that the Executive is entering into this General Release freely, voluntarily, and without duress or coercion. The Executive acknowledges that he has not relied upon the Company employees, officers or directors, counsel, agents or accountants for any legal, tax or other advice, and the Executive has, to the extent the Executive deems necessary, consulted with his own advisors as to these matters. The Executive represents that he has not filed any grievance, charge, claim, or complaint of any kind seeking personal recovery or personal injunctive relief against the Company or any of its owners, officers, directors, employees or agents, with respect to any matter, including but not limited to, his employment with the Company and/or the separation of that employment. Nothing contained in this paragraph shall prohibit the Executive from (a) bringing any action to enforce the terms of this Agreement and General Release; (b) filing a timely charge or complaint with the Equal Employment Opportunity Commission ("EEOC") regarding the validity of this Agreement and General Release; (c) filing a timely charge or complaint with the EEOC or participating in any investigation or proceeding conducted by the EEOC regarding any claim of employment discrimination (although the Executive has waived any right to personal recovery or personal injunctive relief in connection with any such charge or complaint); (d) initiating or engaging in communication with, responding to any inquiry from, or otherwise providing information to, any other federal or state regulatory, self-regulatory or enforcement agency or authority; or (e) seeking or obtaining an award under the whistleblower provisions of the federal securities laws.

The Executive understands that he has twenty-one (21) calendar days within which to consider this General Release before signing it. The Executive also understands that he is free to use as much of the twenty-one (21) calendar day period as he wishes or considers necessary before deciding to sign this General Release. The Executive may revoke his signature of this General Release within seven (7) calendar days of signing it by delivering written notice of revocation to the Director of Human Resources of the Company, 30 Technology Drive South, Warren, New Jersey 07059. If Executive has not revoked his signature of this General Release by written notice delivered within the seven (7) calendar day period, it becomes effective immediately thereafter.

The Executive understands that his failure or refusal to execute this General Release or his timely revocation of this General Release will result in forfeiture of any severance payments and benefits.

BY SIGNING THIS GENERAL RELEASE, EXECUTIVE ACKNOWLEDGES THAT:

HE HAS READ IT;

HE UNDERSTANDS IT AND KNOWS HE IS GIVING UP IMPORTANT RIGHTS;

HE AGREES WITH EVERYTHING IN IT;

HE HAS BEEN ADVISED TO CONSULT WITH AN ATTORNEY PRIOR TO EXECUTING THIS GENERAL RELEASE; AND

HE HAS SIGNED THIS GENERAL RELEASE KNOWINGLY AND VOLUNTARILY.

EXECUTIVE

ALEXANDER MARK SCHOBEL

AQUESTIVE THERAPEUTICS, INC.

By:

Name:

Title:

Exhibit 10.9

THIS EXHIBIT HAS BEEN REDACTED AND IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST. REDACTED MATERIAL IS MARKED WITH [***] AND HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

DATED AUGUST 15, 2008

(1) MONOSOL RX LLC

(2) RECKITT BENCKISER PHARMACEUTICALS INC.

COMMERCIAL EXPLOITATION AGREEMENT

THIS AGREEMENT (the "**Agreement**") is made on the 15th day of August, 2008 between:

PARTIES

(1) MonoSol Rx, LLC, a company organized and existing under the laws of the USA, with offices at 30 Technology Drive, Warren, New Jersey 07059, USA ("**MSX**"),

and

(2) Reckitt Benckiser Pharmaceuticals Inc, a company existing under the laws of the USA with offices at 10710 Midlothian Turnpike, Suite 430, Richmond, Virginia 23235 **(**"**RB**").

WHEREAS, RB wishes to engage MSX to manufacture and supply the Products (as defined below) on the terms of this Agreement and MSX wishes to manufacture and supply the Products to RB on the terms of this Agreement.

IT IS AGREED as follows:

1. **DEFINITIONS**

1.1 In this Agreement the following definitions shall apply, unless the context requires otherwise:

"**Affiliates**" means in relation to a company, any entity controlled by that company or any entity which controls that company or any entity which is controlled by another entity, which also controls that company whether such control is direct or indirect. For the purpose of this definition, a particular company is:

(i) directly controlled by another company or companies if the latter hold/holds in the aggregate fifty percent (50%) or more of (a) the shares carrying votes exercisable at a general meeting (or its equivalent) of the particular company if such company is a corporation issuing voting shares or (b) the control rights or interests if it is not a corporation; and

(ii) indirectly controlled by a company or companies ("the parent company or companies") if a series of companies can be specified, beginning with the parent company or companies and ending with the particular company, so related that each company or companies of the series, except the parent company or companies, is directly controlled by one or more companies earlier in the series.

"**MSX's Affiliates**" and "**RB's Affiliates**" shall be construed accordingly in relation to MSX and RB respectively. MSX's Affiliates shall expressly include MonoSol Rx, Inc., a Delaware corporation.

"**Arising Intellectual Property Rights**" means such Intellectual Property Rights as are created during the conduct of and pursuant to the work performed under this Agreement by either party (or its authorized Sub-Contractor) whether acting alone or in combination with the other party, including, without limitation, any Improvements.

"**Annual Review**" shall have the meaning given in **Clause 7.12.**

"**API**" means the active pharmaceutical ingredient buprenorphine and/or naloxone manufactured by or for RB and/or used in the manufacture of the Product, as further described in the API Specification.

"**API Specification**" means the specification for the API as set out in **Schedule Four Part B** attached to and incorporated by reference in this Agreement and which shall be deemed to include that API shall be manufactured and supplied in accordance with all applicable laws, codes of practice and regulations.

"**Certificate of Analysis**" means in respect of the Product a document, signed by the Quality Manager, setting out the results of the testing and analysis of the Product to which such document refers together with the Product Specification and methods against which, and by which, the tests were performed, and in respect of the API a document, signed by the Quality Manager, setting out the results of the testing and analysis of the API to which such document refers together with the API Specification and methods against which, and by which, the tests were performed.

"**Certificate of Compliance**" means in respect of the Product a document, signed by the Quality Manager, confirming that the Product to which such document refers has been manufactured in accordance with, and in all respects complies with, the Health Registration, the Product Specification and cGMP and, in respect of the API a document, signed by the Quality Manager, confirming that the API to which such document refers has been manufactured in accordance with, and in all respects complies with, the API Specification and cGMP.

"**cGMP**" means current European Good Manufacturing Practice as set out in Commission Directive 200$^{3}/_{9}$4/EC laying down the principles of good manufacturing practice in respect of medicinal products for human use and sale in the European Union, and as set out in the U.S. FDA, 21 Code of Federal Regulations, Parts 210 and 211 in respect of medicinal products for human use and sale in the U.S.

"**Commencement Date**" means the date of this Agreement.

"**Confidential Information**"

means: information concerning the existence and terms of this Agreement and the fact that MSX is manufacturing the Products for RB;

and

information related to Intellectual Property Rights generally, Arising Intellectual Property Rights, Existing Intellectual Property Rights, the API Specification, the Product Specification, formulations and Quality Agreement (all as defined herein), Know How, and data and information of a technical, operational, administrative, financial or business nature, whether oral or in some tangible form, such as in documents, papers, drawings, diagrams, discs, articles, samples, prototypes or otherwise, that is disclosed (intentionally or unintentionally) by one party or its Affiliates to the other party.

"**Cost of Goods Price**" shall have the meaning given in **Clause 7.13**.

"**Delivery Date**" shall have the meaning given in **Clause 4.2**.

"**DMF**" means the drug master file relating to the Product, containing all the information on the validation activities, manufacture, and testing of the Product.

"**Existing Intellectual Property Rights**" means any Intellectual Property Rights owned by or licensed to RB or MSX or their respective Affiliates prior to the Commencement Date or created or resulting after the Commencement Date otherwise than under, or pursuant to, this Agreement.

"**FDA**" means the United States Food and Drug Administration or any successor thereto.

"**Field**" means either (a) opiate (i) agonists, (ii) partial agonists, and (iii) antagonists, in each case alone or in combination with other opiate agonists, partial agonist or antagonists for administration to humans in the treatment of drug addiction, or (b) buprenorphine.

"**Film**" means the dissolvable film material impregnated with the API in the manufacture of the Products.

"**Foil**" means the primary packaging material for the Products.

"**Forecasts**" shall have the meaning given in **Clause 4.1.**

"**Half Year**" means the six month period ending 30 June or 31 December in each calendar year (or such part thereof as the case may be for the initial and final Half Year periods under this Agreement) and the term "**Half Yearly**" shall be construed accordingly.

"**Health Registration**" means the technical, medical and scientific licences, registration, authorisations or approvals required or deemed necessary by any Regulatory Authority for the advertising, distribution, import, export, marketing or sale of the Products in the Territory or any part thereof.

"**Improvements**" means any improvement, modification or adaptation to the Know-How, the Patents or the Products (whether itself patentable or not) created during the conduct of and pursuant to the work performed under this Agreement by either party (or its authorized Sub-Contractor) whether acting alone or in combination with the other party and related to the design, manufacture and supply of the Products.

"**Intellectual Property Rights**" means the patents (including the Patents), applications for patents, utility models, applications for utility models, trade marks or applications for trademarks or trading names (whether or not registered or registrable), rights in Improvements, Know How, designs (registered or unregistered and including applications for registered designs), copyright (including rights in computer software), rights in inventions, the right to claim damages for past infringements of any or all such rights and all rights having equivalent or similar effect wherever situated.

"**Know-How**" means all knowledge, experience, data, technical or commercial information, inventions and all other Intellectual Property Rights (other than the Patents) related to the design, manufacture and supply of Products (including, without limitation, trade secrets, technology, methods of manufacture, specifications, description of manufacturing processes, recopies, formulae or drawings relating to the design, development, manufacture and supply of the Products, and other information).

"**Losses**" means, collectively, any and all claims, liabilities, losses, damages, costs, expenses, including reasonable fees and disbursements of counsel (except as herein limited) and any consultants or experts and expenses of investigation, obligations, liens, assessments, judgments, fines and penalties imposed upon or incurred by an indemnified party under this Agreement.

"**Manufacturing Capacity**" means MSX's capacity to manufacture products (including, without limitation, the Products) using tooling and machines which are in some way used in the manufacture of the Products.

"**Major Raw Materials**" means Raw Materials constituting [***] percent ([***]) or more of the Price.

"**Manufacturing Site**" means MSX's manufacturing site used for the Manufacture of the Products located at 6560 Melton Road, Portage Indiana USA, or such other manufacturing facility as may be agreed in writing between the parties from time to time.

"**Master Manufacturing File**" means the documentary file created by MSX in accordance with cGMP containing information and data on the Product Specification, the purchase of Raw Materials (excluding the API), labelling, testing, packaging, quality control, storage, release and despatch data, formula, procedures and manufacturing records generated in connection with the manufacture of the Product.

"**Milestone Payments**" means the payments to be made by RB to MSX upon the Product Launch in the U.S. and first Product Launch of the Products within any country within the ROW as set out in **Clause 7.10.**

"**Net Sales Value**" means the invoiced sales price of the Products after taking the deductions specified in **Schedule One** attached to and incorporated by reference in this Agreement.

"**Options**" means RB's option to make payments to MSX in accordance with **Clause 7.7** in order to buy out its obligation to continue making payments of the Royalties.

"**Order**" shall have the meaning given in **Clause 4.2.**

"**Packaging Specifications**" means each of the specifications for the packaging of the Products in a pouch/sachet (but for the avoidance of doubt not cartoned) as annexed in **Schedule Four Part A** and as listed in the relevant Quality Agreement signed for the purposes of identification by each party, as amended from time to time.

"**Patents**" means:

(i) the patents and applications for the patents in the MSX Arising Intellectual Property Rights and Existing Intellectual Property Rights and rights of a similar nature in the Territory and relating to the Products, the particulars of which are set out in **Schedule Two** attached to and incorporated by reference in this Agreement; and

(ii) the patents granted in the Territory pursuant to the patent applications in (i) above including any patents for Improvements.

"**Pharma Price Index**" means the Producer Price Index for Finished Goods, Pharmaceutical Preparations, Series Id: WPU0638, issued by the Bureau of Labor Statistics, U.S. Department of Labor, or comparable successor index.

"**Price**" means the price (described by reference in **Schedule One** to stock keeping units) to be charged by MSX to RB in respect of any Products supplied pursuant to this Agreement as set out in **Clause 7.1** (for the avoidance of doubt the Price shall not include any Milestone Payments).

"**Price Change**" means the documented price change in MSX's manufacturing costs from the preceding Year's manufacturing costs of MSX. For purposes of this definition, change in manufacturing costs includes all costs to manufacture the Products, including, without limitation, changes in the cost of Raw Materials (excluding the API) ("**Cost of Raw Materials**"), energy, transportation, legal and regulatory costs. The changes in manufacturing costs shall exclude labour and overhead allocation.

"**Product Launch**" means the first date that the Products are supplied by RB or its agents to a customer in a country within the Territory, save that for the avoidance of doubt such date shall not be before the date on which the Products have been approved and rated by the relevant Regulatory Authority in that country and RB or its Affiliates has obtained a Health Registration in that country.

"**Product Specification**" means each of the specifications for the Products annexed in **Schedule Four Part A** and as listed in the relevant Quality Agreement signed for the purposes of identification by each party, as amended from time to time by mutual written agreement of the parties, and in accordance with which MSX shall manufacture and supply the Products, and which, for the avoidance of doubt, shall from the point of MSX's compliance with its obligations at **Clause 3.14** include the Serialized Product Specifications (as defined in **Clause 3.11**).

"**Products**" means those products which are listed in **Schedule Three** attached to and incorporated by reference in this Agreement or as otherwise agreed by the parties in writing, together with such additional, improved, modified or replacement products as shall be agreed between the parties from time to time in writing as are manufactured by MSX under this Agreement and wherever "Products" is referred to in this Agreement it shall refer to the relevant Product or all Products as the case may be, as listed in **Schedule Three.**

"**Quality Agreement**" means the manual referred to in **Schedule Six** attached to and incorporated by reference in this Agreement, in respect of each of the Products (supplied by RB to MSX and signed for the purposes of identification by each party) containing the technical information for manufacture of the Products along with any and all manufacturing policies of RB together with such manufacturing policies which may be provided by RB or its Affiliates to MSX in writing prior to the Commencement Date or as periodically updated by mutual written agreement of the parties.

"**Quality Manager**" means in respect of the Product the person (independent of the person responsible for production) responsible for the inspection and testing of the Raw Materials, the Film and the Product and for confirming that the manufacture of the Product is in compliance with the requirements of this Agreement; and in respect of the API the person (independent of the person responsible for production) responsible for the inspection and testing of the raw materials used in the manufacture of the API, and the API, and for confirming that the manufacture of the API is in compliance with the requirements of this Agreement.

"**Raw Materials**" means the API, excipients, reagents, solvents, packaging, labelling and other materials used by MSX in connection with the manufacture of the Products.

"**Regulatory Authority**" means any governmental body or agency responsible for the regulation of narcotics or the granting of any health or pricing approvals, Health Registration or reimbursement prices required to be obtained before the Products can be lawfully advertised, imported, distributed, marketed or sold in the Territory or any part thereof (including, without limitation, the FDA in the U.S., the Medicines and Healthcare products Regulatory Agency in the UK and the Transparency Commission in France).

"**ROW**" means the Territory excluding the U.S.

"**Royalty**" means the payments to be made by RB to MSX in respect of the Net Sales Value of the Products as set out in **Clause 7.4**.

"**Sub-Contractors**" means in respect of each of the Products the sub-contractor (if any) listed in **Schedule Five** attached to and incorporated by reference in this Agreement together with any other person or company proposed by MSX as a sub-contractor and agreed to in writing by RB, which agreement shall not be unreasonably withheld, conditioned or delayed.

"**Term**" shall have the meaning set forth in **Clause 2.1.**

"**Territory**" means the world.

"**Tooling**" means any moulds, machines, or equipment required for and specific to the manufacture of the Products under the terms of this Agreement

"**U.S.**" means the United States of America.

"**Year**" means the period from the Commencement Date until the 31 December in the calendar year of the Commencement Date and shall thereafter constitute any period of 365 days (or 366 days if the period includes 29th February) commencing on the 1st day of January in any calendar year.

1.2 Unless otherwise indicated, references to clauses and schedules are references to clauses and schedules in this Agreement.

2. **TERM**

2.1 This Agreement shall be effective from the Commencement Date and shall continue until the latter of (i) the expiration of the last to expire of the Patents; or (ii) in the event that the Patents do not proceed to registration (or are otherwise declared void, terminated or revoked during the seven year period beginning with the Commencement Date), the expiration of the seven year period beginning with the Commencement Date; unless terminated by either party in accordance with the provisions of **Clause 17** (the "**Term**").

3. **MANUFACTURE AND SUPPLY**

3.1 During the Term, MSX shall manufacture and supply RB's requirements of the Products on an exclusive basis and shall manufacture the Products:

3.1.1 in accordance with cGMP, the Product Specification and the processes set out in the Quality Agreement;

3.1.2 in accordance with any legislation applicable to the manufacture of the Products (including without limitation legislation and standards applicable to environmental protection such as waste disposal and any legislation or regulations regarding ePedigree requirements as and when enforced as further described in **Clause 3.13**); and

3:1.3 subject to **Clause 3.3** below, at the Manufacturing Site.

3.2 MSX shall not:

3.2.1 use any site other than the Manufacturing Site for the manufacture of the Products (including the process, plant or equipment used in the manufacture of the Products), without the prior written consent of RB, such consent not to be unreasonably withheld, conditioned or delayed, and RB to cooperate reasonably with MSX in respect of any proposals to utilise new manufacturing sites; and

3.2.2 at any time during the Term carry out any activities that MSX actually knows or should reasonably know shall prejudice the quality, safety or efficacy of the Products.

3.3 The parties acknowledge that MSX intends to use its facility located at 6465 Ameriplex Drive, Portage Indiana 46368 as a manufacturing site for the manufacture of the Products, and RB hereby consents to such site transfer subject to RB conducting a quality review of the Ameriplex Drive site in accordance with **Clause 3.2.1.**

3.4 MSX shall:

3.4.1 only use API supplied from RB in the manufacture of the Products;

3.4.2 ensure that all personnel employed by MSX in the manufacture of the Products are suitably trained, experienced and competent for their respective functions; and

3.4.3 monitor, account for and keep RB regularly informed of the usage and waste of API and MSX shall ensure that in the manufacture of the Products MSX does not waste any more than a set percentage of the API to be determined by the parties in writing acting reasonably and assuming efficient manufacture of the Products.

3.5 Subject to **Clause 7.12**, MSX shall be entitled to obtain the Raw Materials and other components for the manufacture and delivery of the Products from qualified suppliers of its own choosing. In the event that MSX obtains Raw Materials from a third party supplier, MSX shall notify RB and MSX shall consider in good faith (but not be bound by) any reasonable objection by RB timely delivered to MSX as to the qualification of such third party supplier; provided, however, that (subject to **Clause 7.12**) RB shall have no right to object to any financial arrangement reached between MSX and such third party supplier, which shall be determined at the sole discretion of MSX. MSX shall ensure that such Raw Materials and other components are of the requisite standard to comply with the Product Specification and any applicable laws, codes of practice and regulations and the terms of this Agreement. Periodically, MSX will share with RB a list of all suppliers, so RB may voice to MSX any concerns in connection with them.

3.6 Unless otherwise agreed with RB in writing and save for the fact that RB shall be responsible for cartoning the Products once delivered to RB, MSX shall operate on a full service basis (meaning that MSX shall be responsible for the purchase of all Raw Materials (except for API which shall be supplied by RB in accordance with **Clause 4.3** hereof) and the supply of the Products in individual sachet form to RB or its nominee). RB shall only be invoiced for the Cost of Goods Price as set out in **Schedule One** which shall be inclusive of such costs and expenses, including FCA (Incoterms 2000) delivery.

3.7 For the purposes of ensuring that RB has the full protection of its business interests and the ongoing benefit of its and any of its Affiliates' Intellectual Property Rights, and subject to applicable laws, MSX covenants with RB that during the Term it will not, so far as it is aware, without the prior written consent of RB, whether directly or indirectly and whether alone or in conjunction with or on behalf of any other person and whether as principal, shareholder, director, employee, agent, consultant, partner or otherwise:

3.7.1 subject to **Clause 3.9,** canvass, solicit or approach, or cause to be canvassed, solicited or approached, any person for orders of products within the Field who RB informs MSX in writing is or was at any time during the Term:

3.7.1.1 negotiating with RB or any of its Affiliates for the supply by RB or any of its Affiliates of the Products; or

3.7.1.2 an actual customer of RB or any of its Affiliates in respect of the Products;

3.7.2 interfere, or seek to interfere, with the continuation of supplies to RB or any of its Affiliates from any supplier who RB informs MSX in writing has been supplying goods to RB or any of its Affiliates at any time during the Term if such interference causes or would cause that supplier to cease supplying, or materially reduce its supply of those goods; and

3.7.3 directly solicit or entice, or endeavour to solicit or entice, away from RB or its Affiliates, any person employed in a managerial, supervisory, technical or sales capacity by, or who is or who was a consultant to, RB or its Affiliates at a time during the Term; provided, that, general solicitations not directed to a specific individual shall not constitute a breach hereof; and

3.7.4 develop (subject to **Clause 3.9**), manufacture, market or sell any product within the Field.

3.8 For the purposes of ensuring that MSX has the full protection of its business interests and the ongoing benefit of its and any of its Affiliates' Intellectual Property Rights, and subject to applicable laws, RB covenants with MSX that during the Term it will not, without the prior written consent of MSX whether directly or indirectly and whether alone or in conjunction with or on behalf of any other person and whether as principal, shareholder, director, employee, agent, consultant, partner or otherwise:

3.8.1 subject to **Clause 6.5** and **Clause 3.9**, canvass, solicit or approach, or cause to be canvassed, solicited or approached; any person for the manufacture of the Products in the Field;

3.8.2 interfere, or seek to interfere, with the continuation of supplies or Raw Materials to MSX or any of its Affiliates from any supplier who has been supplying supplies or Raw Materials to MSX or any of its Affiliates at any time during the Term if such interference causes or would cause that supplier to cease supplying, or materially reduce its supply of those goods;

3.8.3 directly solicit or entice, or endeavour to solicit or entice, away from MSX or its Affiliates, any person employed in a managerial, supervisory, technical or sales capacity by, or who is or who was a consultant to, MSX or its Affiliates at a time during the Term; provided, that, general solicitations not directed to a specific individual shall not constitute a breach hereof; and

3.8.4 develop (subject to **Clause 3.9**), manufacture, make, have made, market or sell Products outside the Field.

3.9 Each of RB and MSX agrees that at least one year prior to the expiration of the Term it will notify the other of its intent to renew or not to renew this Agreement. In the event that either party elects not to renew this Agreement upon the expiration of the Term, notwithstanding the restriction contained in **Clauses 3.7.1** and **3.7.4** as to MSX and **Clauses 3.8.1** and **3.8.4** as to RB, during the last twelve (12) months of the Term of this Agreement: (i) RB shall have the right to develop Products outside the Field and to canvass, solicit and approach, and cause to be canvassed, solicited and approached, any person for the manufacture of the Products in the Field to commence after the expiration of the Term, and (ii) MSX shall have the right to develop products in the Field and to canvass, solicit and approach, and cause to be canvassed, solicited and approached, any person for the manufacture of products in the Field to commence after the expiration of the Term. Notwithstanding anything to the contrary contained in this Agreement, no notice by either party under this **Clause 3.9** shall reduce or impair the respective obligations of each of the parties under this Agreement for the remainder of the Term except as set forth in this **Clause 3.9.**

3.10 At the option of RB delivered by written notice to MSX at least ninety (90) days prior to the expiration of the Term, MSX shall continue to supply the Products to MSX in accordance with the terms and conditions of this Agreement for a period determined by RB not to exceed six (6) months after the expiration of the Term.

3.11 The parties agree to use their best efforts to implement as soon as possible (including prior to Launch, or if this is not possible, as soon as possible thereafter) an electronic pedigree system in connection with the manufacture and supply of the Products which would satisfy the expected legal requirements of the E-Pedigree regulations of the State of California for the electronic tracking and tracing of prescription drugs through the supply chain, California Business and Professions Code § 4034 *et seq.* (the "**E-Pedigree Regulations**") (currently scheduled to become effective as of January 1, 2011) and in accordance with the Serialized Product Specifications (as defined below). The parties agreement set forth in the preceding sentence shall apply to the manufacture and supply of the Products throughout the Territory; provided that such manufacture and/or supply, as the case may be, is not in violation of any applicable law, code of practice or regulation in any country in the ROW in which instance it shall not apply in such country in the ROW. To that end, RB intends to purchase, or have purchased, technology (including equipment and software) from a third party manufacturer (the "**E-Pedigree Manufacturer**") which consists of a pouch image acquisition and collating system and affixes a unique serialization identifier on the packaging of each saleable unit of the Product/ Part of such technology will be installed at RB's third party packager of the Product (the "**Packager Serialization Technology**") and part of such technology will be purchased by and installed at the facility of MSX's third party Foil supplier (the "**Foil Supplier**") for the Product (the "**Foil Serialization Technology**") (the Foil Serialization Technology together with the Packager Serialization Technology, shall collectively be referred to as the "**Serialization Technology**"). The specifications for serialization of the Product using the Foil Serialization Technology (the "**Serialized Product Specifications**") are set forth in **Schedule Four Part A.1** and shall not be modified without the prior approval of RB. RB acknowledges that the Foil Serialization Technology is newly developed by the E-Pedigree Manufacturer and has never before been installed, tested, or validated by the E-Pedigree Manufacturer and, as a result, the parties are at the time of signing this Agreement unable to guarantee the performance of the Foil Serialization Technology or the effectiveness, value, safety, merchantability or fitness for any particular purpose of the Foil Serialization Technology, or any part thereof, or its impact on the manufacture or supply of the Products under this Agreement. MSX agrees to coordinate the purchase, installation, testing, validation and qualification of the Foil Serialization Technology by the Foil Supplier and to use its best efforts to ensure that the Foil Serialization Technology is purchased, installed, tested, validated and qualified, in order to enable MSX to manufacture and supply the Products in accordance with the Product Specifications (the "**Serialized Products**") for Launch (or if this is not possible as soon as soon as possible thereafter). Thereafter MSX shall manufacture and supply the Serialized Product in accordance with the Serialized Product Specifications subject to the following conditions, which conditions shall be and remain in effect only until such time as (i) MSX shall be required by state law to comply with the E-Pedigree Regulations, or be required by federal law to comply with a comparable electronic pedigree prescription drug supply chain tracking and tracing system, in connection with the manufacture and supply by MSX of Serialized Products under this Agreement (the "**Effective E-Pedigree Regulations**") in accordance with the provision of **Clause 3.13** or (ii) MSX has complied with its obligations under **Clause 3.14** and successfully manufactured such volume of Serialized Products (as specified in **Clause 3.14**) in accordance with the Serialized Product Specification such that MSX shall thereon be responsible for ensuring all Products produced under this Agreement comply with the Serialized Product Specifications (and MSX shall no longer be able to produce to the Non-Serialized Product Specifications (as defined below)), whichever is the earlier:

3.11.1 In the event that the Foil Serialization Technology fails or causes a material adverse impact on the manufacture and supply of the Film or the Products or the timely delivery of same, RB and MSX agree to suspend the use of the Serialization Technology in the manufacture and supply of the Product until the cause of such material adverse impact has been cured or the parties agree in writing to abandon the Serialization Technology, and MSX shall thereafter resume the manufacture and supply of the Products which meet the Product Specifications not including the Serialized Product Specifications, (the "**Non-Serialized Product Specifications**") in accordance with the terms of this Agreement. MSX shall promptly notify RB upon becoming aware of any such failure or material adverse impact. During the period while MSX is manufacturing and supplying the Product (including any Serialized Product or Non-Serialized Product) under this **Clause 3.11, MSX** shall arrange with the Foil Supplier to maintain an appropriate rolling amount of inventory of Foil (the "**Foil Stock**") which is reasonably anticipated as necessary to avoid any material delay In the manufacture and supply of Product in compliance (with the Non-Serialized Product Specifications required as a result of such failure or material adverse impact. RB shall reimburse MSX for the cost of any unused Foil Stock providing that MSX has used reasonable efforts to ensure such unused Foil waste is kept to a minimum;

3.11.2 MSX shall bear no cost for the purchase, installation, implementation, testing, validation or qualification of the Serialization Technology and RB agrees that the Cost of Goods Price shall be simultaneously increased to reflect any and all direct increases incurred by MSX (without mark-up thereof by MSX and based upon supporting documentation from MSX) during the Term in the purchase of Foil manufactured using the Foil Serialization Technology (the "**Serialized Foil**"), whether as an increase in the cost of purchase of the Serialized Foil and/or as an amortization charge by the Foil Supplier for the purchase, installation, implementation, testing, validation, and/or qualification of the Serialization Technology. MSX estimates that the Cost of Goods Price will be initially increased by the sum of (i) [***] per unit of Product for the cost associated with the purchase by MSX of the Serialized Foil plus (ii) [***] per unit of Product for the amortized cost of purchasing the Foil Serialization Technology by the Foil Supplier based upon the purchase by MSX of Serialized Foil required to make [***] of Serialized Products (a total estimated initial cost increase per unit of Product of [***]). The parties agree that if the Cost of Goods Price is initially increased for the amortization of the cost of purchasing the Foil Serialization Technology by the Foil Supplier, when such cost is fully amortized by the Foil Supplier, or if RB has otherwise fully paid MSX or the Foil Supplier all sums due to the Foil Supplier in respect of the Foil Serialization Technology, the Cost of Goods Price per unit of Serialized Product would thereafter be reduced by an amount equal to any such increase in the Cost of Goods Price for the amortized cost of purchasing the Foil Serialization Technology by the Foil Supplier. Such estimates shall not be binding on MSX and shall be adjusted and finalized by MSX upon receipt by MSX from the Foil Supplier of all final costs incurred in purchasing the Foil Serialization Technology, producing and supplying the Serialized Foil and all other related costs and expenses of the Foil Supplier. In the event of any suspension or abandonment of the manufacture and supply of the Serialized Product in accordance with **Clause 3.11.1**, the Cost of Goods Price for the purchase of all Products manufactured and supplied following such suspension or abandonment in accordance with the Non-Serialization Specifications shall revert to the Cost of Goods Price in effect prior to such increase and any unamortized costs for the purchase of the Foil Serialization Technology shall be paid by RB; provided, however, that RB may exercise any right and remedy (and MSX shall assist RB therewith) against the Foil Supplies to dispute such payment in the event that such suspension is not due to a failure of the Serialization Technology but is due to the fault of the Foil Supplier, including failure by the Foil Supplier to manufacture the Foil in accordance with the Serialized Foil specifications agreed to by MSX and the Foil Supplier;

3.11.3 The provisions under **Clause 7.14** relating to RB's rights to obtain pricing for Major Raw Materials from third parties, and MSX's obligations to engage any other supplier or obtain a price reduction from its then-current Foil supplier in the event that a Price Change exceeds the Pharma Price Index shall not apply to any Price Change resulting from the purchase, installation, implementation, testing, validation, and/or qualification of the Foil Serialization Technology until RB has complied with its obligations under **Clause 3.11.7** in respect of identifying and qualifying an alternative secondary supplier for the Serialized Foil and such engagement of an alternate Foil supplier or obtaining a, price reduction from its then current Foil supplier would not result in a breach of the agreement between MSX and its then current Foil supplier. MSX shall remain obliged to show documentary evidence of the Price Change;

3.11.4 MSX makes no representation or warranty with respect to the Serialization Technology including any representation or warranty under **Clause 9** as it may relate to the Foil Serialization Technology;

3.11.5 MSX shall be excused from any and all unfulfilled manufacturing, supply and delivery performance obligations under this Agreement resulting from, relating to or in connection with Foil Serialization Technology including the purchase, installation, implementation, testing, validation, qualification and/or operation of the Foil Serialization Technology; provided, however, that nothing in this **Clause 3.11.5** shall limit MSX's obligation to manufacture and supply Product in compliance with the Non-Serialized Product Specifications as soon as possible in accordance with **Clause 3.11.1** in the event and for such period of time that the parties determine to suspend the manufacture of Serialized Product and, in the event that the parties determine to terminate and abandon the manufacture of Serialized Product in accordance with **Clause 3.11.1;** for the remainder of the Term or the date upon which the E-Pedigree Regulations become effective, whichever is earlier;

3.11.6 MSX shall not be in default or breach under this Agreement, and RB shall not be entitled to withhold payment for non-conforming Products, or to terminate this Agreement for any reason with respect to any delay or incomplete delivery of, failure to deliver or delivery of non-conforming Products relating to, as a result of or in connection with the Foil Serialization Technology (including the purchase, installation, implementation, testing, validation, qualification or failure of the Serialization Technology), except to the extent caused by the breach by MSX of any of its obligations under this **Clause 3.11;**

3.11.7 RB and MSX agree to use commercially reasonable efforts to qualify an FDA approved secondary supplier of the Serialized Foil as soon as practicable after the Commencement Date. It is acknowledged that, due to importance of obtaining a secondary supplier of the Serialized Foil in order to reduce the risk of failure to supply the Serialized Foil, both parties will use their best efforts to qualify such secondary supplier within one (1) year of the FDA approval of the Product or as soon as possible thereafter. The parties further agree that RB shall be responsible for payment to MSX of all costs and expenses incurred by MSX in connection with the qualification of any secondary and/or replacement supplier of Serialized Foil in connection with the manufacture and supply of the Products under this Agreement if RB continues to require that the Products be manufactured and supplied using the Serialization Technology, or any part thereof, or substitute therefore, including without limitation, the cost of the purchase, installation, implementation, testing, validation, and qualification of the Foil Serialization Technology by the secondary and/or replacement supplier.

3.11.8 In addition to the exceptions and exclusions set forth in the foregoing provisions of this **Clause 3.11,** notwithstanding anything to the contrary contained in this Agreement or otherwise, none of the provisions of **Clauses 5.5, 6.5, 6.6, 6.7, 7.9, 10.2, 13.10, 16.2, 17.3.4, 17.3.6,** and **17.4** shall during the course of manufacture under this **Clause 3.11** apply to the Foil Serialization Technology or any event or matter covered therein relating to, resulting from or in connection with the purchase, installation, implementation, testing, validation, qualification and/or failure of the Foil Serialization Technology, and MSX shall have no obligations or responsibilities with respect to the Foil Serialization Technology except as expressly set forth in this **Clause 3.11** which for the avoidance of doubt expressly includes MSX's obligations to manufacture and supply Products in compliance with Non-Serialized Product Specifications as soon as possible in accordance with **Clause 3.11.1** in the event and for such period of time that the parties determine to suspend the manufacture of Serialized Product, and for the remainder of this **Clause 3.11** in the event that the parties determine to terminate the manufacture of Serialized Product in accordance with **Clause 3.11.1**.

3.12 RB acknowledges that MSX shall have no interest in the Serialization Technology and that, MSX shall have no obligations to transfer or grant to RB, or to arrange the transfer or grant to RB of, any interest in the Serialization Technology under any circumstances at any time whether during the Term or upon any expiration or termination of this Agreement for any reason, including, without limitation, the Foil Serialization Technology, and/or any Arising Intellectual Property Rights therein of the Foil Supplier under **Clause 15** except to the extent such interests or Arising Intellectual Property Rights are in the possession or control of MSX and not subject to any third party restrictions on such transfer or grant to RB.

3.13 For the avoidance of doubt, in the event that MSX is required to comply with Effective E-Pedigree Regulations after the Commencement Date, MSX shall (i) use commercially reasonable efforts to deliver the Product serialization data produced by MSX in compliance with the Effective E-Pedigree Regulations in a format which is compatible with RB's Product distribution system; and (ii) from the date on which the Effective E-Pedigree Regulations come into effect (currently scheduled to become effective as of January 1, 2011) be fully responsible for ensuring all Products manufactured and supplied under this Agreement comply with all legislation and regulatory requirements including the Specifications and Serialized Product Specifications as may be amended to ensure compliance with the Effective E-Pedigree Regulations (including without limitation the envisaged requirement to ensure all Products are serialized and thereafter scanned before leaving the Manufacturing Site) and, for the avoidance of doubt, from this date MSX shall under no circumstances (including without limitation those set out **Clauses 3.11.1** to **3.11.8**) be released from any liability arising from the failure to manufacture and supply the Products to such Specifications in accordance with the terms of this Agreement.

3.14 Following the date upon which each of the following has occurred (the "**Product Serialization Acceptance Date**"): (i) successful implementation of the Foil Serialization Technology; (ii) successful production of the Serialized Products in compliance with the Serialized Product Specifications at scale and consistent with applicable Product Order patterns for an uninterrupted period of three (3) consecutive months or a period of six (6) consecutive months after the Product Launch (whichever is the latter); and (iii) qualification of a secondary supplier of Serialized Foil in accordance with **Clause 3.11.7;** the Product Specification for the Products shall thereupon be permanently amended to include the Serialized Product Specifications. For the avoidance of doubt, from and after the Serialization Acceptance Date, MSX shall be responsible for ensuring that the Products manufactured and supplied under this Agreement are in compliance with the Serialized Product Specifications, and MSX shall be responsible for any failure to comply with such Serialized Product Specifications and, for the further avoidance of doubt, from and after the Product Serialization Date MSX shall under no circumstances (including without limitation those set out Clauses 3.11.1 to 3.11.8) be released from any liability arising from the failure to manufacture and supply the Products to such Serialized Product Specifications in accordance with the terms of this Agreement.

4. FORECASTS, ORDERS AND SUPPLY OF THE API

4.1 No less than one (1) month prior to the end of every calendar month, RB shall provide (or cause to be provided from its Affiliates) a forecast of its requirements for the Products for the [***] months (a "**Forecast**"), By way of example, this means that the Forecast for [***] to [***] (inclusive) of any year shall be provided by no later than the end of [***] in the previous year, and the subsequent Forecast for [***] to [***] of any year shall be provided by no later than the end of [***] in the previous year.

4.2 In respect of the [***] months of the Forecast, RB shall specify the date by which the Products are requested to be delivered ("**Delivery Date**"). RB's requirements as set out in the [***] months of the Forecast shall be fixed and shall constitute a firm order binding on MSX (subject to the terms and conditions of this Agreement) for the delivery of, and on RB for the purchase of, those Products specified in the [***] months of the Forecast by the Delivery Date with delivery in accordance with **Clause 5.1** (an "**Order**"). Once MSX receives the Forecast, MSX shall ensure that it has sufficient Raw Materials, packaging components and other materials necessary to manufacture RB's requirements for Products as set out in the Order, and MSX shall use commercially reasonable efforts to acquire sufficient Raw Materials, packaging components and other materials necessary to manufacture [***] percent [(***%)] of RB's requirements as set out in the remaining [***] months of the Forecast. For the avoidance of doubt this means that the Forecast given at the end of [***] shall be a binding Order for [***] and the Forecast given at the end of [***] shall be a binding Order for [***]. To the extent that the Forecast given in [***] would increase the Order for [***] as originally set in [***], MSX agrees to liaise with RB and use reasonable endeavours to meet such increase but failure to supply such increase shall not in any way constitute a breach by MSX of this Agreement and shall not constitute a failure by MSX to deliver an Order on time for the purposes of **Clause 6.4**. Notwithstanding anything to the contrary contained in this Agreement, MSX shall be under no obligation to fill any Order that is for less than [***] units of a Product (the "**Minimum Purchase Requirement**"). RB shall have the right to delay the issuance of any firm Order for a reasonable period of time in order to combine such Order with one or more subsequent Orders for the purpose of meeting the Minimum Purchase Requirement (meaning that in order to meet the [***] unit Minimum Purchase Requirements RB can (subject to compliance with **Clause 7.12**) combine Orders for the same dose Product for different countries (such as [***] 2mg dose units for the UK and [***] 2mg dose units for the US (which therefore require different packaging requirements chargeable under **Clause 7.3.2**)) but cannot combine orders for different dose Products (such as [***] 2mg dose units and [***] 8mg dose units)).

4.3 RB shall supply, or arrange the supply of, API that conforms to the API Specification to MSX at the Manufacturing Site free of charge on the dates and in such quantities as are required by MSX for manufacture of the Products in the Forecasts and in connection with manufacturing validation and site transfer, together with the API's Certificate of Analysis and Certificate of Compliance. Save as may be amended by the mutual written agreement of the parties in accordance with the terms of this Agreement, such supply shall be made by RB to MSX DDP (Incoterms 2000) and on or before the delivery dates reasonably required by MSX in writing. RB will promptly notify MSX of any changes to the safety and handling procedures in relation to the API that are required by applicable law or Regulatory Authorities after the Commencement Date, and MSX shall comply with such changes with respect to all future Orders placed by RB at least ninety (90) days following receipt of notice thereof, or such earlier time as required by applicable law or Regulatory Authority. The purchase orders by MSX for API shall be made and filled in accordance with the procedure specified in **Schedule Seven**. Subject to the terms of this Agreement, MSX shall only use the API to manufacture and test the Product and for no other purpose whatsoever.

4.4 MSX shall test each batch or stock of the API delivered to MSX in accordance with the testing procedure set out in the **Schedule Eight** to determine its conformance with the necessary amounts and API Specification or for contamination during transit. If in the reasonable opinion of MSX, MSX determines that such API is contaminated or does not meet the API Specification or necessary amounts, MSX shall within twenty-one (21) days from the date of completion of such tests notify RB in writing of such defect or non-conformance, including the test results supporting MSX's opinion.

4.5 If RB agrees that the API is contaminated or does not meet the API Specification, RB shall at no charge to MSX replace the defective or non-conforming API with API that meets the API Specification. If RB disagrees with the alleged defective or non-conformity of the API, samples of the alleged defective or non-conforming API shall be retested by an independent laboratory, mutually agreed upon by the parties in writing, to determine compliance with the API Specification. MSX and RB shall be bound by the results of such independent laboratory testing. The costs incurred in connection with independent laboratory's testing of the API shall be borne by MSX if the API in question is found to conform to the API Specification or not defective and by RB if it is found not to conform to the API Specification or be defective. Any delay in the manufacture or supply of Products resulting from RB's failure or delay in supplying API in accordance with the API Specification or MSX's good faith reasonable belief pursuant to **Clause 4.4** and this **Clause 4.5** that the API does not meet the API Specifications or is defective, shall not constitute a default under or breach of this Agreement. The parties agree that in the event that the API is found to be defective, RB shall be responsible, at its costs, to identify and implement such remedial action as is necessary to rectify the issue and ensure that the API meets the API Specification.

4.6 Notwithstanding the terms of any DDP delivery (or any other delivery) of the API by RB to MSX, legal title to the API shall remain with RB after delivery to MSX. MSX shall use reasonable efforts to ensure proper storage and handling of the API once delivered to MSX. Risk of damage to, or loss of, the API shall pass from RB to MSX upon delivery as set out in **Clause 4.3**. MSX shall retain casualty insurance coverage for the expected inventory of the API (amounts expected to be supplied to MSX by RB for manufacture of the Product in the amounts set forth in the Forecasts) to cover damage to or loss of the API for so long as the API remains at MSX's risk.

4.7 In the event that MSX manufactures Products which cannot be sold due to latent defects in the API supplied (and such defects are not caused by MSX's negligent storage or handling), RB shall remunerate MSX for its costs of manufacturing such Products. In the event that MSX manufactures Products which cannot be sold due to latent defects in the API caused by MSX's negligent storage or handling, MSX shall remunerate RB for the Cost of Goods Price for such Products, to the extent such Cost of Goods Price has been paid to MSX for such Products.

5. **DELIVERY OF THE PRODUCTS**

5.1 Unless otherwise specifically stated, the Delivery Date shall be the date by which the Order shall be made available FCA (Incoterms 2000) at MSX's loading dock at the Manufacturing Site, whereupon MSX shall be entitled to invoice RB for Cost of Goods Price in respect of the Products so delivered. An Order may request boxed shipping at an additional handling charge beyond the Cost of Goods Price. No Orders shall be shipped in boxes unless expressly agreed to by MSX in writing. Legal title to the Products and risk of damage to, or loss of, the Products shall pass from MSX to RB upon being made available at MSX's loading dock at the Manufacturing Site on the Delivery Date in accordance with **Clause 5.7**. Any invoices sent to RB under this **Clause 5.1** shall specify the Price in respect of the Products delivered, the quantity of Products delivered, the date of delivery and the amount of VAT or other taxes due in respect of the Products delivered, together with any applicable transportation costs (if any) associated with delivery.

5.2 MSX shall not be liable for any delay or failure to deliver hereunder after the Products leave MSX's loading dock at the Manufacturing Site as set out in **Clause 5.1**.

5.3 Each shipment of Product shall be delivered to RB with:

5.3.1 a Certificate of Analysis and Certificate of Compliance;

5.3.2 in accordance with the Quality Agreement; and

5.3.3 any other documentation required by any applicable rule, law or regulation having jurisdiction over the shipment and supply of the Products.

5.4 RB shall be entitled to reject any Product delivered to RB (or its nominee) without a Certificate of Analysis, Certificate of Compliance or other documentation required under any applicable rule, law or regulation.

5.5 MSX recognises that late delivery of the. Products may have an impact on RB's obligations to its customers. MSX shall make all reasonable efforts to deliver Products by the Delivery Date requested by RB. The Delivery Date shall be reasonable based on MSX's production capacity.

5.6 MSX shall manage any mutually agreed upon changes in writing to the Product Specification and the Packaging Specification, whilst maintaining the supply and delivery performance as set out herein. Changes to the Products shall be made with commercially reasonable speed of implementation, and meet the launch timings mutually agreed upon by the parties in writing or required by applicable law or Regulatory Authority. Inventory levels of Raw Materials, Film and the Products are to be communicated at least ninety (90) days prior to the change and usage agreed with RB in writing before the change is implemented. The parties shall agree in writing to the implementation date at least sixty (60) days prior thereto.

5.7 Legal title and risk in the Products shall pass to RB upon being made available FCA (Incoterms 2000) at MSX's loading dock at the Manufacturing Site on the Delivery Date. MSX shall fully insure the Products (at a valuation based on MSX's cost of manufacture plus the cost of API) for as long as they remain at MSX's risk.

5.8 In the event there is an incomplete delivery of the Products to RB (or its nominee) pursuant to an Order, RB shall notify MSX in writing within twenty-one (21) days, identifying the amount of Product that has not been delivered. MSX shall use commercially reasonable efforts to rectify such incomplete delivery by supplying, the balance of the Products under such Order.

5.9 RB shall inspect and test the Products within thirty (30) calendar days of receipt thereof, and shall be entitled to reject such Products which do not conform to the Product Specification and withhold payment of the Cost of Goods Price for such non-conforming Products by giving written notice to MSX within forty (40) calendar days from receipt of such Products by RB.

5.10 Any written notice of rejection of the Products given by RB shall specify in sufficient detail the manner in which the Products fail to conform. If it is determined by written agreement between the parties (or, in the absence of written agreement of the parties, by an independent laboratory or consultant agreed upon by the parties in writing whose fees shall be paid by the non-prevailing party) that the non-conformity is due to:

5.10.1 damage to the Products caused by RB (or its nominee), including, without limitation, through improper Product storage or transit, after the delivery of the Products to RB (or its nominee), MSX shall have no liability to RB with respect thereto and RB shall promptly pay what is owed for such Products in accordance with the terms of this Agreement; or

5.10.2 the negligence of MSX or breach by MSX of the terms of this Agreement, then MSX shall credit RB's account with the Cost of Goods Price invoiced for such non-conforming Products (or in the event the Cost of Goods Price has been withheld by RB, waive any right to claim the Cost of Goods Price for such non-conforming Products from RB under this Agreement). RB will either return such non-conforming Product to MSX, or lawfully destroy such non-conforming Products (in each case at MSX's written option and cost).

6. CAPACITY, STOCK LEVELS AND TOOLING

6.1 Within six (6) months following the Commencement Date, and thereafter within the first calendar month of each Year, MSX shall provide to RB copies of its disaster recovery and contingency plans.

6.2 MSX shall inform RB when:

6.2.1 the Forecasts; and

6.2.2 any other third party orders for products other than the Products that use any tooling or machines which are used in the manufacture of the Products;

together meet or exceed [***] percent ([***]%) of the Manufacturing Capacity.

6.3 MSX represents and warrants that it will have the capacity to fill RB's requirements for the Products set forth in any Order so long as the amount specified in the Order does not exceed [***] percent ([***]%) of the forecasted volume for such period as set out in the previous Forecast (or such other figure as RB and MSX may agree in writing from time to time). At RB's reasonable written request, MSX shall provide RB with capacity information to demonstrate that the available capacity meets RB's requirements. MSX shall promptly take commercially reasonable action to address to RB's reasonable satisfaction any capacity issues identified in accordance with this **Clause 6.3** and **Clause 6.5.**

6.4 MSX hereby agrees that, in the event that MSX's success in meeting Orders (whether in terms of failure to meet either or both of the volume and/or the Delivery Date specified in the Orders) falls below [***] percent ([***]%) for any consecutive [***] period during which RB places less than [***] Orders (provided that in the case of any Order which exceeds [***] percent ([***]%) of the volume as set out for that period in the previous Forecast, MSX shall only be deemed to have failed to meet that Order for the purposes of this **Clause 6.4** if it fails to deliver on the Delivery Date at least [***] percent ([***]%) of the volume set out in the previous Forecast), MSX shall thereafter hold [***] month stock of the Products, as set out in the latest Forecast, in advance of any Orders from RB.

6.5 In the event that:

6.5.1 MSX's success in meeting Orders (whether in terms of failure to meet either or both of the volume and/or the Delivery Date specified in the Orders) falls below either (i) [***] percent ([***]%) for any consecutive [***] period during which RB places [***] Orders or more, or (ii) [***] percent (***%) for any consecutive [***] period during which RB places less than [***] Orders (provided that in the case of any Order which exceeds [***] percent ([***]%) of the volume as set out for that period in the previous Forecast, MSX shall only be deemed to have failed to meet that Order for the purposes of this **Clause 6.5.1** if it fails to deliver on the Delivery Date at least [***] percent ([***]%) of the volume set out in the previous Forecast); or

6.5.2 if MSX is prevented from performance in view of an event of Force Majeure as set out in **Clause 16.2**;

then RB shall have the right to retain a temporary alternative supplier to manufacture and supply the Product, without prejudicing any other rights RB may have under this Agreement.

6.6 If RB elects to purchase the Product from an alternative supplier in accordance with **Clause 6.5** above, MSX shall, if necessary:

6.6.1 grant RB and the alternative supplier a limited, personal, non-exclusive, royalty-free licence, without the right to sublicense, to use MSX's applicable Intellectual Property Rights for such period as may be necessary for the alternative supplier to be able to supply Products pursuant to the Forecasts; and

6.6.2 use commercially reasonable efforts to promptly transfer such MSX Intellectual Property Rights under **Clause 6.6.1** above subject to confidentiality and intellectual property agreements in the form reasonably satisfactory to MSX.

6.7 MSX shall provide all reasonable assistance regarding the identification, appointment and validation of any proposed alternative supplier of the Products in the event a supply issue under **Clause 6.5** hereof arises. The parties agree to work together in good faith to procure the continued manufacture and supply of the Products from MSX as soon as reasonably practicable following the resolution of the manufacturing problem by MSX.

6.8 At the recommencement of the supply of the Product by MSX pursuant to **Clause 6.7** above, the licence to use MSX Intellectual Property Rights to make, have made and import the Products shall cease immediately thereupon. Supply of all Products to RB by MSX will resume immediately thereupon. Except as otherwise provided in **Clause 6.5** above, RB shall source the Products exclusively from MSX during the Term.

6.9 The provisions of **Clause 6.5** and **6.6** shall not apply, and subject to **Clause 5.9,** RB shall not be entitled to withhold payment for Products, where a delay or failure to deliver arises due to the delay or failure of RB to deliver the quantities of API ordered by MSX, where the API delivered by RB fails to meet the API Specification or is contaminated, or is due to any other delay, fault or failure attributable to RB or any of its Affiliates or assigns and, in each case, MSX shall not be in default under or breach of this Agreement for any corresponding failure or delay in the manufacture or delivery of Products.

6.10 MSX represents and warrants that, subject to **Clause 6.12** and the receipt of binding Orders from RB for such stock materials, it will maintain sufficient stock levels of the Film (which subject to **Clause 6.11** below shall be no less than [***] months) to provide flexibility and to respond in a commercially reasonable manner to increases in RB's demand.

6.11 MSX will use commercially reasonable efforts to carry out such stability testing as is necessary to demonstrate that the storage of the Film (whether in the form of Master Rolls or in Daughter Rolls (being a Master Roll divided into approximately [***] equal rolls)) in accordance with **Clause 6.8** shall not adversely affect the manufacture of the Products and that the Products will remain within the Product Specification and the Packaging Specification. If MSX is unable to demonstrate that the storage of the Film for [***] months or more shall not adversely affect the manufacture of the Products and/or the maintenance of the Products within the Product Specification and the Packaging Specification, it will use commercially reasonable efforts to obtain a suitable shorter duration of commercially reasonably possible storage under the circumstances and the duration specified in **Clause 6.10** shall be adjusted accordingly.

6.12 RB warrants and represents that it shall reimburse MSX for all reasonable third party costs incurred by MSX in storing the Film and carrying out the stability testing as specified in **Clauses 6.10** and **6.11,** respectively. Such costs shall be invoiced by MSX to RB following MSX incurring the obligation to make payment of such costs and these invoices shall be paid by RB within the time set forth in such invoices, but in no event later than thirty (30) days from receipt thereof.

6.13 Where any Tooling is provided or funded by RB, if any (including in accordance with the provisions of **Clause 15.17**), ownership, title and interest in such Tooling shall at all times belong to RB and MSX shall throughout the Term keep and maintain the sign and/or sticker on the Tooling indicating the sole ownership of the property of RB.

7. PRICE AND PAYMENT

7.1 The price for the Products (the "**Price**") shall be as set out in **Clause 7.2** and all references to sums payable shall be in U.S. dollars (USD) unless specifically indicated to the contrary in this Agreement.

7.2 The Price payable by RB to MSX for the Products shall be the Cost of Goods Price for the Year of manufacture, subject to minimum Order price adjustments and additional packaging fees, if any, in accordance with **Clause 7.3 below.**

7.3 RB agrees that, during the Term, the Price for each of the Products shall be adjusted as follows:

7.3.1 the Price for each Product shall be increased in the event that RB fails to satisfy the minimum Order requirements for each Order as set forth below:

(i) each Order that is for [***] or more, but less than [***] units of a Product, the Price for each such Product shall be increased by [***] U.S. dollars (USD$[***]); and

(ii) each Order that is for less than [***] units of a Product, the Price for each such Product shall be increased by [***] U.S. dollars (USD$[***]); and where in this **Clause 7.3 Order shall mean** any Order composed of the same dose Product for different countries (such that a requirement for [***] 2mg dose units for the UK and [***] 2mg dose units for the US would be an Order for [***] units) but shall not include any combination of orders for different dose Products (such that a requirement for [***] 2mg dose units and [***] 8mg dose units would be considered as two separate Orders for [***] units each).

7.3.2 In the event that any Order requests more than one packaging for the Products covered by such Order, RB shall pay a lump sum amount for each additional packaging request in the amount of [***] Dollars (USD $[***]), regardless of the number of units of Product covered by such new packaging request (the "**Packaging Fee**"). For the avoidance of doubt, the parties agree that any Order that is for [***] units of a Product or more shall not be adjusted as to price per each Product by a request under such Order for multiple packaging of such Products but RB will pay any applicable Packaging Fees for such Order.

7.4 Subject to **Clauses 7.5** to **7.7**, in addition to the fees under **Clause 7.1**, RB shall pay to MSX a royalty of the sum of the following:

7.4.1 [***] of the Net Sales Value of the Products sold during the Term in the U.S. up to a maximum annual royalty of USD$9,000,000 (nine million U.S. dollars) per Year of sale (pro rated accordingly for the period from the Product Launch of the Product in the U.S. to the 31st of December in the Year of the Product Launch in the U.S. and from the 1st of January until the expiry of the Royalty obligations in accordance with **Clauses 7.5** in any Year where those obligations expire, if applicable); and

7.4.2 [***] of the Net Sales Value of the Products sold during the Term in the ROW up to a maximum annual royalty of GBP£2,000,000 (two million Pounds Sterling) per Year of sale (pro rated accordingly for the period from the Product Launch of the Product in the ROW to the 31st of December in the Year of the Product Launch in any country within the ROW and from the 1st of January until the expiry of the Royalty obligations in accordance with **Clause 7.6** in any Year where those obligations expire, if applicable).

7.5 The obligations to pay Royalties as set out in **Clause 7.4.1** above shall end upon the occurrence of:

7.5.1 the expiry of all of the Patents in the U.S. and of all patents which issue in the U.S. in respect of any Improvements relating to the MSX Arising Intellectual Property Rights and/or Existing Intellectual Property Rights, as the case may be; or

7.5.2 RB exercising the option under **Clause 7.7.1** in respect of the U.S., whichever is the sooner.

7.6 The obligations to pay Royalties as set out in **Clause 7.4.2** above shall end, on a country by country basis, upon the occurrence of:

7.6.1 the expiry of all of the Patents in the ROW and of all patents which issue in any country within the ROW in respect of any Improvements relating to the MSX Arising Intellectual Property Rights and/or Existing Intellectual Property Rights, as the case may be; or

7.6.2 RB exercising the option under **Clause 7.7.2** in respect of the ROW, whichever is the sooner.

7.7 RB shall have the option upon prior written notice to MSX to stop making payments of the Royalties due under **Clauses 7.4.1** and/or **7.4.2** (the "**Options**") by making payment to MSX of:

7.7.1 with respect to Royalties due under **Clause 7.4.1**, USD$[***] U.S. dollars) immediately upon exercising such Option. The Option under this **Clause 7.7.1** shall be exercisable at any time commencing after the [***] anniversary of the date of the Product Launch of the Product in the U.S.; and/or

7.7.2 with respect to Royalties due under **Clause 7.4.2**, GBP£[***] Pounds Sterling) immediately upon exercising such Option. The Option under this **Clause 7.7.2** shall be exercisable at any time commencing after the [***] anniversary of the date of the Product Launch of the Product in any country of the European Union within the ROW.

Upon making payment to MSX of the amounts stated in **Clause 7.7.1** the obligations to pay Royalties to MSX in respect of the U.S. will immediately cease and upon making payment to MSX of the amounts stated in **Clause 7.7.2** the obligations to pay Royalties to MSX in respect of the ROW will immediately cease. For the avoidance of doubt, the Options granted under **Clauses 7.7.1** and **7.7.2** may be exercised independently of each other.

7.8 For the avoidance of doubt, no credit will be given in respect of Royalties previously paid and where any of the Options are exercised part way through any Half Year Period, RB shall be responsible for making payments of any Royalties due in respect of sales of Products made before the date such of the Options was exercised and shall make such Royalty payments at the end of the Half Year period in which such of the Options was exercised.

7.9 Third Party Claims

7.9.1 If a third party claims that the manufacture and supply of a Product by MSX under this Agreement (including manufacture in accordance with the MSX's Existing Intellectual Property Rights or MSX's Arising Intellectual Property Rights), or the subsequent use and sale of such. Products by RB, infringes any claims of patents of such third party (and such infringement claim is not a claim that (i) the buprenorphine or naloxone component of the Product, and (ii) the manufacture of the buprenorphine or naloxone component of the Product, infringes any claims of patents of such third party) (a "**TP Patent Claim**"), MSX shall be responsible, at its cost and expense, for either defending or settling such TP Patent Claim and paying any judgment recovered by such third party in a suit for such TP Patent Claim (including any amounts for past infringement of such third party's patent by the Product), and using commercially reasonable endeavours to obtain an exclusive license in the Field from such third party that would by the terms of such settlement or exclusive license allow RB the right to continue to sell during the Term such Product in the Field in the jurisdiction or country in which such claim is brought, consistent with the terms and conditions of this Agreement and without any additional royalty or remuneration therefore by RB. In the event that MSX has not successfully defended or settled such TP Patent Claim or obtained such exclusive license, the obligation for payment of Royalty by RB under **Clauses 7.4.1** and **7.4.2** (and, if applicable, **Clause 7.7**) in connection with continued sales of such Product (if any) shall be adjusted as set out in **Clauses 7.9.3.1** and **7.9.3.2**, as applicable, and in the event that the TP Patent Claim is brought more than [***] years after the Commencement Date and RB is prohibited from selling Products (i) in any of the U.S. or that portion of the ROW that constitutes all of the European Union, then RB shall have the right upon [***] days prior written notice to MSX to terminate this Agreement, or (ii) in any other jurisdiction in the Territory, then RB shall have the right upon [***] days prior written notice to MSX to terminate this Agreement as to such other jurisdiction. For purposes of this **Clause 7.9.1**, MSX shall be deemed to have failed to use commercially reasonable efforts to obtain such a licence as set out above if MSX fails or elects not to use such efforts and resources (including, without limitation, the promptness in which such efforts and resources would be applied) consistent with its expression on and before the Commencement Date of MSX's commitment to obtaining such a licence should it be required in order to alleviate as a priority concern of MSX, including expending such additional funds and devoting such additional manpower and other resources as is necessary and appropriate to reasonably assure the grant of such a licence to allow RB to continue to sell during the Term the Products in the Field in the relevant jurisdiction or country and, in any circumstances, which are consistent with the general level of effort and resources that would be used in the pharmaceutical industry for a company with the intention to commercialize and exploit a product critical to the continued success of the company. In the event that despite the use of such endeavours as described above, MSX is unable to obtain the licence described above it shall inform RB of this fact and discuss with RB any further possibilities for the joint resolution of this issue including, without limitation, RB assisting MSX to obtain such a licence (which RB shall be entitled to consider in its absolute discretion) on the assumption that any sums paid by RB (if any) towards obtaining such a licence will be offset against any Royalties to be paid by RB to MSX pursuant to **Clause 7.4**.

7.9.2 If a third party brings a claim of invalidity of the Patents in any part of the Territory, then, subject to **Clause 7.9.4**, MSX shall be responsible for defending such claim, at its cost and expense, and seeking to maintain validity of the Patents and all obligations for payment of a Royalty under **Clauses 7.4.1** and **7.4.2** (and if applicable **Clause 7.7**) in connection with sales of Products following such claim shall be adjusted according to **Clause 7.9.3.1** and **7.9.3.2** below, as applicable, and RB shall have the other rights set forth in **Clause 7.9.3.3.**

7.9.3 For any claim brought by a third party which is successful or not yet finally adjudicated under **Clauses 7.9.1** or **7.9.2**

7.9.3.1 and such third party introduces a product in the Field which gains a market share in the Field of at least a [***] percent ([***]%) but not more than [***] percent ([***]%) in any of (i) the U.S., (ii) that portion of the ROW that constitutes the European Union, or (iii) any other country in the Territory within [***] months after such product introduction (the "**Market Review Period**"), RB's obligation to make such Royalty payments after the expiration of the Market Review Period with respect to sales of such Product in such jurisdiction or country shall be reduced by [***]; or

7.9.3.2 and such party introduces a product in the Field which gains a market share in the Field of [***] percent ([***]%) or more in any of (i) the U.S., (ii) that portion of the ROW that constitutes the European Union, or (iii) any other country in the Territory during the Market Review Period, RB's obligation to make such Royalty payments after the expiration of the Market Review Period and thereafter with respect to sales of such Product in such jurisdiction or country shall be terminated; or

7.9.3.3 if such third party claim is brought within [***] years after the Commencement Date and (i) RB is prohibited from achieving Product Launch in any of the U.S. or that portion of the ROW that constitutes all of the European Union, then RB shall have the right upon thirty (30) days prior written notice to MSX to terminate this Agreement, or (ii) RB is prohibited from selling all Products in any other jurisdiction in the Territory, then RB shall have the right upon thirty (30) days prior written notice to MSX to terminate this Agreement as to such other jurisdiction. Upon termination of this Agreement under this **Clause 7.9.3.3**, RB shall satisfy its obligations under **Clause 18.1.2** and MSX shall indemnify RB for the Losses incurred by RB as a result of such termination up to an amount equal to [***] of the payments made by RB (and its Affiliated Companies) to MSX and its Affiliated Companies in developing the Products (which for the avoidance of doubt shall be all sums paid by RB (and its Affiliated Companies) to MSX excluding sums paid by RB (and its Affiliated Companies) in respect of the purchase of the Products and Royalties under this Agreement including, payments by RB under **Clause 7.7**, if any) prior to such termination. Payment of such amount to RB under this **Clause 7.9.3.3** shall be the sole and exclusive remedy of RB for any termination of this Agreement under this **Clause 7.9.3.3** and, upon payment thereof to RB, MSX shall have no further obligation or liability to RB under this Agreement or otherwise for such third party claim, except for MSX's obligations to pay the costs and expense of defending and settling such third party claim under **Clause 7.9.1.** This **Clause 7.9.3.3** shall not apply to any claim brought by [***] within [***] after the Commencement Date, which claim (and the rights and obligations of MSX and RB relating thereto) shall be solely covered under **Clause 7.10.**

7.9.4 For any such third party claim brought under **Clauses 7.9.1** or **7.9.2** in which such third party is unsuccessful (including a claim brought by [***] as described in **Clause 7.10**), then RB's obligations to make payment of the Royalties shall remain unchanged and shall be in effect in accordance with the terms of this Agreement, subject to the following. If such third party introduces a product in the Field while such claim is being adjudicated and which is thereafter withdrawn from the Field after such adjudication, RB shall make payment of the Royalties (together will all future Royalties due under this Agreement) which would have been paid in accordance with the terms of this Agreement prior to such adjudication, subject to RB's rights in accordance with **Clauses 7.9.3.1** and **7.9.3.2** to reduce or terminate such Royalty payments, as the case may be, for the period prior to such withdrawal and subject to the last sentence of **Clause 7.9.1** in which RB may offset royalties paid by RB to such third party for a license under **Clause 7.9.1,** if any, against Royalties to be paid by RB to MSX pursuant to **Clause 7.4.**

7.9.5 For any such third party claim that is brought alleging the invalidity of the Patents and MSX believes that defending such claim is unnecessary and uneconomical, then save in respect of the US and that portion of the ROW that constitutes all of the Europe Union (in which areas MSX shall be obliged to defend any claims for invalidity), MSX shall seek RB's consent not to defend such actions and RB agrees that such consent shall not be unreasonably withheld, conditioned or delayed.

7.10 In the event that [***] brings a claim that the manufacture and supply of a Product by MSX under this Agreement (including manufacture in accordance with MSX's Existing Intellectual Property Rights or MSX's Arising Intellectual Property Rights) or the subsequent use and sale of such Products by RB, infringes a claim of one of its patents described in Schedule 10 attached hereto (and such infringement claim is not a claim that (i) the buprenorphine or naloxone component of the Product, or (ii) the manufacture of the buprenorphine or naloxone component of the Product, infringes any claims of such patents), MSX shall have all of the obligations to defend, settle and obtain an exclusive license with respect thereto in accordance with the terms of **Clause 7.9.1**. If the claim is brought within one year after the Commencement Date and [***] is successful in its claim, or such claim has not yet been finally adjudicated, and, as a result thereof, RB is prohibited from achieving Product Launch in the US or that portion of the ROW that constitutes all of the European Union, RB shall have the right to terminate this Agreement and, upon such termination, RB shall satisfy its obligations under **Clause 18.1.2** and MSX shall pay to RB as liquidated damages a lump sum amount equal to [***] for all Losses incurred or to be suffered by RB (the "[***] **Settlement**") as a result thereof or in connection therewith. Payment of the [***] Settlement to RB shall be the sole and exclusive remedy of RB for any termination of this Agreement with respect to a claim by [***] under this **Clause 7.10** and, upon payment of the [***] Settlement to RB, MSX shall have no further obligation or liability to RB under this Agreement or otherwise with respect to such [***] claim, except for MSX's obligation to pay for the defense and settlement of such [***] claim, including the payment of any judgement (including for past infringement of [***] patents by the Product, if any) recovered by [***] in a suit for such [***] claim in accordance with **Clause 7.9.1**.

7.11 In addition to the Price, RB shall make a payment to MSX of USD$[***] U.S. dollars) (the "**Milestone Payments**") on each of the following dates:

7.11.1 the Product Launch of the Product in the U.S.; and

7.11.2 the first Product Launch of a Product within any country within the ROW.

For the avoidance of doubt, this shall amount to a maximum total payment of USD$[***] for Milestone Payments.

7.12 For the duration of this Agreement, MSX shall use commercially reasonable efforts to be technically and commercially competitive, taking into account the market for the supply and the cost from other suppliers of product(s) similar to the Products, and shall effect cost reductions and engage in all such technical innovations in respect of the Products which are commercially reasonably possible, taking into account MSX's manufacturing obligations to other parties, capital investment and any other relevant factor as determined by MSX.

7.13 Promptly following the execution and delivery of this Agreement, MSX shall deliver to RB information regarding the Costs of Raw Materials. At least sixty (60) days prior to the beginning of each subsequent Year, the parties shall confer (each, an "**Annual Review**") regarding all costs of manufacturing the Products, including without limitation, Raw Materials, other components, energy, transportation, legal, regulatory and all other hard and soft costs of manufacture, but not labour, in order to determine if cost reductions are appropriate.

7.14 The cost of goods price for the period from the Commencement Date and expiring on the 31St of December in the Year of the Commencement Date shall be the price as set out in **Schedule One** and, unless otherwise agreed by the parties in writing pursuant to this **Clause 7.14,** the cost of goods price for each subsequent Year, shall be increased or decreased in accordance with the Price Change (the "**Cost of Goods Price**"). In the event that the Price Change for a Year exceeds the change in the Pharma Price Index for the same period, RB may, at its option, obtain pricing for one or more of the Major Raw Materials from , third parties who are, to the reasonable satisfaction of MSX, qualified suppliers (as can be demonstrated through written documentation). If the pricing obtained by RB is at least [***] more favourable for a given Year than the costs provided by MSX during such Year, MSX shall engage in a good faith review of the obtained pricing. If MSX, acting with commercial reasonableness (including, without limitation, giving consideration to quality control, shipping fees, import duties, warehousing fees, time of transit, and the cost of certifying, qualifying and testing the Major Raw Materials of such proposed supplier), determines that the pricing obtained by RB is at least [***] more favourable for a given Year, MSX shall, at its sole option, either (i) engage the supplier offering the pricing obtained by RB for such period as the supplier pricing remains at least [***] more favourable, and adjust the Cost of Raw Materials for the given period, or (ii) obtain a price reduction from its then-current supplier to pricing similar (even if less favourable) to the reduced pricing obtained by RB. The parties agree that during the course of such discussions the Price chargeable for the Products shall be the Price for the previous Year as varied according to the Pharma Price Index and that following the determination of the Price in accordance with the above procedure RB shall be responsible to MSX for the payment of any excess sums due to MSX applying such determined price retrospectively against all Orders for the Products during such period. RB shall make such payment within [***] days after determining the Price in accordance with the above procedures. For the avoidance of doubt, MSX acknowledges that in dealing with any third party suppliers of Raw Materials it will not disproportionately allocate any discounts in determining costs charged by the third party supplier for the Raw Materials, when such Raw Materials are purchased from a third party supplier supplying to MSX raw materials to be used by MSX in relation to products other than the Products. MSX hereby agrees that upon reasonable advance written notice to MSX, RB shall have a right to an audit of such records of MSX as is reasonable to ensure that the cost of such rat materials are in compliance with this **Clause 7.14**; provided, that, such access shall be limited to the period ending not more than [***] years prior to the date of such audit and RB shall be responsible for the costs of such audit and MSX shall not charge RB for any of MSX's costs of such audit. For the avoidance of doubt, RB agrees that all information disclosed by MSX under this **Clause 7.14** shall be Confidential Information for the purpose of this Agreement and RB shall ensure that any nominee of RB participating in such audit shall enter into a confidentiality agreement with MSX obligating such nominee to maintain the confidentiality of any information disclosed by MSX pursuant to this **Clause 7.14.**

7.15 All invoices to be sent to RB shall be sent to Accounts Payable, Reckitt Benckiser Pharmaceuticals Inc., 10710 Midlothian Turnpike, Suite 430, Richmond, Virginia 23235.

7.16 RB shall pay invoices in respect of the Cost of Goods Price, together with any other invoices submitted to it pursuant to this Agreement, within [***] of receipt by RB from MSX of a valid VAT (or other applicable similar taxes) invoice therefore.

7.17 If RB is required to withhold any tax, including, but not limited to, the value-added tax (VAT) and any similar taxes that can replace or append the existing ones, then RB shall make payment of the relevant fee after such withholding in accordance with the applicable law. The parties agree to co-operate in all commercially reasonable respects necessary to determine, prior to any such withholding, whether either party is responsible for any taxes in connection with the transactions contemplated under this Agreement and during the Term to take advantage of such double taxation agreement as may be available and the party responsible for securing any certificates or approvals that are necessary for the payment without any withholding of taxes at source is MSX, and all the expenses related to obtaining such certificates or approvals are for the remit of MSX.

7.18 RB shall pay the Royalty for Products (if any) within [***] days of the expiry of the Half Year period in which the relevant Royalties are chargeable. Each Royalty payment shall be accompanied by a statement detailing the calculation of Royalties due to MSX, including, without limitation, the amount of Products sold and the corresponding Royalty amount.

7.19 MSX shall be expressly permitted to assign any sums payable under this **Clause 7**.

7.20 MSX shall have the right to have its independent certified accountants ("**MSX Accountants**") review and verify the accuracy of the records and accounts related to the Royalties (including records of sales as notified to it by its distributor in respect of certain countries within the Territory) hereunder for any Half Year ending not more than [***] years prior to the date of such review (the "**Records**"); provided, that, MSX shall not have the right to conduct more than [***] such inspection in any [***] month period, unless MSX or RB shall have a good faith belief that during such period that a Regulatory Authority inspection is expected, or unless otherwise required by applicable law, regulation rule or Regulatory Authority. Following such review, MSX's accountants shall disclose to RB and MSX whether the Royalties paid to MSX hereunder are correct and accurate, and give details of any discrepancies between the Royalties due under the Records and Royalties paid. MSX shall be responsible for the costs of the MSX Accountants unless the MSX Accountants certify that RB has underpaid Royalties properly due to MSX by [***] or more in the period being audited, in which instance RB shall reimburse MSX for all costs of the MSX Accountants within [***] of receipt of notice of such underpayment. In no event shall the MSX Accountants disclose to MSX information other than whether the Royalties payable by RB were accurate of inaccurate and the amount of any discrepancies due. For the avoidance of doubt, MSX agrees that all information disclosed by RB under this **Clause 7.20** shall be Confidential Information for the purpose of this Agreement and MSX shall ensure that the MSX Accountants shall enter into a confidentiality agreement with RB obligating the MSX Accountants to maintain the confidentiality of any information disclosed by RB pursuant to this **Clause 7.20.**

7.21 In the event that the review conducted under **Clause 7.20** concludes that RB owes to MSX further Royalty payments, RB shall make such additional payments within [***] days of a copy of the MSX Accountants' review being delivered to both parties. In the event that the review conducted under **Clause 7.20** concludes that RB has made Royalty payments to MSX in excess of those required, such excess payments shall be credited against future payments owed by RB to MSX under this Agreement (or, if no such payments are owed, shall be promptly refunded by MSX to RB within [***] days of a copy of the MSX Accountants' review being delivered to MSX).

7.22 During the Term commencing with the period ending at December 31, 2008, RB shall be entitled to receive a rebate on volume purchases of the Products in accordance with the following (the "**Rebate**"):

7.22.1 In the event that RB purchases in any Year in the aggregate more than [***], but less than [***], units of Product, in any combination of one or more Products set forth on **Schedule 3**, RB shall be entitled to receive a Rebate of [***] U.S. dollars (USD$[***]) for each unit of Product over [***] and less than [***] purchased by RB during such Year; and

7.22.2 In the event that RB purchases in any Year in the aggregate [***] units of Products or more, in any combination of one or more Products set forth on Schedule 3, then in addition to the rebate payable under Clause 7.22.1 above, RB shall be entitled to receive a Rebate of [***] U.S. dollars (USD$[***]) for each unit of Product at and in excess of [***] purchased by RB during such Year; and

7.22.3 The Rebate due to RB in any Year, if any, shall be calculated by MSX on or before January 31st of the immediately succeeding Year (the "**Rebate Calculation**"); and

7.22.4 At the option of MSX, exercised in its sole discretion, the Rebate for each Year, if any, shall be either: (i) paid by MSX to RB on or before February 15th of the immediately succeeding Year for which such Rebate Calculation is due; or (ii) granted as a credit by MSX in the amount of such Rebate against the payment or payments of Royalties due by RB after the Rebate Calculation; and

7.22.5 No Rebate under this Agreement, if any, shall result in or entitle RB to any right of set-off, discount or similar reduction of the Price of any Product purchased by RB, or in any other payment due by RB under this Agreement, including, without limitation, any Milestone payment, Option payments, and Royalty payments except as specifically set forth in **Clause 7.22.4**(ii) above. No interim payments of Rebates, if any, due under this Agreement shall be made during the Term except any Rebates due and unpaid by MSX, pursuant to the terms of this Agreement, upon the expiration or termination of this Agreement and not theretofore applied by MSX as a credit against Royalties due and owing by RB upon such expiration or termination.

8. QUALITY DOCUMENTATION AND INSPECTION

8.1 MSX shall manufacture the Products in accordance with this Agreement and in particular with the provisions of **Clause 3.1.1**.

8.2 If MSX has actual knowledge that any aspect of the Product Specification is liable to result in the manufacture of a defective Product which may lead to a liability being incurred, MSX shall, as soon as reasonably practicable, notify RB in writing.

8.3 MSX shall establish and maintain a batch-tracking system to enable it to identify and procure the recall (if necessary) of Products which may be affected in any way by manufacturing and production problems. MSX shall provide details to RB of its batch-tracking system upon RB's reasonable written request to do so.

8.4 MSX shall:

8.4.1 complete the documentation relevant to the manufacture, testing, storage and delivery of the Product in accordance with cGMP and any other reasonable requirements of RB provided to MSX in advance in writing, and shall retain such documentation for a minimum period of six (6) years after delivery of the Product to RB (or its nominee);

8.4.2 permit RB (or its nominee), on reasonable prior written notice to MSX, access to the Manufacturing Site from time to time during the Term as is reasonable (or if required by applicable law, regulation, rule or Regulatory Authority) for the inspection of any documentation relating solely to the manufacture, testing, storage or delivery of the Products, the Raw Materials or the Film for the period ending not more than [***] years prior to the date of such inspection; provided, that, RB shall be responsible for the costs of such inspection and MSX shall not charge RB for MSX's costs of such inspection. For the avoidance of doubt, RB agrees that all information disclosed by MSX under this **Clause 8.4.2** shall be Confidential Information for the purpose of this Agreement and RB shall ensure that any nominee of RB participating in such inspection shall enter into a confidentiality agreement with MSX obligating such nominee to maintain the confidentiality of any information disclosed by MSX pursuant to this **Clause 8.4.2;**

8.4.3 promptly, upon the reasonable written request of RB, provide RB with any Product validation report, including a summary of the analytical results, the stability results, details of any Product failures, process deviations and any out of Product Specification results; and

8.4.4 complete and lodge with the appropriate Regulatory Authorities where required all documentation relating to the export of the Products where delivery involves export from the country of manufacture.

8.5 RB (or its nominee) shall have the right to perform any tests it wishes (at RB's expense) on any Product, Raw Materials or Film at MSX's Manufacturing Site as reasonably requested by RB upon ten (10) days advance written notice to MSX to ensure its compliance with the Product Specification, and without interference with MSX's operations.

8.6 MSX shall, and shall use commercially reasonable efforts to, procure that its Affiliates shall, grant a right of reasonable access to RB (or its nominee) to inspect any records relevant to the manufacture of the Products subject to **Clause 8.4.2** or conduct any tests on the Products, Raw Materials or Film subject to **Clause 8.5.**

8.7 RB shall, and shall use commercially reasonable efforts to procure that any Affiliate or third party API manufacturer shall:

8.7.1 complete the documentation relevant to the manufacture, testing, storage and delivery of the API in accordance with cGMP and any other reasonable requirements of MSX provided to RB in advance in writing, and shall retain such documentation for a minimum period of six (6) years after delivery of the API to MSX (or its nominee);

8.7.2 permit MSX (or its nominee), on reasonable prior written notice to RB, access to the manufacturing site of the API from time to time during the Term as is reasonable (or if required by applicable law, regulation, rule or Regulatory Authority) for the inspection of any documentation relating to the manufacture, testing, storage or delivery of the API for the period ending not more than [***] years prior to the date of such inspection; provided, that, MSX shall be responsible for the costs of such inspection and RB shall not charge MSX for any of RB's costs for such inspection. For the avoidance of doubt, MSX agrees that all information disclosed by RB under this **Clause 8.7.2** shall be Confidential Information for the purpose of this Agreement and MSX shall ensure that any nominee of MSX participating in such inspection shall enter into a confidentiality agreement with RB obligating such nominee to maintain the confidentiality of any information disclosed by RB pursuant to this **Clause 8.7.2**;

8.7.3 promptly, upon reasonable request of MSX, provide MSX with any validation report for any API batch, including a summary of the analytical results, the stability results, details of any such batch failures, process deviations and any out of API Specification results; and

8.7.4 complete and lodge with the appropriate Regulatory Authorities where required all documentation relating to the export of the API where delivery involves export from the country of manufacture.

8.8 MSX shall have the right, but not the obligation, to perform any tests it wishes (at MSX's expense) on any API at the manufacturing site of the API or any other relevant sites as MSX reasonably requests to ensure its compliance with API Specifications.

8.9 RB shall, and shall use commercially reasonable efforts to procure that its Affiliates and any third party API manufacturer shall, grant a right of reasonable access to MSX (or its nominee) to inspect any records relevant to the manufacture of the API subject to **Clause 8.7.2** or conduct any tests on the API subject to **Clause 8.7.4**.

8.10 Each of the parties hereby warrant and represents to the other that (i) it is not debarred under the Generic Drug Enforcement Act of 1992, 21 U.S.C. 335[a] (the "**Generic Drug Enforcement Act**"), and that it has not been convicted of a crime for which it could be debarred under the Generic Drug Enforcement Act; and (ii) it shall not use in any capacity the services of any person debarred under the Generic Drug Enforcement Act, or convicted of a crime for which a person can be debarred under the Generic Drug Enforcement Act.

9. WARRANTIES

9.1 MSX hereby warrants that:

9.1.1 the Manufacturing Site has as of the Commencement Date, and will maintain during the Term, all necessary or appropriate consents, approvals, licences, permits, registrations or authorisations (or waivers) required to manufacture the Products, in accordance with the terms of this Agreement;

9.1.2 it has the necessary facilities, equipment, Know-How, procedures and personnel at the Manufacturing Site to manufacture the Products in accordance with the terms of this Agreement;

9.1.3 any Products manufactured pursuant to this Agreement shall comply with the Product Specification and all provisions as to quality set out in the Quality Agreement;

9.1.4 subject to **Clause 6.9**, at the time that legal title and risk of loss passes to RB pursuant to **Clause 5.7**, the Products manufactured pursuant to this Agreement shall be free from adulteration or contamination and fit for their intended purpose under this Agreement; and

9.1.5 the manufacture of the Products will comply with all applicable national and local laws, rules, regulations and guidelines in force in the jurisdiction of the country of distribution in respect of the manufacture of the Products and, to the knowledge of MSX, there are no circumstances or conditions in existence as of the Commencement Date which would reasonably be expected to prevent continuing compliance of the manufacture of the Products in accordance with the terms of this Agreement with all such national and local laws, rules, regulations and guidelines during the Term.

9.2 MSX further warrants that:

9.2.1 subject to the terms of this Agreement, it will meet all Orders from RB for the Products that are consistent with the terms of this Agreement;

9.2.2 it shall supply the Products within the periods set out in **Clause 5.1**;

9.2.3 it shall convey good title in any Products delivered to RB under this Agreement;

9.2.4 it is duly incorporated and organized and is validly existing under the laws of its jurisdiction of incorporation and has the corporate power and authority to own its assets and to conduct its businesses and to perform its obligations hereunder;

9.2.5 the execution and delivery of this Agreement by it and the completion by it of the transactions contemplated herein do not and will not result in the breach of, or violate any term or provision of, its articles of incorporation or by-laws;

9.2.6 it is not subject to any outstanding injunction, judgement or order of any governmental authority which would prevent or materially delay the transactions contemplated by this Agreement; there are no civil, criminal or administrative claims, actions, suits, demands, proceedings, hearings or investigations pending or, to MSX's knowledge threatened, at law, in equity or otherwise, in, before, or by, any governmental authority which (if successful) would prevent or materially delay MSX's compliance with the provisions of this Agreement;

9.2.7 no dissolution, winding up, bankruptcy, liquidation or similar proceeding has been commenced or is pending or, to MSX's knowledge, proposed in respect of it;

9.2.8 the execution and delivery of this Agreement and the completion of the transactions contemplated herein have been duly approved by appropriate persons within its organisation and this Agreement constitutes the legal, valid and binding obligation of MSX enforceable against it in accordance with its terms;

9.2.9 it or its Affiliates has taken or will take all action as may be required to obtain and maintain, comply and keep current any governmental licences, permits, approvals and/or registrations that are necessary for MSX and/or its Affiliates to manufacture and/or supply the Products and to carry out and perform its obligations under this Agreement;

9.2.10 it shall, at its own cost, diligently prosecute to grant all subsisting patent applications within the Patents so as to secure the broadest monopoly legally and reasonably obtainable within the Field consistent with avoiding serious prejudice to the validity of such granted Patents and provide RB with a patent update report (which shall include details of the renewal dates of all Patents registered) every [***] months during the Term;

9.2.11 it shall for the life of the Patents pay all renewal fees and do all such act: and things as may be necessary to maintain and keep the Patents and shall provide RB with written notice of its intent not to renew at least [***] months before the last day for renewing the Patents; and

9.2.12 it shall not during the Term, save following receipt of written notice that RB does not wish to acquire the Patents in accordance with **Clause 15.13**, abandon any of the Patents or allow any of them to lapse.

9.3 RB hereby warrants that:

9.3.1 RB, the manufacturing site of the API and/or any third party API manufacturer, as applicable, has as of the Commencement Date, and to RB's knowledge will maintain during the Term, all necessary or appropriate consents, approvals, licences, permits, registrations or authorisations (or waivers) required to manufacture the API in accordance with the terms of this Agreement. For the avoidance of doubt this warranty is given without prejudice to RB's obligations to supply API in accordance with the API Specifications;

9.3.2 it and/or any third party API manufacturer, as applicable has the necessary facilities, equipment, Know-How, procedures and personnel at the manufacturing site of the API to manufacture the API in accordance with the terms of this Agreement;

9.3.3 any API delivered pursuant to this Agreement shall comply with the provisions the API Specification;

9.3.4 the API supplied pursuant to this Agreement shall conform to the API Specification and shall be free from adulteration or contamination and fit for its intended purpose under this Agreement;

9.3.5 it and/or any third party API manufacturer, as applicable shall comply with all applicable national and local laws, rules, regulations and guidelines in force in the U.S. and the European Union in respect of the manufacture of the API and, to the knowledge of RB, there are no circumstances or conditions in existence as of the Commencement Date which would reasonably be expected to prevent continuing compliance of the manufacture of the API in accordance with the terms of this Agreement with all such national and local laws, rules, regulations and guidelines during the Term; and

9.3.6 MSX's use of the API in accordance with the terms of this Agreement shall not infringe any third party patent rights or other intellectual property rights which are known by RB (or ought reasonably to be known by RB) to exist as of the Commencement Date.

9.4 RB further warrants that:

9.4.1 it shall supply the API within the time periods set out in **Clause 4.3**;

9.4.2 it is duly incorporated and organized and is validly existing under the laws of its jurisdiction of incorporation and has the corporate power and authority to own its assets and to conduct its businesses and to perform its obligations hereunder;

9.4.3 the execution and delivery of this Agreement by it and the completion by it of the transactions contemplated herein do not and will not result in the breach of, or violate any term or provision of its articles of formation or by-laws;

9.4.4 it is not subject to any outstanding injunction, judgement or order of any governmental authority which would prevent or materially delay the transactions contemplated by this Agreement; there are no civil, criminal or administrative claims, actions, suits, demands, proceedings, hearings or investigations pending or, to RB's knowledge threatened, at law, in equity or otherwise, in, before, or by, any governmental authority which (if successful) would prevent or materially delay RB's compliance with the provisions of this Agreement;

9.4.5 no dissolution, winding up, bankruptcy, liquidation or similar proceeding has been commenced or is pending or, to the knowledge of RB, proposed in respect of it;

9.4.6 the execution and delivery of this Agreement and the completion of the transactions contemplated herein have been duly approved by appropriate persons within its organisation and this Agreement constitutes the legal, valid and binding obligation of RB enforceable against it in accordance with its terms; and

9.4.7 it or its Affiliates has taken or will take all action as may be required or necessary to obtain and maintain, comply and keep current any governmental licences, permits, approvals and/or registrations that are necessary for RB and/or its Affiliates to manufacture and/or supply the API and to carry out and perform its obligations under this Agreement.

9.5 NOTHING IN THIS AGREEMENT SHALL BE CONSTRUED AS A WARRANTY OR REPRESENTATION BY EITHER PARTY (II) REGARDING THE EFFECTIVENESS, VALUE, SAFETY, NON-TOXICITY OR PATENTABILITY OF ANY PATENT TECHNOLOGY, THE PRODUCT OR ANY INFORMATION OR RESULTS PROVIDED BY EITHER PARTY PURSUANT TO THIS AGREEMENT, OR (II) THAT THE PRODUCT WILL BE APPROVED. EACH PARTY EXPRESSLY DISCLAIMS, WAIVES, RELEASES, AND RENOUNCES ANY WARRANTY, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, EXCEPT THOSE EXPRESS WARRANTIES SET FORTH IN THIS AGREEMENT WHICH SHALL REMAIN IN FULL FORCE AND EFFECT IN ACCORDANCE WITH THE TERMS OF THIS AGREEMENT.

10. **INDEMNITY**

10.1 Subject to the limitations in **Clause 22** below, RB shall indemnify, defend and hold harmless MSX, its Affiliates and its and their respective directors, officers, employees, representatives, agents and contractors ("**MSX Parties**") from any and all Losses that result from or arise in connection with any claim, action, suit or proceeding, made or brought by or on behalf of a third party (a "**Claim**") against any of the MSX Parties to the extent the Claim arises from (i) the marketing, distribution or sale of the Products by RB, its Affiliates and its agents, (ii) the use of the Products, (iii) the failure of API to meet the API Specification as a result of defects (latent or otherwise) in, or non-conformance of, the API (save for those defects or non-conformance which would have been discovered but for MSX's failure to perform the tests to be carried out by MSX in accordance with the terms under **Clause 4.4**) or the breach by RB of the warranties set forth in **Clauses 9.3** and **9.4.1**, or (iv) a material breach of this Agreement by RB or any of its Affiliates; provided, that:

10.1.1 the Claim does not arise from the negligence, wilful default or breach of the terms of this Agreement (including the warranties by MSX in **Clause 9**) or the Quality Agreement by the MSX Parties; and

10.1.2 the indemnity shall not extend to any part of a Claim that results from any failure by MSX to promptly notify RB in writing of any matter which may give rise to such a Claim to which this indemnity may apply, where such failure actually causes material prejudice to RB's rights or ability to defend against such Claim.

10.2 MSX shall indemnify, defend and hold harmless RB, its Affiliates, and its and their respective directors, officers, employees and contractors ("**RB Parties**") from any and all Losses that result from or arise in connection with any Claim brought against the RB Parties to the extent the Claim arises from (i) the failure of the Products to meet the Product Specification or the breach by MSX of the warranties set forth in **Clause 9,** or (ii) a material breach of this Agreement by MSX or its Affiliates, provided, that:

10.2.1 the Claim does not arise from the negligence, wilful default or breach of the terms of this Agreement (including the warranties by RB in **Clause 9**) or the Quality Agreement by the RB Parties; and

10.2.2 the indemnity shall not extend to any part of a Claim that results from any failure by RB to promptly notify MSX in writing of any matter which may give rise to such a Claim to which this indemnity may apply, where such failure actually causes material prejudice to MSX's rights or ability to defend against such Claim.

10.3 Each party shall be obliged to promptly notify the other in writing upon becoming aware of any indemnity claims likely to be made by a third party under the terms of this **Clause 10,** and shall promptly exchange all information relating to an indemnity claim to the extent reasonably practicable.

10.4 The indemnifying party shall:

10.4.1 have sole control over the conduct, defense (including the right to select counsel) and settlement of any such Claim; provided that no compromise or settlement may be affected by the indemnifying party that indicates an admission of liability by the indemnified party or requires the indemnified party to make any monetary payments, without the prior written consent of the indemnified party, such consent not to be unreasonably withheld, conditioned or delayed; and

10.4.2 keep the indemnified party fully informed of the progress of the defense of such Claim.

10.5 The indemnified party shall:

10.5.1 cooperate fully with the indemnifying party and its legal representatives in the investigation and defense of any Claim under this Agreement;

10.5.2 not make any admissions or do anything that may compromise or prejudice the defense of such Claim without the prior written consent of the indemnifying party; and

10.5.3 not make any payment or incur any expenses in connection with any such Claim or make any admission or do anything that may compromise or prejudice the defense of the Claim without the prior written consent of the indemnifying party, such consent not to be unreasonably withheld, conditioned or delayed.

10.6 Subject to **Clause 10.5**, in the event a Claim is asserted, the indemnified party may elect to choose counsel independent from that representing the indemnifying party and participate in the Claim, in which case the indemnified party shall be solely responsible for any costs and expenses associated with such counsel including, legal costs, expert fees and all related costs.

10.7 No later than the first shipment of Product to RB for commercial sale, throughout the remainder of the Term and for a period of [***] months after its expiry or termination, the parties shall carry and keep in force a comprehensive general liability insurance policy, including product liability as well as blanket contractual liability coverage. This insurance policy shall provide a liability limit of not less than £[***] for each occurrence or series of related occurrences within any twelve (12) month period. Each party shall, upon the reasonable request of the other, produce satisfactory evidence that all insurance premiums have been paid and kept up to date and are kept in accordance with local insurance laws or regulations from time to time in force. The existence of such insurance shall not be construed as a limitation of either party's liability hereunder.

11. CONFIDENTIAL INFORMATION

11.1 For the avoidance of doubt, RB and MSX may be disclosing Confidential Information belonging to them or their Affiliates on behalf of those Affiliates and those Affiliates may also disclose such information themselves directly.

11.2 "**Discloser**" means either party or any of its Affiliates disclosing Confidential Information to the Recipient.

11.3 "**Recipient**" means either party or any of its Affiliates receiving Confidential Information from the Discloser.

11.4 Each party will disclose to the other such Confidential Information as it considers necessary to further the purpose of this Agreement.

11.5 Each party shall treat all Confidential Information disclosed hereunder with strict confidentiality.

11.6 The Recipient shall only use Confidential Information to further the purpose of this Agreement and for no other purpose.

11.7 The Recipient will not, without the prior written consent of the Discloser, make any notes, sketches, drawings, photographs or copies of any kind of any part of the Confidential Information, except when reasonably necessary for the purposes of this Agreement, in which case such copies will be regarded as Confidential Information of the Discloser.

11.8 The Recipient shall not authorise any third party other than a Sub-Contractors as set forth in **Schedule Five** (and in the case of the API Specification which, for the avoidance of doubt, MSX shall not without the prior written consent of RB disclose or pass to, or allow use by, any party including a Sub-Contractor as set forth in **Schedule Five**) to act on or use in any way any Confidential Information belonging to the Discloser (whether or not such third party is aware of such Confidential Information), shall promptly notify the Discloser if it becomes aware of any third party so acting, and (without prejudice to any of its other obligations) shall provide the Discloser such assistance as the Discloser reasonably requires, at the Discloser's cost and expense, to prevent such third party from so acting.

11.9 The Recipient will not without the prior written consent of the Discloser communicate or otherwise make available the Confidential Information to any third party save in so far as is necessary to make available the Confidential Information (other than the API Specification which for the avoidance of doubt shall be held in the strictest confidence and shall not be disclosed to any third party (otherwise than under **Clause 11.12.6)** without the prior written consent of RB) to a third party for any application for registration of any Intellectual Property Rights that it owns or in connection with the registration of any medicinal product provided that it does not prevent the registration of or destroy any registrable Intellectual Property Right. The Recipient will forthwith notify the Discloser of any such application and the Discloser may (in its absolute discretion) refuse permission to allow publication. The Recipient shall require each third party (including Sub-Contractors) to which it gives Confidential Information of the Discloser, including those covered under **Clause 11.8** and this **Clause 11.9**, to sign, prior to receipt of any of the Discloser's Confidential Information, an agreement of confidentiality having the same obligations on such third party as are placed on the Recipient under this Agreement.

11.10 The Recipient will however be permitted to disclose Confidential Information to those of its officers and employees and/or officers and employees of its Affiliates who are required in the course of their duties to receive and acquire the Confidential Information for the purpose of this Agreement where such Affiliates and/or employees and/or officers are bound by obligations of confidentiality to the Recipient and/or the relevant Affiliate and are first made aware of the other terms of this Agreement. The Recipient will be liable to the Discloser for any breach of the terms of this Agreement by such Affiliates or by their employees or officers.

11.11 The terms of this **Clause 11** will continue beyond the expiration or termination of this Agreement for a period of [***] years, except in relation to the Know-How of the Discloser and the API Specification which shall remain confidential for the duration of its confidential nature.

11.12 The undertakings given in **Clauses 11.4** to **11.11** above shall not apply, in relation to the Recipient, to Confidential Information that:

11.12.1 the Recipient can show by written records was already in the Recipient's possession prior to the Commencement Date and was not obtained under a duty of confidentiality;

11.12.2 the Recipient can show by written records is subsequently developed independently by the Recipient without any reference to or use by the Recipient of Confidential Information disclosed by the Discloser;

11.12.3 is or becomes public knowledge other than through the default of the Recipient;

11.12.4 is disclosed to the Recipient by a third party where such third party did not obtain the same under an obligation of confidence to the Discloser and was not under an obligation of confidence to the Discloser at the time of disclosure;

11.12.5 is approved for release upon the written permission of the Discloser; or

11.12.6 is required by applicable law, rule or regulation including, without limitation, the United States Securities Act of 1933, the Securities Exchange Act of 1934 and related regulations and interpretations thereof (collectively, the "**Securities Laws**") to be disclosed by the Recipient, in which case the Recipient shall first inform the Discloser of all relevant facts relating to such a disclosure and shall provide such opportunity as is reasonable in the circumstances for the Discloser to object to, or limit, such disclosure and will provide reasonable assistance to the Discloser in seeking to prevent or limit such disclosure, except that no such act by the Discloser to object to or limit, or assistance of the Recipient requested by the Discloser, shall interfere with, delay or hinder the Recipient's obligations under Securities Laws.

11.13 Notwithstanding any other provision of this Agreement, neither party shall make any public disclosure or statement relating to the existence, nature, terms, subject matter or other item in connection with this Agreement, except as required by applicable law, rule or regulation (including, without limitation, Securities Laws), and shall follow the procedure stated in **Clause 11.12.6** in connection with issuing such statement.

12. **HEALTH REGISTRATIONS AND QUALITY ASSURANCE**

12.1 RB shall be responsible for obtaining and maintaining the Health Registrations in the Territory and MSX shall provide such assistance as may be reasonably required in connection with obtaining and maintaining such Health Registrations.

12.2 RB shall prepare, submit and maintain any relevant DMF dossiers for the Products and any relevant certificate of suitability for the Products in accordance with cGMP. Upon the reasonable request of MSX, MSX shall be given access to relevant information contained in DMF dossiers or the certificate of suitability necessary for its activities under this Agreement or required by applicable law.

12.3 The parties shall comply, and procure that their Affiliates comply, with their respective obligations set out in the Quality Agreement.

12.4 MSX shall, on reasonable written request by RB to MSX, provide RB with access to the Master Manufacturing File compiled by MSX in connection with the manufacture of the Products for review.

13. **REGULATORY COMPLIANCE, COMPLAINTS AND PRODUCT RECALLS**

13.1 MSX shall promptly and at its own cost:

13.1.1 provide any Regulatory Authority all such documents and information as it may request in relation to the manufacture of the Products;

13.1.2 allow any Regulatory Authority access in relation to the manufacture of the Products to the Manufacturing Site or any other relevant sites for the purpose of an audit or inspection promptly on request by such Regulatory Authority;

13.1.3 respond in a timely manner to any questions of a regulatory nature relating to the manufacture of the Products raised by any Regulatory Authority and copy RB into any such response; and

13.1.4 promptly provide to RB the findings of any such Regulatory Authority audits, inspections or enquires relating to the Manufacturing Site or other sites relevant to the manufacture of the Products.

13.2 If any Regulatory Authority requires any changes to be made to the manufacture of the Products, the process, plant or equipment used in the manufacture of the Products or disposal of residue after such manufacture, MSX shall promptly notify RB and send it copies of any relevant documents. MSX shall consult with RB and shall use commercially reasonable efforts to defer implementation of any such changes until RB has been able to make any appropriate amendments to its Health Registrations as may be necessary for manufacture of the Products by MSX.

13.3 Each party shall notify the other immediately by telephone and confirm in writing within twenty-four (24) hours upon having actual knowledge of any problem relating to the Products including where:

13.3.1 the Products do not comply with the Product Specification or any matter which may affect the safety or efficacy of the Products arising during their manufacture;

13.3.2 the Products are affected by bacteriological or other contamination; or

13.3.3 the Products are affected by significant chemical, physical or other change or deterioration or stability failures.

13.4 Upon written request by a party, the other party shall promptly investigate any problem identified under **Clause 13.3** above or any third party complaint it relation to the Products and shall promptly submit follow-up reports upon the receipt of any new information in connection with the problem or complaint. Upon written request by RB, MSX shall provide reasonable assistance to RB in investigating such problems or complaints. Such investigations by MSX shall include appropriate chemical or microbial analysis of the relevant Product sample (if available), analysis of any retained Product sample or the review of relevant batch documentation. MSX shall provide RB with a written report of its investigations and conclusions [***] days from receipt of RB's written request (including samples, if available) for such investigation. RB shall provide all reasonable assistance to MSX in analyzing any such Product problems or complaints.

13.5 All contact and correspondence with any Regulatory Authority in relation to a Product recall or complaint shall be made and co-ordinated by RB (unless otherwise required by applicable law). MSX shall not contact any Regulatory Authority or other government body in relation to any matter concerning the recall of or complaint concerning the Products, without the prior written consent of RB (unless required to do so by law), such consent not to be unreasonably withheld, conditioned or delayed.

13.6 During the Term:

13.6.1 MSX shall provide RB with copies of any communications (which are known to MSX to exist and are within its possession or control) with any Regulatory Authority specifically relating to the Products;

13.6.2 RB shall provide MSX with copies of relevant communications with any Regulatory Authority in relation to the API or the Products which would impact MSX's obligations under this Agreement; and

13.6.3 If the communications with any Regulatory Authority referred to in this **Clause 13** require or directly lead to any change in or to the Manufacturing Site in so far as such change affects or impacts upon the manufacture of the Products, then MSX shall in every case provide RB with all information relating thereto and in addition shall keep RB regularly updated of all events occurring and all further communications from Regulatory Authorities from time to time.

13.7 MSX shall, on written request by RB, provide RB with reasonable assistance at RB's cost in the event that:

13.7.1 any Regulatory Authority issues a request, directive or order that the Products be recalled, corrected or withdrawn from market; or

13.7.2 a court of competent jurisdiction orders such a recall, correction or withdrawal from market; or

13.7.3 RB determines in its reasonable discretion that the Products shall be recalled, withdrawn from market or corrected for any reason.

13.8 RB shall at all times have sole responsibility for the initiation and co-ordination of any recall of the Products or the issue of corrective statements (unless otherwise required by applicable law or Regulatory Authorities). MSX shall not, without RB's prior written consent, communicate with any Regulatory Authority or other third party in connection with any such recall or complaint (unless required to do so by law). Notwithstanding the above, MSX and RB shall notify the other promptly if any of the Products are suspected or proven to be the subject of a complaint which may require a recall of the Products and the parties shall cooperate with each other in the handling and disposition of such complaint.

13.9 If RB reasonably determines that a recall of the Products is required, the recall strategy shall be reasonably developed by RB and followed by MSX with strict regard to timing. RB shall promptly notify MSX in writing in the event that it deems that a recall of the Products is required.

13.10 MSX shall be responsible for its own and RB's reasonable costs and expenses of all recalls of Products or complaints in the event that such recall or complaint is the result of any negligent act or omission or breach of the terms of this Agreement by MSX.

13.11 RB shall be responsible for its own and MSX's reasonable costs and expenses of all recalls of Products or complaints in the event that such recall or complaint is the result of any negligent act or omission or breach of the terms of this Agreement by RB.

13.12 In the event that a recall of Products results from the joint negligence of RB and MSX, each party shall be responsible for the expenses of such recall in direct proportion to each party's percentage of fault as determined jointly by written agreement of the parties or by a court of competent jurisdiction.

13.13 In the event of a recall being initiated by a Regulatory Authority, where the scope of the recall is directed at all Products and where the purpose of such recall is not attributable to the fault of either RB or MSX, RB shall be responsible for MSX's expenses properly and necessarily incurred directly in connection with the recall.

13.14 Provided that MSX has stocks of usable API, MSX shall use commercially reasonable efforts, subject to other MSX contractual commitments, in attempting to supply RB with replacement Products during the handling and disposition of such recall.

14. AD HOC INSPECTION TESTING AND SAMPLES

14.1 Notwithstanding the provisions of **Clause 13** above, upon the reasonable written request of RB, MSX shall promptly, at RB's cost, submit samples of the Products for RB's approval before the Products are delivered. Such samples shall be marked by MSX for identification.

14.2 On reasonable request and notice in writing, RB shall be entitled, without interfering with MSX's operations, to inspect and test the Products during manufacture, processing and storage and MSX shall at its own cost provide or shall procure the provision of all such facilities as may reasonably be required by RB including access to MSX's premises.

14.3 The exercise by RB of its rights pursuant to **Clauses 14.1** or **14.2** shall not prejudice RB's right to reject, pursuant to the terms of this Agreement, any Products which do not comply with the Product Specification or the provisions of this Agreement (except the API Specification), or represent RB's assumption of liability in any manner whatsoever with respect to such non-compliant Products.

15. INTELLECTUAL PROPERTY RIGHTS AND LABELLING

15.1 Nothing in this Agreement shall affect the ownership of any Existing Intellectual Property Rights which one party agrees to make available to the other during the Term and, save as otherwise set out in this Agreement, neither party shall have the right to use or exploit the Existing Intellectual Property Rights of the other party.

15.2 MSX hereby grants RB and its Affiliates during the Term the exclusive (including to the exclusion of MSX) and only right and license (with the right to grant sub-licenses thereunder) under MSX's Existing Intellectual Property Rights to use and sell any product, including the Products, in the Field throughout the Territory. During the remainder of the Term after payment of Royalties stops under **Clause 7** (or otherwise in accordance with the terms of this Agreement) in the Territory or any portion thereof, as applicable, this license shall thereafter become royalty-free in the Field in that portion of the Territory, as applicable.

15.3 During the Term, MSX shall not assign or license any of MSX Existing Intellectual Property Rights to other parties for the use or sale of products within the Field.

15.4 If, during the Term, either party (or any agent or authorised Sub-Contractor of it) develops or creates (whether with or without others and whether jointly with the other party or not) any Arising Intellectual Property Rights, it will forthwith disclose any such Arising Intellectual Property Rights to the other party. To this extent, MSX warrants to RB that in the event of MSX using any agent (including without limitation and authorised Sub-Contractor) for the performance of any tasks under this Agreement it has in place, or will put in place, agreements with such agents which provide that any Arising Intellectual Property Rights within the Field created in the performance of such tasks shall belong to RB.

15.5 Any Arising Intellectual Property Rights (including without limitation any Arising Intellectual Property Rights created by MSX acting alone or in combination with RB) in the Field will belong to RB. To the extent that MSX would otherwise be the owner in whole or in part of any such rights, MSX shall promptly, upon request by RB, assign the entire right, title and interest to any and all such Arising Intellectual Property Rights to RB for a consideration of one Pound Sterling. In cases where MSX owns Arising Intellectual Property Rights within the Field which cannot be assigned, MSX will grant RB an irrevocable, perpetual, exclusive (including to the exclusion of MSX) royalty-free license (with the right to grant sub-licenses thereunder) under such Arising Intellectual Property Rights solely within the Field throughout the Territory. Other than as set forth in the first three sentences of this **Clause 15.5,** MSX shall own and, unless otherwise agreed in writing by MSX, RB shall not have or be granted under this Agreement any right, title or interest to, in or under, any Arising Intellectual Property Rights.

15.6 Claims of patent applications filed by RB shall be limited to the Field. To the extent that registered patent protection is obtained which is broader than the Field, RB grants MSX a royalty-free worldwide exclusive (including to the exclusion of RB) license, with rights to sublicense, outside the Field under the registered protection or applications therefor, which shall last for the duration of the registered protection or application therefor, to carry out all acts which would otherwise be prohibited due to RB's patent protection outside the Field.

15.7 Any Arising Intellectual Property Rights (including without limitation any Arising Intellectual Property Rights created by RB acting alone or in combination with MSX) other than those covered by **Clause 15.5** above will belong to MSX. To the effect that RB would otherwise be the owner in whole or in part of any such rights, RB shall promptly upon request by MSX assign with full title guarantee the entire right, title and interest to any and all such Arising Intellectual Property Rights to MSX for a consideration of one Pound Sterling. In cases where RB owns Arising Intellectual Property Rights which cannot be assigned, such as a claim which falls outside the Field, RB will grant MSX a royalty-free, worldwide exclusive (including to the exclusion of RB) license, with rights to sublicense, outside the Field.

15.8 Claims of patent applications filed by MSX shall be limited to being outside the Field. To the extent that registered patent protection is obtained which is within the Field, MSX grants RB a royalty-free worldwide exclusive (including to the exclusion of MSX) license, with rights to sublicense, within the Field under the registered protection or applications therefor, which shall last for the duration of the registered protection or application therefor, to 'carry out all acts which would otherwise be prohibited due to MSX's patent protection within the Field.

15.9 By way of illustration of **Clauses 15.5** through and including **Clause 15.8** and **Clause 15.10**, if the parties were to create an improved formulation for certain types of common compounds which would speed the production time for the product, RB would have all Arising Intellectual Property Rights (including the exclusive right to use or to license) within the Field and MSX would have all Arising Intellectual Property Rights (including the exclusive right to use or to license) outside of the Field. For the avoidance of doubt, following termination of this Agreement then, subject to any future written agreement of the parties expressly to the contrary, RB would have rights to the Arising Intellectual Property Rights within the Field but no rights to any Arising Intellectual Property Rights outside the Field or MSX's Existing Intellectual Property Rights, and MSX would have rights to Arising Intellectual Property Rights outside the Field but no rights to the Arising Intellectual Property Rights within the Field or any of RB's Existing Intellectual Property Rights.

15.10 The parties agree that, in order (i) to allow RB to apply for, prosecute or maintain any registered protection for RB's rights in the Arising Intellectual Property as identified in **Clause 15.5** and (ii) to allow MSX to apply for, prosecute or maintain any registered protection for MSX's rights in the Arising Intellectual Property as identified in **Clause 15.7**, each in a manner which does not prejudice the prospects for registered protection of the other party. Each party shall work with and cooperate with the other prior to any disclosure of, or patent application filing for, any Arising Intellectual Property Right and shall act in accordance with **Schedule Nine**.

15.11 During the Term, MSX will not assign or license any of MSX's Existing Intellectual Property Rights to other parties for use in the Field.

15.12 During the Term, except during the last twelve (12) month period thereof if the parties have elected not to extend the Term of this Agreement in accordance with the terms of **Clause 3.9,** and whether in isolation or for or with others, MSX shall not carry out research or research work related to the Field, other than pursuant to this Agreement.

15.13 During the Term, in the event that MSX shall decide that it no longer wishes to apply for, prosecute or maintain any registered protection for any of MSX Existing Intellectual Property Rights for any country, it shall forthwith notify RB. If RB indicates to MSX that it wishes to take an assignment of such Existing Intellectual Property Rights within the Field, it shall so notify MSX who agrees to conduct good faith negotiations in attempting to reach a resolution to assign such Existing Intellectual Property Rights within the Field to RB. For the avoidance of doubt, this includes any registered protection which MSX is entitled to claim priority from an earlier application at the end of the Paris Convention priority period. If such Existing Intellectual Property Rights are assigned to RB, and to the extent that registered patent protection is obtained which is broader than the Field, RB will grant MSX an irrevocable, perpetual, exclusive (including to the exclusion of RB), royalty-free license (with the right to grant sub-licenses thereunder) under such registered protection or applications therefor outside the Field and throughout the Territory. Notwithstanding anything to the contrary, MSX is under no obligation to assign such Existing Intellectual Property Rights to RB.

15.14 During the Term and upon its knowledge of the occurrence of any infringement or suspected or threatened infringement of any of the Patents, the Arising Intellectual Property rights or the Existing Intellectual Property Rights in the Product or in the Field, or of any proceedings or suspected or threatened proceedings for the revocation or involving the validity of any of the Intellectual Property Rights, the party with this knowledge shall notify the other and provide all details within its knowledge with respect to the same and thereafter upon receipt of a written request the parties will assist each other in taking such steps as either party may reasonably consider to be appropriate at the expense of the party that considers such steps to be appropriate.

15.15 For the purpose of protecting the Intellectual Property Rights, each party shall also procure that its Affiliates shall comply with **Clause 3** and this **Clause 15**.

15.16 Each party undertakes that it shall not at any time during the Term or after the termination or expiration of this Agreement knowingly do or suffer to be done any act or thing which may impair the rights of the other party in its Intellectual Property Rights and further undertakes that it shall not represent that it has any title to or right of ownership in the Intellectual Property Rights of the other party.

15.17 MSX shall manufacture the Products incorporating such layout, content, design, trade marks and artwork as may be reasonably directed by RB in writing. RB shall bear the cost of designing the layout, content and appearance of the labelling, inserts and packaging, including costs of Tooling, used solely in connection with the Products.

15.18 Except as may be required by any Regulatory Authority, MSX shall not make any change or modification to the Products' packaging or labelling, including the layout, content, design, trade marks or artwork used in connection with such packaging or labelling without the prior written consent of RB.

15.19 RB may, on reasonable prior written notice, change any part of the packaging or labelling of the Products. In the event that such change results in any write-off of the cost of Raw Materials, RB shall bear the cost of such write-off to the extent that such Raw Materials were reasonably required to meet RB's Forecasts.

15.20 In the event of any packaging or labelling changes, MSX shall, if requested in writing by RB, either destroy (in accordance with all applicable laws) or deliver to RB any Products which are to be written off. RB is to bear the cost of such write off for such Products at: (1) the Cost of Goods Price for such Products if the packaging or labelling change was at RB's choice; or (2) the manufacturing costs for such Products if the packaging or labelling change was done to meet a change in legal requirements. In addition to the foregoing, in either case, RB shall reimburse MSX for the acquisition costs of any unused packaging materials which can no longer be used for the Products to the extent that such Raw Materials were reasonably required to meet RB's Forecasts.

15.21 For the avoidance of doubt, in the event of any packaging or labelling changes pursuant to **Clause 15.18** or **Clause 15.19**, upon receipt of written notice of such changes, MSX shall inform and keep RB informed of the stock levels of the Products and relevant Raw Materials and packaging components in order that RB may decide how it wishes to proceed under **Clauses 15.18** and **15.19**.

15.22 All copyright and other Intellectual Property Rights in any artwork and origination work supplied by RB or its nominee for the labelling, packaging and, where applicable, package inserts for the Products is and shall remain the property of RB or its nominee absolutely. MSX shall not supply or manufacture any such packaging or other components or finished Products or confusingly similar packaging or products other than to RB or as it may direct. Subject to RB being able to incorporate the trademark of MSX as set out in **Schedule Eleven** (or such variation thereto as is reasonably suggested by MSX and approved by RB, such approval not to be unreasonably withheld, conditioned or delayed) on the back of secondary packaging (being packaging containing one or more of the Products and of an appropriate size for such requirements) without impeding the artwork and information required by Regulatory Authorities to be placed on such secondary packaging, RB shall include the MSX trademark on the reverse of such secondary packaging with the size and location approved by RB (such approval not to be unreasonable withheld, conditioned or delayed but shall remain subject to RB's obligations to place information required by Regulatory Authorities on such secondary packaging).

16. **FORCE MAJEURE**

16.1 If either party is prevented or delayed in the performance of any of its obligations under this Agreement as a result of civil commotion, strike (but excluding industrial action or strikes by employees of either party) embargo, governmental legislation or regulation, riot, invasion, war, threat of or preparation for war, fire, explosion, storm, flood, earthquake, subsidence, epidemic or other natural physical disaster or other event beyond the reasonable control of a party that has not occurred as a result of its negligence or other act or omission ("**Force Majeure Event**"), it shall notify the other party, in writing, of the same as soon as practicable, fully detailing the background to, and all relevant matters connected with, such Force Majeure Event, together with such evidence thereof that it reasonably can give and specifying the period for which such prevention or delay can reasonably be expected to continue. The affected party shall use commercially reasonable efforts to remove or overcome such Force Majeure Event as quickly as possible and shall also use its commercially reasonable efforts to mitigate the impact of such Force Majeure Event of the other party. Subject to **Clause 16.2,** if a party shall have fully complied with its obligations under this **Clause 16.1**, it shall be excused from performance of its unfulfilled obligations under this Agreement from the start date of the Force Majeure until such Force Majeure Event no longer pertains.

16.2 If a Force Majeure Event prevents performance by a party of any obligations hereunder for a continuous period in excess of [***] weeks, the other party shall be entitled to terminate this Agreement by written notice at any time after such [***] week period provided the relevant Force Majeure Event remains subsisting at the time such notice is given.

17. **TERMINATION**

17.1 This Agreement may be terminated at any time upon either party giving to the other [***] days notice in writing if the other party commits a material breach of the terms of this Agreement and (where such breach is capable of remedy) fails to remedy such breach within [***] days of receiving written notice from the other party specifying the breach and requiring its remedy.

17.2 This Agreement may be terminated by either party, immediately on written notice to the other, if;

17.2.1 the other party shall go into liquidation whether voluntary or compulsory or is dissolved or becomes insolvent or if a petition shall be presented or an order made for the appointment of an administrator or if a receiver, administrative receiver or manager shall be appointed over any part of its assets or undertaking which appointment is not dismissed within thirty (30) days of having been made; or

17.2.2 any distress, execution, sequestration or other process is levied or enforced upon or sued out against the property of the other party which is not discharged within thirty (30) days.

17.3 This Agreement may be terminated by RB, forthwith upon written notice to MSX, in the event that:

17.3.1 any applicable Regulatory Authority, state or local regulatory approvals, laws, ordinances or regulations, present or future, state that the Manufacturing Site is not suitable, or ceases to be suitable, for the manufacture of the Products; or

17.3.2 the Product is not suitable for Manufacture by MSX due to environmental, health or safety reasons; or

17.3.3 any of RB's Health Registrations for the Products is suspended or withdrawn; or

17.3.4 it is determined that the formulation, use or sale of the Products infringes any third party Intellectual Property Rights; or

17.3.5 RB is unable to demonstrate bio-equivalence between the Products and its Suboxone product; or

17.3.6 MSX is unable to provide stability data demonstrating, and obtain appropriate authorisation specifying, a shelf life of the finished Products (i.e. Products packed in accordance with the Packaging Specification) at least equivalent to [***] months; or

17.3.7 RB exercises its right to terminate in accordance with the terms of **Clause 7.9**.

17.4 This Agreement may be terminated by RB, forthwith upon written notice to MSX, in the event that MSX's cumulative on-time Product delivery falls below eighty percent (80%) during any six (6) month period as specified in **Clause 6.5.1**, provided that the reason for such failure is not due to the failure of RB to deliver the API on time or to any other fault or failure attributable to RB or its Affiliates or their respective assigns or sublicensees.

17.5 This Agreement may be terminated by MSX, forthwith upon written notice to RB:

17.5.1 In the event that following RB's filing of a New Drug Application ("**NDA**") for FDA approval of the Product (which shall be filed on the assumption that both parties will act reasonably to obtain such filing) and after the expiry of the six (6) month period commencing with RB's receipt of final response from the FDA regarding RB's NDA filing, RB fails to use its commercially reasonable efforts to obtain and diligently pursue all approvals from the FDA as required by this Agreement. For purposes of this **Clause 17.5.1**, RB shall be deemed to have failed to use commercially reasonable efforts to obtain all approvals from the FDA as required by this Agreement if RB fails or elects not to use such efforts and resources (including, without limitation, the promptness in which such efforts and resources would be applied) consistent with its expression of commitment and intent regarding its regulatory strategy for the commercialization exploitation of the Products, on and before the Commencement Date, as a priority of its and its Affiliates product development program, including expending such additional funds and devoting such additional manpower and other resources as is necessary and appropriate to reasonably assure the timely grant of such approvals to effect the transactions contemplated under this Agreement and, in any circumstances, which are consistent with the general level of effort and resources that would be used in the pharmaceutical industry for a company similar in size and scope and with the intention to commercialize and exploit a product critical to the continued success of the company. The parties understand and agree that RB shall not be construed as failing to use commercially reasonable efforts for delays caused solely by the FDA in its review of the applications for U.S. Regulatory Approvals by RB if RB is diligently and timely responding to requests and demands by the FDA relating to such applications;

17.5.2 In the event that RB fails to make reasonable efforts toward a Product Launch in the U.S. after obtaining all necessary approvals from the relevant Regulatory Authorities within six (6) months after obtaining such approvals; or

17.5.3 In the event that RB fails to reach minimum sales of the Products of at least USD$15,000,000 (fifteen million U.S. dollars) within twenty-four (24) months from the Product Launch set forth in **Clause 17.5.2** above.

17.6 This Agreement may be terminated by MSX, forthwith upon written notice to RB, in the event that MSX notifies RB that supplies of the API do not meet the API Specification in accordance with **Clause 4.4** and have not done so during the previous consecutive three (3) month period, and RB has not implemented an action plan and remedied the failure to supply the API to the API Specification in accordance with **Clause 4.5** within three (3) months after the end of such three (3) month period.

17.7 This Agreement may be terminated by RB if a majority percentage of the issued share capital, or control of the management or voting rights, of MSX is taken over or acquired (collectively, a "**Change in Control**") by any third party or parties operating within the Field or expropriated or nationalised.

18. CONSEQUENCES OF TERMINATION

18.1 Upon termination or expiry of this Agreement for whatever reason, MSX shall:

18.1.1 at the written request of RB, use its best endeavours to novate the contracts for the supply of all Raw Materials, Film, packaging components and other materials used in the production of the Products to RB, or as RB may direct, and to meet any request from RB required to transfer production or any registrations or licences or approvals relating to the Products to RB, its Affiliates or any third party approved in writing by RB;

18.1.2 release and make available for immediate collection by or on behalf of RB, and RB shall forthwith purchase from MSX, (i) all finished Products (including stocks maintained in accordance with **Clause 6.4**) at the Cost of Goods Price and/or (ii) the Raw Materials at the relevant cost of Raw Materials, each as determined in the previous Annual Review;

18.1.3 promptly deliver to RB (or its nominee) a copy of the Master Manufacturing File;

18.1.4 in the case of termination of this Agreement by RB under **Clauses 17.1**, **17.2**, **17.3.1**, **17.3.2**, **17.3.6**, **17.3.7**, **17.4**, and **17.7** promptly provide to RB all relevant Intellectual Property which is necessary or reasonably useful for the manufacture of the Product in the Field by a qualified third party manufacturer including, but not limited to, those specified in **Clause 6.6,** subject to confidentiality and intellectual property agreements in the form reasonably satisfactory to MSX; MSX not to unreasonably withhold or delay the execution of such agreements;

18.1.5 promptly collect, pack and make ready for delivery to RB all Tooling provided by or funded by RB, and follow all reasonable directions of RB with respect to the disposition of such Tooling, such delivery being at RB's cost, and the risk of loss or damage to such Tooling shall pass to RB at the time of removal from MSX's facility; and

18.1.6 promptly procure the delivery to RB of, or at RB's request destroy, all copies in its possession of all Confidential Information which is in documentary or other tangible form (including all copies thereof) and which has been disclosed to MSX together with all material relating to that Confidential Information prepared by, or on behalf of, MSX and, at RB's written request, undertake to RB in writing that it has complied with the provisions of this **Clause 18**.

19. ASSIGNMENT AND THIRD PARTY RIGHTS

19.1 Except as expressly provided herein, neither the benefits nor the obligations of this Agreement (or any agreement hereunder) or of any provision of it may be assigned or transferred (including sub-contracting other than sub-contracting to the Sub-Contractors listed on **Schedule Five**) by either party without the prior written consent of the other.

19.2 Without MSX's consent, this Agreement (including any agreements hereunder) shall be assignable by RB to any Affiliate and to any purchaser of all or a substantial part of the business of RB to which this Agreement relates and in the event of such assignment and written assumption by such purchaser, RB shall with effect from such assignment be released from its obligations hereunder and all references in this Agreement to RB shall be changed to mean its assigns.

19.3 Any Affiliate of RB may place Orders for Products under this Agreement and may accordingly in their own right enforce the provisions of this Agreement, as though it were RB; provided, that (a) each Affiliate of RB that places an Order for Products shall by doing so be deemed to have assumed RB's obligations under this Agreement for purposes of such Order, and (b) RB shall remain obligated for the performance of all of the obligations of RB and the applicable Affiliate of RB arising from this **Clause 19.3**.

19.4 MSX may, without the prior consent of RB, assign this Agreement (and any agreements hereunder): (i) to any purchaser of all or a substantial part of the assets or business of MSX to which this Agreement relates, or (ii) to MonoSol Rx, Inc., and, in each such case, MSX shall with effect from such assignment be released from its obligations hereunder and all references in this Agreement to MSX shall be deemed to include its assigns.

19.5 MSX may, without the prior consent of RB, assign its rights and/or benefits under this Agreement or any provision of it, including, without limitation, any Royalties and/or any other payments due MSX, to any third party, including, without limitation, MonoSol Rx, Inc. or other Affiliate of MSX; provided, that in the event of such assignment under this **Clause 19.5**, MSX shall remain obligated for the performance of all of the obligations of MSX arising under this Agreement.

20. **NOTICES**

20.1 Any notice or other communication to be given under this Agreement shall be delivered personally, sent by first-class, pre-paid post or by fax to the following numbers and addresses:

RECKITT BENCKISER		With a copy to
Addressee	[***]	[***]
	[***]	[***]
Fax	[***]	[***]
Address	10710 Midlothian Turnpike, Suite 430 Richmond, VA 23235	10710 Midlothian Turnpike, Suite 430 Richmond, VA 23235

MONOSOL RX, LLC		With a copy to
Addressee	Senior Vice President – Business Development [***]	[***]
Fax	30 Technology Drive Warren,	[***]
Address	NJ 07059	Day Pitney LLP *By Courier:* 200 Campus Drive Florham Park, New Jersey 07932 Or *By Mail:* P.O. Box 1945 Morristown, New Jersey 07962

and shall be deemed to have been served upon delivery to the above addresses (if served by hand), three (3) working days following postage to such addresses (if sewed by first-class pre-paid post), and upon transmission of the fax correctly sent to the above number (provided that the sender has proof of transmission and any notice sent after 16:30 shall be deemed to have been served on the recipient the next working day).

21. MISCELLANEOUS

21.1 If there are any inconsistencies between the terms and conditions set forth in this Agreement and the terms and conditions set forth in any quotation, Order, acknowledgement or invoice, the terms and conditions of this Agreement shall prevail.

21.2 This Agreement, the Product Specification, Packaging Specification, API Specification, or any Order may only be amended, modified or varied by the parties by an instrument in writing signed on behalf of each of the parties.

21.3 The waiver by either party of any right under this Agreement or of any failure to perform or breach hereof by the other party shall not constitute or be deemed to be a waiver of any other or future right hereunder or of any other failure to perform or breach hereof by such other party, whether of a similar or dissimilar nature.

21.4 The expiration or earlier termination of this Agreement will not operate to release either party hereto from its obligations which are expressed to or implicitly survive such expiration or termination (including, without limitation, **Clauses 9**, **10**, **11**, **12**, **13**, **15**, **18**, **20**, or **22** and any regulatory obligations imposed by Regulatory Authorities to the extent that these obligations by their terms require the parties to continue to perform such obligations beyond such expiration or termination), or from any liability which has already accrued to the other party as of the date of expiration or termination or which may thereafter accrue in respect of any act, omission or default occurring prior to expiration or termination.

21.5 Nothing in this Agreement shall constitute or be deemed to constitute the creation of a partnership, agency, or employer/employee relationship between the parties.

21.6 This Agreement, together with the Development Agreement for a Pharmaceutical Film between the parties dated 11 December 2006 (and associated amendments, collectively, the "**Development Agreement**"), Product Specification, API Specification, Quality Agreement and the Schedules attached hereto, constitute the entire agreement and understanding of the parties and supersede any previous agreement between RB and MSX and their Affiliates in relation to the subject matter of this Agreement. To the extent of any conflict or inconsistency between the Development Agreement and/or the Quality Agreement and this Agreement, the terms and conditions of this Agreement shall supersede and control such conflict and/or inconsistent term or condition of the Development Agreement and/or the Quality Agreement, as the case may be save that in the event that the Quality Agreement imposes an additional or greater responsibility than that contained in this Agreement, such additional or greater responsibility shall prevail and be binding on the parties.

21.7 If any provision of this Agreement is held by any court or other competent authority to be invalid or unenforceable in whole or in part it shall be deemed severed from this Agreement and the validity of the other provisions and the remainder of the provision in question shall not be affected.

21.8 This Agreement may be executed in one or more counterparts, all of which shall be considered as one and the same agreement and shall become effective when one or more counterparts have been signed by each of the parties.

21.9 All royalties, taxes and duties imposed or levied on any Products delivered hereunder shall be for the account of and paid by MSX to the point where the Products have been delivered FCA in accordance with **Clause 5.7**. All royalties, taxes and duties imposed or levied on the Products after such delivery shall be for the account of and paid by RB.

22. LIMITATION OF LIABILITY

22.1 Notwithstanding any provision of this Agreement to the contrary (save in respect of any liability for personal injury or death resulting from a party's negligence), in no event shall either party be liable to the other, or have any obligation to the other, as the case may be, for any consequential or indirect damages or Losses (including any loss of profits suffered by RB or MSX) however caused and on any theory of liability, regardless of any failure of essential purpose of any remedy available under this Agreement. For the avoidance of doubt, notwithstanding the foregoing limitation of liability, MSX shall 'remain liable for performance of its obligations as set out under **Clauses 7.9.3.3** and **7.10** and the foregoing limitation of liability shall not be applicable to consequential or indirect damages or Losses (including, without limitation, lost profits incurred by the indemnified party) suffered or incurred by an indemnified party as a direct result of any failure by the indemnifying party to perform its obligations under this Agreement which the indemnified party can demonstrate is due to wilful misconduct by the indemnifying party or any of its employees or Affiliates; provided, however, that the parties acknowledge and agree that any act or omission of the indemnifying party or any of its employees or Affiliates done in good faith shall not be and shall not be construed to be wilful misconduct of the indemnifying party or any of its employees or Affiliates. The indemnified party shall inform the indemnifying party in writing of its intent to seek damages pursuant to the foregoing sentence and provide the indemnifying party with reasonable opportunity to remediate any such Loss; provided that nothing in this sentence shall relieve the indemnifying party from performing its obligations in accordance with the terms of this Agreement.

23. LAW AND JURISDICTION

23.1 This Agreement shall be governed by and construed in accordance with the laws of the State of Delaware, United States of America, save as to conflict of law provisions, and the parties hereby agree to submit to the jurisdiction of the federal courts located in the State of Delaware.

24. **CODE OF CONDUCT**

24.1 MSX and RB shall discuss at each Annual Review RB's Code of Conduct as published as at the time of such Annual Review and ways in which MSX may seek to be consistent with such Code of Conduct to the extent such Code of Conduct does not conflict with the laws of employment practices in the United States and the State of Indiana.

Signed for and on behalf of Reckitt Benckiser Pharmaceuticals Inc.

/s/Shaun Thaxter

Name: Shaun Thaxter
Title: President RB Pharma U.S.
Date: 8/18/08

Signed for and on behalf of MonoSol Rx, LLC

/s/Alexander M. Schobel

Name: Alexander M. Schobel
Title: President & CEO
Date: 8/18/08

Schedule One

Cost of Goods Price

USD$[***] per pouched single dose Product

Net Sales Value

The Net Sales Value shall mean, in any case where a Product is sold or commercially disposed of for value by RB, its Affiliates or distributors, the gross invoiced sales price for such Product to third parties, on an arm's length basis, less the following discounts: (a) customary trade, quantity and trade discounts, charge backs, Medicare or other governmental rebates and customary rebates actually taken or allowed; (b) credits or allowances given or made for the rejection or return of any previously sold Product; (c) to the extent included and separately invoiced in such gross invoice price, any tax or government charge imposed and paid on sale, delivery or use of such Product including, without limitation, any value added or similar tax or government charge, but not including any tax levied with respect to income; and (d) to the extent included and separately invoiced in such gross invoice price any reasonable or documented transport charges.

Schedule Two

Patents

Filed MSRX IP Covering Reckitt-Benckiser
Current Film Formulations and Processes

[***]

Schedule Three

Products

A pouched single dose of the following products:

Buprenorphine Active Ingredient

2 mg

8 mg

12 mg

16 mg

Buprenorphine plus Naloxone Active Ingredient

2 mg Buprenorphine + 0.5 mg Naloxone

8 mg Buprenorphine + 2 mg Naloxone

12 mg Buprenorphine + 3 mg Naloxone

16 mg Buprenorphine + 4 mg Naloxone

Schedule Four

Specifications

PART A

Product and Packaging Specifications

These specifications are as attached in the following pages

[***]

MonoSol R_X, LLC	[***]	Rev. 1	Page: 1 of 1	[***]
[***]			[***]	[***]

Test	Method	Specification
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]

	Name	Department	Signature	Date
Prepared by:	[***]	[***]	[***]	[***]
Reviewed by:	[***]	[***]	[***]	[***]
Approved by:	[***]	[***]	[***]	[***]
Approved by:	[***]	[***]	[***]	[***]

[***]

Test	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]

	Name	Department	Signature	Date
Prepared by:	[***]	[***]	[***]	[***]
Reviewed by:	[***]	[***]	[***]	[***]
Approved by:	[***]	[***]	[***]	[***]
Approved by:	[***]	[***]	[***]	[***]
Approved by:	[***]	[***]	[***]	[***]
Approved by:	[***]	[***]	[***]	[***]

[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]

MonoSol R_x, LLC	[***]	Rev. 1	Page: 1 of 2	[***]
[***]			[***]	[***]

[***]

	Name	Department	Signature	Date
Prepared by:	[***]	[***]	[***]	[***]
Reviewed by:	[***]	[***]	[***]	[***]
Approved by:	[***]	[***]	[***]	[***]
Approved by:	[***]	[***]	[***]	[***]

TEST	Method	Specification
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]

[***]

	Name	Department	Signature	Date
Prepared by:	[***]	[***]	[***]	[***]
Reviewed by:	[***]	[***]	[***]	[***]
Approved by:	[***]	[***]	[***]	[***]
Approved by:	[***]	[***]	[***]	[***]
Approved by:	[***]	[***]	[***]	[***]
Approved by:	[***]	[***]	[***]	[***]

Test	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]

[***]	[***]	[***]	[***]

MonoSol R_x, LLC	[***]	Rev. 1	Page: 1 of 1	[***]
[***]			[***]	[***]

[***]

TEST	Method	Specification
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]

	Name	Department	Signature	Date
Prepared by:	[***]	[***]	[***]	[***]
Reviewed by:	[***]	[***]	[***]	[***]
Approved by:	[***]	[***]	[***]	[***]
Approved by:	[***]	[***]	[***]	[***]

[***]

Test	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]

	Name	Department	Signature	Date
Prepared by:	[***]	[***]	[***]	[***]
Reviewed by:	[***]	[***]	[***]	[***]
Approved by:	[***]	[***]	[***]	[***]
Approved by:	[***]	[***]	[***]	[***]
Approved by:	[***]	[***]	[***]	[***]

MonoSol R_x, LLC	[***]	Rev. 1	Page: 1 of 1	[***]
[***]			[***]	[***]

[***]

TEST	Method	Specification
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]

	Name	Department	Signature	Date
Prepared by:	[***]	[***]	[***]	[***]
Reviewed by:	[***]	[***]	[***]	[***]
Approved by:	[***]	[***]	[***]	[***]
Approved by:	[***]	[***]	[***]	[***]

[***]

Test	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]

	Name	Department	Signature	Date
Prepared by:	[***]	[***]	[***]	[***]
Reviewed by:	[***]	[***]	[***]	[***]
Approved by:	[***]	[***]	[***]	[***]
Approved by:	[***]	[***]	[***]	[***]
Approved by:	[***]	[***]	[***]	[***]

MonoSol R_x, LLC	[***]	Rev. 1	Page: 1 of 1	[***]
[***]			[***]	[***]

TEST	Method	Specification
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]

	Name	Department	Signature	Date
Prepared by:	[***]	[***]	[***]	[***]
Reviewed by:	[***]	[***]	[***]	[***]
Approved by:	[***]	[***]	[***]	[***]
Approved by:	[***]	[***]	[***]	[***]

MonoSol R_x, LLC	[***]	Rev. 1	Page: 1 of 1	[***]
[***]			[***]	[***]

[***]

Test	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]

	Name	Department	Signature	Date
Prepared by:	[***]	[***]	[***]	[***]
Reviewed by:	[***]	[***]	[***]	[***]
Approved by:	[***]	[***]	[***]	[***]
Approved by:	[***]	[***]	[***]	[***]
Approved by:	[***]	[***]	[***]	[***]
Approved by:	[***]	[***]	[***]	[***]

MonoSol R_x, LLC	[***]	Rev. 1	Page: 1 of 1	[***]
[***]			[***]	[***]

[***]

Test	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]

	Name	Department	Signature	Date
Prepared by:	[***]	[***]	[***]	[***]
Reviewed by:	[***]	[***]	[***]	[***]
Approved by:	[***]	[***]	[***]	[***]
Approved by:	[***]	[***]	[***]	[***]
Approved by:	[***]	[***]	[***]	[***]
Approved by:	[***]	[***]	[***]	[***]

MonoSol R_x, LLC	[***]	Rev. 2	Page: 1 of 1	[***]
[***]			[***]	[***]

[***]

TEST	Method	Specification
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]
[***]	[***]	[***]

	Name	Department	Signature	Date
Prepared by:	[***]	[***]	[***]	[***]
Reviewed by:	[***]	[***]	[***]	[***]
Approved by:	[***]	[***]	[***]	[***]
Approved by:	[***]	[***]	[***]	[***]

MonoSol R_x, LLC	[***]	Rev. 1	Page: 1 of 1	[***]
[***]			[***]	[***]

[***]

Test	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]

	Name	Department	Signature	Date
Prepared by:	[***]	[***]	[***]	[***]
Reviewed by:	[***]	[***]	[***]	[***]
Approved by:	[***]	[***]	[***]	[***]
Approved by:	[***]	[***]	[***]	[***]
Approved by:	[***]	[***]	[***]	[***]
Approved by:	[***]	[***]	[***]	[***]

[***]

Test	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]
[***]	[***]	[***]	[***]

	Name	Department	Signature	Date
Prepared by:	[***]	[***]	[***]	[***]
Reviewed by:	[***]	[***]	[***]	[***]
Approved by:	[***]	[***]	[***]	[***]
Approved by:	[***]	[***]	[***]	[***]
Approved by:	[***]	[***]	[***]	[***]
Approved by:	[***]	[***]	[***]	[***]

AMENDMENT NO. 1
COMMERCIAL EXPLOITATION AGREEMENT

THIS AMENDMENT NO. 1 (this "**Amendments**'') is made on the 19th day of August, 2009 (the "**Effective Date**") between:

PARTIES

(1) MonoSol Rx, LLC, a company organized and existing under the laws of the USA, with offices at 30 Technology Drive, Warren, New Jersey 07059, USA ("**MSX**"),

and

(2) Reckitt Benokiser Pharmaceuticals Inc., a company existing under the laws of the USA with offices at 10710 Midlothian Turnpike, Suite 430, Richmond, Virginia 23235 ("**RB**").

WHEREAS, MSX and RB entered into a Commercial Exploitation Agreement, dated August 15, 2008 (the "**Agreement**"), pursuant to which RB engaged MSX to manufacture and supply the Products on the terms of the Agreement and MSX agreed to manufacture and supply the Products to RB on the terms of the Agreement; and

WHEREAS, for valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the· parties mutually desire to amend and modify certain terms and conditions of the Agreement as set forth in this Amendment.

IT IS AGREED as follows:

A. Capitalized terms used In this Amendment without definition shall have the respective meanings ascribed thereto in the Agreement.

B. The parties hereby agree that from the Effective Date through and until March 31, 2010 (the "**Expedited Release Approval Period**"), MSX shall manufacture and supply RB's requirements of the Products for the U.S. in accordance with the SUBOXONE® Sublingual Film — Batch Transfer and Batch Release Approval Process (the "**Expedited Release Approval Process**"), a copy of which is annexed hereto as Schedule B and made a part hereof. As between MSX and RB, RB shall be solely responsible for ensuring that the Products are not released for commercial distribution by RB or its secondary packager(s) until the prerequisites for release set forth in the Expedited Release Approval Process have been satisfied. RB shall indemnify, defend and hold harmless MSX Parties pursuant to **Clause 10** of the Agreement from any and all Losses that result from or arise in connection with any Claim against any of the MSX Parties to the extent the Claim arises from a release of Product by RB or its secondary packager(s) during the Expedited Release Approval Period in violation of the Expedited Release Approval Process. RB shall accept all shipments of Product subject to the Expedited Release Approval Process. The parties acknowledge and agree that MSX's release of Product under the Expedited Release Approval Process deviates from the release process set forth in the underlying Agreement and Quality Agreement and that, as such, such deviation by MSX shall not constitute a violation of the underlying Agreement or the Quality Agreement.

C. This Amendment shall be governed by and construed in accordance with the laws of the State of Delaware, United States of America, save as to conflict of law provisions, and the parties hereby agree to submit to the Jurisdiction of the federal courts located in the State of Delaware.

D. Except as expressly set forth herein, all other terms and provisions of the Agreement shall remain in full force and effect without modification or change.

Signed for and on behalf Reckitt Benckiser Pharmaceuticals Inc.

/s/ Shaun Thaxter

Name: Shaun Thaxter
Title: President

Date:

Signed for and on behalf of MonoSol Rx, LLC

/s/ Mark Schobel

Name: Mark Schobel
Title: CEO

Date:

SCHEDULE B

SUBOXONE® SUBLINGUAL FILM – BATCH TRANSFER AND BATCH APPROVAL PROCESS

[***]

THIS EXHIBIT HAS BEEN REDACTED AND IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST. REDACTED MATERIAL IS MARKED WITH [***] AND HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

AMENDMENT NO. 2
COMMERCIAL EXPLOITATION AGREEMENT

THIS AMENDMENT NO. 2 (the "**Amendment**") is made effective as of the 13th day of November, 2009 (the "**Effective Date**") between:

PARTIES

(1) MonoSol Rx, LLC, a company organized and existing under the laws of the USA, with offices at 30 Technology Drive, Warren, New Jersey 07059, USA ("**MSX**"),

and

(2) Reckitt Benckiser Pharmaceuticals Inc., a company existing under the laws of the USA with offices at 10710 Midlothian Turnpike, Suite 430, Richmond, Virginia 23235 ("**RB**").

WHEREAS, MSX and RB entered into a Commercial Exploitation Agreement, dated August 15, 2008, as amended by Amendment No. 1, dated August 19, 2009 (the "**Agreement**"), pursuant to which RB engaged MSX to manufacture and supply the Products on the terms of the Agreement and MSX agreed to manufacture and supply the Products to RB on the terms of the Agreement; and

WHEREAS, for valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties mutually desire to amend and modify certain terms and conditions of the Agreement as set forth in this Amendment.

IT IS AGREED as follows:

A. Capitalized terms used in this Amendment without definition shall have the respective meanings ascribed thereto in the Agreement. This Amendment shall apply solely to Products supplied for sale or other uses in the U.S. and shall not be construed to amend, modify or change the Agreement as it relates to any Products supplied for sale or other uses the ROW, except as otherwise specifically set forth in this Amendment.

B. The parties acknowledge and agree that, as of the Effective Date, the Price payable by RB to MSX for purchases of Products for the U.S. shall be fixed at USD$[***] per pouched single dose Product, subject only to price adjustments pursuant to **Clause 7.3** and **Clause 7.23** of the Agreement (a new provision to the Agreement as set forth in Section K below) (the "**Fixed Purchase Price**"), until the earlier of either: (i) RB's acceptance of the delivery of the One Hundred and Thirtieth Million (130,000,000) unit of Product for the U.S., or (ii) January 1, 2011 (the "**Fixed Purchase Price Period**"). The parties further acknowledge and agree that, as of the Effective Date, RB shall not be entitled to receive any Rebate on any Products purchased for the U.S. during the Term pursuant to **Clause 7.22**; however, all of RB's purchases of Products during the Term, including without limitation, RB's purchases of Products for the U.S., shall be included in and counted towards the calculation of RB's aggregate volume purchases of Product in any Year for purposes of determining RB's entitlement to the Rebates on purchases of Products during the Term in the ROW pursuant to **Clause 7.22**. By way of example, if during any one Year, RB purchases [***] units of Product for the U.S. and [***] units of Product for the ROW, for an aggregate purchase of [***] units of Product, RB would be entitled to receive a Rebate of [***] U.S. Dollars (USD$[***]) per unit of Product for the [***] units of Product for the ROW [***] on the units of Product for the U.S, By way of further example, if during any one Year, RB purchases [***] units of Product for the U.S. and [***] units of Product for the ROW, for an aggregate purchase of [***] units of Product, RB would be entitled to receive a Rebate of [***] U.S. Dollars (USD$[***]) per unit of Product for the first [***] units of Product for the ROW and a Rebate of [***] U.S. Dollars (USD$[***]) per unit of Product for the second [***] units of Product for the ROW but no Rebate on the units of Product for the U.S.

C. The parties hereby agree that the definition of "Cost of Goods Price" under **Clause 1.1** of the **DEFINITIONS** section of the Agreement shall be amended and restated as follows:

"**Cost of Goods Price**" shall have the meaning given in **Clause 7.14**.

D. The parties hereby agree to amend the **DEFINITIONS** section of the Agreement to include the definition of "**Quarter Year**" under **Clause 1.1** as set forth below:

"**Quarter Year**" means the three month period ending 31 March, 30 June, 30 September, or 31 December in each calendar year (or such part thereof as the case may be for the initial and final Quarter Year periods under this Agreement).

E. The parties hereby agree that **Clause 2.1** set forth in the **TERM** section of the Agreement shall be amended and restated in its entirety to read as follows:

2.1 This Agreement shall be effective beginning as of the Commencement Date and shall continue, unless earlier terminated by either party in accordance with the provisions of **Clause 17**, for a period of seven (7) years (the "**Initial Term**"). Upon expiration of the Initial Term, this Agreement shall thereafter automatically renew for successive one (1) year periods (each, a "Renewal Term") on a continuous basis, unless and until RB delivers to MSX written notice of RB's intent not to renew the Agreement, which notice must be delivered at least one (1) year prior to the expiration of the Initial Term or of a Renewal Term (the Initial Term, together with any Renewal Terms, are hereinafter collectively referred to as the "**Term**"). In no case shall the Term of this Agreement extend beyond the expiration date of the last to expire of the Patents, without the written consent of both parties.

F. The parties hereby agree that Clause 6.3 set forth in the **CAPACITY, STOCK LEVELS AND TOOLING** section of the Agreement shall be amended and restated in its entirety to read as follows:

6.3.1 MSX represents and warrants that it will have the capacity to fill RB's requirements for the Products set forth in any Order so long as the amount specified in the Order does not exceed [***] percent ([***]) of the forecasted volume for such period as set out in the previous Forecast (or such other figure as RB and MSX may agree in writing from time to time). In addition to the foregoing, MSX covenants, represents and warrants that it shall take commercially reasonable action to promptly validate and obtain cGMP approval of its Melton Road and Ameriplex facilities for the manufacture of the Products at the [***] batch size and that, by no later than [***] months after the date on which the new drug application for the Products is approved by the FDA (the "**Capacity Increase Deadline**"), MSX will have the capacity to manufacture and supply to RB up to [***] units of the Products for the U.S. per Quarter Year [***] units of the Products for the U.S. per Year). At RB's reasonable written request, MSX shall provide RB with capacity information to demonstrate that the available capacity meets RB's requirements of Product. MSX shall promptly take commercially reasonable action to address to RB's reasonable satisfaction any capacity issues identified in accordance with this **Clause 6.3** and **Clause 6.6**.

6.3.2 To ensure RB of Product supply continuity for the U.S. and ROW and in support of an extended shelf-life for the Products, MSX agrees that: (i) upon execution of this Amendment, it shall provide all necessary support to RB in order to expeditiously validate and obtain cGMP approval of an RB-designated third party packaging facility with the capability to package the Products [***]; and (ii) in the event that MSX cannot supply RB's requirements for Products in the U.S. and/or ROW because MSX either does not have the capacity or capability to package sufficient Product [***] or Product [***], as determined by the longest Product shelf-life, to meet RB's requirements, then RB shall have the right to source packaging of the Products from the RB-designated third party packager but only until such time as MSX is able to meet RB's requirements for Products; and (iii) further to subsection (ii) of this **Clause 6.32**, MSX will supply to RB such quantities of unpackaged Product (i.e., the finished substrate) in bulk rolls, as needed by RB (within the capacity limits set forth in the Agreement), to meet RB's requirements for Product in accordance with the terms of this Agreement.

G. The parties hereby agree that **Clause 7.4.1** set forth in the **PRICE AND PAYMENT** section of the Agreement shall be amended and restated in its entirety to read as follows:

7.4.1 [*** [percent ([***]%) of the Net Sales Value of the Products sold during the Term in the U.S. per Year up to a not to exceed amount of Twenty Million U.S. Dollars (USD$20,000,000) per Year. Once the aggregate Royalties paid by RB to MSX with respect to Products sold in the U.S., inclusive of the Royalty prepayment pursuant to **Clause 7.18** and the advance on Royalties pursuant to **Clause 7.24**, equal Forty Seven Million U.S. Dollars (USD$47,000,000), RB's obligation to pay any further Royalties to MSX with respect to Products sold in the U.S. shall immediately and permanently cease; and

H. The parties hereby agree that Clause 7.5.2 set forth in the **PRICE AND PAYMENT** section of the Agreement shall be amended and restated in its entirety to read as follows:

7.5.2 The aggregate Royalties paid by RB to MSX with respect to Products sold in the U.S., inclusive of the Royalty prepayment pursuant to **Clause 7.18** and the advance on Royalties pursuant to **Clause 7.24**, reaching the amount of Forty Seven Million U.S. Dollars (USD$47,000,000).

I. The parties hereby agree that **Clause 7.7** set forth in the **PRICE AND PAYMENT** section of the Agreement shall be amended to delete: (i) the reference to **Clause 7.4.1** in the first sentence, (ii) **Clause 7.7.1** in its entirety, and (iii) the last two sentences of **Clause 7.7** and replace these sentences with the following provision: "Upon making payment to MSX of the amounts stated in **Clause 7.7.2** the obligations to pay Royalties to MSX in respect of the ROW will immediately cease."

J. The parties hereby agree that Clause 7.16 set forth in the PRICE AND PAYMENT section of the Agreement shall be amended and restated in its entirety to read as follows:

7.16 Invoices shall be paid in accordance with the following payment schedule:

7.16.1 RB shall pay invoices in respect of the Cost of Goods Price for the U.S., together with any other invoices submitted to it pursuant to this Agreement for the U.S. prior to the expiry of the 2010 Year, within [***] of receipt by RB from MSX of a valid invoice therefore (reflecting applicable sales tax, if any). RB shall thereafter pay invoices in respect of the Cost of Goods Price for the U.S., together with any other invoices submitted to it pursuant to this Agreement for the U.S. for the remainder of the Term, within [***] of receipt by RB from MSX of a valid invoice therefore (reflecting applicable sales tax, if any); *provided, however*, that, commencing after the Price reduction in respect of the U.S. pursuant to Clause 7.23 below takes effect, RB shall thereafter pay for the remainder of the Term such invoices [***] of receipt by RB from MSX of a valid invoice therefore (reflecting applicable sales tax, if any).

7.16.2 RB shall pay invoices in respect of the Cost of Goods Price for the ROW, together with any other invoices submitted to it pursuant to this Agreement for the ROW, within [***] of receipt by RB from MSX of a valid invoice therefore (reflecting applicable sales tax, if any).

K. The parties hereby agree that **Clause 7.18** set forth in the **PRICE AND PAYMENT** section of the Agreement shall be amended and restated in its entirety to read as follows:

7.18 RB shall pay the Royalty for Products (if any) pursuant to **Clause 7.4.1** within [***] of the expiry of the Quarter Year period in which the relevant Royalties are chargeable. Once the aggregate Royalties paid by RB to MSX with respect to Products sold in the U.S., inclusive of the advance on Royalties pursuant to **Clause 7.24**, equal [***] U.S. Dollars (USD[***]), RB shall, within [***] days, prepay to MSX [***] U.S. Dollars (USD$[***]) on a non-refundable basis, which prepayment shall be credited by MSX against future Royalties payable by RB for Products sold in the U.S. Upon making the prepayment of [***] U.S. Dollars (USD$[***]) to MSX, RB's obligation to pay any further Royalties to MSX with respect to Products sold in the U.S. shall immediately and permanently cease. RB shall pay the royalty for Products (if any) pursuant to **Clause 7.4.2** within [***] of the expiry of the Half Year period in which the relevant Royalties are chargeable. Each Royalty payment shall be accompanied by a statement detailing the calculation of Royalties due to MSX, including, without limitation, the amount of Products sold and the corresponding Royalty amount.

L. The parties hereby agree that the **PRICE AND PAYMENT** section of the Agreement shall be amended to include a new **Clause 7.23**, which shall be set forth as follows:

7.23 Upon the payment by RB to MSX of [***] U.S. Dollars (USD$[***]) of Royalties for the U.S. (including the prepayment of Royalties pursuant to **Clause 7.18**), the then current Price payable by RB to MSX for purchases of Products in the U.S. shall automatically and immediately be reduced by [***] percent ([***]%) and this reduced Price shall thereafter remain in effect for a period of one (1) year before it is subject to adjustment pursuant to the terms of the Agreement.

M. the parties hereby agree that the **PRICE AND PAYMENT** section of the Agreement shall be amended to include a new **Clause 7.24**, which shall be set forth as follows:

7.24 RB agrees to pay MSX an advance of [***] U.S. Dollars (USD$[***]) on the Royalties payable to MSX pursuant to **Clause 7.4.1** upon receiving approval of its new drug application (NDA) for the Products from the FDA. MSX hereby agrees that RB shall be entitled to receive interest on this advance in the amount of [***] percent ([***]%) per annum and that the total amount of the advance, plus accumulated interest, shall be credited against the Royalties payable by RB to MSX pursuant to **Clause 7.4.1**.

N. Except as expressly set forth herein, all other terms and provisions of the Agreement shall remain in full force and effect without modification or change. This Amendment shall be made a part of, and incorporated by reference into, the Agreement and shall be subject to the terms and provisions thereof, except as expressly set forth herein.

Signed for and on behalf Reckitt Benckiser Pharmaceuticals Inc.

/s/ Shaun Thaxter

Name: Shaun Thaxter
Title: President
Date: November 13, 2009

Signed for and on behalf of MonoSol Rx, LLC

/s/ Mark Schobel

Name: Mark Schobel
Title: CEO
Date: November 13, 2009

THIS EXHIBIT HAS BEEN REDACTED AND IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST. REDACTED MATERIAL IS MARKED WITH [***] AND HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

AMENDMENT NO. 3
COMMERCIAL EXPLOITATION AGREEMENT

THIS AMENDMENT NO. 3 (this "**Amendment**") is made on the 30th day of March 2010 (the "**Effective Date**") between:

PARTIES

(1) MonoSol Rx, LLC, a company organized and existing under the laws of the USA, with offices at 30 Technology Drive, Warren, New Jersey 07059, USA ("**MSX**"),

and

(2) Reckitt Benckiser Pharmaceuticals Inc., a company existing under the laws of the USA with offices at 10710 Midlothian Turnpike, Suite 430, Richmond, Virginia 23235 ("**RS**").

WHEREAS, MSX and RB entered into a Commercial Exploitation Agreement, dated August 15, 2008 (the "**Agreement"**), pursuant to which RB engaged MSX to manufacture and supply the Products on the terms of the Agreement and MSX agreed to manufacture and supply the Products to RB on the terms of the Agreement; and

WHEREAS, for valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties mutually desire to amend and modify certain terms and conditions of the Agreement as set forth in this Amendment.

IT IS AGREED as follows:

A. Capitalized terms used in this Amendment without definition shall have the respective meanings ascribed thereto in the Agreement.

B. The parties hereby agree that from the Effective Date through and until May 31, 2010 (the "**Expedited Release Approval Period**"), MSX shall manufacture and supply RB's requirements of the Products for the U.S. in accordance with the SUBOXONE® Sublingual Film — Batch Transfer and Batch Release Approval Process (the "**Expedited Release Approval Process**"), a copy of which is annexed hereto as **Schedule B** and made a part hereof. As between MSX and RB, RB shall be solely responsible for ensuring that the Products are not released for commercial distribution by RB or its secondary packager(s) until the prerequisites for release set forth in the Expedited Release Approval Process have been satisfied. . RB shall indemnify, defend and hold harmless MSX Parties pursuant to Clause 10 of the Agreement from any and all Losses that result from or arise in connection with any Claim against any of the MSX Parties to the extent the Claim arises from a release of Product by RB or its secondary packager(s) during the Expedited Release Approval Period in violation of the Expedited Release Approval Process. RB shall accept all shipments of Product subject to the Expedited Release Approval Process. The parties acknowledge and agree that MSX's release of Product under the Expedited Release Approval Process deviates from the release process set forth in the underlying Agreement and Quality Agreement and that, as such, such deviation by MSX shall not constitute a violation of the underlying Agreement or the Quality Agreement.

C. This Amendment shall be governed by and construed in accordance with the laws of the State of Delaware, United States of America, save as to conflict of law provisions, and the parties hereby agree to submit to the jurisdiction of the federal courts located in the State of Delaware.

D. Except as expressly set forth herein, all other terms and provisions of the Agreement shall remain in full force and effect without modification or change.

Signed for and on behalf Reckitt Benckiser Pharmaceuticals Inc.

/s/ Shaun Thaxter

Name: Shaun Thaxter
Title: President

Date:

Signed for and on behalf of MonoSol Rx, LLC

/s/ Mark Schobel

Name: Mark Schobel
Title: CEO

Date:

SCHEDULE B

SUBOXONE® SUBLINGUAL FILM – BATCH TRANSFER AND BATCH APPROVAL PROCESS

[***]

AMENDMENT NO. 4
COMMERCIAL EXPLOITATION AGREEMENT

THIS AMENDMENT NO. 4 (this "**Amendment**") is made on the 13th day of October 2010 (the "**Effective Date**") between:

PARTIES

(1) MonoSol Rx, LLC, a company organized and existing under the laws of the USA, with offices at 30 Technology Drive, Warren, New Jersey 07059, USA ("**MSX**"),

and

(2) Reckitt Benckiser Pharmaceuticals Inc., a company existing under the laws of the USA with offices at 10710 Midlothian Turnpike, Suite 430, Richmond, Virginia 23235 ("**RB**").

WHEREAS, MSX and RB entered into a Commercial Exploitation Agreement, dated August 15, 2008 as amended by Amendment No, 1 thereto on August 19, 2009, Amendment No. 2 thereto on November 13, 2009, and Amendment No. 3 thereto on March 30, 2010 (collectively, the "**Agreement'**), pursuant to which RB engaged MSX to manufacture and supply the Products on the terms of the Agreement and MSX agreed to manufacture and supply the Products to RB on the terms of the Agreement; and

WHEREAS, for valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties mutually desire to amend and modify certain terms and conditions of the Agreement as set forth in this Amendment.

IT IS AGREED as follows:

A. Capitalized terms used in this Amendment without definition shall have the respective meanings ascribed thereto in the Agreement.

B. The parties hereby agree that from the Effective Date through and until December 31, 2010 (the "**Expedited Release Approval Period**"), MSX shall manufacture and supply RB's requirements of the Products for the U.S. in accordance with the SUBOXONE4 Sublingual Film — Batch Transfer and Batch Release Approval Process (the "**Expedited Release Approval Process**"), a copy of which is annexed hereto as **Schedule B** and made a part hereof. As between MSX and RB, RB shall be solely responsible for ensuring that the Products are not released for commercial distribution by RB or its secondary packager(s) until the prerequisites for release set forth in the Expedited Release Approval Process have been satisfied. RB shall indemnify, defend and hold harmless MSX Parties pursuant to Clause 10 of the Agreement from any and all Losses that result from or arise in connection with any Claim against any of the MSX Parties to the extent the Claim arises from a release of Product by RB or its secondary packager(s) during the Expedited Release Approval Period in violation of the Expedited Release Approval Process. RB shall accept all shipments of Product subject to the Expedited Release Approval Process. The parties acknowledge and agree that MSX's release of Product under the Expedited Release Approval Process deviates from the release process set forth in the underlying Agreement and Quality Agreement and that, as such, such deviation by MSX shall not constitute a violation of the underlying Agreement or the Quality Agreement.

C. This Amendment shall be governed by and construed in accordance with the laws of the State of Delaware, United States of America, save as to conflict of law provisions, and the parties hereby agree to submit to the jurisdiction of the federal courts located in the State of Delaware.

D. Except as expressly set forth herein, all other terms and provisions of the Agreement shall remain in full force and effect without modification or change.

Signed for and on behalf Reckitt Benckiser Pharmaceuticals Inc.

/s/ Shaun Thaxter

Name: Shaun Thaxter
Title: President

Date: 10/18/10

Signed for and on behalf of MonoSol Rx, LLC

/s/ Mark Schobel

Name: Mark Schobel
Title: CEO

Date: 10/19/10

SCHEDULE B

SUBOXONE® SUBLINGUAL FILM – BATCH TRANSFER AND BATCH APPROVAL PROCESS

[***]

AMENDMENT NO. 5
COMMERCIAL EXPLOITATION AGREEMENT

THIS AMENDMENT NO. 5 (this "**Amendment**") is made on the 15th day of December 2010 (the "**Effective Date**") between:

PARTIES

(1) MonoSol Rx, LLC, a company organized and existing under the laws of the USA, with offices at 30 Technology Drive, Warren, New Jersey 07059, USA ("**MSX**"),

and

(2) Reckitt Benckiser Pharmaceuticals Inc., a company existing under the laws of the USA With office's at 10710 Midlothian Turnpike, Suite 430, ROMEO, Virginia 23235 ("**RB**").

WHEREAS, MSX and RB entered into A Commercial Exploitation Agreement, dated August 15, 2005 as amended by Amendment No. 1 thereto do August 19, 2009, Amendment No, 2 thereto on November 13, 2009, Amendment No, 3 thereto on March 30, 2010, and Amendment No. 4 thereto on October 13, 2010 (collectively the "**Agreement**"), pursuant to which RB engaged MSX to manufacture and supply the Products on the terms of the Agreement and MSX agreed to manufacture and supply the Products to RB on the terms of the Agreement; and

WHEREAS, for valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties mutually desire to amend and modify certain terms and conditions of the Agreement as set forth in this Amendment.

IT TS AGREED as follows:

A. Capitalized terms used In. this Amendment without definition Shell have the respective meanings ascribed thereto in the Agreement.

B. The parties hereby agree that **Clause 7.16** set forth in the **PRICE AND PAYMENT** section of the Amendment No. 2 dated November 13, 2009 shall be amended and restated in its entirety to read as follows;

7.16 Invoices shall be paid in accordance with the following payment schedule:

7.16.1 RB shall pay Invoices in reaped of the Cost of Goods Price for the U.S., together with any other invoices submitted to it pursuant to this Agreement for the U.S. prior to the expiry of the 2010 Year, within [***] of receipt by RB from MSX of a valid invoice therefore (reflecting applicable sales tax, if any). RB shall pay invoices in respect of the Cost of Goods Price for the U.S., together with any other invoices submitted to it pursuant to this Agreement for the U.S. from January 1, 2011 to March 31, 2011, within [***] of receipt by RB from MSX of a valid invoice therefore (reflecting applicable safes tax, if any). RB shall thereafter pay invoices, in respect of the Cost of Goods Price for the U.S., together with, any other invoices submitted to pursuant to this Agreement for the U.S. for the remainder-of the Term, within [***] of receipt by RB from MSX of a valid invoice therefore (reflecting applicable sales tax, if any) provided, however, that, commencing after the Price reduction in respect of the U.S. pursuant to Clause 7:23 of the Amendment No. 2 dated November 13, 2002 takes effect, RB shall thereafter pay for the remainder of the Term such invoices [***] days of receipt by RB from MSX of a valid invoice therefore (reflecting applicable sales tax, if any).

7.16.2 RB shall pay invoices in respect of the Cost of Goods Price for the ROW, together with any other invoices submitted to if pursuant to this Agreement for the ROW, within [***] of receipt by RB from MSX of a valid invoice therefore (reflecting applicable sales fax, if any).

C. This Amendment shall be governed by and construed In accordance with the laws of the State of Delaware, United States of America, save as to conflict of law provisions, and the parties hereby agree to submit to the jurisdiction of the federal courts located In the State of Delaware.

D. Except as expressly set forth herein, all other terms and provisions the Agreement shall remain in full force and effect without modification or change.

Signed for and on behalf Reckitt Benckiser Pharmaceuticals Inc.

/s/ Shaun Thaxter

Name: Shaun Thaxter
Title: President

Date: 12/16/10

Signed for and on behalf of MonoSol Rx, LLC

/s/ Mark Schobel

Name: Mark Schobel
Title: CEO

Date:

THIS EXHIBIT HAS BEEN REDACTED AND IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST. REDACTED MATERIAL IS MARKED WITH [***] AND HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

AMENDMENT NO. 6
COMMERCIAL EXPLOITATION AGREEMENT

THIS AMENDMENT NO. 6 (this "**Amendment**") is made on the 9th day of December 2011 (the "**Effective Date**") between:

PARTIES

(1) MonoSol Rx, LLC, a company organized and existing under the laws of the USA, with offices at 30 Technology Drive, Warren, New Jersey 07059, USA ("**MSX**"),

and

(2) Reckitt Benckiser Pharmaceuticals Inc., a company existing under the laws of the USA with offices at 10710 Midlothian Turnpike, Suite 430, Richmond, Virginia 23235 ("**RB**").

WHEREAS, MSX and RB entered into a Commercial Exploitation Agreement, dated August 15, 2008, as amended (collectively, the "**Agreement**"), pursuant to which RB engaged MSX to manufacture and supply the Products on the terms of the Agreement and MSX agreed to manufacture and supply the Products to RB on the terms of the Agreement; and

WHEREAS, MSX currently maintains an existing packaging line pursuant to which MSX currently packages the Products at MSX's Melton Road facility (the "**Melton Road Packaging Line**"); and

WHEREAS, MSX has acquired a second packaging line more particularly described in Schedule 1 to this Amendment (the "**Ameriplex Packaging Line**") from [***] for use at MSX's Ameriplex facility for which capital investment is required to upgrade the Ameriplex facility, install the Ameriplex Packaging Line and validate the packaging of the Products on the Ameriplex Packaging Line to cGMP requirements; and

WHEREAS, RB has agreed to contribute towards such further capital investment in the Ameriplex Packaging Line in exchange for, *inter alia*, certain guarantees with respect to MSX's capacity to fill RB's requirements for the Products on the terms herein set forth;

WHEREAS, for valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties mutually desire to supplement, amend and/or modify certain terms and conditions of the Agreement as set forth in this Amendment.

IT IS AGREED as follows:

A. Capitalized terms used in this Amendment without definition shall have the respective meanings ascribed thereto in the Agreement.

B. RB shall provide up to [***] US Dollars ($[***]) in funding for the required build-out of the Ameriplex facility and installation of the Ameriplex Packaging Line (the "**Funding**"). The cost estimates for such build-out and installation are set forth on **Schedule 1** to this Amendment and are derived from that certain engineering study dated October 27, 2010 issued by [***] The Funding shall be made by RB to MSX in immediately available funds to an account designated by MSX as follows:

[***] to be paid on January 10, 2012;

[***] upon the achievement of certain milestones related to the build-out of the Ameriplex facility and installation of the Ameriplex Packaging Line, which milestones shall be agreed to by the parties in writing subsequent to the execution of this Amendment; and

The balance of the project costs incurred by MSX, not to exceed [***] of the total Funding, upon completion of the build-out and installation of the Ameriplex Packaging Line and receipt of all FDA approvals needed for commercial packaging of the Products to cGMP requirements.

C. RB and MSX shall agree upon key suite build-out features of the Ameriplex Packaging Line and RB shall have the right to approve the cGMP suite build-out and the installation plans relating thereto, such approval not to be unreasonably withheld, delayed or conditioned. Selection of and negotiations with engineering and construction providers shall be undertaken jointly by MSX and RB; provided that, MSX shall have final approval rights with respect to the retention of any engineering and construction providers within the scope of the cost estimates referred to in paragraph B. of this Amendment.

D. RB and MSX mutually agree that certain activities related to the build-out of the Ameriplex facility and installation of the Ameriplex Packaging Line, including, but not limited to, engineering support, process work and qualification, may be performed more efficiently by MSX resources and that if such efficiencies can quantified, then the activities should be performed by MSX resources and reimbursed by RB as part of the Funding; provided, however, that the final decision on entitlement for reimbursement shall be at RB's discretion and that the performance of such activities by MSX resources follows certain agreed principles, including, but not limited to, the following:

Said activities, if performed by MSX employees, would not be part of their normal duties or responsibilities, hence not part of MSX fixed costs;

MSX can quantify that said activities would be performed more efficiently if carried out by MSX resources; and Said activities could be done by duly qualified temporary workers hired by MSX.

E. In exchange for RB's contribution of the Funding: (i) MSX will increase its current annual capacity commitment under Clause 6.3 of the Agreement from [***] units of the Products for the U.S. per Quarter Year (i.e., [***] units of the Products for the U.S. per Year) to [***] units of the Products for the U.S. and ROW combined per Quarter Year (i.e., [***units of the Products for the U.S. and ROW combined per Year), with the intent of the parties being to utilize the Ameriplex Packaging Line as the primary line such that the majority of units of the Products shall be packaged on the Ameriplex Packaging Line; and (ii) MSX agrees to undertake commercially reasonable efforts to support peaks in demand of Product of up to [***] units of Products per month.

F. MSX shall have the right to use excess capacity on the Ameriplex Packaging Line for the packaging of other products for its other customers; provided, however, that RB's production requirements and service levels are not impacted. With respect to the Ameriplex Packaging Line only, any capacity utilized by MSX for the packaging of other commercial products shall be subject to the payment by MSX to RB of a fee of $[***] per unit of packaged product, subject to the total fees receivable by RB shall not exceed the amount of Funding provided by RB hereunder. For the sake of clarity, MSX shall not be subject to the per unit fee for non-commercial usage of the Ameriplex Packaging Line.

G. In the event of a business interruption impacting the Ameriplex Packaging Line, MSX hereby agrees to utilize the Melton Road Packaging Line line as a contingency / business continuity solution, subject to MSX's other commercial commitments, for quantities of Product of up to [***] units for U.S. and ROW per Year. In the event of a business interruption impacting the Melton Road Packaging Line, MSX hereby agrees to utilize the Ameriplex Packaging Line as a contingency / business continuity solution, subject to MSX's other commercial commitments, for quantities of Product of up to [***] units for U.S. and ROW per Year.

H. From and after the date of this Amendment, other than as set forth In this paragraph H, RB shall place Orders for Product as: (i) [***] batch sizes; and (ii) a maximum of [***] SKU changeovers per batch or a maximum of [***] SKUs per batch (the "**Ordering Criteria**"). The parties shall create a joint project team to develop and have in 'place the most cost-effective solution of packaging small runs by March 31, 2013.

I. The parties hereby agree that Clause 7.3.2 set forth in the **PRICE AND PAYMENT** section of the Agreement shall be amended and restated in its entirety to read as follows:

7.3.2 In the event that any Order requests more than one packaging for the Products covered by such Order, RB shall pay a lump sum amount for each additional packaging request in an amount of [***] Dollars (USD $[***]), regardless of the number of units of Product covered by such new packaging request (the "**Packaging Fee**"). RB and MSX will review the documented costs for additional packaging ("**Changeover Costs**") on an annual basis and increase or decrease the Packaging Fee based on the annual increase or decrease in Changeover Costs. For Orders containing SKU runs of [***] doses or less RB will pay the actual documented Changeover Costs by run as provided by MSX, which actual documented Changeover Costs are expected to be [***]) or less.

J. Consistent with Section 7.12 of the Agreement, MSX will, together with RB, examine the costs associated with the Ameriplex Packaging Line on annual basis to determine if Product cost reductions are commercially reasonable based upon equipment or environmental improvements; provided, however, that such obligation on the part of MSX shall cease if and when the payments made by MSX to RB equal the full amount of the Funding provide by RB hereunder.

K. MSX may buy out its obligations under paragraph E to utilize the Ameriplex Packaging Line as the primary line at any point within [***] years of the Effective Date of the Amendment in return for payment to RB of an amount equal to the amount of Funding provided by RB hereunder net of any payments made by MSX to RB in respect to paragraph F. On the [***] anniversary of the Effective Date of the Amendment, MSX's obligation to utilize the Ameriplex Packaging Line as the primary line will cease.

L. This Amendment shall be governed by and construed in accordance with the laws of the State of Delaware, United States of America, save as to conflict of law provisions, and the parties hereby agree to submit to the jurisdiction of the federal courts located in the State of Delaware.

M. Except as expressly set forth herein, all other terms and provisions of the Agreement shall remain in full force and effect without modification or change.

Signed for and on behalf Reckitt Benckiser Pharmaceuticals Inc.

/s/ Shaun Thaxter

Name: Shaun Thaxter
Title: President

Date:

Signed for and on behalf of MonoSol Rx, LLC

/s/ Keith Kendall

Name: Keith Kendall
Title: COO

Date: 12/9/01

SCHEDULE 1

[***]

THIS EXHIBIT HAS BEEN REDACTED AND IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST. REDACTED MATERIAL IS MARKED WITH [***] AND HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

AMENDMENT NO. 7
COMMERCIAL EXPLOITATION AGREEMENT

THIS AMENDMENT NO. 7 (this "**Amendment**") is made on the ___ day of December 2012 (the "**Amendment Effective Date**") between:

PARTIES

(1) MonoSol Rx, LLC, a company organized and existing under the laws of the USA, with offices at 30 Technology Drive, Warren, New Jersey 07059, USA ("**MSX**"),

and

(2) Reckitt Benckiser Pharmaceuticals Inc., a company existing under the laws of the USA with offices at 10710 Midlothian Turnpike, Suite 430, Richmond, Virginia 23235 ("**RB**").

WHEREAS, MSX and RB entered into a Commercial Exploitation Agreement, dated August 15, 2.008, as amended (collectively, the "**Agreement**"), pursuant to which RB engaged MSX to manufacture and supply the Products on the terms of the Agreement and MSX agreed to manufacture and supply the Products to RB on the terms of the Agreement; and

WHEREAS, for valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties mutually desire to amend and modify certain terms and conditions of the Agreement as set forth in this Amendment.

IT IS AGREED as follows:

A. Capitalized terms used in this Amendment without definition shall have the respective meanings ascribed thereto in the Agreement.

B. From and after the Amendment Effective Date, an additional formulation of Product is hereby added to Schedule 3 of the Agreement as follows:

- 4 mg Buprenorphrine + 1 mg Naloxone

C. The Cost of Goods Price for the 2012 and 2013 Years of manufacture per pouched single dose of Product for the following dosage strengths will be as follows:

· 4 mg Buprenorphine + 1 mg Naloxone (US)	$[***]
· 4 mg Buprenorphine + 1 mg Naloxone (ROW)	$[***]
· 12 mg Buprenorphine + 3 mg Naloxone (US)	$[***]
· 12 mg Buprenorphine + 3 mg Naloxone (ROW)	$[***]

D. The Cost of Goods Price per pouched single dose of Product for the 2013 Year of manufacture for the following dosage strengths will be as follows:

· 2 mg Buprenorphine + 0.5 mg Naloxone (US)	$[***]
· 2 mg Buprenorphine + 0.5 mg Naloxone (ROW)	$[***]
· 8 mg Buprenorphine + 2 mg Naloxone (US)	$[***]
· 8 mg Buprenorphine + 2 mg Naloxone (ROW)	$[***]

E. As of the Amendment Effective Date, MSX will conduct a representative batch sampling of no less than [***] doses per batch and no more than [***] doses per batch of 8 mg Buprenorphine + 2 mg Naloxone and 12 mg Buprenorphine + 3 mg Naloxone for each such batch commenced on or after the Amendment Effective Date. The batch sampling quantities may be adjusted by written agreement from both parties. [***].

F. For the 12 mg Buprenorphine + 3 mg Naloxone Product, MSX will warehouse Product until RB has provided MSX written instructions either to ship the Product or have the Product destroyed ("**Disposition Instructions**"). RB shall provide the Disposition Instructions to MSX within ten (10) business days after receipt by RB of the Summary Findings from the Visual Sampling unless RB has commercially reasonable questions on a given batch or seeks further clarification on existing data from a particular batch in order to aid RB in making a decision in which case MSX will make available an appropriate level of management to respond to RB. If RB does not provide the required Disposition Instructions within ten (10) business days of MSX having provided responses to commercially reasonable inquiries made by RB, then RB will have the subject batch shipped to a third party of RB's choosing for further warehousing (such Product, "**12 mg Warehoused Product**"). The Order for a batch will be fulfilled per Section 5.1 of the Agreement and legal title shall pass to RB per Section 5.7 of the Agreement upon MSX providing a Certificate of Analysis to RB. MSX will invoice RB upon providing a Certificate of Analysis to RB and RB shall pay the full batch Price plus associated Sampling Charges for all 12 mg Buprenorphine + 3 mg Naloxone Product with a Certificate of Analysis in accordance with the terms of the Agreement regardless of the associated Disposition Instructions. In the event that RB subsequently elects to have the 12 mg Warehoused Product destroyed, RB shall cause the Product to be shipped (at RB's cost) to MSX along with instructions to destroy the Product and MSX shall destroy the Product (at MSX's cost). Notwithstanding the foregoing, each shipment of Product (including 12 mg Warehoused Product) delivered by MSX shall comply with **Clause 5.3** of the Agreement.

G. For the 8 mg Buprenorphine + 2 mg Naloxone Product, MSX will warehouse Product until the summary findings from the Visual Sampling have been provided to RB. For batches with a **Visual Sampling Level** [***] of [***]% or less, MSX will ship Product per **Clause 5.1** of the Agreement and RB shall pay for all Product with a Certificate of Analysis. MSX will warehouse 8 mg Buprenorphine + 2 mg Naloxone Product for an additional ten (10) business days where the Visual Sampling Level for a batch exceeds [***]%. RB shall provide MSX with Disposition Instructions within said ten (10) business day period unless RB submits to MSX commercially reasonable questions on a given batch or seeks further clarification on existing data from a particular batch in order to aid RB in making a decision, in which case MSX will make available an appropriate level of management to answer commercially reasonable questions on a given batch or provide further clarification on existing data from a particular batch in order to aid RB in making a decision. RB shall provide the required Disposition Instructions to MSX within five (5) business days of MSX having provided responses to commercially reasonable inquiries made by RB during the ten (10) business day period referenced in the immediately preceding sentence. If the Disposition Instructions provided to MSX require destruction of the Product, then MSX shall dispose of the subject batch and the parties respective liability for costs associated with the destroyed batch shall be as set forth below:

[***]	**[***]**
[***]	[***]
[***]	[***]
[***]	[***]

Responsibility for costs associated with destroyed batches with Visual Sampling Level above [***]% which are in process as of the Amendment Effective Date shall be as follows: (i) for batch [***] (produced in July) MSX shall be responsible for all MSX costs and all API costs shall be the responsibility of RB; (ii) for batch [***] (presently warehoused at Sharp) RB shall accept the batch; (iii) for batch [***] MSX shall be responsible for all MSX costs and all API costs shall he split equally by MSX and RB; and (iv) all other remaining in process batches will be subject to this Amendment.

If the Disposition Instructions provided to MSX require shipment of the Product, then MSX will ship Product per Clause 5.1 of the Agreement and RB shall pay for all Product with a Certificate of Analysis. Notwithstanding the foregoing, each shipment of Product (including 8 mg Warehoused Product) delivered by MSX shall comply with Clause 5.3 of the Agreement.

H. Both parties acknowledge and agree that nothing in this Amendment relieves either party of its responsibilities to undertake commercially reasonable efforts to continuously improve the Products. Accordingly, the parties agree to establish and convene a joint technical team (the "**JTT**") consisting of members from each party who have the requisite expertise to analyze manufacturing and Product data, customer complaints on an ongoing basis, and utilize the Annual Product Review Process to continuously improve the Products. The parties hereby further agree that the JTT will meet on a quarterly basis and the first meeting of the JTT shall be convened within thirty (30) days of the Amendment Effective Date. MSX agrees to work diligently and in good faith, through the JTT, to improve the manufacturing process and quality of the Product output on [***] of the production line. The JTT shall also work in good faith to evaluate the merits and feasibility of a robust Product reformulation and shall work in good faith to agree upon a commercially viable plan for such Product reformulation. The JTT may also, from time-to—time, with both parties written approval, develop other specific and limited projects to improve the overall quality of the existing Product or manufacturing process.

I. The parties hereby agree that **Clause 3.4.3** set forth in the **MANUFACTURE AND SUPPLY** section of the Agreement shall be amended and restated in its entirety to read as follows:

monitor, account for and keep RB regularly informed of the usage and waste of API. MSX will act reasonably to ensure maintenance of an overall yield percentage (the "**Yield Target**"), defined as the actual strips produced before samples divided by the theoretical strips available based on the amount of defect free API used in manufacturing. For the avoidance of doubt, this includes any API dispensed and/or used for commercial production regardless of whether film strips were yielded from said use but excluding API associated with batches destroyed based on Visual Sampling data. The parties will work in good faith to identify commercially reasonable Yield Targets for dosage strengths, batch sizes, and SKU configurations within ninety (90) days of the Amendment Effective Date. On an annual basis, MSX and RB will review and reconcile results against the Yield Target and MSX will, within thirty (30) days, remunerate RB for RB's documented API costs on an annual basis to the extent MSX falls below the Yield Target. For the sake of clarity, the formula for calculating API costs owed will be Yield Target minus the actual yield times the API costs. The parties hereby agree that Clause 3.4.3 of the Agreement represents the sole mechanism for MSX reimbursement of API to RB associated with manufacturing usage and waste.

J. The parties hereby agree that **Clause 4.6** set forth in the **FORECASTS, ORDERS AND SUPPLY OF THE API** section of the Agreement shall be amended and restated in its entirety to read as follows:

Notwithstanding the terms of any DDP delivery (or any other delivery) of the API by RB to MSX, legal title to the API shall remain with RB after delivery to MSX. MSX shall use reasonable efforts to ensure proper storage and handling of the API once delivered to MSX and prior to manufacturing. Risk of damage to, or loss of, the API shall pass from RB to MSX upon delivery as set out in Clause 4.3. MSX shall retain casualty insurance coverage for the expected inventory of the API (amounts expected to be supplied to MSX by RB for manufacture of the Product in the amounts set forth in the Forecasts) to cover damage to or loss of the API during storage for so long as the API remains at MSX's risk. For the sake of clarity, the responsibilities of the parties with respect to usage and waste of API during manufacturing is covered under Clause 3.4.3 and this Clause 4.6 is in no way intended to address API usage and waste during manufacturing.

K. The parties hereby agree that **Clause 4.7** set forth in the **FORECASTS, ORDERS AND SUPPLY OF THE API** section of the Agreement shall be amended to include the following sentence at the end of the paragraph:

For the sake of clarity, MSX's obligation to remunerate RB under this Clause 4.7 is limited to the amount paid to MSX by RB and shall not include remuneration for RB's API cost.

L. RB agrees to waive any API loss claims to MSX for batches made prior to the Amendment Effective Date.

M. This Amendment shall be governed by and construed in accordance with the laws of the State of Delaware, United States of America, save as to conflict of law provisions, and the parties hereby agree to submit to the jurisdiction of the federal courts located in the State of Delaware.

N. Except as expressly set forth herein, all other terms and provisions of the Agreement shall remain in full force and effect without modification or change.

Signed for and on behalf Reckitt Benckiser Pharmaceuticals Inc.

/s/ Shaun Thaxter

Name: Shaun Thaxter
Title: President

Date: 12/1/12

Signed for and on behalf MonoSol Rx, LLC

/s/ Keith Kendall

Name: Keith Kendall
Title: COO

Date:

THIS EXHIBIT HAS BEEN REDACTED AND IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST. REDACTED MATERIAL IS MARKED WITH [***] AND HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

ADDENDUM A TO COMMERCIAL EXPLOITATION AGREEMENT:
SUBOXONE STRIP DEVELOPMENT AGREEMENT

This Addendum A to Commercial Exploitation Agreement: Suboxone Strip Development Agreement (the "Addendum") is entered into as of this 14th day of October, 2013 the ("Addendum Effective Date"), by and between Reckitt Benckiser Pharmaceuticals Inc., with offices at 10710 Midlothian Turnpike, Suite 430, Richmond, VA 23235 ("RB") and MonoSol Rx, LLC, with offices at 30 Technology Drive, Warren, NJ 07059 ("MSX").

BACKGROUND AND PURPOSE OF PROJECT

A. The parties entered into a Commercial Exploitation Agreement dated August 15, 2008, as amended (the "Agreement").

B. Pursuant and subject to the Agreement, the parties now wish to enter into an addendum to the Agreement relating to the development and potential commercialization of improved formulations of the Products;

C. This Addendum relates to a research and development project to develop and potentially commercialize improved formulations of the Products having a higher degree of product stability which MSX would manufacture and supply to RB pursuant to the terms of the Agreement. The parties intend that the Price for these improved formulations be the same as the Price which RB is currently paying for existing Products with the same API and dosage strengths, (subject only to variations in costs with respect to Raw Materials, Direct Labor, Release Testing, or use of manufacturing line time; provided however, that MSX shall validate with competent evidence any increase in costs with respect to Raw Materials, Direct Labor, Release Testing, or use of manufacturing line time).

NOW, THEREFORE, for and in consideration of the mutual covenants contained herein, the parties hereto agree as follows:

1. Capitalized Terms

Capitalized terms used in this Addendum without definition shall have the same meanings ascribed to those terms in the Agreement.

2. Addendum is Part of Agreement

This Addendum is hereby incorporated into and made a part of the Agreement as if fully set forth therein, and is subject to the terms of the Agreement.

Without limiting the foregoing and for the avoidance of doubt, rights to and ownership of any inventions and other intellectual property developed or created as a result of the work performed hereunder shall be governed by the Intellectual Property Rights provisions of the Agreement.

3. Services and Payment

MSX shall perform the services set forth in the attached Appendix A (the "Services"), which is hereby incorporated by reference and made a part of this Addendum as if fully set forth herein.

MSX represents and warrants that it will perform the Services in accordance with prevailing industry standards. MSX further represents and warrants that all personnel who perform the Services shall have appropriate training, experience and qualifications.

In consideration for performing the Services, MSX shall receive payments as set forth herein and in Appendix A and Appendix B. Appendix B is hereby incorporated by reference and made a part of this Addendum as if fully set forth herein.

The initial payment will be invoiced by MSX upon Signing (as defined below) and will be due upon receipt of said invoice by RB.

Subsequent payments will be invoiced by MSX upon completion of all applicable criteria and will be due [***] after receipt of said invoice by RB. In the event of any good faith disputes with respect to any such invoice, RB shall pay the undisputed portion of any such invoice within this time period.

4. Project Specifics

Project milestones and timelines as well as associated payments are outlined in Appendix A.

4.1. Payment Triggers

RB's obligation to make a payment for services rendered pursuant to each milestone phase is triggered by either the commencement or the completion of a milestone activity, as outlined in Appendix A and further described herein.

In order to receive payments for an applicable milestone activity whereby payment is due on "commencement of the activity" MSX shall first provide RB a project plan outlining critical activities and a definitive time period for the commencement of the milestone phase, which plan must be accepted in writing by RB (such approval not to be unreasonably withheld or delayed).

If payment is due upon completion, MSX shall first provide RB with written confirmation of completion, which confirmation shall be deemed accepted by RB unless RB delivers to MSX a written deficiency notice within twenty-one (21) business days of RB's receipt of written confirmation of completion. Any such deficiency notice delivered by RB hereunder shall contain a level of detail sufficient for MSX to assess the deficiency and propose a plan of corrective action to address the deficiency. In the event a deficiency notice is delivered by RB under this Section 4.1, the parties shall endeavor to agree promptly upon a corrective action plan and payment of the milestone payment in question will not be required and the milestone shall not be deemed completed until such time as the deficiency is remedied in accordance with the corrective action plan; provided that the time periods during which RB is responsible for responding under this Section 4.1 (i.e., the period of up to 21 business days during which RB is reviewing MSX's proposed completion of a milestone) shall not be counted for purposes of MSX's eligibility for any Milestone Bonus Payment or the assessment of any Milestone Reduction Penalty set forth in Appendix A.

As used in Sections 4.2 and 4.3 below (and elsewhere in this Addendum), the completion of a milestone or a project activity is considered to include both the completion of the specified activities by MSX and their acceptance by RB as set forth above.

4.2. Bonus Payments

RB will pay milestone bonus payments described in this Section 4.2 ("Milestone Bonus Payments") to MSX where MSX has completed all project activities as outlined in the project plan pertaining to a particular project milestone a minimum of [***] in advance of the specified target delivery date, with larger bonuses payable if MSX completes all project activities pertaining to a particular milestone a minimum of [***] in advance of the specified target delivery date. The Milestone Bonus Payment column indicates the percentage of the bonus, with the number to the left of the diagonal indicating the percentage bonus (expressed as a percentage of the base milestone payment) if the milestone is completed a minimum of [***] before the target date and the (smaller) percentage to the right of the diagonal line indicating the percentage bonus payment if the milestone is completed a minimum of [***] in advance of target date.

As an example, the Milestone Bonus Payment for the "Analytical Toolkit" phase is written "[***]% / [***]%," and the target delivery date is described as "[***]" and the Milestone Amount is $[***]. ("Signing" is the date on which the later to be executed of the [***] and the [***] is fully executed by both parties).

If MSX completes all of the activities in the Analytical Toolkit milestone a minimum of [***] prior to the target delivery date, i.e., no more than [***] from Signing, MSX would receive a bonus payment of [***]% of the milestone payment. In such case, its bonus payment would be $[***] ([***]% x $[***] = $[***]) in addition to the base milestone payment of $[***], which means that that total amount payable for this milestone to MSX would be $[***].

If MSX completes all of the activities in the Analytical Toolkit milestone a minimum of [***] prior to the target delivery date, i.e., no more than [***] from Signing, MSX would receive a bonus payment of [***]% of the milestone payment. In such case, its bonus payment would be $[***] ([***]% x $[***] = $[***]) in addition to the base milestone payment of $[***], which means that that total amount payable for this milestone to MSX would be $[***].

For the avoidance of doubt, bonus payments for completion of a particular milestone are not cumulative. MSX might receive either a [***] bonus or a [***] bonus, but it could not receive both bonuses for completing a single milestone (although MSX might receive separate bonuses, or penalties, for completing other milestones specified in Appendix A early or late, as applicable.)

4.3. Penalty Payment Reductions

Subject to Section 4.1 of this Addendum, milestone reduction penalties described in this Section 4.3 ("Milestone Reduction Penalties") will be deducted from the amounts payable to RB if MSX exceeds the applicable target delivery date for successfully completing all project activities pertaining to a particular milestone by more than [***], with larger reduction penalties if MSX exceeds the applicable Target Delivery Date for successfully completing all project activities pertaining to a particular milestone by more than [***]. The Milestone Reduction Penalty column indicates the percentage of the penalty, with the number to the left of the diagonal line indicating the percentage penalty if MSX completes the project activities more than [***] after the target date and the (larger) percentage to the right of the diagonal line indicating the percentage penalty if MSX completes the project activities more than [***] after the target date.

As an example, the Milestone Reduction Penalty for the "Analytical Toolkit" phase is written "[***]% / [***]%," and the target delivery date is described as "[***] from Signing" and the Milestone Amount is $[***].

If MSX completes all of the project activities in the Analytical Toolkit milestone at least [***] after the target delivery date, i.e., a minimum of [***] from Signing, MSX would receive a reduction penalty of [***]% of the milestone payment. In such case, its reduction penalty would be $[***] ([***]% x $[***] = $[***]) deducted from the base milestone payment of $[***], which means that that total amount payable for this milestone to MSX would be $[***].

If MSX completes all of the project activities in the Analytical Toolkit milestone at least [***] after the target delivery date, i.e., a minimum of [***] from Signing, MSX would receive a reduction penalty of [***]% of the milestone payment. In such case, its reduction penalty would be $[***] ([***]% x $[***] = $[***]) deducted from the base milestone payment of $[***], which means that that total amount payable for this milestone to MSX would be $[***].

4.4. Termination and Termination Fee

MSX may terminate this Addendum at any time with or without cause during the "Pre-Signing" and "Analytical Toolkit" phases of the project only by giving written notice of termination to RB.

4.4.1 RB may terminate this Addendum or any individual milestone phase at any time with or without cause by giving written notice of termination to MSX. Each individual milestone phase, except the "Pre-Signing" and "Analytical Toolkit" milestones, requires the payment of a termination fee by RB (as specified in Appendix A) in the event that RB terminates the applicable milestone phase of the project, along with the milestone payment associated with any active and ongoing work. Any termination notice by RB shall specify the particular milestone phase or phases being terminated. In the event that RB terminates the entire project or multiple milestone phases at substantially the same time, RB shall pay only a single termination fee, which shall be equal to the largest individual termination fee applicable to any of the terminated milestone phases in addition to the milestone payments associated with any active and ongoing work (i.e., as an illustrative example, in the event that RB elects to pursue the optional "Delivery of [***]" milestone phase (termination fee = $[***]) and then subsequently terminates that phase, and, at substantially the same time, RB terminates the "[***]" milestone phase (termination fee = $[***]), then, in addition to the milestone payments associated with any active and ongoing work, RB would owe MSX a single termination fee of $[***], which is the largest individual termination fee applicable to any of the terminated milestone phases).

4.4.2 In addition to the amounts specified in 4.4.1 above, RB will make the following termination payments to MSX if RB without cause terminates either the entire Addendum or the milestone phases specified below prior to making the applicable milestone payments:

Batch Manufacture milestones

[***] *Manufacture of [***] validation batches:* Payment of $[***] for each batch manufactured in conformance with applicable specifications prior to termination (up to a maximum of $[***]).

[***]*:* Payment of $[***] for each batch manufactured in conformance with applicable specifications prior to termination (up to a maximum of $[***]).

[***]*:* Payment of $[***] for each batch manufactured in conformance with applicable specifications prior to termination (up to a maximum of $[***]).

[***]*:* Provide cGMP hand-cut samples for clinical PK studies: Payment of $[***] for manufacture of cGMP clinical supplies manufactured in conformance with applicable specifications prior to termination.

Stability Test milestones

[***]*:* Payment of $[***] upon both (i) manufacture of formulation in conformance with applicable specifications prior to termination and (ii) demonstration that such formulation satisfies applicable [***] stability standards (even if this [***] period concludes after termination by RB).

[***]*:* Payment of $[***] upon (i) manufacture of formulation in conformance with applicable specifications prior to termination and (ii) demonstration that such formulation satisfies applicable [***] stability standards (even if this [***] period concludes after termination by RB).

For the avoidance of doubt, in no case will the total amount payable by RB under this Section 4.4.2 with respect to any particular milestone exceed the total amount which would have been payable if MSX had completed such milestone in the absence of termination by RB,

Termination of this Addendum by either party does not, by itself, affect the remaining portions of the Agreement, nor does it affect any obligations of the parties under this Addendum which survive termination of the Addendum pursuant to the Agreement, including without limitation, the obligation of RB to pay for milestone payments as and when due under this Addendum.

4.5. Inclusions and Exclusions

For all milestones except the "Pre-Signing" and "Analytical Toolkit" milestones, any project activities involving the design of improved formulations prepared by MSX shall include stability analyses performed on sample materials front sample batches and formulations at the following time periods: [***]. The costs of the performance of stability analyses at these intervals are covered and included in the applicable milestone payment, and no additional payments by RB for these stability analyses shall be required. If, however, RB requests stability analyses at time intervals beyond those specified in the previous sentence, additional reasonable charges for the cost of performing the additional requested stability analyses would apply.

Capital purchases required for final solutions (e.g., "[***]") are not included in the milestone payments, and would be an additional charge. If purchased by MSX, the costs of such capital purchases would be passed through (without markup) to RB.

Except as expressly stated in this Section 4.5 (regarding extra stability tests, capital purchases for [***]) or in Section 4.4 (regarding termination fees), the milestone payments specified for each activity shall be all-inclusive for all project activities pertaining to a particular milestone to be completed. Work outside the scope of such project activities, and the additional fees associated therewith, would require a separate written agreement by both parties.

4.6. Optional Activities

The activities classed as "optional" in Appendix A can only be commenced upon prior written approval by RB.

4.7. API

RB shall timely provide MSX with all necessary API free of charge. In the event that RB fails to provide API meeting the API Specification in a timely manner and MSX can demonstrate that such failure caused delays in MSX's ability to perform its obligations under this Addendum and MSX notifies RB of such delays in writing at the time such delays are occurring, then MSX may deduct the amount of time its performance of a particular milestone activity was delayed by such failure from the total amount of time MSX took to complete a particular milestone activity for purposes of determining whether MSX receives a bonus or penalty for its performance of the particular milestone under Appendix A. Failure of RB to timely deliver API or at all shall not be used by RB as grounds to avoid its obligation to make any milestone payment provided for in this Addendum.

5. Project Management

5.1. MSX shall be responsible for the project management and for providing appropriate resources to deliver the project. RB shall be responsible for (1) attending monthly project update meetings either in person or via teleconference, (2) providing timely decisions on items requested by MSX, and (3) providing appropriate RB expertise on the project.

5.2. MSX is to present RB with a written project plan which shall be updated on a monthly basis.

5.3. Additionally, MSX shall give verbal updates on a monthly basis. This is to take place in the form of a monthly teleconference or alternatively face-to-face meeting with participation and attendance by the joint technical team ("JTT") and the supply team.

5.4. The JTT shall consist of an equal number of members front MSX and RB, shall guide the project team and provide technical support when needed.

6. Pricing of Commercial Products

Any products, designs or formulations which are developed pursuant to this Addendum or the performance of the Services herein and which are approved for commercial sale by at least one Regulatory Authority in at least one country or jurisdiction, or which have been supplied by RB or its agents to at least one customer (collectively, "Addendum Products") shall be considered "Products" as defined in Clause 1.1 of the Agreement and treated as Products for purposes of the Agreement and this Addendum except as expressly stated in the last two paragraphs of this Section 6.

Without limiting the foregoing, the parties agree that the Price payable by RB to MSX for any Addendum Product shall be the same as the then-current Cost of Goods Price for the "analogous Products" as set forth in Clauses 7.2 and 7.14 of the Agreement. An "analogous Product" refers to a Product containing the same amount of Buprenorphine API and dosage strength as an Addendum Product. As an illustrative example, if at a given time the then-current U.S. Cost of Goods Price per pouched single dose of pre-existing Product containing 2 mg Buprenorphine were $[***] and the then-current ROW Cost of Goods Price per pouched single dose of pm-existing Product containing 2 mg Buprenorphine were $[***], then the U.S. price of an Addendum Product containing an API of 2 mg Buprenorphine would also be $[***] per pouched single dose and the ROW price of an Addendum Product containing an API of 2 mg Buprenorphine would also be $[***] per pouched single dose). For the avoidance of doubt, the titles on pricing set forth in this paragraph apply both at the time of Product Launch of an Addendum Product and at all other times.

As the sole exception to the foregoing, in the event that the cost with respect to Raw Materials, Direct Labor, and/or manufacturing line time required to produce an Addendum Product is more or less expensive than that required to produce the analogous Product, then at the request of either party, the price of such Addendum Product shall be increased or decreased (as applicable) on a purely pass-through basis (without any markup by MSX) to account solely for the variations in costs with respect to Raw Materials, Direct Labor, Release Testing, or use of manufacturing line time; provided however, that MSX shall validate with competent evidence any increase in costs with respect to Raw Materials, Direct Labor, Release Testing, or use of manufacturing line time.

The parties acknowledge and agree that RB has completely fulfilled and satisfied its obligations under the Agreement to pay Royalties on Products sold in the U.S. Accordingly, RB shall have no obligation to make any royalty payments for any Products, including any Addendum Products, sold in the U.S. The parties acknowledge and agree that RB has continuing obligations to pay Royalties on the Net Sales Value of Products, including Addendum Products, sold in the ROW, pursuant to Section 7.4.2 of the Agreement.

7. CONFLICTING TERMS

In the event of a conflict between this Addendum and the Agreement, the Agreement shall govern. In the event of a conflict between this Addendum and an Appendix to this Addendum, this Addendum shall govern.

8. EFFECTIVE DATE

This Addendum shall be effective as of the Addendum Effective Date.

9. GOVERNING LAW; JURISDICTION

This Addendum shall be governed by and construed in accordance with the laws of the State of Delaware, United States of America, save as to conflict of law provisions, and the parties hereby agree to submit to the jurisdiction of the federal courts located in the State of Delaware.

IN WITNESS WHEREOF, the parties have caused this Addendum to be executed as of the Addendum Effective Date.

MonoSol Rx, LLC

/s/ Keith Kendall

Keith Kendall

Print Name

President - COO

Print Title

Reckitt Benckiser Pharmaceuticals, Inc.

/s/ Shaun Thaxter

Shaun Thaxter

Print Name

CEO

Print Title

APPENDIX A				
Milestone	**Milestone Amount**	**Target Delivery Date**	**Milestone Bonus Payment[1]**	**Milestone Reduction Penalty[2]**
[***]	[***]	[***]		
[***]	[***]	[***]		
Analytical Toolkit				
[***]	[***]	[***]	[***]	[***]
[***]				
[***]				
[***]	[***]	[***]	[***]	[***]
[***]	[***]			
[***]	[***]			
[***]	[***]			
[***]				
	[***]			
[***]				
[***]	[***]	[***]	[***]	[***]
[***]				
[***]				
[***]	[***]	[***]	[***]	[***]
[***]				
[***]	[***]	[***]	[***]	[***]
[***]				
[***]	[***]	[***]	[***]	[***]
[***]	[***]			
[***]	[***]			
[***]	[***]			
[***]				
	[***]			
[***]				
[***]	[***]	[***]	[***]	[***]
[***]		[***]		
[***]				
[***]	[***]	[***]	[***]	[***]

[***]

APPENDIX B

[***]

	0	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23
[***]	[***]																							
[***]							[***]																	
[***]	[***]	[***]																						
[***]	[***]									[***]				[***]							[***]			
[***]	[***]				[***]					[***]				[***]							[***]			
[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]	[***]

THIS EXHIBIT HAS BEEN REDACTED AND IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST. REDACTED MATERIAL IS MARKED WITH [***] AND HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

ADDENDUM B TO COMMERCIAL EXPLOITATION AGREEMENT:
SUBOXONE STRIP DEVELOPMENT AGREEMENT

This Addendum B to Commercial Exploitation Agreement: Suboxone Strip Development Agreement (this "Addendum B") is entered into as of this 30th day of July, 2014 the "("Addendum Effective Date"), by and between Reckitt Benckiser Pharmaceuticals Inc., with offices at 10710 Midlothian Turnpike, Suite 430, Richmond, VA 23235 ("RB") and MonoSol Rx, LLC, with offices at 30 Technology Drive, Warren, NJ 07059 ("MSX").

BACKGROUND AND PURPOSE OF PROJECT

A. The parties entered into a Commercial Exploitation Agreement dated August 15, 2008, as amended (the "Agreement").

B. The parties entered into Addendum A to the Agreement as of October 15, 2013 relating to the development and potential commercialization of improved formulations of the Products ("Appendix A").

C. Pursuant and subject to the Agreement, the parties now wish to amend Addendum A by entering into a further addendum to the Agreement relating to: (i) the accelerated completion of scale-up work and manufacture of the [***] registration batches of the current development formulation of [***] Suboxone Sublingual Film containing [***] and the new development formulation, to be mutually agreed, of [***] Suboxone Sublingual Film containing [***] (the "[***]") without [***] as outlined under Addendum A in order to facilitate an accelerated launch of Suboxone Sublingual Film in [***]; and (ii) a reformulation program for Suboxone Sublingual Film ([***] or [***] as determined by RB).

NOW, THEREFORE, for and in consideration of the mutual covenants contained herein, the parties hereto agree as follows:

1. Capitalized Terms

Capitalized terms used in this Addendum without definition shall have the same meanings ascribed to those terms in the Agreement.

2. Addendum is Part of Agreement

This Addendum B is hereby incorporated into and made a part of the Agreement as if fully set forth therein, and is subject to the terms of the Agreement.

Without limiting the foregoing and for the avoidance of doubt rights to and ownership of any inventions and other intellectual property developed or created as a result of the work performed hereunder shall be governed by the Intellectual Property Rights provisions of the Agreement.

3. Project Specifics

3.1. Scope of Work

Within the scope of work set forth in this Addendum B, the following shall apply;

MSX will undertake the scale-up and manufacture of [***] registration batches each for the [***] and [***] dosage strengths required by Addendum A at MSX's [***] facility ("[***]").

As part of the scale-up work for each dosage strength, MSX will use commercially reasonable efforts to identify critical process parameters and in-process controls with limits where a control is deemed necessary. Parameters and control limits will be mutually agreed upon in writing between MSX and RB.

As part of the scale-up work for each dosage strength, MSX will use commercially reasonable efforts to conduct an appropriate [***] experiment to establish the working range for [***]. RB and MSX will agree upon the experiment design in writing prior to the start of the experiment.

All methods utilized in the mutually agreed finished product specification (the "Finished Product Specification") will be validated prior to the delivery of the [***] data for Suboxone [***] Film registration batches.

MSX represents and warrants that it will perform the work under this Addendum B in accordance with prevailing industry standards. MSX further represents and warrants that all personnel who perform work under this Addendum B shall have appropriate training, experience and qualifications.

3.2. Timeline and Payments

Assuming this Addendum B is executed and delivered by the parties on or before August 1, 2014, the [***] registration batches will be placed on stability by October 22, 2014 and the [***] registration batches will be placed on stability by December 31, 2014. (If this Addendum B is not executed and delivered by August 1, then for each day after August 1 before this Addendum B is executed and delivered, the timelines of the previous sentence for placing the registration batches on stability will be pushed back by an equivalent number of days). RB acknowledges that the timeline represents an accelerated approach and that any additional batches (above and beyond the batches described in Section 3.1 or in Addendum A) required to obtain scale-up manufacturing at [***] may impact the timeline. MSX will use commercially reasonable efforts to ensure that the registration batches meet the Finished Product Specifications; however, RB acknowledges and agrees that the accelerated approach outlined in this Addendum B increases the risk of the registration batches failing to meet the Finished Product Specifications. RB will make prompt payment to MSX upon the completion of the registration batches as outlined under Addendum A regardless of the final performance of the batches unless the registration batch failure(s) are due to MSX's gross negligence, intentional misconduct or breach of this Addendum B, Addendum A or the Agreement.

The parties recognize that the accelerated scope of work and timeline requested by RB related to the [***] product under this Addendum B has a significant impact on MSX's business. In order to appropriately compensate MSX for this impact, RB will pay MSX [***]. MSX shall invoice RB and RB shall make payment [***] upon the execution and delivery of this Addendum B.

With the exception of the [***] milestone, all other milestones and payments contemplated under Addendum A and any existing statements of work between the parties shall continue to apply. (The [***] milestone, and any associated payment obligations to the extent not already paid on the part of RB, are hereby cancelled). MSX will credit RB [***] against the [***] for the [***] milestone payment already received by MSX under Addendum A.

RB and MSX will undertake a [***] for Suboxone Sublingual Film ([***] or [***] as determined by RB; the "[***]"). RB and MSX will build a project plan for the [***] and begin work by the earlier of (i) the reported outcome of the planned clinical PK study for Suboxone [***] Film or (ii) [***]. MSX will complete the Reformulation Program at a cost to RB of no more than [***] Thousand Dollars ($[***]).

Payments will be invoiced by MSX upon completion of all applicable criteria and will be due [***] after receipt of said invoice by RB.

For all purposes of this Addendum B, the term "completion" as applied to the fulfillment by MSX of any obligation of any obligations under either Addendum A or this Addendum B shall have the same meaning as defined in Section 4.1 of Addendum A.

In the event of any good faith disputes with respect to any such invoice, RB shall pay the undisputed portion of any such invoice within this time period.

3.3. Termination and Termination Fee

MSX may terminate this Addendum B by giving [***] written notice of termination to RB if RB shall fail to make any undisputed payment to MSX as and when due under this Addendum B and such failure remains uncured at the end of such [***] notice period.

RB may terminate this Addendum B at any time with or without cause by giving written notice of termination to MSX. In the event that RB terminates this Addendum B, or otherwise fails to start the Reformulation Program (defined in Appendix A) by October 1, 2015, RB shall pay MSX a termination fee of One Million Dollars ($1,000,000) upon the effective date of the applicable triggering event (such fee is in lieu of, and not in addition to, any otherwise applicable termination fee under Addendum A).

Termination of this Addendum B by either party does not, by itself, affect the remaining portions of the Agreement, including without limitation Addendum A, nor does it affect any obligations of the parties under this Addendum B which survive termination of this Addendum B pursuant to the Agreement, including without limitation, the obligation of RB to make payments as and when due under this Addendum B.

3.4. Inclusions and Exclusions

Work outside the scope of this Addendum B or the unmodified portions of Addendum A, and the additional fees associated therewith, would require a separate written agreement by both parties.

3.5. Quality

RB will identify and introduce to MSX the Qualified Person (the "QP") that RB has assigned to the launch of Suboxone Sublingual Film [***] as soon as is practicable. The QP will engage with MSX on a plan of action for preparing for the necessary [***] regulatory filings.

3.6. Product Risk

RB will be responsible for the product defect risks either associated intrinsically with the [***] or the associated manufacturing process, in each case provided it is carried out in compliance with the mutually agreed upon written process parameters and in-process controls as defined in MSX's manufacturing batch record.

Any recalls or regulatory actions taken as a result of such [***] product defects will be at RB's expense except to the extent such product defects result from MSX's failure to follow GMP or the mutually agreed upon written process parameters and in-process controls as defined in MSX's manufacturing batch record, or from MSX's gross negligence, willful misconduct or breach of the Agreement or any Addendum thereof.

Product defect risk for the [***] will revert to the terms set forth in the Agreement upon the earlier of (1) the commercial launch of [***] developed by MSX using an appropriate [***] (although this is not part of the immediate RB strategy) and (2) the usage of [***] doses in the marketplace.

4. CONFLICTING TERMS

In the event of a conflict between this Addendum B and the Agreement, the Agreement shall govern. In the event of a conflict between this Addendum B and Addendum A, this Addendum B shall govern.

5. EFFECTIVE DATE

This Addendum B shall be effective as of the Addendum Effective Date.

6. GOVERNING LAW; JURISDICTION

This Addendum B shall be governed by and construed in accordance with the laws of the State of Delaware, United States of America, save as to conflict of law provisions, and the parties hereby agree to submit to the jurisdiction of the federal courts located in the State of Delaware.

IN WITNESS WHEREOF, the parties have caused this Addendum B to be executed as of the Addendum Effective Date.

MonoSol Rx, LLC

/s/ Keith Kendall

Keith Kendall

Print Name

COO

Print Title

Reckitt Benckiser Pharmaceuticals, Inc.

/s/ Mark W. Crossley

Mark Crossley

Print Name

Global Finance Director

Print Title

THIS EXHIBIT HAS BEEN REDACTED AND IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST. REDACTED MATERIAL IS MARKED WITH [***] AND HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

AMENDMENT NO. 8
COMMERCIAL EXPLOITATION AGREEMENT

THIS AMENDMENT NO. 8 (this "**Amendment**") is made as of the 12th day of January 2017 (the "**Effective Date**") between:

PARTIES

(1) MonoSol Rx, LLC, a company organized and existing under the laws of Delaware with offices at 30 Technology Drive, Warren, New Jersey 07059 ("**MSX**"),

and

(2) Indivior Inc. (formerly, Reckitt Benckiser Pharmaceuticals Inc.), a company organized and existing under the laws of Delaware with offices at 10710 Midlothian Turnpike, Suite 430, Richmond, Virginia 23235 ("**Indivior**").

MSX and Indivior are each referred to herein sometimes as a "**Party**" and, collectively, as the "**Parties**".

WHEREAS, MSX and Indivior entered into a Commercial Exploitation Agreement, dated August 15, 2008, as amended from time to time (collectively referred to herein as the "**Agreement**"), pursuant to which, among other things, Indivior engaged MSX to be the exclusive manufacturer and supplier of the Products on the terms of the Agreement and MSX agreed to manufacture and supply the Products to Indivior on the terms of the Agreement; and

WHEREAS, Indivior is interested in commercializing and marketing an authorized generic version of the Products through an identified authorized third party distributor; and

WHEREAS, Indivior desires to engage MSX to manufacture and supply the authorized generic Products, and MSX desires to manufacture and supply the authorized generic Products, on the terms and conditions of the Agreement and this Amendment.

NOW, THEREFORE, in consideration of the premises and the mutual agreements, covenants, and conditions set forth in this Amendment, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound hereby, agree to amend and modify certain terms and conditions of the Agreement as set forth in this Amendment.

IT IS AGREED as follows:

A. **Definitions**. Capitalized terms used in this Amendment without definition shall have the respective meanings ascribed thereto in the Agreement. For purposes of the Agreement, the defined term "Products" shall be deemed to include the authorized generic Products and Schedule Three of the Agreement shall be deemed to be revised to list the authorized generic Products and, as such, whenever the term Product or Products is used in the Agreement, said terms shall be construed to mean and include the authorized generic Products and be subject to all of the terms and conditions of the Agreement.

B. **Project Fee**. In consideration for the manufacture and supply of the authorized generic Products, Indivior shall pay MSX, in addition to the Price for the authorized generic Products in accordance with Section E below, the sum of six million dollars ($6,000,000) payable as follows:

1. Four million dollars ($4,000,000) previously paid by Indivior to MSX on May 25, 2016 upon commencement of manufacture of the authorized generic Products; and

2. Two million dollars ($2,000,000) upon (i) execution of this Amendment and (ii) execution of the agreement referred to in Section D below.

C. **Restrictive Covenant**. Notwithstanding anything to the contrary contained in this Agreement, the parties agree that, in addition to, and not in limitation of, any other restrictive covenants contained in the Agreement, during the last [***] months of the Term, and for a period of [***] after the expiration or termination of the Term, neither party shall, directly or indirectly, enter into any agreement or arrangement with [***] or any of the Affiliates of [***], or its or their respective successors and/or assigns, for the development, manufacture, marketing, promotion, distribution, offering for sale, sale, offering for license, license or similar activity of the Products in the Field. For the avoidance of doubt, the Parties agree that nothing contained in this Restrictive Covenant is intended to prohibit or prevent the continued manufacture and supply of authorized generic Product by MSX in accordance with the Agreement and this Amendment during the last [***] of the Term.

D. **Delivery of the Products**.

1. The following shall be added to **Clause 5.1**:

   For the avoidance of doubt, MSX agrees to deliver authorized generic Products directly to Indivior in accordance with the terms of **Clause 5** of the Agreement. Indivior shall ensure that any designated authorized generic third party distributor shall enter into a non-disclosure agreement with MSX and Indivior, in form and substance acceptable to MSX, which obligates such designated authorized generic third party distributor, among other things, to maintain the confidentiality of any MSX Confidential Information that may be disclosed by or on behalf of MSX pursuant to this **Clause 5**.

E. **Pricing**. For the avoidance of doubt, pricing for the supply of authorized generic Products equals the current U.S. Cost of Goods Price set forth below:

	Cost/strip
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

The Price payable by Indivior to MSX for the authorized generic Products shall be adjusted according to Section 7.3 of the Agreement.

F. **Batch Tracking System**. The Parties acknowledge that MSX shall not be obligated to establish and maintain a batch-tracking system that identifies the authorized generic Products for any purpose except as required by the FDA.

G. **No Third Party Beneficiaries**. This Amendment is for the sole benefit of the Parties and their respective successors and assigns permitted under the Agreement, and nothing herein, express or implied, is intended to or shall confer upon any other person or entity (including, without limitation, any authorized third party distributor of authorized generic Products) any legal or equitable right, benefit or remedy of any nature whatsoever under the Agreement or this Amendment by reason of or with respect to this Amendment.

H. **Governing Law**. This Amendment shall be governed by and construed in accordance with the laws of the State of Delaware, United States of America, save as to conflict of law provisions, and the parties hereby agree to submit to the jurisdiction of the federal courts located in the State of Delaware.

I. **Survival**. Except as expressly set forth herein, all other terms and provisions of the Agreement shall remain in full force and effect without modification or change.

Signed for and on behalf Indivior Inc.

/s/ Cary Claiborne

Name: Cary Claiborne
Title: CFO
Date: 1/20/17

Signed for and on behalf of MonoSol Rx, LLC

/s/ Keith Kendall

Name: Keith Kendall
Title: CEO
Date: 1/16/17

Exhibit 10.10

THIS EXHIBIT HAS BEEN REDACTED AND IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST. REDACTED MATERIAL IS MARKED WITH [***] AND HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

AGREEMENT

This Agreement (this "Agreement"), dated as of September 24, 2017, is by and between MonoSol Rx, LLC, a Delaware limited liability company ("MonoSol"); and Indivior Inc., a Delaware corporation, and Indivior UK Limited, a corporation organized under the laws of England and Wales, as successors in interest to Reckitt Benckiser Pharmaceuticals Inc. and RB Pharmaceuticals Limited, respectively (collectively, "Indivior").

MonoSol and Indivior are each sometimes referred to herein individually as a "Party" and are referred to collectively as the "Parties."

WITNESSETH:

WHEREAS, MonoSol and Indivior Inc. are parties to the Commercial Exploitation Agreement, dated August 15, 2008, as amended (the "Commercial Exploitation Agreement"); and

WHEREAS, MonoSol, in the Commercial Exploitation Agreement, has granted certain exclusive rights to Indivior Inc. and its Affiliates, including an exclusive license under MonoSol patents to use and sell Suboxone® (buprenorphine and naloxone) film, a pharmaceutical product containing the active ingredients buprenorphine hydrochloride and naloxone hydrochloride; and

WHEREAS, Indivior Inc., in the Commercial Exploitation Agreement, has granted certain exclusive rights to MonoSol including an exclusive right to manufacture Suboxone® (buprenorphine and naloxone) film, a pharmaceutical product containing the active ingredients buprenorphine hydrochloride and naloxone hydrochloride; and

WHEREAS, the Parties seek to clarify the scope of their relationship, including certain rights and obligations that may be impacted by the possible sale, offer for sale, or distribution of a Generic Buprenorphine Product, as defined below, in the United States, by a Third Party, as defined below.

NOW, THEREFORE, for good and valuable consideration, the sufficiency and receipt of which are hereby acknowledged, the Parties intending to be legally bound do hereby agree as follows:

ARTICLE 1: DEFINITIONS

1.1. The capitalized terms used in this Agreement shall have the meanings defined in this Article or elsewhere in this Agreement.

1.2. Unless the context requires otherwise, words referred to in the singular include the plural and vice versa, the words “include,” “includes” and “including” will be deemed to be followed by the phrase “without limitation” (unless already present), the words “herein,” “hereof’ and “hereunder,” and words of similar import, will be construed to refer to this Agreement in its entirety and not to any particular provision hereof, and the word “or” is used in the inclusive sense (and/or).

1.3. The term “Affiliate” shall mean, with respect to a Party, any entity or person that, directly or indirectly through one or more intermediaries, controls, is controlled by, or is under common control with such Party at any time for so long as such entity or person controls, is controlled by or is under common control with such Party. For purposes of this definition, “control” means (a) ownership, directly or through one or more intermediaries, of (i) more than fifty percent (50%) of the shares of stock entitled to vote for the election of directors, in the case of a corporation, or (ii) more than fifty percent (50%) of the equity interests in the case of any other type of legal entity or status as a general partner in any partnership, or (b) any other arrangement whereby an entity or person has the right to elect a majority of the board of directors or equivalent governing body of a corporation or other entity or the right to direct the management and policies of a corporation or other entity.

1.4. The term “Approved Suboxone Product” shall mean any product sold, offered for sale or distributed pursuant to New Drug Application (“NDA”) No. 22-410.

1.5. The term “Generic Buprenorphine Product” shall mean a film dosage drug product containing the buprenorphine and naloxone moieties that is sold, offered for sale or distributed under an ANDA or an application pursuant to 21 U.S.C. § 355(b)(2) that refers to the Approved Suboxone Product as the reference-listed drug.

1.6. The term “Third Party” shall mean any entity or person that is not a Party or an Affiliate of a Party.

ARTICLE 2: PAYMENTS FROM INDIVIOR TO MONOSOL

2.1. Five (5) business days following the date the Parties fully execute this Agreement, Indivior agrees to make a non-refundable payment of USD$17,000,000 (seventeen million U.S. dollars) to MonoSol.

2.2. On February 1, 2018, Indivior will make a non-refundable payment of USD$8,000,000 (eight million U.S. dollars) to MonoSol.

2.3. Starting on January 1, 2018, Indivior shall make [***] payments to MonoSol of USD$[***] ([***] U.S. dollars) [***]; *provided, however*, that the payment obligation on Indivior pursuant to this Section shall immediately cease, and be null and void, on the first date a Third Party sells, offers for sale, or distributes an unlicensed Generic Buprenorphine Product in the United States.

2.4. Starting on April 1, 2019, and through and including the first date a Third Party sells, offers for sale, or distributes a Generic Buprenorphine Product in the United States, Indivior shall make [***] payments equal to [***] of the net revenue earned by Indivior on sales of Suboxone sublingual film in the United States for the previous [***] with payment made within [***] after the start of the current [***], where:

(A) the total amount Indivior pays to MonoSol in a calendar year shall be not less than USD$[***] U.S. dollars) (“Minimum Annual Payment”), and

(B) Notwithstanding the foregoing, Indivior's obligation to make the Minimum Annual Payment shall immediately cease, and be null and void, once the total amount of the payments made from Indivior to MonoSol under this Article 2.4 is equal to USD$[***] U.S. dollars).

(C) MonoSol shall have annual audit rights for royalty payments as outlined in the Commercial Exploitation Agreement.

2.5. On the date a new patent issues to MonoSol or a new claim is asserted by MonoSol from an existing patent and/or a divisional, reissue, continuation, or continuation-in-part of a MonoSol patent application with new claims that cover Suboxone® (buprenorphine and naloxone) film, Indivior shall make a one-time, non-refundable payment of USD$[***] U.S. dollars) to MonoSol in [***] installments; provided, that the applicable conditions to payment are satisfied. The [***] installment of USD$[***] ([***] U.S. dollars) shall be paid within [***] days of the date a new patent issues to MonoSol or a new claim is asserted by MonoSol from an existing patent and/or a divisional, reissue, continuation, or continuation-in-part of a MonoSol patent application with new claims that cover Suboxone® (buprenorphine and naloxone) film, and the [***] installment of USD$[***] ([***] U.S. dollars) shall be paid within [***] days after the first (1st) anniversary of the issuance provided the new patent or new claim is valid and enforceable on this anniversary date. Within [***] days of the date a second new patent issues to MonoSol or a second new claim is asserted by MonoSol from a different existing patent and/or a divisional, reissue, continuation, or continuation-in-part of a MonoSol patent application with new claims that cover Suboxone® (buprenorphine and naloxone) film, Indivior shall make a [***] payment of USD$[***] U.S. dollars) to MonoSol in [***] installments; provided, that the applicable conditions to payment are satisfied. The [***] installment of USD$[***] U.S. dollars) shall be paid within [***] days of the date a second new patent issues to MonoSol or a second new claim is asserted by MonoSol from a different existing patent and/or a divisional, reissue, continuation, or continuation-in-part of a MonoSol patent application with new claims that cover Suboxone® (buprenorphine and naloxone) film, and the [***] installment of USD$[***] ([***] U.S. dollars) shall be paid within [***] days after the first (1st) anniversary of the issuance provided the second new patent or second new claim is valid and enforceable on this anniversary date. [***].

2.6. In the event a Third Party sells, offers for sale, or distributes a licensed Generic Buprenorphine Product in the United States pursuant to a settlement agreement with Indivior prior to January 1, 2023, then Indivior will make a one-time non-refundable payment equal to USD$75,000,000 (seventy five million U.S. dollars), minus total cumulative payments paid by Indivior to MonoSol under this Agreement as of the first date of entry of said licensed Third Party Generic Buprenorphine Product, paid in [***] installments by January 1, 2023, beginning [***] days following the first date of entry of a licensed Third Party Generic Buprenorphine Product. Notwithstanding the foregoing, the payment obligation on Indivior pursuant to this Section shall cease, and be null and void, if the sale, offer for sale, or distribution of a licensed Third Party Generic Buprenorphine Product is triggered by the sale, offer for sale, or distribution of an unlicensed Third Party Generic Buprenorphine Product.

2.7. On January 1, 2023, Indivior will make a non-refundable payment of USD$[***] ([***] U.S. dollars) to MonoSol; provided, however, that if the first date a Third Party sells, offers for sale, or distributes an unlicensed Generic Buprenorphine Product in the United States occurs before January 1, 2023, then the payment obligation of Indivior pursuant to this Section shall immediately cease, and be null and void.

2.8. Notwithstanding the foregoing payment provisions, the Parties agree and acknowledge that the total cumulative amounts payable under the terms of this Agreement by Indivior to MonoSol shall be capped at USD$75,000,000 (seventy five million U.S. dollars), provided the new patents or new claims pursuant to Article 2.5 hereof are issued, or be capped at USD$[***] U.S. dollars), if no new patents or new claims pursuant to Article 2.5 hereof are issued, and shall not, under any circumstances, exceed the applicable stated amount.

2.9. Notwithstanding the payment obligations set forth herein, if, at any time during the term of this Agreement, a Third Party sells, offers for sale, or distributes an unlicensed Generic Buprenorphine Product in the United States where Indivior has legal recourse to challenge the sale, offer for sale, or distribution of said product at the United States Court of Appeals for the Federal Circuit ("At-Risk Launch"), then any payments that would otherwise have become due under this Agreement by Indivior from the date of such At-Risk Launch through the date that the Federal Circuit Court of Appeals issues a ruling enjoining said Third Party from selling, offering for sale or distributing a Generic Buprenorphine Product ("At-Risk Launch Period") shall immediately cease, and be null and void, such that no further payments under this Agreement from Indivior to MonoSol shall be required to be made during the At-Risk Launch Period. If [***], any payments cancelled under this Agreement during such At-Risk Launch Period, shall be paid to MonoSol by Indivior [***] within [***] days of [***]. For clarity, Indivior's obligation to pay MonoSol for any payments cancelled during the At-Risk Launch period shall not exceed [***]. For further clarity, once the At-Risk Launch Period ends, all payments owed by Indivior to MonoSol under this Agreement shall be reinstated.

2.10. Notwithstanding the payment obligations set forth herein, if, at any time during the term of this Agreement, a Third Party sells, offers for sale, or distributes an unlicensed Generic Buprenorphine Product in the United States where Indivior has no legal recourse to challenge the sale, offer for sale, or distribution of said product at the Federal Circuit Court of Appeals, then Indivior's payment obligations under this Agreement shall immediately cease, and be null and void, such that no further payments under this Agreement from Indivior to MonoSol shall be required. For the sake of clarity, the Commercial Exploitation Agreement shall remain in effect for the term thereof.

2.11. Indivior agrees to use reasonable efforts, with the objective of prevailing, to exercise its rights to enforce and protect intellectual property relating to Generic Buprenorphine Products. If an unauthorized and/or unlicensed Third Party sells, offers for sale, or distributes a Generic Buprenorphine Product in the United States, but later discontinues such activities as a result of Indivior's exercising its rights to enforce and protect intellectual property regarding those activities, whether through (1) the issuance of an injunction or damages award from a court of competent jurisdiction, or (2) the resolution of intellectual property rights in an agreement between the Third Party and Indivior, all payments owed to MonoSol under this Article 2 shall be retroactively reinstated.

ARTICLE 3: LICENSE AND ENFORCEMENT

3.1. Subject to the limitations of Article 3.2 below, if and to the extent that Indivior does not already hold the sole, exclusive and irrevocable right and entitlement to pursue, assert, enforce, litigate, settle and resolve all causes of action (whether known or unknown or whether currently pending, filed or otherwise) and all other enforcement rights involving Generic Buprenorphine Products ("the Enforcement Rights"), MonoSol, for itself and its Affiliates, hereby confirms that Indivior and its Affiliates hold and may exercise all such Enforcement Rights, and in connection with any settlement or other resolution of any such causes of action may sublicense rights to make, have made, use, sell or import a Generic Buprenorphine Product under any of the MonoSol patents, present and future, licensed to Indivior under the Commercial Exploitation Agreement. At the request of Indivior, MonoSol will execute and deliver such other instruments and do and perform such other acts as may be necessary or desirable for effectuating or confirming the provisions of this Article. For clarity, this foregoing Article 3.1 does not alter or affect the supply and/or manufacturing arrangements between Indivior and MonoSol, as provided for under the Commercial Exploitation Agreement, with respect to the Approved Suboxone Product, and this foregoing Article 3.1 does not change the rights and obligations of Indivior and MonoSol under the Commercial Exploitation Agreement with respect to MonoSol's supply and/or manufacturing of the Approved Suboxone Product. If Indivior terminates this Agreement, and Indivior seeks to engage another party to manufacture the Approved Suboxone Product, nothing in this Agreement prevents MonoSol from seeking to enforce its intellectual property rights in suing either Indivior or that third party manufacturer, or both, consistent with the Commercial Exploitation Agreement, nor does anything in this Agreement prevent Indivior from contesting any such suit brought by MonoSol. For further clarity, nothing in this Agreement prohibits MonoSol, upon termination of the Commercial Exploitation Agreement, from manufacturing any product in the Field, as defined in the Commercial Exploitation Agreement, for anyone anywhere in the world, nor does anything in this Agreement prevent Indivior from contesting MonoSol's entitlement to engage in such manufacturing.

3.2. MonoSol agrees not to assert its rights regarding any agreements by Indivior with any Third Party under which a sale, offer for sale, or distribution of a Generic Buprenorphine Product by that Third Party would occur on or after [***]. For the sake of clarity, MonoSol does not waive any such rights regarding any agreements by Indivior with any Third Party under which a sale, offer for sale, or distribution of a Generic Buprenorphine Product by a Third Party would occur prior to [***].

ARTICLE 4: BREACH AND INDEMNIFICATION

4.1. Indivior hereby agrees to indemnify MonoSol and to hold it harmless with respect to all costs, including attorneys' fees and expert fees, and any penalties or monetary damages arising out of or relating to any investigation, enforcement action, and administrative or court proceeding regarding or relating to this Agreement under the Clayton Act § 7A, 15 U.S.C. § 18a and its implementing rules and regulations. For clarity, this Article 4.1 does not apply to any pre-existing investigations, enforcement actions, and administrative or court proceedings and applies only to the terms of this Agreement.

ARTICLE 5: MISCELLANEOUS

5.1. Confidentiality: Except as (a) required by statute, ordinance or regulation, (b) required pursuant to compulsory legal process, or (c) necessary for the exercise of the rights granted to the Parties under this Agreement, neither the Parties nor their Affiliates shall publicly announce or otherwise disclose to Third Parties any of the terms of this Agreement without the prior written approval of the other Party, not to be unreasonably withheld, conditioned or delayed. If a Party intends to disclose information relating to this Agreement because it is required to do so in order to comply with a statute, ordinance or regulation or compulsory legal process, including, without limitation, its reporting requirements under the Securities Exchange Act of 1934, as amended, such Party shall give the other Party at least three (3) business days' prior notice in writing of the text of the intended disclosure, unless such statute, ordinance, regulation or compulsory legal process would require earlier disclosure, in which event the notice shall be provided as early as practicable. A Party that determines that it is required to file this Agreement with the Securities and Exchange Commission or any other governmental authority, including any court proceeding, shall request confidential treatment with respect to the terms of this Agreement, shall consult in good faith with the other Party regarding such confidential treatment and shall use commercially reasonable efforts to have redacted from any publicly available version such provisions as the Parties may agree. Notwithstanding anything to the contrary above, each Party may disclose the terms of this Agreement to its respective Affiliates, and its and their respective insurers, lenders, attorneys, accountants, and prospective and actual acquirers, subject to such Affiliates, insurers, lenders, attorneys, accountants and prospective and actual acquirers undertaking to keep the terms of this Agreement strictly confidential in accordance with confidentiality terms at least as restrictive as the terms hereof.

5.2. Notice: Any notice or other communication to be given under this Agreement shall be given in the same manner identified in Article 2.1 of the Commercial Exploitation Agreement.

5.3. Modification: This Agreement may only be amended, modified, or varied by the Parties by an instrument in writing signed on behalf of each of the Parties.

5.4. Waiver: No waiver of a breach, failure of any condition, or any right or remedy, contained in or granted by the provisions of this Agreement shall be effective unless it is in writing and signed by the Party waiving the breach, failure, right or remedy. No waiver of any breach, failure, right or remedy shall be deemed a waiver of any other breach, failure, right or remedy, whether or not similar, nor shall any waiver constitute a continuing waiver unless the writing so specifies.

5.5. No Agency: Nothing in this Agreement shall constitute or be deemed to constitute the creation of a partnership, agency, or employer/employee relationship between the parties.

5.6. Entire Agreement: This Agreement represents the entire understanding and agreement between the Parties with regard to the matters addressed herein.

5.7. Enforceability: If any provision of this Agreement is held by any court or other competent authority to be invalid or unenforceable in whole or in part for any reason, the Parties agree to use commercially reasonable efforts to negotiate a provision, in replacement of the provision held illegal, unenforceable, or invalid, that is consistent with applicable law and accomplishes, as nearly as possible, the original intention of the Parties with respect thereto. In any event, the provision held illegal, unenforceable, or invalid shall be deemed severed from this Agreement and the validity of the other provisions and the remainder of the provision in question shall not be affected.

5.8. Counterparts. This Agreement may be executed in any number of counterparts, and through pdf, facsimile or photocopy signatures. Each counterpart shall be deemed an original instrument, but all counterparts together shall be considered as one and the same agreement.

5.9. Governing Law: This Agreement and the rights and obligations of the Parties under this Agreement shall be governed and construed in accordance with the laws of the State of Delaware, without regard to its choice-of-law or conflicts-of-law principles that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction, and the Parties agree to submit to the jurisdiction of the federal courts located in the State of Delaware.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the Parties, through their authorized officers, have executed this Agreement as of the Signing Date.

Signed for and on behalf of Indivior Inc.:

By:	/s/ Shaun Thaxter
Name:	Shaun Thaxter
Title:	CEO
Date:	9/23/17

Signed for and on behalf of Indivior UK Limited:

By:	/s/ Richard Simkin
Name:	Richard Simkin
Title:	CCO
Date:	9/23/17

Signed for an on behalf of MonoSol Rx, LLC:

By:	/s/ Keith Kendall
Name:	Keith Kendall
Title:	CEO
Date:	9/24/17

Exhibit 10.14

AQUESTIVE THERAPEUTICS, INC.
2018 EQUITY INCENTIVE PLAN

Adopted by the Board of Directors June 15, 2018

Approved by the Stockholders June 27, 2018

AQUESTIVE THERAPEUTICS, INC.

2018 EQUITY INCENTIVE PLAN

Section 1. Purpose of the Plan. The purpose of the 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 the Company's success and a closer identity with it, and to encourage ownership of the Company's shares by such Employees, Consultants and Non-Employee Directors.

Section 2. Definitions. As used herein, the following definitions shall apply:

2.1. "*Award*" means the grant of Options, SARs, Restricted Stock, Restricted Stock Units, Performance Stock, Performance Stock Units and Other Stock-Based Awards under the Plan.

2.2. "*Award Agreement*" means the written agreement, instrument or document evidencing an Award.

2.3. "*Board*" means the Board of Directors of the Company.

2.4. "*Cause*" means, as determined in the sole discretion of the Board or Committee,

(a) if the applicable Participant is party to an effective employment, consulting, severance or similar agreement with the Company or a Subsidiary, and such term is defined therein, "Cause" shall have the meaning provided in such agreement;

(b) if the applicable Participant is not a party to an effective employment, consulting, severance or similar agreement or if no definition of "Cause" is set forth in the applicable employment, consulting, severance or similar agreement, "Cause" shall have the meaning provided in the applicable Award Agreement;

(c) if neither (a) nor (b) applies, then "Cause" shall mean (i) engaging in (A) willful or gross misconduct or (B) willful or gross neglect; (ii) the indictment for, conviction of, or plea of guilty or no contest to, a felony, or a crime involving any of the following: moral turpitude, dishonesty, breach of trust, unethical business conduct or a crime involving the Company or any of its Subsidiaries; (iii) fraud, misappropriation or embezzlement; (iv) the Participant's abuse of illegal drugs or other controlled substances or the Participant's habitual intoxication while providing services for the Company or any of its Subsidiaries; or (v) the Participant's material breach of any written policy of the Company or any of its Subsidiaries.

2.5. "*Change in Control*" means, unless otherwise provided in an Award Agreement, after the Effective Date:

(a) the acquisition in one or more transactions (whether by purchase, merger, amalgamation or otherwise) by any "Person" (as such term is used for purposes of Section 13(d) or Section 14(d) of the Exchange Act, but excluding, for this purpose, (i) the Company or any of its Subsidiaries, (ii) any employee benefit plan of the Company or any of its Subsidiaries or (iii) an entity owned, directly or indirectly, by the stockholders of the Company in substantially the same proportions as their ownership of shares of the Company) of "Beneficial Ownership" (within the meaning of Rule 13d-3 under the Exchange Act), of more than fifty percent (50%) of the combined voting power of the Company's then outstanding voting securities;

(b) a change in the composition of the Board such that the individuals who as of any date constitute the Board (the "*Incumbent Board*") cease to constitute a majority of the Board at any time during the 12-month period immediately following such date; provided, however, that if the election, or nomination for election by the Company's stockholders, of any new director was approved by a vote of at least a majority of the Incumbent Board, such new director shall be considered as a member of the Incumbent Board, and provided further that any reductions in the size of the Board that are instituted voluntarily by the Incumbent Board shall not constitute a Change in Control, and after any such reduction the "Incumbent Board" shall mean the Board as so reduced;

(c) a complete liquidation or dissolution or winding up of the Company (other than pursuant to a transaction in which the assets of the Company are distributed to an entity owned, directly or indirectly, by the stockholders of the Company in substantially the same proportions as their ownership of shares of the Company); or

(d) the sale, directly or indirectly, of all or substantially all of the Company's assets (determined on a consolidated basis), other than to a Person described in clauses (i), (ii) or (iii) of Section 2.5(a) above.

Notwithstanding the foregoing, a restructuring, reorganization or similar or analogous event in which the stockholders of the Company immediately before such event have "Beneficial Ownership" (within the meaning of Rule 13d-3 under the Exchange Act) of the Company (or its successor) immediately after such event in substantially the same proportions as their ownership of Shares of the Company immediately before such event shall not constitute a Change in Control.

2.6. "*Code*" means the Internal Revenue Code of 1986, as amended.

2.7. "*Company*" means Aquestive Therapeutics, Inc., a Delaware corporation, or any successor corporation or company.

2.8. "*Committee*" means the Compensation Committee of the Board, provided that the Committee shall at all times have at least two members, each of whom shall be a "non-employee director" as defined in Rule 16b-3 under the Exchange Act and an "independent director" under the rules of any applicable stock exchange.

2.9. "*Consultant*" means a natural person (within the meaning of Form S-8 of the Securities Act) who provides bona fide services to the Company or any of its Subsidiaries other than in connection with the offer or sale of Shares or other securities or shares in a capital-raising transaction and is not engaged in activities that directly or indirectly promote or maintain a market for the Company's Shares or other securities.

2.10. "*Disability*" means,

(a) if the applicable Participant is party to an effective employment, consulting, severance or similar agreement with the Company or a Subsidiary, and such term is defined therein, "Disability" shall have the meaning provided in such agreement;

(b) if the applicable Participant is not a party to an effective employment, consulting, severance or similar agreement or if no definition of "Disability" is set forth in the applicable employment, consulting, severance or similar agreement, "Disability" shall have the meaning provided in the applicable Award Agreement;

(c) if neither (a) nor (b) applies, then "Disability" shall mean the inability to engage in any substantial gainful activity by reason of any physical or mental impairment which can be expected to result in death or which has lasted or can be expected to last for a continuous period of not less than 12 months.

2.11. "*Effective Date"* means the date that the Plan is approved by the stockholders of the Company.

2.12. "*Employee*" means an officer or other employee of the Company or a Subsidiary, including without limitation a director who is such an employee.

2.13. "*Exchange Act*" means the Securities Exchange Act of 1934, as amended.

2.14. "*Fair Market Value*" means, on any given date (i) if the Shares are listed on any established stock exchange or a national market system, including without limitation the NASDAQ Global Market, the closing sales price for such Shares as quoted on such exchange or system on the day of determination, as reported in *The Wall Street Journal* or such other source as the Committee deems reliable (or, if no closing sales price was reported on that date, on the last trading date such closing sales price was reported); (ii) if clause (i) does not apply, then if the Shares are regularly quoted by a recognized securities dealer but selling prices are not reported, the mean between the high bid and low asked prices for the Shares on the day of determination (or, if no bids and asks were reported on that date, on the last trading date such bids and asks were reported); or (iii) if neither clause (i) nor clause (ii) applies, such value as the Committee in its discretion may in good faith determine in accordance with Section 409A of the Code and the regulations thereunder (and, with respect to Incentive Stock Options, in accordance with Section 422 of the Code and the regulations thereunder).

2.15. "*Good Reason*" means,

(a) if the applicable Participant is party to an effective employment, consulting, severance or similar agreement with the Company or a Subsidiary, and such term is defined therein, "Good Reason" shall have the meaning provided in such agreement;

(b) if the applicable Participant is not a party to an effective employment, consulting, severance or similar agreement or if no definition of "Good Reason" is set forth in the applicable employment, consulting, severance or similar agreement, "Good Reason" shall have the meaning provided in the applicable Award Agreement;

(c) if neither (a) nor (b) applies, then "Good Reason" shall mean, following a Change in Control, (i) a material diminution in the Participant's base salary or target bonus, in either case, from that in effect immediately prior to such Change in Control; (ii) a material diminution in the Participant's authority, duties, or responsibilities, in any case, from those as in effect immediately prior to such Change in Control; or (iii) a relocation of the Participant's principal place of employment or service to a location that increases his/her one-way commute distance by more than thirty-five (35) miles from that in effect immediately prior to such Change in Control provided, in all cases of clauses (i) through (iii) above, that the Participant has notified the Committee in writing of such condition within ninety (90) days following its first occurrence, the Company has failed to remedy such condition within thirty (30) days following the date of such notice, and the Participant terminates his or her employment or service with the Company or any if its Subsidiaries within ninety (90) days following the end of such thirty-day cure period.

2.16. "*Incentive Stock Option*" means an Option or portion thereof that (i) is designated as an Incentive Stock Option and (ii) meets the requirements of an incentive stock option as defined in Section 422 of the Code.

2.17. "*Incumbent Director*" means a director who either (i) is a member of the Board as of the Effective Date or (ii) is elected, or nominated for election, to the Board with the affirmative votes of at least a majority of the Incumbent Directors at the time of such election or nomination.

2.18. "*Non-Employee Director*" means a member of the Board or any board of directors or managers (or similar body) of a Subsidiary, in any case, who is not an Employee.

2.19. "*Non-Qualified Option*" means an Option or portion thereof that is designated as not being an Incentive Stock Option or that does not otherwise qualify as an Incentive Stock Option.

2.20. "*Option*" means a right granted under Section 6.1 of the Plan to purchase a specified number of Shares at a specified price. An Option may be an Incentive Stock Option or a Non-Qualified Option; provided, however, that unless otherwise explicitly stated in an Award Agreement, each Option is hereby designated as a Non-Qualified Option.

2.21. "*Other Stock-Based Award*" means a right granted under Section 6.7 of the Plan.

2.22. "*Participant*" means any Employee, Non-Employee Director or Consultant who receives an Award.

2.23. "*Performance Goal*" means any goal established by the Committee in its sole discretion, the attainment of which is substantially uncertain at the time such goals are established. If the Committee determines that a change in the business, operations, corporate structure or capital structure of the Company or a Subsidiary, or the manner in which any such entity conducts its business, or other events or circumstances render any Performance Goal unsuitable, the Committee may modify such Performance Goal and/or the related minimum, target, maximum and/or other levels of achievement, in whole or in part, as the Committee deems appropriate and equitable.

2.24. "*Performance Period*" means the period selected by the Committee during which the performance of the Company, any Subsidiary, any department of the Company or any Subsidiary, or any individual is measured for the purpose of determining the extent to which a Performance Goal has been achieved.

2.25. "*Performance Stock*" means Shares awarded by the Committee under Section ~~6.6~~ of the Plan that are subject to one or more Performance Goals.

2.26. "*Performance Stock Unit*" means the right granted under Section 6.5 of the Plan to receive, on the date of settlement, one Share or an amount equal to the Fair Market Value of one Share, which right is subject to one or more Performance Goals. Performance Stock Units may be settled in cash, Shares or any combination thereof; provided, however, that unless otherwise provided in an Award Agreement, Performance Stock Units shall be settled in Shares.

2.27. "*Person*" means an individual, corporation, partnership, association, limited liability company, estate or other legal entity.

2.28. "*Plan*" means the Aquestive Therapeutics, Inc. 2018 Equity Incentive Plan herein set forth, as amended from time to time.

2.29. "*Restricted Stock*" means a Share awarded by the Committee under Section 6.3 of the Plan.

2.30. "*Restricted Stock Unit*" means the right granted under Section 6.4 of the Plan to receive, on the date of settlement, an amount equal to the Fair Market Value of one Share. An Award of Restricted Stock Units may be settled in cash, Shares or any combination of the foregoing, as determined by the Committee in its sole discretion; provided, however, that unless otherwise provided in an Award Agreement, Restricted Stock Units shall be settled in Shares.

2.31. "*Restriction Period*" means the period during which Performance Stock, Performance Stock Units, Restricted Stock and Restricted Stock Units are subject to forfeiture.

2.32. "*Retirement*" means a Participant's termination of employment with the Company and its Subsidiaries for any reason (other than death or by the Company or a Subsidiary for Cause) after the Participant has attained age 60 with at least 10 years of continuous employment with the Company or a Subsidiary thereof.

2.33. "*SAR*" means a stock appreciation right awarded by the Committee under Section 6.2 of the Plan.

2.34. "*Securities Act*" means the Securities Act of 1933, as amended.

2.35. "*Share*" means one share of the Company's common stock, par value $0.001 per share.

2.36. "*Subsidiary*" means any corporation, partnership, joint venture, company or other business entity of which 50% or more of the outstanding voting power is beneficially owned, directly or indirectly, by the Company.

2.37. "*Ten Percent Stockholder*" means a Person who on any given date owns, either directly or indirectly (taking into account the attribution rules contained in Section 424(d) of the Code), shares possessing more than 10% of the total combined voting power of all classes of shares of the Company or a Subsidiary.

Section 3. Eligibility. Any Employee, Non-Employee Director or Consultant shall be eligible to receive an Award under the Plan, as determined in the sole discretion of the Committee; provided, however, that only persons who are Employees may be granted Incentive Stock Options.

Section 4. Administration and Implementation of the Plan.

4.1. The Plan and all Award Agreements shall be administered by the Committee. Any action of the Committee in administering the Plan or an Award Agreement shall be final, conclusive and binding on all Persons, including without limitation the Company, its Subsidiaries, Participants, Persons claiming rights from or through Participants and stockholders of the Company. No member of the Committee (or any person to whom the Committee has delegated authority to act under the Plan) shall be personally liable for any action, determination, or interpretation taken or made in good faith by the Committee (or such person) with respect to the Plan or any Awards granted hereunder, and all members of the Committee (and such persons to whom the Committee has delegated authority to act under the Plan) shall be fully indemnified and protected by the Company in respect of any such action, determination or interpretation to the fullest extent permitted by law.

4.2. Subject to the provisions of the Plan, the Committee shall have full and final authority in its discretion to (i) select the Employees, Non-Employee Directors and Consultants who will receive Awards pursuant to the Plan; provided that Awards granted to Non-Employee Directors who are on the Board shall be subject to ratification by the Board; (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 granted under the Plan (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, based in each case on such considerations as the Committee shall determine) 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 Plan and Award Agreements, and adopt, amend and rescind such rules, regulations, guidelines, forms of agreements and instruments relating to the Plan and Award Agreements as it may deem necessary or advisable; (ix) construe and interpret the Plan and Award Agreements; and (x) make all other determinations as it may deem necessary or advisable for the administration of the Plan and Award Agreements. Notwithstanding anything in the Plan or an Award Agreement to the contrary, no underwater Option or underwater SAR may be repriced, replaced or regranted through cancellation, nor may any underwater Option or underwater SAR be repurchased for cash, in any case, without the approval of the stockholders of the Company, provided that nothing herein shall prevent the Committee from taking any action provided for in Sections 7 and 8.

4.3. To the extent permitted by applicable law and the Company's by-laws, the Committee may delegate some or all of its authority with respect to the Plan and Awards to any executive officer of the Company or any other person or persons designated by the Committee, in each case, acting individually or as a committee, provided that the Committee may not delegate its authority hereunder to any person to make Awards to (a) Employees who are (i) subject to the requirements of Rule 16b-3 of the Exchange Act or (ii) officers or other Employees who are delegated authority by the Committee pursuant to this Section 4.3 or (b) members of the Board. Any delegation hereunder shall be subject to the restrictions and limits that the Committee specifies at the time of such delegation or thereafter in its sole discretion. The Committee may at any time rescind the authority delegated to any person pursuant to this Section 4.3. Any action undertaken by any such person or persons in accordance with the Committee's delegation of authority pursuant to this Section 4.3 shall have the same force and effect as if undertaken directly by the Committee.

4.4. Notwithstanding any other provision to the contrary, Awards granted to Non-Employee Directors who are on the Board shall be administered by the Board, and any authority reserved under the Plan for the Committee with regard to Awards granted to Non-Employee Directors who are on the Board shall be exercised by the Board.

4.5. Notwithstanding anything contained in the Plan to the contrary, for so long as the Common Stock is publicly traded on a national securities exchange with sufficient public float and to the extent permitted by applicable law, the Committee shall ensure that a program is in place to offer Participants the opportunity to engage in broker-assisted sales of shares of Common Stock to allow Participants to pay the exercise price of, and withholding taxes relating to, Awards; provided that Participants who are subject to Section 16 of the Exchange Act with respect to the Company shall be permitted to direct the Company in their discretion to withhold Shares from those otherwise due with respect to an Award to pay the exercise price and withholding taxes relating to such Award. Only whole shares of Common Stock shall be withheld, and the number of shares of Common Stock withheld shall be based on the Fair Market Value of the Common Stock on the date on which the event giving rise to such share withholding occurs.

Section 5. Shares Subject to the Plan.

5.1. Subject to adjustment as provided in Section 8 hereof, the total number of shares of Common Stock available for Awards under the Plan as of the Effective Date shall be 4,100,000 (the "*Plan Limit*"); provided, however, that on January 1, 2019 and each January 1st thereafter prior to the termination of the 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 31st and (y) such lesser number as the Board may determine in its discretion. Up to 4,100,000 shares available for Awards under the Plan may be issued pursuant to Incentive Stock Options (the "*ISO Limit*"), provided that on January 1, 2019 and each January 1st thereafter prior to the termination of the Plan, the ISO 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 31st, (y) 4,100,000 shares and (z) such lesser number as the Board may determine in its discretion. The maximum value (determined as of the grant date) of the Shares underlying Awards granted to any Non-Employee Director who is on the Board 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 appointed to the Board. For purposes of determining the number of shares available for Awards under the 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. Common Stock 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 of Common Stock issued by the Company through the assumption or substitution of outstanding grants from an acquired company shall not reduce the shares of Common Stock available for Awards under the Plan.

5.2. If any Shares subject to an Award under the 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 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 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.

Section 6. Awards. Awards may be granted on the terms and conditions set forth in this Section 6. In addition, the Committee may impose on any Award or the settlement or exercise thereof, at the grant date or thereafter, such additional terms and conditions, not inconsistent with the provisions of the Plan, as the Committee shall determine, including without limitation terms requiring forfeiture of unvested Awards in the event of a Participant's termination of employment or other service with the Company or any Subsidiary; provided, however, that the Committee shall retain full power to accelerate or waive any such additional term or condition as it may have previously imposed (provided that, in any case, any such action is permitted under Code Section 409A). The right of a Participant to exercise or receive a grant or settlement of any Award, and the timing thereof, may be subject to such Performance Goals as may be determined by the Committee. Each Award, and the terms and conditions applicable thereto, shall be evidenced by an Award Agreement.

6.1. 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 exercise price, as provided in the applicable Award Agreement. Options may be either Incentive Stock Options or Non-Qualified Options; provided that Incentive Stock Options may not be granted to Non-Employee Directors or Consultants. The grant of Options shall be subject to the following terms and conditions:

(a) *Exercise Price*. The price per Share at which Shares may be purchased upon exercise of an Option shall be determined by the Committee and specified in the Award Agreement, but shall be not less than the Fair Market Value of one Share on the grant date (or 110% of the Fair Market Value of one Share on the grant date in the case of an Incentive Stock Option granted to a Ten Percent Stockholder).

(b) *Term of Options.* The term of an Option shall be specified in the Award Agreement, but shall in no event be greater than ten years from the grant date (or five years from the grant date in the case of an Incentive Stock Option granted to a Ten Percent Stockholder).

(c) *Exercise of Option.* Each Award Agreement with respect to an Option shall specify the time or times at which an Option may be exercised in whole or in part and the terms and conditions applicable thereto, including without limitation (i) a vesting schedule which may be based upon the passage of time, attainment of Performance Goals or a combination thereof, (ii) whether the exercise price for an Option shall be paid in cash, with Shares, with any combination of cash and Shares, or with other legal consideration that the Committee may deem appropriate and to the extent permitted by applicable law, (iii) the methods of payment, which may include payment through cashless and net exercise arrangements, to the extent permitted by applicable law and (iv) the methods by which, or the time or times at which, Shares will be delivered or deemed to be delivered to Participants upon the exercise of such Option. Payment of the exercise price shall in all events be made within three days after the date of exercise of an Option.

(d) *Termination of Employment or Other Service*. Unless otherwise provided in an Award Agreement or an effective employment, consulting, severance or similar agreement with the Company or a Subsidiary, and except as otherwise provided in Section 7.2 hereof, upon a Participant's termination of employment or other service with the Company and its Subsidiaries, the unvested portion of such Participant's Options shall cease to vest and shall be forfeited (with no compensation due to the Participant) and the vested portion of such Participant's Options shall remain exercisable by the Participant or the Participant's beneficiary or legal representative, as the case may be, for a period of (i) 90 days in the event of a termination by the Company or a Subsidiary for Cause, (ii) one year in the event of a termination due to death or Disability, by the Company or a Subsidiary without Cause, by the Participant for Good Reason or as the result of the Participant's Retirement and (iii) six months in the event of the Participant's resignation without Good Reason and not due to Retirement; provided, however, that in no event shall any Option be exercisable after its stated term has expired.

(e) *Incentive Stock Options*. Each Participant awarded an Incentive Stock Option under the Plan shall notify the Company in writing immediately after the date he or she makes a "disqualifying disposition" (as defined in Section 421(b) of the Code) of any Shares acquired pursuant to the exercise of such Incentive Stock Option. The Company may, if determined by the Committee and in accordance with procedures established by it, retain possession of any Shares acquired pursuant to the exercise of an Incentive Stock Option as agent for the applicable Participant until the end of any period during which a disqualifying disposition could occur, subject to complying with any instructions from such Participant as to the sale of such Shares. The aggregate Fair Market Value, determined as of the grant date, for Awards granted under the Plan (or any other stock or share option plan required to be taken into account under Section 422(d) of the Code) that are intended to be Incentive Stock Options which are first exercisable by the Participant during any calendar year shall not exceed $100,000. To the extent an Award purporting to be an Incentive Stock Option exceeds the limitation in the previous sentence or does not otherwise qualify as an Incentive Stock Option, the portion of the Award in excess of such limit or that does not so qualify shall be a Non-Qualified Option.

(f) *No Dividend Equivalent Rights*. No Participant shall be entitled to dividend equivalent rights or payments with respect to any Shares underlying the Participant's Options.

6.2. Stock Appreciation Rights. A SAR shall confer on the Participant a right to receive, upon exercise thereof, 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 Committee, but which may never be less than the Fair Market Value of one Share on the grant date. No payment from the Participant shall be required to exercise a SAR. The grant of SARs shall be subject to the following terms and conditions:

(a) *General*. Each Award Agreement with respect to a SAR shall specify the number of SARs granted, the grant price of the SAR, the time or times at which the SAR may be exercised in whole or in part (including without limitation vesting upon the passage of time, the attainment of Performance Goals, or a combination thereof), the method of exercise, the method of settlement (in cash, Shares or a combination thereof), the method by which Shares will be delivered or deemed to be delivered to Participants (if applicable) and any other terms and conditions of the SAR.

(b) *Termination of Employment or Other Service*. Unless otherwise provided in an Award Agreement or an effective employment, consulting, severance or similar agreement with the Company or a Subsidiary, and except as otherwise provided in Section 7.2 hereof, upon a Participant's termination of employment or other service with the Company and its Subsidiaries, the unvested portion of such Participant's SARs shall cease to vest and shall be forfeited (with no compensation due to the Participant) and the vested portion of such Participant's SARs shall remain exercisable by the Participant or the Participant's beneficiary or legal representative, as the case may be, for a period of (i) 90 days in the event of a termination by the Company or a Subsidiary for Cause, (ii) one year in the event of a termination due to death or Disability, by the Company or a Subsidiary without Cause, by the Participant for Good Reason or as the result of the Participant's Retirement and (iii) six months in the event of the Participant's resignation without Good Reason and not due to Retirement; provided, however, that in no event shall any SAR be exercisable after its stated term has expired.

(c) *Term*. The term of a SAR shall be specified in the Award Agreement, but shall in no event be greater than ten years from the grant date.

(d) *No Dividend Equivalent Rights*. No Participant shall be entitled to dividend equivalent rights or payments with respect to any Shares underlying the Participant's SARs.

6.3. Restricted Stock. An Award of Restricted Stock is a grant by the Company of a specified number of Shares to the Participant, which Shares are subject to forfeiture upon the occurrence of specified events during the Restriction Period. Such an Award shall be subject to the following terms and conditions:

(a) *General*. Each Award Agreement with respect to Restricted Stock shall specify the duration of the Restriction Period and/or each installment thereof, the conditions under which the Restricted Stock may be forfeited to the Company, and the amount, if any, the Participant must pay to receive the Restricted Stock. Such restrictions may include a vesting schedule based upon the passage of time.

(b) *Transferability*. During the Restriction Period, the transferability of Restricted Stock shall be prohibited or restricted in the manner and to the extent prescribed in the applicable Award Agreement. Such restrictions may include, without limitation, rights of repurchase or first refusal in the Company or provisions subjecting the Restricted Stock to a continuing substantial risk of forfeiture in the hands of any transferee.

(c) *Stockholder Rights*. Unless otherwise provided in the applicable Award Agreement, during the Restriction Period the Participant shall have all the rights of a stockholder with respect to Restricted Stock, including, without limitation, the right to receive dividends thereon (whether in cash or Shares) and to vote such Shares of Restricted Stock in accordance with the Company's by-laws. Dividends may, in the discretion of the Committee, be paid currently or subject to the same restrictions as the underlying Restricted Stock (and the Committee may, in its sole discretion, withhold any cash dividends paid on Restricted Stock until the restrictions applicable to such Restricted Stock have lapsed); provided, however, that dividends paid on unvested Restricted Stock that is subject to Performance Goals shall not be paid or released unless and until the applicable Performance Goals have been achieved.

(d) *Termination of Employment or Other Service*. Unless otherwise provided in an Award Agreement or an effective employment, consulting, severance or similar agreement with the Company or a Subsidiary, and except as otherwise provided in Section 7.2 hereof, upon a Participant's termination of employment or other service with the Company and its Subsidiaries for any reason, the unvested portion of each Award of Restricted Stock granted to such Participant shall be forfeited with no compensation due the Participant.

(e) *Additional Matters*. Upon the Award of Restricted Stock, the Committee may direct the number of Shares subject to such Award be issued to the Participant or placed in a restricted stock account (including without limitation an electronic account) with the transfer agent and in either case designating the Participant as the registered owner. The certificate(s), if any, representing such Shares shall be physically or electronically legended, as applicable, as to sale, transfer, assignment, pledge or other encumbrances during the Restriction Period and, if issued to the Participant, returned to the Company to be held in escrow during the Restriction Period. In all cases, the Participant shall sign a stock power or share transfer form (as appropriate) endorsed in blank to the Company to be held in escrow during the Restriction Period.

6.4. Restricted Stock Units. Restricted Stock Units are solely a device for the measurement and determination of the amounts to be paid to a Participant under the Plan. Restricted Stock Units do not constitute Shares and shall not be treated as (or as giving rise to) property or as a trust fund of any kind; provided, however, that the Company may establish a bookkeeping reserve to meet its obligations hereunder or a trust or other funding vehicle that would not cause the Plan to be deemed to be funded for tax purposes or for purposes of Title I of the Employee Retirement Income Security Act of 1974, as amended. The right of any Participant in respect of an Award of Restricted Stock Units shall be no greater than the right of any unsecured general creditor of the Company. The grant of Restricted Stock Units shall be subject to the following terms and conditions:

(a) *Restriction Period*. Each Award Agreement with respect to Restricted Stock Units shall specify the duration of the Restriction Period, if any, and/or each installment thereof and the conditions under which such Award may be forfeited to the Company. Such restrictions may include a vesting schedule based upon the passage of time.

(b) *Termination of Employment or Other* Service. Unless otherwise provided in an Award Agreement or an effective employment, consulting, severance or similar agreement with the Company or a Subsidiary, and except as otherwise provided in Section 7.2 hereof, upon a Participant's termination of employment or other service with the Company and its Subsidiaries for any reason, the unvested portion of each Award of Restricted Stock Units credited to such Participant shall be forfeited with no compensation due the Participant.

(c) *Settlement*. Unless otherwise provided in an Award Agreement (i) an Award of Restricted Stock Units shall be settled in Shares, provided that any fractional Restricted Stock Units shall be settled in cash and (ii) subject to the Participant's continued employment or other service with the Company or a Subsidiary from the grant date through the expiration of the Restriction Period (or applicable portion thereof), the vested portion of an Award of Restricted Stock Units shall be settled within 60 days after the expiration of the Restriction Period (or applicable portion thereof).

(d) *Stockholder Rights*. Nothing contained in the Plan shall be construed to give any Participant rights as a stockholder with respect to an Award of Restricted Stock Units (including, without limitation, any voting, dividend or derivative or other similar rights). Notwithstanding the foregoing, the Committee may provide in an Award Agreement that amounts equal to any dividends declared during the Restriction Period on the Shares represented by an Award of Restricted Stock Units will be credited to the Participant's account and settled in Shares at the same time (and subject to the same forfeiture restrictions) as the Restricted Stock Units to which such dividend equivalents relate (with the number of Shares released in payment of such dividend equivalents to equal the amount of dividend equivalents then being settled, divided by the Fair Market Value of one Share on the settlement date of such dividend equivalents).

6.5. Performance Stock Units. Performance Stock Units are solely a device for the measurement and determination of the amounts to be paid to a Participant under the Plan. Performance Stock Units do not constitute Shares and shall not be treated as (or as giving rise to) property or as a trust fund of any kind; provided, however, that the Company may establish a bookkeeping reserve to meet its obligations hereunder or a trust or other funding vehicle that would not cause the Plan to be deemed to be funded for tax purposes or for purposes of Title I of the Employee Retirement Income Security Act of 1974, as amended. The right of any Participant in respect of an Award of Performance Stock Units shall be no greater than the right of any unsecured general creditor of the Company. The grant of Performance Stock Units shall be subject to the following terms and conditions:

(a) *Restriction Period*. Each Award Agreement with respect to Performance Stock Units shall specify the duration of the Performance Period and the Restriction Period, if any, and/or each installment thereof, the Performance Goals applicable to the Performance Stock Units and the conditions under which the Performance Stock Units may be forfeited to the Company. Such restrictions shall include a vesting schedule based on the attainment of one or more Performance Goals.

(b) *Termination of Employment or Other Service*. Unless otherwise provided in an Award Agreement or an effective employment, consulting, severance or similar agreement with the Company or a Subsidiary, and except as otherwise provided in Section 7.2 hereof, upon a Participant's termination of employment or other service with the Company and its Subsidiaries for any reason, the unvested portion of each Award of Performance Stock Units credited to such Participant shall be forfeited with no compensation due the Participant.

(c) *Settlement*. Unless otherwise provided in an Award Agreement, subject to the Participant's continued employment or other service with the Company or a Subsidiary from the grant date through the expiration of the Restriction Period (or applicable portion thereof), the vested portion of an Award of Performance Stock Units shall be settled within 60 days after the expiration of the Restriction Period (or applicable portion thereof).

(d) *Stockholder Rights*. Nothing contained in the Plan shall be construed to give any Participant rights as a stockholder with respect to an Award of Performance Stock Units (including, without limitation, any voting, dividend or derivative or other similar rights). Notwithstanding the foregoing, the Committee may provide in an Award Agreement that amounts equal to any dividends declared by the Company during the Restriction Period on the Shares represented by an Award of Performance Stock Units will be credited to the Participant's account and settled in cash or Shares at the same time (and subject to the same forfeiture restrictions and Performance Goals) as the Performance Stock Units to which such dividend equivalents relate (with the number of Shares released in payment of such dividend equivalents to equal the amount of dividend equivalents then being settled, divided by the Fair Market Value of one Share on the settlement date of such dividend equivalents).

6.6. Performance Stock. An Award of Performance Stock is a grant by the Company of a specified number of Shares to the Participant, which Shares are conditional on the achievement of Performance Goals during the Performance Period and subject to forfeiture upon the happening of specified events during the Restriction Period. An Award of Performance Stock shall be subject to the following terms and conditions.

(a) *General*. Each Award Agreement with respect to Performance Stock shall specify the duration of the Performance Period and the Restriction Period, if any, and/or each installment thereof, the Performance Goals applicable to the Performance Stock and the conditions under which the Performance Stock may be forfeited to the Company, and the amount, if any, the Participant must pay to receive the Performance Stock.

(b) *Transferability*. During the Restriction Period, if any, the transferability of Performance Stock shall be prohibited or restricted in the manner and to the extent prescribed in the applicable Award Agreement. Such restrictions may include, without limitation, rights of repurchase or first refusal in the Company or provisions subjecting the Performance Stock to a continuing substantial risk of forfeiture in the hands of any transferee.

(c) *Stockholder Rights*. Unless otherwise provided in the applicable Award Agreement, during the Restriction Period the Participant shall have all the rights of a stockholder with respect to Performance Stock, including, without limitation, the right to receive dividends thereon (whether in cash or Shares), but only to the extent that Performance Stock vests based on the achievement of Performance Goals, and to vote such shares of Performance Stock. Dividends shall be subject to the same restrictions (and Performance Goals) as the underlying Performance Stock and the Committee shall withhold any cash dividends paid on Performance Stock until the Performance Goals are achieved and restrictions applicable to such Performance Stock have lapsed.

(d) *Termination of Employment or Other Service*. Unless otherwise provided in an Award Agreement or an effective employment, consulting, severance or similar agreement with the Company or a Subsidiary, and except as otherwise provided in Section 7.2 hereof, upon a Participant's termination of employment or other service with the Company and its Subsidiaries for any reason, the unvested portion of each Award of Performance Stock granted to such Participant shall be forfeited with no compensation due the Participant.

6.7. Other Stock-Based Awards. The Committee is authorized, subject to limitations under applicable law, to grant to Participants any type of Award (in addition to those Awards provided in Sections 6.1, 6.2, 6.3, 6.4, 6.5 and 6.6 hereof) that is payable in, or valued in whole or in part by reference to, Shares, and that is deemed by the Committee to be consistent with the purposes of the Plan, including, without limitation, fully vested Shares and dividend equivalents.

Section 7. Change in Control.

7.1. General. Unless otherwise provided in an Award Agreement or an effective employment, consulting, severance or similar agreement with the Company or a Subsidiary, a Change in Control shall 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 company (or its direct or indirect parent) does not agree to assume an outstanding Award or does not agree to substitute or replace such Award 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, (ii) the ordinary equity securities underlying the assumed or substituted Award would not be registered and publicly traded on a U.S. securities exchange immediately following such Change in Control or (iii) the Change in Control is not approved by a majority of the Incumbent Directors immediately prior to such Change in Control, then the 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 "non-qualified deferred compensation" within the meaning of Code Section 409A, 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 Code Section 409A, 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 Code Section 409A 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 shall be cancelled with no payment due the Participant and (e) take such other actions as the Committee deems appropriate. If any action is taken with respect to any Award under items (a) through (e) of this Section 7.1 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 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. The judgment of the Committee with respect to any matter referred to in this Section 7.1 shall be conclusive and binding upon each Participant without the need for any amendment to the Plan or any Award or Award Agreement. Notwithstanding the foregoing, no Award that constitutes "non-qualified deferred compensation" (within the meaning of Section 409A of the Code) shall be payable upon the occurrence of a Change in Control unless such Change in Control satisfies the requirements of Treasury Regulation Section 1.409A-3(i)(5).

7.2. Termination Following a Change in Control. Notwithstanding anything contained in the Plan to the contrary, 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 may be determined by the Committee prior to a Change in Control, in the event that Awards under the Plan are assumed in connection with a Change in Control or are substituted with new awards, in either case, pursuant to Section 7.1 above, and a Participant's employment or other service with the Company and its Subsidiaries is terminated by the Company or a Subsidiary 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, (i) the unvested portion of such Participant's Awards (including without limitation any awards received in substitution of an Award) shall 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 (including without limitation options and stock or share appreciation rights received in substitution of an Award) shall remain exercisable by the Participant or the Participant's beneficiary or legal representative, as the case may be, for a period of one-year thereafter (but not beyond the stated term of such Option or SAR), (iii) all Restricted Stock Units and Performance Stock Units (including without limitation restricted stock units and performance stock units received in substitution of an Award) shall be settled within 30 days after such termination and (iv) all Other Stock-Based Awards (including without limitation any received in substitution of an Award) shall be settled within 30 days after such termination; provided, however, that with respect to clauses (iii) and (iv), if settlement of such Awards on the date described in this Section 7.2 would violate Code Section 409A, then such Award instead shall be settled in full at the time it otherwise would have been settled in connection with a termination of employment or service without Cause, for Good Reason or due to death or Disability, as applicable.

Section 8. Adjustments upon Changes in Capitalization.

8.1. In order to prevent dilution or enlargement of the rights of Participants under the Plan as a result of any share dividend, recapitalization, forward share split or reverse share split, reorganization, spin-off, extraordinary or unusual cash distribution or other similar or analogous non-reciprocal corporate transaction or event between the Company and its shareholders that affects the Shares, the Committee shall adjust (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 Plan (including without limitation any of the specific limitations under Section 5 hereof), and (iv) the exercise or grant price relating to any Award. Any such adjustment shall be made in an equitable manner which reflects the effect of such transaction or event.

8.2. In addition, the Committee is authorized (but not obligated) to make adjustments in the terms and conditions of, and the criteria included in, Awards, including any Performance Goals, in recognition of unusual or nonrecurring events (including, without limitation, events described in Section 8.1) affecting the Company or any Subsidiary, or in response to changes in applicable laws, regulations, or accounting principles.

8.3. If Sections 7 and 8 could both apply to an event, Section 7 shall control.

Section 9. Termination and Amendment.

9.1. Changes to the Plan and Awards. The Board may amend, alter, suspend, discontinue, or terminate the Plan without the consent of the Company's stockholders or Participants, except that any such amendment, alteration, suspension, discontinuation or termination shall be subject to the approval of the Company's stockholders if (i) such action would increase the number of Shares subject to the Plan (other than in connection with adjustments under Section 8.1), (ii) such action would decrease the price at which Awards may be granted, (iii) such stockholder approval is required by any applicable federal, state or foreign law or regulation or the rules of any stock exchange or automated quotation system on which the Shares may then be listed or quoted, or (iv) the Board may otherwise, in its discretion, determine to submit such other changes to the Plan to the Company's stockholders for approval; provided, however, that except as provided in Section 18, without the consent of an affected Participant, no amendment, alteration, suspension, discontinuation, or termination of the Plan may materially and adversely affect the rights of such Participant under any outstanding Award unless such amendment, alteration, suspension, discontinuation or termination is required by law or regulation, or the rules of any applicable securities exchange or automated quotation system.

9.2. The Committee may waive any conditions or rights under, or amend, alter, suspend, discontinue, or terminate, any Award theretofore granted and any Award Agreement relating thereto; provided, however, that except as provided in Section 18, without the consent of an affected Participant, no such amendment, alteration, suspension, discontinuation, or termination of any Award may materially and adversely affect the rights of such Participant under such Award unless such amendment, alteration, suspension, discontinuation or termination is required by law or regulation, or the rules of any applicable securities exchange or automated quotation system.

9.3. Notwithstanding anything in Section 8 or this Section 9 to the contrary, any Performance Goal applicable to an Award shall not be deemed a fixed contractual term, but shall remain subject to adjustment by the Committee, in its discretion at any time in view of the Committee's assessment of the Company's strategy, performance of comparable companies, and other circumstances.

9.4. No Repricing. Notwithstanding anything in the Plan or an Award Agreement to the contrary, no underwater Option or underwater SAR may be repriced, replaced or regranted through cancellation, nor may any underwater option or underwater SAR be repurchased for cash, in any case, without the approval of the stockholders of the Company, provided that nothing herein shall prevent the Committee from taking any action provided for in Sections 7 and 8.

Section 10. No Right to Award, Employment or Service. No Employee, Consultant or Non-Employee Director shall have any claim to be granted any Award under the Plan, and there is no obligation that the terms of Awards be uniform or consistent among Participants. Neither the Plan nor any action taken hereunder shall be construed as giving any Participant any right to be retained in the employ or service of the Company or any Subsidiary. For purposes of the Plan, a transfer of employment or service between the Company and its Subsidiaries shall not be deemed a termination of employment or service; provided, however, that individuals employed by, or otherwise providing services to, an entity that ceases to be a Subsidiary shall be deemed to have incurred a termination of employment or service, as the case may be, as of the date such entity ceases to be a Subsidiary unless such individual becomes an employee of, or service provider to, the Company or another Subsidiary as of the date of such cessation. A change in status from Employee to Consultant shall be deemed to be a termination of employment, unless otherwise determined by the Committee. The Committee may adopt rules and make determinations on how a leave of absence will impact an Award, including, without limitation, tolling the vesting schedule or treating such leave of absence as a termination of employment or other service.

Section 11. Taxes. Each Participant must make appropriate arrangement for the payment of any taxes relating to an Award granted hereunder. The Company or any Subsidiary is authorized to withhold from any payment relating to an Award under the Plan, including without limitation from a distribution of Shares, amounts of withholding and other taxes due in connection with any transaction involving an Award, and to take such other action as the Committee may deem advisable to enable the Company, its Subsidiaries and Participants to satisfy obligations for the payment of withholding taxes and other tax obligations relating to any Award (including without limitation withholding from any payroll or other payment due to a Participant). This authority shall include the ability to withhold or receive Shares or other property and to make cash payments in respect thereof in satisfaction of a Participant's tax obligations. Withholding of taxes in the form of Shares with respect to an Award shall not occur at a rate that equals or exceeds the rate that would result in such Award being subject to liability accounting treatment.

Section 12. Limits on Transferability; Beneficiaries. No Award or other right or interest of a Participant under the Plan shall be (i) pledged, encumbered, or hypothecated to, or in favor of, or subject to any lien, obligation, or liability of such Participant to, any party, other than the Company or any Subsidiary, or (ii) assigned or transferred by such Participant other than by will or the laws of descent and distribution, and such Awards and rights shall be exercisable during the lifetime of the Participant only by the Participant or (with respect to Awards other than Incentive Stock Options) his or her guardian or legal representative. Notwithstanding the foregoing, to the extent permitted by applicable law and the rules of any applicable stock exchange, Non-Qualified Options, SARs, Performance Stock, Restricted Stock and any other Award that is not "deferred compensation" within the meaning of Code Section 409A shall be transferable, without consideration, to immediate family members (i.e., children, grandchildren or spouse), to trusts for the benefit of such immediate family members and to partnerships or similar entities in which such Participant and his or her family members are the only partners, members or equityholders (any vesting and other conditions relating to such Awards shall be unaffected by such transfer). The Committee may attach to such transferability feature such terms and conditions as it deems necessary to further the purposes of the Plan. In addition, a Participant may, in the manner established by the Committee, designate a beneficiary (which may be a Person or a trust) to exercise the rights of the Participant, and to receive any distribution, with respect to any Award upon the death of the Participant. A beneficiary, guardian, legal representative or other Person claiming any rights under the Plan from or through any Participant shall be subject to all terms and conditions of the Plan and any Award Agreement applicable to such Participant, except as otherwise determined by the Committee, and to any additional restrictions deemed necessary or appropriate by the Committee.

Section 13. Foreign Nationals. Without amending the Plan, Awards may be granted to Employees, Consultants and Non-Employee Directors 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 Plan as may, in the judgment of the Committee, be necessary or desirable to further the purpose of the Plan. Moreover, the Committee may approve such supplements to, or sub-plans, amendments, restatements or alternative versions of, the Plan as it may consider necessary or appropriate for such purposes without thereby affecting the terms of the Plan as in effect for any other purpose, provided that no such supplements, sub-plans, amendments, restatements or alternative versions shall include any provisions that are prohibited by the terms of the Plan, as then in effect, unless the Plan could have been amended to eliminate such prohibition without further approval by the stockholders of the Company.

Section 14. Securities Law Requirements.

14.1. No Shares may be issued hereunder if the Company shall at any time determine that to do so would (i) violate the listing requirements of an applicable securities or stock exchange, or adversely affect the registration or qualification of the Company's Shares under any state or federal law, or (ii) require the consent or approval of any regulatory or supervising body or stockholders. In any of the events referred to in clause (i) or clause (ii) above, the issuance of such Shares shall be suspended and shall not be effective unless and until such listing, registration, qualifications, consents or approval shall have been effected or obtained free of any conditions not acceptable to the Company in its sole discretion, notwithstanding any termination of any Award or any portion of any Award during the period when issuance has been suspended (provided, however, that if permitted under Code Section 409A, the Committee may toll the expiration date of an Award such that it will not terminate during any such period of suspension).

14.2. For purposes of ensuring compliance with applicable securities laws or for other legal compliance purposes, the Committee may require, as a condition to the issuance of Shares hereunder, representations, warranties and agreements to the effect that such Shares are being purchased or acquired by the Participant for investment only and without any present intention to sell or otherwise distribute such Shares, and that the Participant will not dispose of such Shares in transactions which, in the opinion of counsel to the Company, would violate the registration provisions of the Securities Act and the rules and regulations thereunder.

Section 15. Termination. Unless earlier terminated, the Plan shall terminate with respect to the grant of new Awards on the earlier of the 10-year anniversary of the Effective Date or the 10-year anniversary of the date the Plan was approved by the Board, and no Awards under the Plan shall thereafter be granted; provided that no such termination shall adversely impact Awards that were granted prior to such termination.

Section 16. Fractional Shares. The Company will not be required to issue any fractional Shares pursuant to the Plan. The Committee may provide for the elimination of fractions and settlement of such fractional Shares in cash, in its sole discretion.

Section 17. Discretion. In exercising, or declining to exercise, any grant of authority or discretion hereunder, the Committee may consider or ignore such factors or circumstances and may accord such weight to such factors and circumstances as the Committee alone and in its sole judgment deems appropriate and without regard to the effect such exercise, or declining to exercise such grant of authority or discretion, would have upon the affected Participant, any other Participant, any Employee, any Consultant, any Non-Employee Director, the Company, any Subsidiary, any affiliate, any stockholder or any other Person.

Section 18. Code Section 409A. The Plan and all Awards are intended to comply with, or be exempt from, Code Section 409A and all regulations, guidance, compliance programs and other interpretative authority thereunder, and shall be interpreted in a manner consistent therewith. Notwithstanding anything contained herein to the contrary, in the event any Award is subject to Code Section 409A, the Committee may, in its sole discretion and without a Participant's prior consent, amend the Plan and/or Award, adopt policies and procedures, or take any other actions as deemed appropriate by the Committee to (i) exempt the Plan and/or any Award from the application of Code Section 409A, (ii) preserve the intended tax treatment of any such Award or (iii) comply with the requirements of Code Section 409A. In the event that a Participant is a "specified employee" within the meaning of Code Section 409A, and a payment or benefit provided for under the Plan would be subject to additional tax under Code Section 409A if such payment or benefit is paid within six (6) months after such Participant's separation from service (within the meaning of Code Section 409A), then such payment or benefit shall not be paid (or commence) during the six (6) month period immediately following such Participant's separation from service except as provided in the immediately following sentence. In such an event, any payments or benefits that would otherwise have been made or provided during such six (6) month period and which would have incurred such additional tax under Code Section 409A shall instead be paid to the Participant in a lump-sum, without interest, on the earlier of (i) the first business day of the seventh month following the month in which such Participant's separation from service occurs or (ii) the tenth business day following such Participant's death (but not earlier than if such delay had not applied). A Participant's right to receive any installment payments under an Award Agreement, including without limitation as the result of any deferral of an Award in accordance with Code Section 409A, shall be treated as a right to receive a series of separate payments and, accordingly, each such installment payment shall at all times be considered a separate and distinct payment as permitted under Code Section 409A. Notwithstanding anything contained in the Plan or in an Award Agreement to the contrary, neither the Company, any member of the Committee nor any Subsidiary shall have any liability or obligation to any Participant or any other Person for taxes, interest, penalties or fines (including without limitation any of the foregoing resulting from the failure of any Award granted hereunder to comply with, or be exempt from, Code Section 409A). Any Award that is to be settled or paid upon a termination of employment or service and that constitutes "non-qualified deferred compensation" under Code Section 409A shall not be paid or settled unless such termination of employment or service constitutes a "separation from service" within the meaning of Code Section 409A.

Section 19. Governing Law. The validity and construction of the Plan and any Award Agreements entered into thereunder shall be construed and enforced in accordance with the laws of the State of Delaware, without giving effect to the conflict of laws principles thereof.

Section 20. Recoupment. Any Award granted pursuant to the Plan (and all Shares acquired thereunder) shall be subject to mandatory repayment and clawback pursuant to the terms of the Company's clawback policy, if any, as in effect from time to time, and as may otherwise be required by law or the rules of any applicable securities exchange. Additional recoupment and clawback policies may be provided in the Participant's Award Agreement.

Section 21. Employment Agreements. In the event of any conflict between the terms of the Plan or an Award, on the one hand, and the terms of a Participant's employment agreement with the Company or a Subsidiary on the other hand, the terms of such employment agreement shall control.

Section 22. Effective Date. The Plan shall become effective upon the Effective Date, and no Award shall become exercisable, realizable or vested prior to the Effective Date.

[*End of Document*]

Exhibit 10.15

AQUESTIVE THERAPEUTICS, INC.

EMPLOYEE STOCK PURCHASE PLAN

Adopted by the Board of Directors June 15, 2018
Approved by the Stockholders June 27, 2018

AQUESTIVE THERAPEUTICS, INC.
EMPLOYEE STOCK PURCHASE PLAN

SECTION 1. PURPOSE OF THE PLAN.

The Aquestive Therapeutics, Inc. Employee Stock Purchase Plan (the "**Plan**") is intended to provide Eligible Employees (as defined below) the opportunity to increase their proprietary interest in Aquestive Therapeutics, Inc. (the "**Company**") by conveniently purchasing shares of the Company's common stock, par value $0.001 per share (the "**Stock**"). The Plan is composed of two components: a 423 Component and a Non-423 Component. The 423 Component is intended to qualify under Section 423 of the Internal Revenue Code of 1986, as amended (the "**Code**"). Accordingly, the provisions of the 423 Component will be construed in a manner consistent with the requirements of Section 423 of the Code. The Plan also authorizes participation in the Plan under the Non-423 Component under terms that do not meet the requirements of Section 423 of the Code. The Company shall be permitted to grant rights to purchase Stock under separate offerings not having identical terms (provided that such terms are not inconsistent with the terms of the Plan and, with respect to an offering under the 423 Component, the requirements of Section 423 of the Code), and offerings may run concurrently (in whole or in part) with each other. Each offering under the Non-423 Component shall be separate and distinct from (and shall not be included in or be part of) any offering under the 423 Component, and each offering to a Participating Company shall be treated as an offering that is separate from any other offering made to another Participating Company, in each case, even if such offerings are running concurrently (in whole or in part) and/or have common terms and conditions.

SECTION 2. DEFINITIONS.

(a) "**423 Component**" means the portion of the Plan under which any right to purchase Stock shall be granted in a manner that is intended to satisfy the requirements of Section 423 of the Code.

(b) "**Affiliate**" means any branch or representative office or other disregarded entity of the Company or a Subsidiary, as determined by the Committee, whether now or hereafter existing.

(c) "**Board**" means the Board of Directors of the Company, as constituted from time to time.

(d) "**Change in Control**" shall have the meaning set forth in the Company's most recently adopted equity incentive plan, as in effect from time to time (and shall include a "Change of Control" as defined in any such plan); provided, that until the Aquestive Therapeutics, Inc. 2018 Equity Incentive Plan is replaced with a successor plan that includes a definition of Change in Control or Change of Control, Change in Control shall mean an event described in Sections 2.5(a) through 2.5(d) of the Aquestive Therapeutics, Inc. 2018 Equity Incentive Plan.

(e) "**Committee**" means the duly constituted committee appointed by the Board to administer the Plan, as described in Section 3. If no such committee is appointed, the Compensation Committee of the Board shall be the Committee.

(f) "**Compensation**" means all of an Eligible Employee's base salary or wages. "Compensation" shall exclude (i) commissions, bonuses and special incentive payments, (ii) equity compensation and income attributable to equity-based awards (including, without limitation, amounts realized from the exercise of any stock option and any dividends paid with respect to equity awards), (iii) all non-cash items, (iv) pre-tax contributions made by the Participant under Sections 401(k) or 125 of the Code or under any similar arrangements available under laws outside the United States and (v) allowances and other miscellaneous payments, including, without limitation, moving or relocation allowances, cost-of-living equalization payments, car allowances, tuition reimbursements, imputed income attributable to cars or life insurance, severance pay, fringe benefits, and benefits received under employee benefit plans. The Committee shall determine whether a particular item not listed in this Section 2(f) is included in Compensation.

(g) "**Effective Date**" means the date that the Plan is approved by the stockholders of the Company.

(h) "**Eligible Employee**" means any individual who (i) is an Employee of a Participating Company, (ii) does not own 5% or more of the total combined voting power or value of all classes of stock of the Company or any Parent or Subsidiary, including, for purposes of this provision, through application of the rules of Section 424(d) of the Code and (iii) is not a "highly compensated employee" (within the meaning of Section 414(q) of the Code) that is subject to Section 16 of the Securities Exchange Act of 1934, as amended. The foregoing notwithstanding, an individual who is a citizen or resident of a jurisdiction other than the United States (even if he or she is also a citizen of the United States or a resident alien) shall not be considered an Eligible Employee if, as determined in the sole discretion of the Committee, (i) his or her participation in the Plan is prohibited by the laws or regulations of any country which has jurisdiction over him or her or (ii) compliance with the laws and regulations of the foreign country that has jurisdiction over him or her would cause the Plan or an offering under the 423 Component to violate Section 423 of the Code.

(i) "**Employee**" means an individual who is a common-law employee of a Participating Company and, if such employee is employed in the United States, whose earnings are reported on a Form W-2. For the avoidance of doubt, the term "Employee" shall not include any consultant, independent contractor or non-employee director of a Participating Company.

(j) "**Fair Market Value**" means, on any given date (i) if the Stock is listed on any established U.S. stock exchange or a U.S. national market system, the closing sales price for such Stock (or, if no closing sales price was reported on that date, as applicable, on the last preceding trading date such closing sales price was reported) as quoted on such exchange or system on the day of determination, as reported in *The Wall Street Journal* or such other source as the Committee deems reliable; (ii) if (i) does not apply, then if the Stock is regularly quoted by a recognized U.S. securities dealer but selling prices are not reported, the mean between the high bid and low asked prices for the Stock on the day of determination (or, if no bids and asks were reported on that date, as applicable, on the last preceding trading date such bids and asks were reported); or (iii) if (i) and (ii) do not apply, such value as the Committee in its discretion may in good faith determine in accordance with Section 423 of the Code.

(k) "**Non-423 Component**" means the portion of the Plan under which the right to purchase Stock may be granted in a manner that is not intended to satisfy the requirements of Section 423 of the Code.

(l) "**Offering Period**" means a period with respect to which the right to purchase Stock may be granted under the Plan, as determined pursuant to Section 4(a).

(m) "**Parent**" has the meaning given to such term under U.S. Treasury Regulation Section 1.424-1(f). As used in this Plan, "Parent" shall mean a Parent of the Company.

(n) "**Participant**" means an Eligible Employee who elects to participate in the Plan, as provided in Section 4(b).

(o) "**Participating 423 Company**" means any of the following that is designated by the Committee as participating in the 423 Component: (i) the Company, (ii) any present or future Parent or (iii) any present or future Subsidiary.

(p) "**Participating Company**" means each Participating 423 Company and Participating Non-423 Company.

(q) "**Participating Non-423 Company**" means any of the following that is designated by the Committee as participating in the Non-423 Component: (i) the Company, (ii) any present or future Parent, (iii) any present or future Subsidiary or (iv) any present or future Affiliate. Unless determined otherwise by the Committee, only entities incorporated or formed outside of the United States shall be Participating Non-423 Companies.

(r) "**Plan Account**" means the account established for each Participant pursuant to Section 8(a).

(s) "**Purchase Price**" means the price at which Participants may purchase Stock under the Plan, as determined pursuant to Section 8(b).

(t) "**Subsidiary**" means a subsidiary corporation of the Company as that term is defined in Section 424(f) of the Code.

SECTION 3. ADMINISTRATION OF THE PLAN.

(a) **General**. The Plan shall be administered by the Committee. To the extent permitted by applicable law, the Committee may delegate some or all of its authority with respect to the Plan to any executive officer of the Company or any other person or persons designated by the Committee, in each case, acting individually or as a committee.

(b) **Committee Authorities**. The Committee shall have the exclusive power and authority to administer the Plan, including without limitation the right and power to interpret the provisions of the Plan and make all determinations deemed necessary or advisable for the administration of the Plan (including, without limitation, a determination as to whether a Change in Control has occurred, whether to designate the Company, a Parent or Subsidiary as a Participating 423 Company or as a Participating Non-423 Company and whether to establish separate offerings). All such actions, interpretations and determinations which are done or made by the Committee shall be final, conclusive and binding on the Company, the Participating Companies, the Participants and all other parties and shall not subject the Committee (or its members) to any liability.

SECTION 4. ENROLLMENT AND PARTICIPATION.

(a) **Offering Periods**. Two Offering Periods shall commence in each calendar year, which shall be the periods commencing on January 1 and ending on June 30 and commencing on July 1 and ending on December 31; provided, however, that the first Offering Period may commence on a different date as determined by the Committee, but shall end on June 30 of the year commenced if commenced prior to June 30 or on December 31 of the year commenced if commenced after June 30.

(b) **Enrollment**. Any individual who, on the day preceding the first day of an Offering Period, qualifies as an Eligible Employee may elect to become a Participant in the Plan for such Offering Period by executing the enrollment form prescribed for this purpose by the Committee. The enrollment form shall be filed with the Company or its designee according to procedures established by the Committee.

(c) **Duration of Participation**. Once enrolled in the Plan, a Participant shall continue to participate in the Plan (according to the elections made on the Participant's most recently-filed enrollment form) until he or she ceases to be an Eligible Employee, withdraws from the Plan under Section 6(a) or reaches the end of the Offering Period in which his or her contributions were discontinued under Section 5(c) or Section 9(b). A Participant who discontinued his or her contributions under Section 5(c) or withdrew from the Plan under Section 6(a) may again become a Participant, if he or she then is an Eligible Employee, by following the procedure described in Section 4(b). A Participant whose employee contributions were discontinued automatically under Section 9(b) shall automatically resume participation at the beginning of the next Offering Period in which such Participant's participation would not be limited by Section 9(b), if he or she then is an Eligible Employee.

SECTION 5. EMPLOYEE CONTRIBUTIONS.

(a) **Frequency of Employee Contributions**. A Participant may make contributions to the Plan for purchasing shares of Stock by means of payroll deductions (unless payroll deductions are not permitted under applicable laws or regulations or unless the Company determines that another means of making employee contributions is necessary or appropriate for legal or administrative reasons).

(b) **Amount of Employee Contributions**. An Eligible Employee shall designate on the enrollment form the portion of his or her Compensation that he or she elects to contribute to the Plan with respect to the applicable Offering Period. Such portion shall be a whole percentage of the Eligible Employee's Compensation, on an after-tax basis, but not less than 1% nor more than 25% of the Eligible Employee's Compensation with respect to the applicable Offering Period. A Participant may not change the rate of his or her contributions during an Offering Period unless the Participant seeks (i) to discontinue contributions under Subsection (c) or (ii) to withdraw from the Plan under Section 6(a), and, in either such case, the Company will cease contributions on behalf of the Participant as soon as reasonably practicable (which shall not be until the payroll period following receipt of the applicable form or later).

(c) **Discontinuing Employee Contributions**. A Participant may discontinue contributions by filing a new enrollment form. Any contributions made from payroll shall cease as soon as reasonably practicable (which shall not be until the payroll period following receipt or later). A Participant who has discontinued employee contributions may not resume such contributions until the next Offering Period. If a Participant discontinues contributions, previously made contributions shall remain in the Participant's Plan Account (and will be used to purchase shares) unless and until the Participant withdraws from the Plan in accordance with the provisions of Section 6.

SECTION 6. WITHDRAWAL FROM THE PLAN.

(a) **Withdrawal**. A Participant may elect to withdraw from the Plan by filing the prescribed form with the Company or its designee at any time before the last day of an Offering Period. As soon as reasonably practicable thereafter, contributions shall cease and all employee contributions made by the Participant for the current Offering Period shall be refunded to the Participant in cash, without interest. No partial withdrawals shall be permitted.

(b) **Re-enrollment After Withdrawal**. A former Participant who has withdrawn from the Plan shall not be a Participant until he or she re-enrolls in the Plan under Section 4(b). Re-enrollment shall be effective only at the commencement of an Offering Period.

SECTION 7. CHANGE IN EMPLOYMENT STATUS.

(a) **Termination of Employment**. Termination of employment with a Participating Company, or otherwise ceasing to be an Eligible Employee, for any reason, including death, shall be treated as an automatic withdrawal from the Plan under Section 6(a), unless, with respect to an offering under the Non-423 Component, otherwise required by applicable laws or regulations. A transfer from one Participating Company to another shall not be treated as a termination of employment.

(b) **Leave of Absence**. For purposes of the Plan, employment shall not be deemed to terminate when the Participant goes on a military leave, a sick leave or another *bona fide* leave of absence, if the leave was approved by a Participating Company in writing or if such leave of absence is protected under applicable laws or regulations. Employment shall be deemed to terminate in any event when the approved leave ends, unless the Participant immediately returns to work.

(c) **Death**. In the event of the Participant's death, any amounts then held in the Participant's Plan Account and any shares of Stock then held in the Participant's name by the Company or the broker designated by the Company shall be paid or transferred to the Participant's estate or as otherwise required by applicable laws of descent and distribution, or as may be otherwise provided pursuant to Section 8(e).

SECTION 8. PLAN ACCOUNTS AND PURCHASE OF SHARES.

(a) **Plan Accounts**. The Company shall maintain a Plan Account on its books in the name of each Participant. Whenever an amount is contributed to the Plan, such amount shall be credited to the Participant's Plan Account. Amounts credited to Plan Accounts shall not be trust funds and may be commingled with the general assets of the Company or any Parent or Subsidiary and applied to general corporate purposes, unless otherwise required by applicable law or regulation. Unless required by applicable law or regulation, no interest will be paid or credited with respect to any amounts held in a Participant's Plan Account.

(b) **Purchase Price**. The Purchase Price for each share of Stock purchased at the close of an Offering Period shall be the lesser of:

(i) 85% of the Fair Market Value of such share on the last day of such Offering Period; or

(ii) 85% of the Fair Market Value of such share on the first day of such Offering Period.

The Committee may round the Purchase Price up (but not down) to a whole cent, and in no event shall the Purchase Price be less than the par value of the shares of Stock being purchased.

(c) **Number of Shares Purchased**. As of the last day of each Offering Period, each Participant shall be deemed to have elected to purchase the number of shares of Stock calculated in accordance with this Subsection (c), unless the Participant has withdrawn from the Plan under Section 6(a) or Section 7. The amount then in the Participant's Plan Account shall be divided by the Purchase Price, and the number of shares that results shall be purchased with the funds in the Participant's Plan Account. The foregoing notwithstanding, no Participant shall purchase more than 5,000 shares of Stock (subject to adjustment pursuant to Section 14(b)) with respect to any Offering Period (or, if the Board determines that a different number of Offering Periods shall commence in each calendar year in accordance with Section 4(a), a proportionate number of shares of Stock (subject to adjustment pursuant to Section 14(b)) with respect to any Offering Period) nor more than the amounts of Stock set forth in Sections 9(b) and 14(a). The Committee may determine with respect to all Participants that any fractional share, as calculated under this Subsection (c), shall be (i) rounded down to the next lower whole share (with the Purchase Price for such fractional share to be carried over to the next Offering Period as provided in Section 8(g)) or (ii) credited as a fractional share. To the extent permitted by law, the Committee may adjust the individual share limit set forth in this Section 8(c) from time to time without shareholder approval, provided that any such change shall not apply until the Offering Period commencing after such change is made.

(d) **Available Shares Insufficient**. In the event that the aggregate number of shares of Stock that all Participants elect to purchase during an Offering Period exceeds the maximum number of shares of Stock remaining available for issuance under Section 14(a), then the number of shares of Stock each Participant shall purchase shall be determined by multiplying the number of shares of Stock available for issuance by a fraction, the numerator of which is the number of shares of Stock that such Participant has elected to purchase and the denominator of which is the number of shares of Stock that all Participants have elected to purchase.

(e) **Issuance of Shares**. Shares of Stock shall be issued either in book entry form or in certificates. Certificates, if any, representing the shares of Stock purchased by a Participant under the Plan shall be issued to the Participant, or book entry in the Participant's name shall be made, as soon as reasonably practicable after the close of the applicable Offering Period, except that the Committee may determine that such certificates shall be held for each Participant's benefit by a broker designated by the Committee. Shares may be registered in the name of the Participant or jointly in the name of the Participant and his or her spouse as joint tenants with right of survivorship or as community property or in such other manner of taking title as may be permitted under applicable law or regulation; provided, however, that unless otherwise required by applicable law or specified by the Participant in writing, shares of Stock purchased under the Plan will be registered in the name of the Participant.

(f) **Transfer of Shares**. If certificates representing shares of Stock are not otherwise issued to the Participant in connection with the purchase of such shares at the end of an Offering Period, a Participant may elect to transfer any number of shares of Stock previously purchased under the Plan by providing notification and transfer instructions to Company or the broker designated by the Company, in accordance with procedures established under the Plan. As soon as administratively practicable following receipt of a Participant's election to transfer shares of Stock, the Company or the designated broker shall cause a transfer of the shares or a certificate representing the number of shares to be transferred to be delivered to the Participant or a broker designated by the Participant.

(g) **Unused Cash Balances**. Any amount remaining in the Participant's Plan Account that represents the Purchase Price for whole shares that could not be purchased by reason of Subsection (c) above, Section 9(b) or Section 14(a) or otherwise shall be refunded to the Participant in cash, without interest, promptly after the end of the applicable Offering Period.

SECTION 9. LIMITATIONS ON STOCK OWNERSHIP.

(a) **Five Percent Limit**. Any other provision of the Plan notwithstanding, no Participant shall be granted a right to purchase Stock under the Plan if such Participant, immediately after his or her election to purchase such Stock, would own stock possessing 5% or more of the total combined voting power or value of all classes of stock of the Company or any Parent or Subsidiary. For purposes of this Subsection (a), the following rules shall apply:

(i) the attribution rules of Section 424(d) of the Code shall be applied in determining ownership of Stock;

(ii) each Participant shall be deemed to own any stock that he or she has a right or option to purchase under this Plan or any other plan or arrangement; and

(iii) each Participant shall be deemed to have the right to purchase under this Plan with respect to each Offering Period 5,000 shares of Stock (as adjusted pursuant to Section 8(c)), subject to adjustment pursuant to Section 14(b).

(b) **Dollar Limit**. Any other provision of the Plan notwithstanding, consistent with Treasury Regulation Section 1.423-2(i), no Participant shall purchase Stock under this Plan and all other employee stock purchase plans of the Company or any Parent or Subsidiary at a rate that exceeds $25,000 in fair market value of the Stock (determined at the time the option is granted) for each calendar year in which any option granted to the Participant is outstanding at any time.

For purposes of this Subsection (b), the Fair Market Value of Stock shall be determined as of the beginning of the Offering Period in which such Stock is purchased. Employee stock purchase plans not described in Section 423 of the Code shall be disregarded. If a Participant is precluded by this Subsection (b) from purchasing additional Stock under the Plan, then his or her employee contributions shall automatically be discontinued, and shall resume (in accordance with the Participant's most recently-filed enrollment form) at the beginning of the earliest Offering Period in which this Section 9(b) would not prohibit such participation, provided that he or she then is an Eligible Employee.

SECTION 10. RIGHTS NOT TRANSFERABLE.

The rights of any Participant under the Plan, or the interest in any Stock or moneys to which any Participant may be entitled under the Plan, shall not be transferable by voluntary or involuntary assignment or by operation of law, or in any manner other than by beneficiary designation or the laws of descent and distribution. If a Participant attempts to transfer, assign or otherwise encumber his or her rights or interest under the Plan, other than as permitted by this Section 10, such act shall be treated as an election by the Participant to withdraw from the Plan under Section 6(a).

SECTION 11. NO RIGHTS AS AN EMPLOYEE.

Nothing in the Plan or in any right granted under the Plan shall confer upon the Participant any right to continue in the employ of a Participating Company for any period of specific duration or interfere with or otherwise restrict in any way the rights of the Participating Companies or of the Participant, which rights are hereby expressly reserved by each, to terminate his or her employment at any time and for any reason, with or without cause, to the fullest extent permitted by applicable laws or regulations.

SECTION 12. NO RIGHTS AS A STOCKHOLDER.

A Participant shall have no rights as a stockholder with respect to any shares of Stock that he or she may have a right to purchase under the Plan until such shares have been purchased on the last day of the applicable Offering Period.

SECTION 13. SECURITIES LAW REQUIREMENTS.

Shares of Stock shall not be issued under the Plan unless the issuance and delivery of such shares comply with (or are exempt from) all applicable requirements of law, including, without limitation, the U.S. Securities Act of 1933, as amended, the rules and regulations promulgated thereunder, all state securities laws and regulations, any applicable non-U.S. securities laws and regulations, and the regulations of any stock exchange or other securities market on which the Company's securities are then traded.

SECTION 14. STOCK OFFERED UNDER THE PLAN.

(a) **Authorized Shares**. The aggregate number of shares of Stock available for purchase under the Plan as of the Effective Date shall be 250,000, and on January 1st of each year during which the Plan is in effect, the number of shares available for purchase under the Plan shall be increased by the lesser of (x) 1.0% of the number of shares of Stock outstanding as of the immediately preceding December 31 (calculated on a fully diluted basis) and (y) such lesser number of shares of Stock as the Board may determine, in each case, as subject to adjustment as provided in this Section 14. Shares of Stock issued under the Plan may be shares already outstanding or newly issued or treasury shares.

(b) **Changes in Capitalization**. In the event of a reorganization, recapitalization, stock split, spin-off, split-off, split-up, stock or extraordinary cash dividend or other distribution, combination of shares, merger, amalgamation, consolidation or any other change in the corporate structure of the Company, or a sale by the Company of all or part of its assets, the Committee shall make such adjustments to the aggregate number of shares of Stock offered under the Plan, the maximum annual increase number in clause (y) of Section 14(a), the share limitation described in Section 8(c) (and the corresponding number of shares specified in clause (iii) of Section 9(a)) and/or the price of shares that any Participant has elected to purchase under the Plan as may be necessary to prevent the dilution or enlargement of Participants' rights. The Plan shall in no event be construed to restrict in any way the Company's right to undertake a dissolution, liquidation, merger, amalgamation, consolidation or other reorganization or corporate transaction of any kind or type.

(c) **Change in Control**. Any other provision of the Plan notwithstanding, immediately prior to the effective time of a Change in Control, the Plan shall terminate and shares shall be purchased pursuant to Section 8 as if the Offering Period during which such Change in Control occurs was scheduled to end on the day immediately preceding such Change in Control, unless the Plan is expressly assumed by the surviving corporation, the buyer or an affiliate of the foregoing. In addition, in anticipation of a Change in Control, the Committee may take any action under the Plan as it deems necessary or appropriate, including, without limitation, terminating the Plan and preventing Participants from continuing or increasing their contributions to the Plan.

SECTION 15. WITHHOLDING

To the extent any payments or distributions under the Plan are determined by any Participating Company to be subject to U.S. Federal, state or local taxes, or the taxes of a jurisdiction other than the United States, the Participating Company is authorized (but not obligated) to withhold any required taxes. The Participating Company may satisfy any withholding obligation by (i) withholding shares of Stock purchased under the Plan; (ii) withholding from the proceeds from the sale of shares of Stock purchased under the Plan, either through a voluntary sale or through a mandatory sale arranged by the Company; (iii) deducting cash from a Participant's Plan Account; (iv) deducting cash from a Participant's other cash compensation payable to him or her by any Participating Company or (v) any other method deemed appropriate by the Participating Company, in each case, as approved by the Committee. A Participant's election to participate in the Plan authorizes any Participating Company to take any of the actions described in the preceding sentence.

SECTION 16. GOVERNING LAW

To the extent that U.S. Federal laws do not otherwise control, the validity and construction of the Plan shall be construed and enforced in accordance with the laws of the State of Delaware, without giving effect to the choice of law principles thereof.

SECTION 17. NON-423 COMPONENT AND SUB-PLANS

The Board and/or the Committee may adopt procedures and sub-plans to this Plan that are necessary or appropriate to permit or facilitate participation in the Plan by Eligible Employees who are employed or located in a jurisdiction other than the United States or to generally operate the Plan in jurisdictions outside the United States (provided that such would not result in (i) the Plan failing to be eligible to qualify under Section 423 of the Code or (ii) any offering under the 423 Component not complying with Section 423 of the Code). Without limiting the generality of, but consistent with, the foregoing, the Board and/or the Committee are expressly authorized to adopt rules, procedures, and sub-plans, which, for purposes of the Non-423 Component, may be beyond the scope of Section 423 of the Code, regarding, without limitation, eligibility to participate in the Plan, excluding Employees in certain countries under the Non-423 Component (even if employed by a Participating Company), handling and making of employee contributions under the Plan, satisfying payroll taxes, determining beneficiaries, withholding procedures and issuances of Stock, any of which may vary from time to time and between jurisdictions, as determined by the Board and/or the Committee.

SECTION 18. TAX QUALIFICATION.

The 423 Component is intended to be exempt from the application of Section 409A of the Code under Section 1.409A-1(b)(5)(ii) of the U.S. Treasury Regulations. Purchases of stock by Participants who are U.S. taxpayers participating in the Non-423 Component are intended to be exempt from the application of Section 409A of the Code under the short-term deferral exception and any ambiguities will be construed and interpreted in accordance with such intent. Subject to the provisions of this Section 18, Participants who are U.S. taxpayers participating in the Non-423 Component shall be subject to such terms and conditions as shall permit his or her participation in the Plan to satisfy the requirements of the short-term deferral exception to Section 409A of the Code, including the requirement that the shares subject to the right to purchase Stock under the Plan be delivered within the short-term deferral period. The foregoing notwithstanding, neither the Company nor any Parent or Subsidiary shall have any liability to a Participant or any other person if the right to purchase Stock under the Plan that is intended to be exempt from or compliant with Section 409A of the Code is not so exempt or compliant or for any action taken by the Committee, the Board, the Company or any Parent or Subsidiary in relation thereto. Although the Company may endeavor to (i) qualify the 423 Component or Non-423 Component for special tax treatment under the laws and regulations of the United States or of a jurisdiction other than the United States or (ii) avoid adverse tax treatment (e.g., under Section 409A of the Code), the Company makes no representation to that effect and expressly disavows any covenant to maintain special or to avoid unfavorable tax treatment, any other provision of the Plan notwithstanding, including this Section 18. The Company and each Parent and Subsidiary shall be unconstrained in their corporate activities without regard to any potentially negative tax impact on any one or more Participants.

SECTION 19. SEVERABILITY.

If any particular provision of the Plan is found to be invalid or otherwise unenforceable, such provision shall not affect the other provisions of the Plan, and the Plan shall be construed in all respects as if such invalid provision were omitted.

SECTION 20. AMENDMENT AND TERMINATION.

The Board shall have the right to amend, suspend or terminate the Plan, and to shorten an Offering Period (and refund Participant contributions in the event of any such shortening, suspension or termination) at any time and without notice. Except as provided in Section 14, any increase in the aggregate number of shares of Stock to be issued under the Plan shall be subject to approval by a vote of the stockholders of the Company. In addition, any other amendment of the Plan shall be subject to approval by a vote of the stockholders of the Company to the extent required by applicable law, rule or regulation, including, without limitation, Section 423 of the Code.

[End of Document]

Exhibit 10.17

STOCK OPTION AGREEMENT
UNDER THE AQUESTIVE THERAPEUTICS, INC.
2018 EQUITY INCENTIVE PLAN

THIS STOCK OPTION AGREEMENT (this "***Agreement***") between Aquestive Therapeutics, Inc. (the "***Corporation***" or the "***Company***") and the individual specified on the Notice of Grant (the "***Optionee***") is made as of the date of grant specified on the Notice of Grant to which this Agreement is attached (the "***Grant Notice***"). The date of grant specified on the Grant Notice is referred to herein as the "***Grant Date***."

RECITALS

WHEREAS, the Corporation maintains the Aquestive Therapeutics, Inc. 2018 Equity Incentive Plan (the "***Plan***") for the benefit of its employees, directors and consultants; and

WHEREAS, the Plan permits the Corporation to award options with respect to shares of the Corporation's common stock, $0.[____] par value per share ("***Shares***"), subject to the terms of the Plan.

NOW, THEREFORE, in consideration of these premises and the agreements set forth herein, the parties, intending to be legally bound hereby, agree as follows:

1. Award of Option. The Corporation hereby grants to the Optionee, as of the Grant Date, the option (the "***Option***") to purchase the number of Shares specified on the Grant Notice (the "***Option Shares***"). The Option is subject to the terms set forth herein, and the terms of the Plan, which terms and provisions are incorporated herein by reference. Capitalized terms used but not otherwise defined herein shall have the meanings ascribed to such terms in the Plan.

2. Type of Option. If the Grant Notice indicates that the grant type is "ISO," then the Option is intended to be an Incentive Stock Option described by Section 422 of the Internal Revenue Code of 1986, as amended (the "***Code***"). Notwithstanding the designation of this Option as either an Incentive Stock Option or non-qualified stock option, the Corporation makes no representation as to the treatment of the Option under any federal, state, local or foreign tax law and the Corporation has not advised the Optionee on such matters. If the Grant Notice does not specify the grant type as "ISO," or if any portion of the Option cannot qualify as an Incentive Stock Option, then the Option (or such portion of the Option, as applicable) shall not be an Incentive Stock Option.

3. Term of Option.

(a) Term. The term of the Option shall commence on the Grant Date and end on the Expiration Date specified on the Grant Notice, or on such earlier date as provided in the Plan and Section 3(b) below (the "***Term***").

(b) Termination of Employment. Upon the Optionee's termination of employment with the Company and its Subsidiaries, the unvested portion of the Option shall cease to vest and shall be forfeited and the vested portion of the Option shall remain exercisable by the Optionee or the Optionee's beneficiary or legal representative, as the case may be, for a period of (i) 90 days in the event of a termination by the Company or a Subsidiary for Cause, (ii) one year in the event of a termination due to death or Disability, by the Company or a Subsidiary without Cause, by the Optionee for Good Reason or as the result of the Optionee's Retirement and (iii) six months in the event of the Optionee's resignation without Good Reason and not due to Retirement; provided, however, that no part of the Option shall be exercisable after the Expiration Date. The entire unexercised portion of the Option, whether or not vested, shall be forfeited immediately upon the Optionee's termination by the Company or a Subsidiary for Cause.

4. Exercise Price. The cost to the Optionee to purchase, pursuant to this Agreement, one Option Share is the Exercise Price specified on the Grant Notice (subject to adjustment as set forth in the Plan).

5. Vesting; Exercise of Option. The Option will be exercisable during the Term only to the extent that it is then vested and then only in accordance with the terms and provisions of the Plan and this Agreement.

(a) Vesting. The Option will vest and become exercisable in accordance with the vesting schedule set forth on the Grant Notice. Except as provided in Section 7.2 of the Plan, upon the Optionee's termination of employment with the Corporation and its Subsidiaries for any reason, the unvested portion of the Option shall be immediately forfeited with no compensation due to the Optionee.

(b) Method of Exercise. The Optionee may exercise the Option by providing written notice to the Corporation stating the election to exercise the Option. Such written notice shall be signed by the Optionee and shall be delivered in person or by certified mail to the Secretary of the Corporation or such other Person as may be designated by the Corporation. The written notice shall be accompanied by (i) payment of the Exercise Price and (ii) payment of, or arrangement of payment of, all applicable withholding taxes as provided in Section 9 below. Payment of the purchase price shall be by cash, certified or bank check, the cashless exercise program adopted by the Committee and applicable to Optionee (if then in effect as required by the Plan) or such other consideration and method of payment as may be authorized by the Committee pursuant to the Plan. Following exercise, any certificate(s) for Option Shares shall be registered in the name of the Optionee (or his or her heirs or beneficiary, as applicable).

(c) Partial Exercise. The Option, to the extent vested, may be exercised in whole or in part; provided, however, that any exercise may apply only with respect to whole numbers of Option Shares.

(d) Restrictions on Exercise. Upon a Change in Control, the right to exercise the Option shall be subject to Sections 7.1 and 7.2 of the Plan. The Option shall not be exercised if the issuance of the Option Shares upon such exercise would constitute a violation of any applicable federal or state securities laws or other laws or regulations. As a further condition to the exercise of the Option, and in addition to any other requirements set forth in this Agreement, the Corporation may require the Optionee to make any other representation or warranty to the Corporation as may be required by or advisable under any applicable law or regulation.

(e) Termination of Option. Upon the end of the Term, any portion of the Option that remains unexercised shall be forfeited and cancelled with no compensation due to the Optionee.

6. Transferability of Option. The Option may be transferred only as provided in Section 12 of the Plan. If the Optionee dies during the Term, the terms of this Agreement and the Plan will be binding upon the executors, administrators, legal guardians, representatives, estate and heirs of the Optionee, whether testamentary heirs or heirs by intestacy.

7. Conditions on All Transfers of Option Shares. Notwithstanding anything to the contrary contained in this Section 7, no Transfer of an Option Share shall be made, or, if attempted or purported to be made, shall be effective, unless and until the Corporation is satisfied that the Transfer will not violate any federal or state securities law or any other law or agreement (including this Agreement). If the Transfer would violate any such law or agreement and the Optionee nevertheless attempts or purports to engage in a Transfer of Option Shares, then the Corporation shall not recognize such Transfer on the books and records of the Corporation and such Transfer will be null and void *ab initio*. In addition, the Optionee will be liable to the Corporation for damages, if any, which may result from such attempted or purported Transfer.

8. No Promise of Employment. Neither the Plan nor the Option nor the holding of Option Shares will confer upon the Optionee any right to continue in the employ or other service of the Corporation or any Subsidiary, or limit, in any respect, the right of the Corporation or any Subsidiary to discharge the Optionee at any time, with or without Cause and with or without notice.

9. Withholding. The Optionee shall be responsible for making appropriate provision for all taxes required to be withheld in connection with the Option or the exercise thereof (including, without limitation, through the cashless exercise program adopted by the Committee and applicable to Optionee (if then in effect as required by the Plan)). Such responsibility shall extend to all applicable federal, state, local and foreign withholding taxes. The Corporation or its Subsidiaries, in their sole discretion, shall have the right to retain the number of shares whose Fair Market Value equals the amount to be withheld in satisfaction of the applicable withholding taxes (or to withhold from any payroll or other amounts otherwise due to the Optionee the amount of withholding taxes due in connection with the exercise of the Option).

10. The Plan. The Optionee has received a copy of the Plan (a copy of which is attached hereto as Exhibit A), has read the Plan and is familiar with its terms, and hereby accepts the Option subject to all of the terms and provisions of the Plan, as amended from time to time, and this Agreement. Pursuant to the Plan, the Committee is authorized to interpret the Plan and to adopt rules and regulations not inconsistent with the Plan as it deems appropriate. The Optionee hereby agrees to accept as binding, conclusive and final all decisions or interpretations of the Committee with respect to the Plan, this Agreement, the Option Shares or any agreement relating to the Option or the Option Shares. In the event of a conflict or inconsistency between the Plan and this Agreement, the terms of the Plan shall control.

11. Governing Law. This Agreement will be construed in accordance with the laws of the State of Delaware, without regard to the application of the principles of conflicts of laws of Delaware or any other jurisdiction.

12. Severability. All provisions of this Agreement are distinct and severable and if any clause shall be held to be invalid, illegal or against public policy, the validity or the legality of the remainder of this Agreement shall not be affected thereby, and the remainder of this Agreement shall be interpreted to give maximum effect to the original intention of the parties hereto.

13. Amendment. Subject to the provisions of the Plan, this Agreement may only be amended by a writing signed by each of the parties hereto.

14. Section 16 Override. Notwithstanding anything contained in the Plan or this Agreement to the contrary, if Optionee is subject to Section 16 of the Exchange Act with respect to the Company at the time of the exercise of the Option, Optionee shall be permitted to direct the Company in Optionee's sole discretion to withhold Shares from those otherwise due with respect to the exercise of the Option to pay the exercise price and withholding taxes relating to the exercise of the Option. Only whole shares of Common Stock shall be withheld and the number of shares of Common Stock withheld shall be based on the Fair Market Value of the Common Stock on the date of exercise.

15. Entire Agreement. This Agreement, together with the Grant Notice and the Plan, and the other exhibits attached thereto or hereto, represents the entire agreement between the parties hereto relating to the subject matter hereof, and merges and supersedes all prior and contemporaneous discussions, agreements and understandings of every nature relating to the award of the Option to Optionee by the Corporation.

* * * * *

EXHIBIT A

Aquestive Therapeutics Inc. 2018 Equity Incentive Plan

NOTICE OF GRANT AND OPTION AGREEMENT

Company Information:	**Optionee:**
Aquestive Therapeutics, Inc.	[NAME]
[Address]	[ADDRESS] [CITY, STATE, ZIP] [Country]
Phone: [_____]	Phone: [_____]
Fax: [_____]	Email: [_____]

Plan Name:	Aquestive Therapeutics, Inc. 2018 Equity Incentive Plan	Date of Grant:	[_____]
Grant Type:	[ISO] [NQSO]	Expiration Date:	[_____]
Option Number:	[___]		
Number of Shares Underlying Option:	[_____]		
Vesting Type:	Other	Exercise Price:	$[_____]
Vesting Start Date:	[_____]	Total Option Price:	$[_____]

Vesting Schedule:

Date Vested	Shares Vested
[_____]	[_____]
[_____]	[_____]
[_____]	[_____]
[_____]	[_____]
[_____]	[_____]
[_____]	[_____]
[_____]	[_____]
[_____]	[_____]
Total:	[_____]

By your signature and the Company's signature below, you and the Company agree that the Option specified in this Grant Notice is granted under and governed by the terms and conditions of the Aquestive Therapeutics, Inc. 2018 Equity Incentive Plan, as amended from time to time, and the Option Agreement, all of which are attached and made a part of this Grant Notice.

OPTIONEE:	AQUESTIVE THERAPEUTICS, INC.
Name: [_____]	By: [_____]
Date: _____	Date: _____

Exhibit 10.18

RESTRICTED STOCK UNIT AGREEMENT
UNDER THE AQUESTIVE THERAPEUTICS, INC.
2018 EQUITY INCENTIVE PLAN

THIS RESTRICTED STOCK UNIT AGREEMENT (this "***Agreement***") between Aquestive Therapeutics, Inc. ("***Aquestive***") and the individual specified on the Notice of Grant (the "***Grantee***") is made as of the date of grant specified on the Notice of Grant to which this Agreement is attached (the "***Grant Notice***"). The Date of Grant specified on the Grant Notice is referred to herein as the "***Grant Date***."

RECITALS

WHEREAS, Aquestive maintains the Aquestive Therapeutics, Inc. 2018 Equity Incentive Plan (as it may be amended from time to time, the "***Plan***") for the benefit of its employees, directors and consultants; and

WHEREAS, the Plan permits Aquestive to award restricted stock units with respect to shares of Aquestive's common stock, $0.001 par value per share ("***Shares***"), subject to the terms of the Plan.

NOW, THEREFORE, in consideration of these premises and the agreements set forth herein, the parties, intending to be legally bound hereby, agree as follows:

1. Award of RSUs. Aquestive hereby grants to the Grantee, as of the Grant Date, the number of restricted stock units specified on the Grant Notice (the "***RSUs***"). With respect to each RSU, the Grantee will be entitled to receive one Share upon the settlement of such RSU (the "***RSU Shares***"). The RSUs are subject to the terms set forth herein, and the terms of the Plan, which terms and provisions are incorporated herein by reference. Capitalized terms used but not otherwise defined herein shall have the meanings ascribed to such terms in the Plan.

2. Vesting; Settlement.

(a) The RSUs shall be unvested upon the Grant Date and shall vest in 36 equal monthly installments, commencing on the last business day of the month immediately following the month in which the Grant Date occurs and continuing for each of the next 35 months immediately following such month (with vesting to occur on the last business day of any such month), subject to Grantee's continued employment with Aquestive from the Grant Date through the applicable vesting date; provided, however, that (i) in the event that prior to the date on which all of the RSUs have become fully vested, Grantee's employment is terminated by Aquestive other than for Cause, is terminated by Aquestive due to Grantee's Disability, is terminated as the result of Grantee's death or is terminated by Grantee for Good Reason, then all RSUs that are unvested as of such date shall immediately vest in full upon such termination of employment and (ii) vesting and settlement of fractional RSUs shall be delayed until a whole number of RSUs have become vested. If the Grantee's employment with Aquestive is terminated by Aquestive for Cause or by the Grantee without Good Reason, then all RSUs that are unvested as of the date of such termination of employment shall be forfeited with no payment or other compensation due to the Grantee.

(b) Unless required to be delayed pursuant to the third and fourth sentences of Section 18 of the Plan, an RSU shall be settled by delivery to Grantee of one Share as soon as reasonably practicable following the date on which such RSU becomes vested and in any event within 30 days after the vesting date.

(c) Prior to the settlement of the RSUs, the Grantee shall have no rights of a stockholder with respect to the RSU Shares, including, without limitation, the right to receive dividends with respect to such RSU Shares or the right to vote such RSU Shares. Notwithstanding the foregoing or anything contained in this Agreement to the contrary, upon the settlement of any RSU, the Grantee shall be entitled to receive a number of additional Shares equal to the quotient of (x) the per Share amount of dividends with a record date during the period commencing on the Grant Date and ending on the date immediately preceding such settlement date, multiplied by the number of RSUs then being settled and (y) the Fair Market Value of one Share on the date immediately preceding the settlement date (provided (i) any fractional share instead shall be paid in cash and (ii) if there are not sufficient Shares under the Plan, such dividend equivalents instead shall be paid in cash). The right to any such Shares or cash payments will be forfeited upon the forfeiture of the RSU to which they relate, with no compensation or other payment due to Grantee.

3. Transferability of RSUs. The RSUs may not be sold, pledged, assigned, hypothecated, gifted, transferred or disposed of in any manner either voluntarily or involuntarily by operation of law, other than by will or by the laws of descent and distribution or except as and to the extent permitted by Section 12 of the Plan

4. Conditions on All Transfers of RSU Shares. Notwithstanding anything to the contrary contained in this Agreement or the Plan, no Transfer of an RSU Share shall be made, or, if attempted or purported to be made, shall be effective, unless and until Aquestive is satisfied that the Transfer will not violate any federal or state securities law or any other law or agreement (including this Agreement). If the Transfer would violate any such law or agreement and the Grantee nevertheless attempts or purports to engage in a Transfer of RSU Shares, then Aquestive shall not recognize such Transfer on the books and records of Aquestive and such Transfer will be null and void *ab initio*. In addition, the Grantee will be liable to Aquestive for damages, if any, which may result from such attempted or purported Transfer.

5. No Promise of Employment or Other Service. Neither the Plan nor the RSUs nor the holding of RSU Shares will confer upon the Grantee any right to continue in the employ or other service of Aquestive or any Subsidiary, or limit, in any respect, the right of Aquestive or any Subsidiary to discharge the Grantee at any time, with or without Cause and with or without notice.

6. Withholding. In order to satisfy the Grantee's tax withholding obligations relating to the RSUs, Aquestive shall retain the whole number of Shares from those otherwise being delivered in settlement of the RSUs whose Fair Market Value on the date of settlement equals the amount required to be withheld, provided that the Grantee shall be responsible for making arrangements to satisfy any additional required withholding resulting from any fractional Share not being withheld (and Aquestive and its Subsidiaries shall have the right to withhold from any payroll or other amounts otherwise due to the Grantee the amount of such withholding taxes due). Withholding shall occur at the minimum required tax withholding rates.

7. Section 409A. It is intended that the RSUs and this Agreement be exempt from Section 409A of the Code or, to the extent not so exempt, comply with the requirements of Section 409A of the Code, and this Agreement shall be interpreted consistently with the foregoing without resulting in any increase in the amounts owed hereunder by Aquestive or any Subsidiary. [Notwithstanding anything contained in the Plan or this Agreement to the contrary, except as specifically provided in Section [__] of Grantee's employment agreement with Aquestive, dated as of [____], 2018 (as amended and/or restated from time to time, the "***Employment Agreement***"), neither Aquestive nor any Subsidiary shall have any liability or obligation to the Grantee or to any other person or entity for taxes, interest, penalties or fines relating to the RSUs, the RSU Shares, this Agreement or the Plan (including any of the foregoing resulting from the failure of this Agreement to be exempt from or comply with Section 409A of the Code).]

8. The Plan. The Grantee has received a copy of the Plan, has read the Plan and is familiar with its terms, and hereby accepts the RSUs subject to all of the terms and provisions of the Plan, as amended from time to time, and this Agreement. Pursuant to the Plan, the Committee is authorized to interpret the Plan and to adopt rules and regulations not inconsistent with the Plan as it deems appropriate. The Grantee hereby agrees to accept as binding, conclusive and final all decisions or interpretations of the Committee with respect to the Plan, this Agreement, the RSUs, the RSU Shares or any agreement relating to the RSUs or the RSU Shares. In the event of a conflict between the terms of the Plan and the terms of this Agreement, the terms of the Plan shall control.

9. Governing Law. This Agreement will be construed in accordance with the laws of the State of Delaware, without regard to the application of the principles of conflicts of laws of Delaware or any other jurisdiction.

10. Severability. All provisions of this Agreement are distinct and severable and if any clause shall be held to be invalid, illegal or against public policy, the validity or the legality of the remainder of this Agreement shall not be affected thereby, and the remainder of this Agreement shall be interpreted to give maximum effect to the original intention of the parties hereto.

11. Amendment. Subject to the provisions of the Plan, this Agreement may only be amended by a writing signed by each of the parties hereto.

12. Entire Agreement. This Agreement, together with the Grant Notice and the Plan, and the other exhibits attached thereto or hereto, represents the entire agreement between the parties hereto relating to the subject matter hereof, and merges and supersedes all prior and contemporaneous discussions, agreements and understandings of every nature relating to the award of the RSUs to Grantee by Aquestive. [The Grantee expressly acknowledges and agrees that the grant of the RSUs covered by this Agreement satisfies all of Aquestive's obligations under Section [___] of the Employment Agreement, and from and after the Grant Date, Grantee no longer has any rights under Section [____] of the Employment Agreement.]

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

The Board of Directors
Aquestive Therapeutics, Inc.:

We consent to the use of our report included herein and to the reference to our firm under the heading “Experts” in the prospectus.

/s/ KPMG LLP

New York, New York
July 15, 2018