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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2020

OR

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

For the transition period from _____ to _____

Commission File Number: 001-38599

Aquestive Therapeutics, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**82-3827296**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification Number)
30 Technology Drive, Warren, NJ	**07059**
(Address of Principal Executive Offices)	(Zip Code)

(908) 941-1900
(Registrant's Telephone Number, Including Area Code)

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

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.001 per share	AQST	NASDAQ Global Market

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

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

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

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

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

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

Large accelerated filer ☐	Accelerated filer ☐
Non-accelerated filer ☒	Smaller reporting company ☒
	Emerging growth company ☒

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

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

As of June 30, 2020, the last day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the common stock held by non-affiliates of the registrant was approximately $102.3 million based on the closing price of the registrant's common stock on such date.

The number of outstanding shares of the registrant's par value $0.001 common stock as of the close of business on March 5, 2021 was 36,213,969.

The registrant intends to file a definitive proxy statement pursuant to Regulation 14A in connection with its 2021 Annual Meeting of Shareholders within 120 days of the end of its fiscal year ended December 31, 2020. Portions of such definitive proxy statement are incorporated by reference into Part III of this Annual Report on Form 10-K.

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PART I

Forward-Looking Statements

This Annual Report on Form 10-K and certain other communications made by us include forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "believe," "anticipate," "plan," "expect," "estimate," "intend," "may," "will," or the negative of those terms, and similar expressions, are intended to identify forward-looking statements.

These forward-looking statements include, but are not limited to, statements regarding the advancement and related timing of Libervant™ and AQST-108-SF through the regulatory and development pipeline; the focus on growing the Company's commercial sales of Sympazan® and continuing to manufacture Suboxone® and other licensed products; the ability to address the concerns identified in the FDA's Complete Response Letter dated September 25, 2020 regarding the New Drug Application for Libervant and obtain FDA approval of Libervant for U.S. market access; clinical trial timing and plans for AQST-108-SF; the 2021 financial outlook; and business strategies, market opportunities, and other statements that are not historical facts. These forward-looking statements are also subject to the uncertain impact of the COVID-19 global pandemic on our business including with respect to our clinical trials including site initiation, patient enrollment and timing and adequacy of clinical trials; on regulatory submissions and regulatory reviews and approvals of our product candidates; pharmaceutical ingredients and other raw materials supply chain, manufacture and distribution; sale of and demand for our products; our liquidity and availability of capital resources, customer demand for our products and services; customers' ability to pay for goods and services; and ongoing availability of an appropriate labor force and skilled professionals. Given these uncertainties the Company is unable to provide assurance that operations can be maintained as planned prior to the COVID-19 pandemic.

These forward-looking statements are also based on our current expectations and beliefs and are subject to a number of risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. Such risks and uncertainties include, but are not limited to, risks associated with the Company's development work, including any delays or changes to the timing, cost and success of our product development activities and clinical trials and plans; risk of delays in regulatory advancement through the FDA of Libervant and our other drug candidates or failure to receive approval, including the failure to receive orphan drug exclusivity; risk that a competitor obtains other FDA marketing exclusivity that blocks U.S. market access for Libervant or any of our other product candidates; risk inherent in commercializing a new product (including technology risks, financial risks, market risks and implementation risks and regulatory limitations); risks and uncertainties concerning the revenue stream from the monetization of the Company's royalty rights for the product KYNMOBI®, as well as the achievement of royalty targets worldwide or in any jurisdiction and certain other commercial targets required for contingent payments under the KYNMOBI monetization transaction; risk of development of our sales and marketing capabilities; risk of sufficient capital and cash resources, including access to available debt and equity financing and revenues from operations, to satisfy all of our short-term and longer-term cash requirements and other cash needs, at the times and in the amounts needed; risk of failure to satisfy all financial and other debt covenants and of any default; risk related to government claims against Indivior for which we license, manufacture and sell Suboxone® and which accounts for the substantial part of our current operating revenues; risks related to the outsourcing of certain marketing and other operational and staff functions to third parties; risk of the rate and degree of market acceptance of our product and product candidates; the success of any competing products including generics, risk of the size and growth of our product markets; risk of compliance with all FDA and other governmental and customer requirements for our manufacturing facilities; risks associated with intellectual property rights and infringement claims relating to the Company's products; risk of unexpected patent developments; risk of legislation and regulatory actions and changes in laws or regulations affecting our business; risk of loss of significant customers; risks related to legal proceedings including patent infringement, securities, investigative, product safety or efficacy and antitrust litigation matters; risk of product recalls and withdrawals; the COVID-19 pandemic and its impact on our business; uncertainties related to general economic, political, business, industry, regulatory and market conditions and other unusual items; and other uncertainties affecting the Company including those described in the "Risk Factors" section and in other sections included in this Annual Report on Form10-K, in our Quarterly Reports on Form 10-Q, and in our Current Reports on Form 8-K filed with the Securities and Exchange Commission (SEC). Given these uncertainties, you should not place undue reliance on these forward-looking statements, which speak only as the date made. All subsequent forward-looking statements attributable to us or any person acting on our behalf are expressly qualified in their entirety by this cautionary statement. The Company assumes no obligation to update forward-looking statements, or outlook or guidance after the date of this Annual Report whether as a result of new information, future events or otherwise, except as may be required by applicable law. Readers should not rely on the forward-looking statements included in this Annual Report as representing our views as of any date after the date of the filing of this Annual Report on Form 10-K.

These forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to differ materially from those expressed or implied by these statements. These factors include the matters discussed and referenced in Part I-Item 1A. Risk Factors of this Form 10-K.

Item 1. Business

References

Aquestive Therapeutics, Inc., a Delaware corporation, was formed effective on January 1, 2018 via the conversion of MonoSol Rx, LLC, a Delaware limited liability company and predecessor to Aquestive Therapeutics, Inc., into a C corporation and a simultaneous name change to Aquestive Therapeutics, Inc. (referred to in this Annual Report on Form 10-K as the "January 2018 Conversion"). Our principal executive offices are located at 30 Technology Drive, Warren, New Jersey 07059 and our telephone number is 908-941-1900. Unless the context otherwise indicates, references to "Aquestive", "AQST", "we", the "Company", "us" and "our" in this Annual Report on Form 10-K refers to Aquestive Therapeutics, Inc.

Overview

We are a pharmaceutical company focused on developing and commercializing differentiated products which leverage our proprietary PharmFilm® technology to meet patients' unmet medical needs and to solve patients' therapeutic problems. We have five products approved by the U.S. Food and Drug Administration (FDA), both proprietary and out-licensed, as well as a late-stage proprietary product pipeline focused on the treatment of central nervous system, or CNS, diseases and an earlier stage pipeline including treatment of anaphylaxis. Our licensees market their products in the U.S. and in some instances outside the U.S. The Company markets its proprietary product in the U.S. We believe that our proprietary and licensed products address the needs of these patient populations and the shortcomings of available treatments create opportunities for the development and commercialization of meaningfully differentiated medicines.

Our largest commercialized licensed product to date is Suboxone®, a sublingual film formulation of buprenorphine and naloxone, for the treatment of opioid dependence. We have a sole and exclusive worldwide agreement with our licensee for this product, Indivior Inc., to manufacture Suboxone. In early 2019, certain third-party pharmaceutical companies launched, at risk, generic film products for buprenorphine-naloxone. As of January 31, 2021, Suboxone branded products retain approximately 40% of film market share as generic film-based products have penetrated this market. Indivior accounted for 57% of our total revenues during fiscal year 2020. Our total revenue mix is expected to shift in coming years to a higher proportionate share of proprietary product sales as we continue to grow Sympazan® revenues and pursue the launch of other products in our pipeline, assuming FDA approvals.

We manufacture all of our licensed and proprietary products at our FDA, Australian Government Department of Health's Therapeutics Goods Administration, or TGA, 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 2.2 billion doses of Suboxone since 2010. Not all collaborative or licensed products of the Company that may be commercially launched in the future will necessarily be manufactured by us, such as the case with KYNMOBI®.

PharmFilm® – Our Oral Film Technology

We are presently the worldwide leader in oral film drug delivery and manufacturing, having historically supplied the substantial majority 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 includes at least 250 issued patents worldwide, of which at least 45 are U.S. patents, and more than 90 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, formulations 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 processes enable PharmFilm® to be engineered to fit a variety of target product profiles in order to best address unmet patient needs 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.

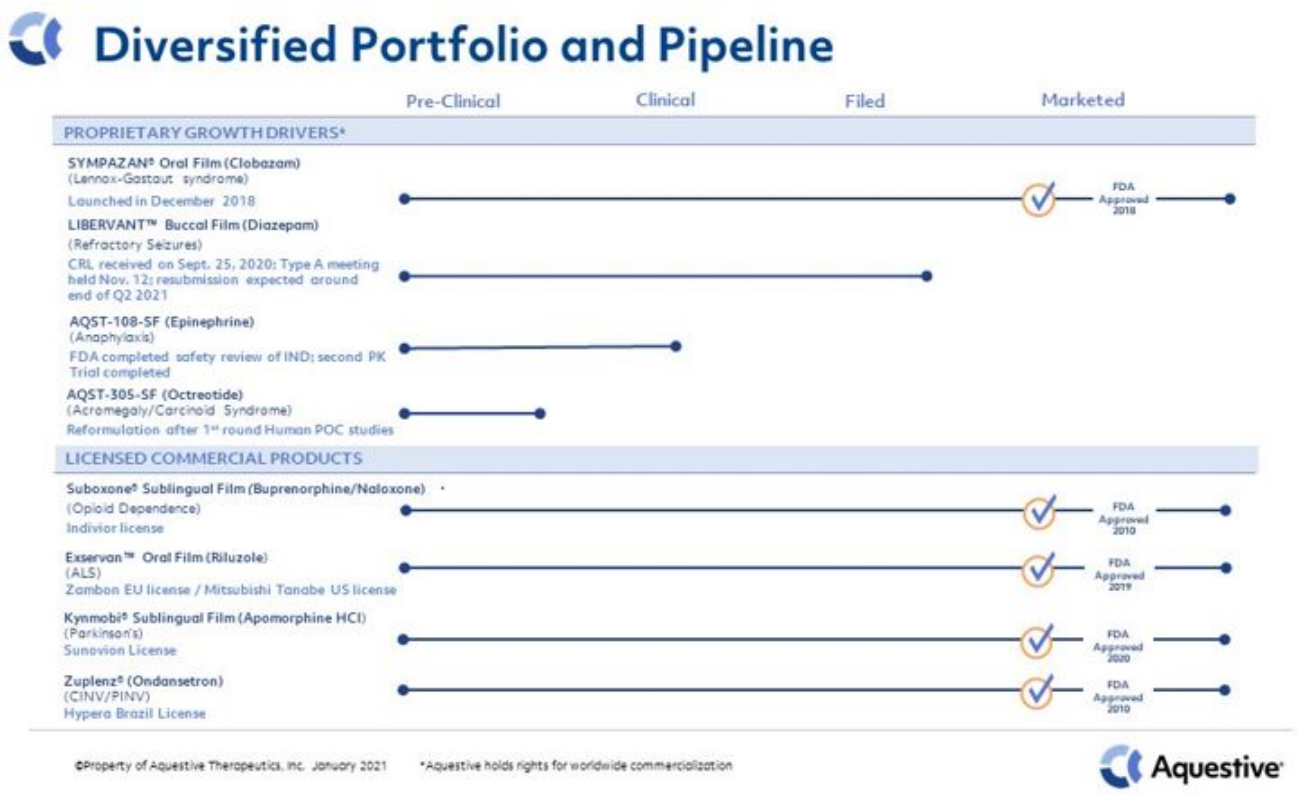
We believe the innovative nature of our drug delivery platform has the potential to offer a number of meaningful advantages to patients, caregivers and physicians compared to current standard of care therapies, including:

- preferred alternative to more invasive drug administration methods such as injection, rectal or nasal applications;
- faster, or at least equivalent, onset of action;
- ease of administration and availability (no device required, no gel to transport);
- 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 to meet patients’ unmet medical needs and to solve patients’ therapeutic problems. 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 Product Portfolio and Pipeline

The following table outlines our pipeline of products and product candidates.



Sympazan®, Zuplenz®, PharmFilm® and the Aquestive logo are registered trademarks of Aquestive Therapeutics, Inc. All other registered trademarks referenced herein are the property of their respective owners.

Proprietary Growth Drivers

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 ensures consistent therapeutic dosing. We believe that these characteristics will permit us to achieve the desired patient outcomes, while potentially reducing the total cost of patient care.

Our two most advanced assets within our proprietary CNS portfolio, focused in epilepsy, are as follows:

- **Sympazan®** – an oral soluble film formulation of clobazam used for the treatment of seizures associated with a rare, intractable form of epilepsy known as Lennox-Gastaut syndrome, or LGS, was approved by the FDA on November 1, 2018. We commercially launched Sympazan in December 2018. Sympazan was launched as a precursor and complement to our product candidate Libervant™ and continues to progress on key performance metrics including prescriber growth, repeat prescribers, quarterly growth in retail shipments and covered lives. We developed Sympazan as an alternative to the Onfi® brand and generic clobazam products, which were previously only available in either tablet form or liquid suspensions. LGS patients often have difficulty swallowing pills and large volume suspensions lead to uncertain and inconsistent dosing. These challenges increase the burden of care, particularly for patients that have difficulty swallowing or who may be combative or resistant during treatment administration. We believe that Sympazan addresses these treatment obstacles because it is mucoadhesive, dissolves rapidly and cannot be easily spit out.

- **Libervant™** – a buccally, or inside of the cheek, administered soluble film formulation of diazepam is our most advanced proprietary investigational product candidate, which we intend to self-commercialize, subject to FDA approval for U.S. market access. Aquestive is developing Libervant as an alternative to device-dependent rescue therapies currently available to patients with refractory epilepsy, which are a rectal gel and newly approved nasal sprays. In late September 2020, we received a complete response letter (“CRL”) from the FDA focusing on dosing issues in certain weight groups. At a Type A meeting with the FDA in November, the FDA confirmed that these issues may be addressed by utilizing modeling and simulations for an updated dosing regimen. The Company resubmitted a revised weight-based dosing regimen with modeling and simulations in December 2020. As recently announced, the FDA provided feedback on the December submission which provided clarity regarding the information that the Agency expected to see in the Company’s population pharmacokinetic model and safety data as it relates specifically to the patient population included in the studies. The Company will be working on the NDA to provide a resubmission in a form that the Company believes will be acceptable to the FDA. Based upon the FDA’s feedback at the Type A meeting as well as further guidance from the Agency, the Company continues to believe that no further clinical studies are necessary. The Company expects to resubmit its NDA at the end of the second quarter of 2021. Once the NDA is resubmitted, the Company anticipates a six month review process. We are seeking to demonstrate that Libervant will, if approved by the FDA, represent a “major contribution to patient care” within the meaning of FDA regulations and guidance, as compared to available treatment options, as the first, non-device delivered, oral diazepam-based product available to manage seizure clusters in epilepsy patients. However, overcoming the orphan drug marketing exclusivity is difficult to establish, with limited precedent, and there can be no assurance that the FDA will agree with our position seeking to overcome such marketing exclusivity and approve Libervant for U.S. market

access. Further, there can be no assurance that a competitor will not obtain other FDA marketing exclusivity that blocks U.S. market access for Libervant. Any failure to obtain FDA approval of and to demonstrate clinical superiority for Libervant would have a material adverse effect on our business, financial condition and results of operations in 2021 and later. More details on this product approval are described in the “Competition” section of this Item I. Business of this Form 10-K.

Complex Molecule Portfolio

We have also developed a proprietary pipeline of complex molecule-based products as alternatives to invasively administered standard of care injectable therapeutics addressing large market opportunities beyond CNS indications.

The active programs in our complex molecule portfolio are:

- **AQST-108-Sublingual Film (or SF)** – using Aquestive's proprietary PharmFilm® technologies, is a "first of its kind" oral sublingual film formulation delivering systemic epinephrine that is in development for the treatment of anaphylaxis. The Company submitted an IND for AQST-108-SF to the FDA on June 23, 2020. The FDA confirmed that the drug candidate will be reviewed under the 505(b)(2) regulatory approval pathway. We expect that this pathway will provide the means to more expedient and less costly development and filing. We recently completed a second pharmacokinetic (PK) trial for AQST-108-SF. The Phase 1 study featured a 4-treatment crossover design that compared the pharmacokinetics, safety and pharmacodynamics of epinephrine administered in a sublingual film to that of epinephrine administered via both subcutaneous and intramuscular injections in 28 healthy adult subjects. Based on top-line results, AQST-108-SF was generally well-tolerated, with adverse events observed that are consistent with the known adverse events profile for epinephrine. AQST-108-SF also achieved a similar time to maximal concentrations, or Tmax, when compared to both the subcutaneous and intramuscular injections of epinephrine. The first PK trial for AQST-108-SF was a single ascending dose study that compared pharmacokinetics, safety and pharmacodynamics of epinephrine administered in a sublingual film at ascending dose levels in 6-12 healthy adult subjects per dose level. In this study AQST-108-SF was generally well tolerated, with adverse events observed that are consistent with the known adverse events profile for epinephrine. The data from both this Phase 1 PK trial and the previous trials collectively demonstrate that AQST-108-SF can consistently deliver epinephrine sublingually and, after receiving AQST-108-SF, all subjects had measurable plasma concentrations of epinephrine. We have already submitted our dossier to Health Canada for a third Phase 1 PK trial and plan on commencing the study as soon as we receive the necessary documentation. Epinephrine is the standard of care in the treatment of anaphylaxis and is currently administered via subcutaneous or intramuscular injection. The current market leader is a single-dose, pre-filled automatic injection device. As a result of administration via subcutaneous or intramuscular injection, many patients and their caregivers are reluctant to use currently available products, resulting in increased hospital visits and overall cost of care to treat anaphylactic events. The data from the Company's previously completed Phase 1 dose escalation study demonstrated that AQST-108-SF achieved similar ranges of mean values of maximum concentration (Cmax) and time to reach maximum concentration (Tmax) to that reported for injectables provided a greater total exposure (AUC0-t; area under the curve) than that reported for the injectables and had less interpatient variability when compared to the degree of variation (CV%) data reported for injectables, and was well tolerated, with no study participants discontinuing participation due to an adverse event. We believe that, as a result of its sublingual administration, AQST-108-SF will improve patient compliance and lower the total cost of care.

- **AQST-305-SF** – is 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 in 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 toward 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 in the treatment cycle. AQST-305 has shown promising preclinical and human proof of concept results. While we focus our efforts on Libervant and AQST-108-SF in the short-term, we have taken the necessary steps to prepare AQST-305-SF for additional research trials.

Licensed Commercial Products and Product Candidates

Our portfolio also includes products and product candidates that we have licensed, or will seek to license, or for which we have licensed our intellectual property for commercialization. In the years ended December 31, 2020 and 2019, our licensed product portfolio generated $40.2 million and $49.7 million in revenue to Aquestive, respectively. Those products include:

- **Suboxone®** – a sublingual film formulation of buprenorphine and naloxone, respectively an opioid agonist and antagonist, that is marketed in the United States and internationally for the treatment of opioid dependence. Suboxone Sublingual Film was launched by our licensee, Indivior Inc., or Indivior, in 2010. Suboxone Sublingual Film is the most prescribed branded product in its category and was the first sublingual film product for the treatment of opioid dependence. We are the sole and exclusive supplier and manufacturer of Suboxone Sublingual Film and have produced over 2.2 billion doses of Suboxone since its launch in 2010. As of January 31, 2021, Suboxone branded products retain approximately 40% film market share as generic film-based products have penetrated this market. We have filed patent infringement lawsuits against certain companies relating to generic film-based products for buprenorphine-naloxone. More details regarding these lawsuits are described in Part II Item 8. Financial Statements and Supplementary Data, Note 20. Contingencies.

- **Exservan®** (riluzole) – has been developed, utilizing our proprietary PharmFilm technology, for the treatment of amyotrophic lateral sclerosis (ALS). We believe that Exservan, via our orally administered dosage form, can bring meaningful assistance to patients who are diagnosed with ALS and face difficulties swallowing traditional forms of medication. Exservan was approved by the FDA on November 22, 2019. During the fourth quarter of 2019, we announced the grant of a license to Zambon S.p.A. for the development and commercialization of Exservan Oral Film in the European Union (EU) for the treatment of ALS. Zambon is a multinational pharmaceutical company with a focus on the CNS therapeutic area. Under the terms of the license agreement, an upfront payment was paid to Aquestive for the development and commercialization rights of Exservan in the EU, and Aquestive will be paid development and sales milestone payments and low double-digit royalties on net sales of the product in the EU. Zambon is responsible for the regulatory approval and marketing of Exservan in the countries where Zambon seeks to market the product, and Aquestive will be responsible for the development and manufacture of the product.

  In January 2021, we announced our exclusive license to Mitsubishi Tanabe Pharma Holdings America, Inc. ("MTHA") for the commercialization in the United States of Exservan. MTHA is a multinational pharmaceutical company with a focus on patients with ALS. Under the terms of the MTHA license agreement, upfront payments were paid to Aquestive with additional payments due upon the occurrence of certain milestone events in advance of launch. Aquestive will also be paid double-digit royalties on net sales of the product in the United States and will earn revenue pursuant to the exclusive supply agreement. The product is expected to launch in mid-2021. Exservan may potentially fulfill a critical need for ALS patients, given it can be administered safely and easily, twice daily, without water.

- **KYNMOBI®**– a sublingual film formulation of apomorphine, which is a dopamine agonist developed to treat episodic off-periods in Parkinson's disease. We licensed our intellectual property to Cynapsus Therapeutics, Inc., a company that was acquired by Sunovion Pharmaceuticals Inc., or Sunovion, for the commercialization of KYNMOBI under an Agreement dated April 1, 2016, as amended (the "Sunovion License Agreement"). KYNMOBI was approved by the FDA on May 21, 2020 and commercially launched by Sunovion in September 2020. On November 3, 2020, we entered into a Purchase and Sale Agreement (the "Monetization Agreement") with MAM Pangolin Royalty, LLC, an affiliate of Marathon Asset Management ("Marathon"). Under the terms of the Monetization Agreement, we sold all of our contractual rights to receive royalties and milestone payments due under the Sunovion License Agreement related to Sunovion's apomorphine product, KYNMOBI®. Through December 31, 2020, the Company received $50.0 million in gross proceeds pursuant to the Monetization Agreement, inclusive of an upfront payment of $40.0 million and the achievement of the first milestone payment of $10.0 million. Under the Monetization Agreement, additional aggregate contingent payments of up to $75.0 million may be due the Company upon the achievement of worldwide royalty and other commercial targets within a specified timeframe, which could result in total potential gross proceeds under the Monetization Agreement of $125.0 million.

- **Zuplenz** – an oral soluble film formulation of ondansetron, a 5-HT antagonist approved for the treatment of nausea and vomiting associated with chemotherapy and post-operative recovery. Ondansetron is available as branded and generic products as intravenous injections, intramuscular injections, orally dissolving tablets, oral solution tablets, and film. We licensed commercial rights for Zuplenz to Hypera in Brazil. We licensed commercial rights for Zuplenz to Fortovia Therapeutics (previously Midatech Pharma PLC) in the United States, Canada, and China. Fortovia launched Zuplenz in the United States in 2015. We had been the sole and exclusive manufacturer of Zuplenz for Fortovia. On August 31, 2020 Fortovia filed a Chapter 11 bankruptcy proceeding in the Bankruptcy Court for the Eastern District of North Carolina. On January 29, 2021, the Bankruptcy Court approved an agreement pursuant to which the license and supply agreement between Aquestive and Fortovia was terminated, and all rights to commercialize Zuplenz returned to us, effective January 30, 2021. While not expected to be a material product for the Company, we are seeking a new partner to commercialize Zuplenz in the United States.

Market Overview

Epilepsy

Epilepsy is a chronic CNS disorder characterized by recurrent seizure activity. There are 3.4 million people in the United States suffering from epilepsy. According to IQVIA data, antiepileptic medications generated billions of dollars of sales in the United States in 2019. The direct (medical) and indirect (lost wages and productivity) annual costs associated with epileptic patients in the United States are significant.

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 may 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 has historically been marketed as a product administered rectally and more recently, a nasal spray product was introduced to the market. Although the rectal gel has been the preferred drug prescribed by physicians, its rectal administration presents a particular challenge for patients. As a result, only approximately 100,000 patients out of 1.2 million potential patients who could benefit from this treatment currently use this therapy. The remaining sufferers either pursue less effective treatments or forego treatment altogether. We have been developing Libervant as an alternative to the device-dependent rescue therapies currently available to patients with refractory epilepsy. See "Our Product Portfolio and Pipeline" above and "Competition" below in this Item 1. Business of this Form 10-K for additional information concerning the Libervant FDA approval process and market access issues.

There are multiple epileptic syndromes including LGS, which is a rare, intractable form of epilepsy affecting approximately 48,000 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 (branded name Onfi) is available in both a tablet and suspension formulation. Generic versions of the clobazam tablet and suspension formulation are available to patients, as well. Clobazam generated combined sales revenue of $263 million with more than 658,000 prescriptions filled in 2020. Sympazan was developed to reduce the burden associated with drug administration and cost.

Anaphylaxis

Anaphylaxis is a severe systemic allergic reaction that can be triggered by certain foods, medications, insect stings 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 is a potentially life-threatening systemic allergic reaction, with an estimated incidence of 50 to 112 episodes per 100,000 people per year. The frequency of hospital admissions for anaphylaxis has increased 500-700% in the last 10-15 years. The most common causes of reactions that can include anaphylaxis are medications, foods (such as peanuts), and venom from insect stings. 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.

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, as well as several auto-injector products. A branded form of epinephrine known as the EpiPen®, which utilizes a proprietary auto-injector device administered through a deep intramuscular injection, represents over 60% of the current branded market on a prescription volume basis. 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. Auto-injectors can be inconvenient to transport and many patients and caregivers dislike injections as a delivery method. In addition, in the past, manufacturing issues that resulted in injector malfunctions had led to patient concern regarding the reliability of auto-injectors. Proper dosing and the ability to effectively administer epinephrine in a timely, reliable manner is critical for patients experiencing anaphylaxis as well as other acute allergic reactions. However, we believe that 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-SF, a "first of its kind" oral sublingual film formulation delivering systemic epinephrine that is in development as a rescue medicine for the treatment of anaphylaxis using Aquestive's proprietary PharmFilm® technologies, to improve patient compliance and lower the total cost of care. 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 will improve patient compliance. Subject to our achieving regulatory approval of this product candidate, which we cannot assure, we believe AQST-108-SF 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.

Manufacturing and Product Supply

We operate two manufacturing and primary packaging facilities located in Portage, Indiana, where we currently manufacture proprietary CNS products, as well as our licensed products, Suboxone and Exservan, on an exclusive basis. These facilities are expected to have a combined capacity to accommodate the production of our proprietary and licensed products, as well as our pipeline product candidates, without any current need for additional infrastructure. We will continue to consider our anticipated facilities and infrastructure needs as our product development grows. We have produced over 1.0 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 are subject to various regulatory requirements, such as the regulations of the FDA, the DEA, the EU and other foreign health authorities such as the TGA. We are required to register our facilities and adhere to current Good Manufacturing Practices (cGMP) standards. These standards require 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. Failure to comply with these and other statutory and

regulatory requirements subjects a manufacturer to possible legal or regulatory action, including warning letters, the seizure or recall of products, injunctions, consent decrees placing significant restrictions on or suspending manufacturing operations and civil and criminal penalties. Adverse events with the product or product complaints must be reported and could result in the imposition of market restrictions through labeling changes or in product removal. Product approvals may be withdrawn if compliance with regulatory requirements is not maintained or if problems concerning safety or efficacy of the product occur following approval.

We purchase our raw materials, including active pharmaceutical ingredients, from qualified, approved vendors both domestically and internationally. While we typically source raw materials from the lowest cost provider whenever possible, we continue to pursue a multi-supplier strategy for all of our critical raw materials, where available or appropriate. Our product packaging foil is supplied by a single manufacturer. Such manufacturer utilizes multiple manufacturing facilities for production of our packaging foil. We may 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 contract research organizations, or 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. Additionally, we continue to outsource secondary packaging and third-party logistics for our proprietary products.

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 partnership or license 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 have approval and are seeking approval.

The biotechnology and pharmaceutical industries are characterized by rapid evolution and advancements of technologies, intense competition and strong defense of intellectual property. Any products and product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. Key product features that would affect our ability to effectively compete with other therapeutics include the efficacy, safety and convenience of our products and the ease of use and effectiveness of any companion diagnostics. The level of generic competition and the availability of reimbursement from government and other third-party payors will also significantly affect the pricing and competitiveness of our products.

On January 10, 2020, a competitor of Aquestive obtained FDA approval of its diazepam nasal spray drug candidate and was granted orphan-drug-exclusivity for this drug commencing as of January 10, 2020. A company that obtains FDA approval for a designated orphan drug receives orphan market exclusivity for that drug for the designated indication for a period of seven years from the grant date in the United States. This orphan drug exclusivity approval prevents a subsequent product seeking FDA approval from being marketed in the United States during the exclusivity period for the same active moiety for the same orphan drug indication except in the case where the drug candidate sponsor is able to demonstrate, and the FDA concludes, that the later drug is “clinically superior” to the approved products (*e.g.*, safer, more effective, or providing a major contribution to patient care) within the meaning of FDA regulations and guidance. In assessing whether a drug candidate sponsor has demonstrated that its drug candidate provides a “major contribution to patient care” over and above the currently approved drugs, which is evaluated by the FDA on a case by case basis, there is no single objective standard and the FDA may, in appropriate circumstances, consider such factors as convenience of treatment location, duration of treatment, patient comfort, reduced treatment burden, advances in ease and comfort of drug administration, longer periods between doses, and potential for self-administration. We are seeking to demonstrate that Libervant will, if approved by the FDA for U.S. market access, represent a “major contribution to patient care” within the meaning of FDA regulations and guidance, to manage seizure clusters in epilepsy patients. However, such a demonstration to overcome such seven-year market exclusivity is difficult to establish, with limited precedent, and there can be no assurance that the FDA will agree with our position seeking to overcome such marketing exclusivity and approve Libervant for U.S. market access. There is also a risk that a competitor could obtain other FDA marketing exclusivity that blocks U.S. market access for Libervant. Any failure to obtain FDA approval of and to demonstrate clinical superiority for Libervant would have a material adverse effect on our business, financial condition and results of operations in 2021 and later.

Material Agreements

Commercial Exploitation Agreement with Indivior

In August 2008, we entered into a Commercial Exploitation Agreement with Reckitt Benckiser Pharmaceuticals, Inc. (with subsequent amendments collectively, the “Indivior License Agreement”). Reckitt Benckiser Pharmaceuticals, Inc. was later succeeded to in interest by Indivior Inc. Pursuant to the Indivior License Agreement, we have agreed to manufacture and supply Indivior’s requirements of Suboxone for 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 with Indivior. Additionally, we are required to obtain Active Pharmaceutical Ingredients ("API") for the manufacture of Suboxone directly from Indivior. The Indivior License Agreement specifies a maximum 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 scaled rebates on its purchases.

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 (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 limited to the life of the related United States or international patents. In 2012, Indivior exercised its right to buy out its future royalty obligations for sales within the United States under the Indivior License Agreement. Indivior remains obligated to pay royalties for all sales outside the United States.

The Indivior License Agreement contains customary contractual termination provisions, including with respect to a filing for bankruptcy or corporate dissolution, an invalidation of intellectual property surrounding Suboxone, and commission of a material breach of the Indivior License Agreement by either party. Additionally, Indivior may terminate the Indivior License Agreement 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 either party provides the other 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 (the "Indivior Supplemental Agreement"). Pursuant to the Indivior Supplemental Agreement, we conveyed to Indivior all 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 buprenorphine 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. Through February 20, 2019, the date of launch of the competing generics of Dr. Reddy's Labs and Alvogen, we received an aggregate of $40.75 million from Indivior under the Indivior Supplemental Agreement. Further payments under the Indivior Supplemental Agreement are suspended until adjudication of related patent infringement litigation is finalized. If such litigation is successful, in addition to the amounts already received as described in the foregoing, we may receive up to an additional $34.25 million consisting of (i) up to $33.0 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) the additional $1.25 million that was earned through the issuance of additional process patent rights to us. The aggregate payments under this Indivior Supplemental Agreement are capped at $75.0 million.

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 that 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 57% of our total revenue for the year ended December 31, 2020 and 86% of the total revenue in 2019.

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 Pharmaceuticals, Inc, or Sunovion), referred to as the Sunovion License Agreement, pursuant to which Sunovion obtained 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 apomorphine for the treatment of off episodes in Parkinson's disease patients. Sunovion used this intellectual property to develop its apomorphine product, KYNMOBI®, which was approved by the FDA on May 21, 2020 and commercially launched by Sunovion in September 2020. The FDA approval triggered Sunovion's obligation to remit payment of $4.0 million (the "FDA Approval Milestone Payment") which was received in September 2020 and is included in License and royalty revenues for the year ended December 31, 2020.

In consideration of the rights granted to Sunovion under the Sunovion License Agreement, we have received aggregate payments totaling $22.0 million to date. In addition to the upfront payment of $5.0 million we have also earned an aggregate of $17.0 million in connection with specified regulatory and development milestones in the United States and Europe (the "Initial Milestone Payments"). As a result of the Monetization Agreement, we are no longer entitled to receive the remaining contingent royalty or milestone payments related to the net sales thresholds of KYNMOBI·. During the second quarter of 2020, we recorded revenues of $8.0 million for minimum royalties due under the Sunovion License Agreement, reflected in License and royalty revenues for year-ended December 31, 2020.

Effective March 16, 2020, we entered into a first amendment (the "First Amendment") to the Sunovion Agreement. The Amendment provides for the following: (i) inclusion of the United Kingdom and any other country currently in the European Union (EU) that later withdraws as a member country of the EU for the purpose of determining the satisfaction of the condition triggering the obligation to pay the third milestone due under the Sunovion License Agreement, (ii) extension of the date after which Sunovion has the right to terminate the Sunovion License Agreement for convenience from December 31, 2024 to March 31, 2028, (iii) modification of the effective inception date of the first minimum royalty due from Sunovion to us from January 1, 2020 to April 1, 2020, and (iv) modification of the termination provisions to reflect our waiver of our right to terminate the Sunovion License Agreement in the event that KYNMOBI® was not commercialized by January 1, 2020. The Sunovion License Agreement will continue until terminated by Sunovion in accordance with the termination provisions of the First Amendment. The Sunovion License Agreement continues (on a country-by-country basis) until the expiration of all applicable licensed patents. Upon termination of the Sunovion License Agreement, all rights to intellectual property granted to Sunovion to develop and commercialize apomorphine-based products will revert back to us.

Effective as of October 23, 2020, we entered into a Second Amendment to the Sunovion License Agreement for the purpose of clarifying the rights and obligations of the parties with respect to the prosecution and maintenance of the patents covered under the Sunovion License Agreement and to provide that, on and after March 31, 2028, in respect of any jurisdiction or jurisdictions covered under the Sunovion License Agreement, Sunovion may terminate its rights to the licensed Patents under the Sunovion License Agreement upon 180 days prior written notice.

Purchase and Sale Agreement with Marathon - KYNMOBI® Monetization

On November 3, 2020, we entered into a Purchase and Sale Agreement (the "Monetization Agreement") with MAM Pangolin Royalty, LLC, an affiliate of Marathon Asset Management ("Marathon"). Under the terms of the Monetization Agreement, we sold all of our contractual rights to receive royalties and milestone payments due under the Sunovion License Agreement related to Sunovion's apomorphine product, KYNMOBI®. Through December 31, 2020, the Company received $50.0 million in gross proceeds pursuant to the Monetization Agreement, inclusive of an upfront payment of $40.0 million and the achievement of the first milestone payment of $10.0 million. Under the Monetization Agreement, additional aggregate contingent payments of up to $75.0 million may be due the Company upon the achievement of worldwide royalty and other commercial targets within a specified timeframe, which could result in total potential gross proceeds under the Monetization Agreement of $125.0 million.

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 by the Company and KemPharm in April 2011. Under this termination arrangement, we have the right to participate in any and all value that KemPharm may derive from the commercialization or any other monetization of KemPharm's KP 415 and KP 484 compounds or their derivatives. Among these monetization transactions are those related to any business combinations involving KemPharm and collaborations, royalty arrangements, or other transactions from which KemPharm may realize value from these compounds. During September 2019, we received $1.0 million from our 10% share of milestone payments received by KemPharm under its licensing of KP 415 and KP 484 to a third party. We also received a payment of $0.5 million under this arrangement during June 2020 in connection the FDA's acceptance of a NDA filing for KP 415. On March 2, 2021 KemPharm announced FDA approval of KP 415 (AZTARYS™) a new once-daily treatment for ADHD. Our share of the milestone payments associated with KP 415 approval and the achievement of certain targeted labeling goals may reach $4.8 million.

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 EU 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 drug 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 7 years in the United States and 10 years in the EU . 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 250 issued patents worldwide, of which at least 45 are U.S. patents, and more than 90 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® formulations of tadalafil, diazepam, clobazam, riluzole, epinephrine and octreotide. These patents and, if issued as patents, pending patent applications will likely expire between 2022 and 2040. 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 likely expire by 2040. The projected expiration dates exclude any patent term adjustment or patent term extension.

PharmFilm® – Our Oral Film Technology

Our PharmFilm® technology is covered by at least 8 patent families. These patent families provide process, composition of matter protection for our PharmFilm® technology, and comprise at least 50 issued patents worldwide, of which at least 19 are U.S. patents, and related pending patent applications worldwide. The patents and pending patent applications, if issued as patents, will likely expire between 2022 and 2040, excluding any patent term adjustment or patent term extension.

The PharmFilm® technology patents and/or patent applications 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 licensee programs. For example, encompassed within our platform technology patents and/or patent applications 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 and/or patent applications further cover the products Suboxone and Zuplenz, as well as our formulations of the molecules apomorphine and tadalafil, which are part of our licensed programs. The expiration dates for patents covering these products and product candidates, and for pending applications if issued as patents, extend from 2022 to 2040, 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.

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 relationship with us be kept confidential and not be disclosed to third parties except in specific circumstances, nor used outside the scope of their employment. 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 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 areas.

Regulatory

FDA Approval Process

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

FDA approval is required before any new 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 a New Drug Application, or 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 current good manufacturing, or 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 institutional review board, or 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 includes 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 the Prescription Drug User Fee Act, or 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 and possibly conducts a sponsor inspection, 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. The review by the FDA is two months for a Class I resubmission and six months for a Class 2 resubmission. 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, or Risk Evaluation and Mitigation Strategy, 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 similar procedures in reviewing NDA supplements as it does in reviewing NDAs.

Post-Approval Requirements

Ongoing adverse event reporting and submission of periodic reports are required following FDA approval of an NDA. The FDA also may require post-marketing testing, known as Phase 4 testing, REMS, and surveillance to monitor the effects of an approved product, or the FDA may place conditions on an approval that could restrict the distribution or use of the product. In addition, quality control, drug manufacture, packaging, and labeling procedures must continue to conform to cGMPs and NDA specifications after approval. Drug manufacturers and certain of their subcontractors are required to register their establishments with FDA and obtain licenses from certain state agencies. Registration with the FDA subjects entities to periodic unannounced inspections by FDA, during which the agency inspects manufacturing facilities to assess compliance with cGMPs or other applicable laws, such as adverse event recordkeeping and reporting. Accordingly, manufacturers must continue to expend time, money, and training and compliance efforts in the areas of production and quality control to maintain compliance with cGMPs or other applicable laws, such as adverse event recordkeeping and reporting requirements. Regulatory authorities may require remediation, 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 or new concerns are subsequently discovered. In addition, other regulatory action, including, among other things, warning letters, the seizure of products, injunctions, consent decrees placing significant restrictions on or suspending manufacturing operations, civil penalties, and criminal prosecution may be pursued.

In addition, any distribution of prescription drug products 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 the FDA pursuant to the DSCSA. Until the 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 new chemical entity, or NCE, which is a drug that contains an active moiety that has not been approved by the 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 can bring actions under the Federal False Claims Act and certain states have enacted laws modeled after the Federal False Claims Act.

In addition to the privacy and security requirements of 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), HIPPA also expanded and created several additional federal crimes, including healthcare fraud and false statements relating to healthcare matters. The healthcare fraud statute prohibits, among other things, knowingly and willfully executing a scheme to defraud any healthcare benefit program, including private third-party payors. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false, fictitious or fraudulent statement or 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 market 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 changed the way healthcare is financed by both governmental and private insurers and significantly impacted 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 in which manufacturers must agree to offer 50% (increased to 70% pursuant to the Bipartisan Budget Act of 2018, effective as of 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, 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 impacted 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.

Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the PPACA, and we expect there will be additional challenges and amendments to the PPACA in the future. Various portions of the PPACA are currently undergoing legal and constitutional challenges in the United States Supreme Court, the Trump administration issued various Executive Orders which eliminated cost-sharing subsidies and various provisions that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices; and Congress has introduced several pieces of legislation aimed at significantly revising or repealing the PPACA. It is unclear whether the PPACA will be overturned, repealed, replaced, or further amended.

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. Pursuant to the

Coronavirus Aid, Relief, and Economic Security Act, also known as the CARES Act, these reductions are suspended from May 1, 2020 through December 31, 2020 due to the COVID-19 pandemic. As the legislation currently stands, the reductions went back into effect January 2021 and will remain in effect through 2030 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. On July 24, 2020, President Trump signed four Executive Orders directing the Secretary of HHS to: (1) eliminate protection under an Anti-Kickback Statute safe harbor for certain retrospective price reductions provided by drug manufacturers to sponsors of Medicare Part D plans or pharmacy benefit managers that are not applied at the point-of-sale; (2) allow the importation of certain drugs from other countries through individual waivers, permit the re-importation of insulin products, and prioritize finalization of FDA's December 2019 proposed rule to permit the importation of drugs from Canada; (3) ensure that payment by the Medicare program for certain Medicare Part B drugs is not higher than the payment by other comparable countries (depending on whether pharmaceutical manufacturers agree to other measures); and (4) allow certain low-income individuals receiving insulin and epinephrine purchased by a Federally Qualified Health Center, or FQHC, as part of the 340B drug program to purchase those drugs at the discounted price paid by the FQHC. On October 1, 2020, the FDA issued its final rule allowing importation of certain prescription drugs from Canada. On September 13, 2020, President Trump signed an Executive Order directing HHS to implement a rulemaking plan to test a payment model, pursuant to which Medicare would pay, for certain high-cost prescription drugs and biological products covered by Medicare Part B, no more than the most-favored-nation price (i.e., the lowest price) after adjustments, for a pharmaceutical product that the drug manufacturer sells in a member country of the Organization for Economic Cooperation and Development that has a comparable per-capita gross domestic product. While some proposed measures will require authorization through additional legislation to become effective, Congress has indicated that they will continue to pursue new legislative and/or administrative measures to control drug costs, including price or patient reimbursement constraints, discounts, restrictions on certain access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. With the election of a new Presidential administration, it is unclear at this time to predict what legislative initiatives the President and Congress may propose related to drug pricing. 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

The commercial success of our products and product candidates, if and when approved, is partially dependent on the availability of coverage and adequate reimbursement from public (i.e., federal and state government) and private (i.e., commercial) payors. These third-party payors may deny coverage or reimbursement for a product or therapy, either in whole or in part, if they determine that the product or therapy was not medically appropriate or necessary. Also, third-party payors will continue to control costs by limiting coverage through the use of formularies and other cost-containment mechanisms, and the amount of reimbursement for particular procedures or drug treatments.

As discussed above, the cost of pharmaceuticals continues to generate substantial governmental and third-party payor interest. We expect that the pharmaceutical industry will experience pricing pressures, given the trend toward managed healthcare, the increasing influence of managed care organizations, and additional regulatory and legislative proposals. Our results of operations and business could be adversely affected by current and future third-party payor policies, as well as healthcare legislative reforms.

Additionally, we must offer discounted pricing or rebates on purchases of pharmaceutical products under various federal and state healthcare programs, including: the Centers for Medicare & Medicaid Services' Medicaid Drug Rebate Program, Medicare Part B Program and Medicare Part D Coverage Gap Discount Programs, the U.S. Department of Veterans Affairs' Federal Supply Schedule Program, and the Health Resources and Services Administration's 340B Drug Pricing Program. We must also report specific prices to government agencies under healthcare programs, such as the Medicaid Drug Rebate Program and Medicare Part B Program. The calculations necessary to determine the prices reported are complex and the failure to report prices accurately may expose us to penalties.

Some third-party payors also require pre-approval of coverage for new or innovative drug therapies before they will reimburse healthcare providers who use such therapies. While we cannot predict whether any proposed cost-containment measures will be adopted or otherwise implemented in the future, including any changes to any Medicare reimbursement program, these requirements or any announcement or adoption of such proposals could have a material adverse effect on our ability to obtain adequate prices for our product candidates and to operate profitably.

In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. There can be no assurance that our products will be considered medically reasonable and necessary for a specific indication, that our products will be considered cost-effective by third-party payors, that an adequate level of reimbursement will be available, or that the third-party payors' reimbursement policies will not adversely affect our ability to sell our products profitably.

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 Annual Report on Form 10-K.

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. While we believe we are in compliance with applicable environmental and other regulations, 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 and Human Capital

As of December 31, 2020, we had 187 colleagues employed at the Company (including contract and temporary workers). All of these colleagues are located in the U.S. Of these colleagues, 19 are directly involved in research and development, 88 are involved in manufacturing operations, 80 are involved in commercialization and sales and general and administrative activities.

We are subject to local labor laws and regulations with respect to our employees in the jurisdictions in which they are employed. 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 colleagues are not represented by a labor union. We do not have individual written employment contracts with most of our colleagues and based on feedback generally believe that our colleagues are engaged and see Aquestive as an attractive workplace.

Our values - compliance, collaboration, integrity and high performance - are built on the foundation that the colleagues we hire and the way we treat one another promote creativity, innovation and productivity, which spur the Company's success. Providing market competitive pay and benefit programs, opportunities to participate in the success they help create, while engaging colleagues in important dialog regarding organizational performance, we create a culture of inclusion in which all colleagues have the opportunity to thrive.

Item 1A. Risk Factors

Investing in our common stock involves significant risk and investors should carefully consider the risks described below, together with all other information included or referenced in this Annual Report on Form 10-K. There are numerous and varied risks, known and unknown, that may prevent us from achieving our goals. The risks described below are not the only ones we will face. In addition to the other information in this Annual Report on Form 10-K, any of the factors set forth below could significantly and negatively affect our business, financial condition, results of operations or prospects and the trading price of our stock. This section contains forward-looking statements. You should refer to the explanation of the qualifications and limitations on forward-looking statements beginning on page 1 of this Annual Report on Form 10-K. The dollar amounts presented in this section are depicted in thousands.

Summary of Risk Factors

Material risks that may affect our business, operating results and financial condition include, but are not necessarily limited to, those relating to:

- we have incurred significant operating losses since inception and cannot assure you that we will ever achieve or sustain profitability;
- our business and operations may be adversely affected by the COVID-19 pandemic;
- we may fail to obtain regulatory approvals to market our products in the United States or in other countries;
- we may fail to obtain orphan drug status or other marketing exclusivity approvals for our product candidates;
- we will need to raise substantial funds in the future, and these funds may not be available on acceptable terms or at all. A failure to obtain this necessary capital when needed could force us to delay, limit, scale back or cease some or all operations;
- the development of pharmaceutical products involves a lengthy and expensive process, with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of any product;
- if our competitors are better able to develop and market products for the diagnosis and treatment of diseases of the central nervous system that are safer, more effective, less costly, easier to use or otherwise more attractive than our Pharmfilm technology, our business will be adversely impacted;
- even if our products are approved for commercial sale, if we are unable to expand our sales and marketing infrastructure, we may not be successful in commercializing our products in the United States;
- our ability to commercialize our product candidates will depend in part on the extent to which reimbursement will be available from government and health administration authorities, private health maintenance organizations and health insurers, and other healthcare payors;
- we have entered into, and may enter into collaborations, licensing arrangements, joint ventures, strategic alliances or partnerships with third-parties that may not result in the development of commercially viable products or the generation of significant future revenues;
- we are and will be dependent on third-party contract research organizations to conduct all of our clinical trials. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if the third parties need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our preclinical development activities or clinical trials may be extended, delayed, suspended or terminated and we may not be able to obtain regulatory approval for any of our product candidates;
- our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel;
- our ability to protect our intellectual property and proprietary technology is uncertain;
- we may be subject to damages resulting from claims that we, or our employees, have wrongfully used or disclosed alleged trade secrets of our competitors or are in breach of non-competition or non-solicitation agreements with our competitors;
- our products and operations are subject to extensive governmental regulation, and failure to comply with applicable requirements could cause our business to suffer; and
- if we issue more shares of our Common Stock to raise capital, our current stockholders will incur substantial dilution.

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 and, to date we have focused primarily on developing a broad product portfolio.

Some of our product candidates will require substantial additional development time and resources before we are able to receive regulatory approvals, implement commercialization strategies and begin generating revenue from product sales. Our commercialization efforts for our self-developed product and product candidates are still in their early stages and we may not generate substantial revenue from sales of our self-developed product and product candidates in the near term, if ever.

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, proceeds from our debt facilities, and from revenues from certain product licenses and collaborations and from our self-developed product. The extent of future net losses will depend, in part, on the rate of future expenditures and our ability to generate revenue.

The development, regulatory approval process, and commercialization of drug candidates involve significant risk and significant uncertainty, including matters over which we have no control. 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. We expect to incur substantial expenses going forward, which we expect will increase as we expand our development, commercialization activities and product portfolio. Some of the expenses we expect to incur going forward 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, sales, marketing, medical and management information systems personnel, including personnel to support our product development and commercialization efforts and to support our transition to operations as a public company; and
- experiencing incremental costs due to delays or encountering any issues with any of the above, including, but not limited to, failed or not fully successful trials, complex results, safety issues or other regulatory challenges.

We expect to continue to incur net losses for at least the next few years as we pursue the development, commercialization and marketing of our proprietary product candidates. Our net losses may fluctuate significantly from period to period, depending on regulatory approval developments concerning both our late-stage and earlier-stage product candidates, the timing of our planned clinical trials and expenditures on our other research and development, as well as our commercialization activities. We expect our expenses will continue to be substantial in 2021 and future periods as we continue, subject to any delay as a result of the coronavirus pandemic, to:

- focus on the approval of Libervant for marketing in the U.S. and, subsequently, if approved, which we cannot assure, its commercialization,
- continue to clinically develop AQST-108-SF along the 505(b)(2) approval pathway, having begun PK clinical trials during the third quarter of 2020, subject to any delay from the coronavirus pandemic; and
- continue to grow Sympazan revenues as a precursor and complement to the eventual launch of Libervant, if approved for U.S. market access, which we cannot assure.

We expect to continue to manage the timing and level of expenses in light of the declining Suboxone revenues, offset in part by increasing revenue contributions from Sympazan, while focusing on the development and commercialization of Libervant and AQST-108-SF and their subsequent commercialization, if approved by the FDA for U.S. market access.

Until we become profitable, if ever, we expect to need to raise significant additional capital in the future through equity or debt issuances, or both, to continue to manage our expenses to extend our capital runway, in order to further the development, regulatory approval, commercialization and marketing of our products and product candidates, and to conduct our business. We have no committed sources of additional capital, and there can be no assurance that such needed capital or debt financing will be available on favorable terms, or at all. We may seek to obtain additional capital in the future through the issuance of our common stock, through other public or private equity or debt financings, through potential non-dilutive capital raising events that may result from royalty streams that may be realizable from our licensed products or licensed intellectual property, through collaborations or licensing arrangements with other companies, and through the sale of assets, including product, product candidates, plants or other tangible assets, or by other means, if available. We may not be able to raise additional capital or other funding 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 would experience dilution, and debt financings, if available (and subject to all of the existing restrictions and conditions under the Indenture) may involve increased restrictive covenants and increased fixed payments or may otherwise further constrain our financial flexibility. To the extent that we raise additional funds through collaborative or licensing 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 licensees generally will depend upon our achievement of negotiated development and regulatory milestones. Failure to achieve these milestones may harm our future capital position.

We will need substantial additional capital to fund our operations, which may not be available on acceptable terms, if at all.

The Company's cash requirements for 2021 and beyond include expenses related to continuing development and clinical evaluation of its products, manufacture and supply costs, costs of regulatory filings, patent prosecution expenses and litigation expenses, expenses related to commercialization of our products, as well as costs to comply with the requirements of being a public company operating in a highly regulated industry. As of December 31, 2020, we had $31.8 million of cash and cash equivalents.

On November 3, 2020, we entered into a Purchase and Sale Agreement (the "Monetization Agreement") with MAM Pangolin Royalty, LLC, an affiliate of Marathon Asset Management ("Marathon"). Under the terms of the Monetization Agreement, we sold all of our contractual rights to receive royalties and milestone payments due under the Sunovion License Agreement related to Sunovion's apomorphine product, KYNMOBI®. KYNMOBI®, an apomorphine film therapy for the treatment of off episodes in Parkinson's disease patients, received approval from the U.S. Food and Drug Administration (FDA) on May 21, 2020. In exchange for the sale of these rights, we received an upfront payment of $40.0 million and an additional payment of $10.0 million through the achievement of the first milestone. We have received an aggregate amount of $50.0 million through December 31, 2020 under the Monetization Agreement.

Under the Monetization Agreement, additional aggregate contingent payments of up to $75.0 million may be due to us upon the achievement of worldwide royalty and other commercial targets within a specified timeframe, which could result in total potential proceeds of $125.0 million.

With the upfront proceeds of the monetization, we repaid $22.5 million of the Senior Secured Notes due 2025 (the "12.5% Notes"), and issued $4.0 million of new 12.5% Notes in lieu of paying a prepayment premium on the early repayment of the 12.5% Notes, reducing the aggregate principal balance of 12.5% Notes outstanding to $51.5 million. In addition, the holders of the 12.5% Notes agreed to extend to December 31, 2021 our ability to access, at our option, an additional $30.0 million of 12.5% Notes re-openers under the Indenture. The first $10.0 million senior notes re-opener represents a commitment of such amount by current holders of 12.5% Notes, at our option, contingent upon FDA approval of our product candidate Libervant. A second $20.0 million senior notes re-opener represents a right, at our option, to market to current holders of our 12.5% Notes, and/or other lenders, additional senior notes up to such amount, contingent upon FDA approval of Libervant for U.S. market access. If and to the extent that we access these re-openers, we will grant warrants to purchase up to 714,000 shares of common stock, with the strike price calculated based on the 30-day volume weighted average closing price of our common stock at the warrant grant date. In addition, as of the closing of this transaction, we issued to the holders of the 12.5% Notes warrants to purchase 143,000 shares of our common stock.

We may not be able to raise additional capital or secure other funding on terms acceptable to us, or at all, and any failure to raise additional capital or other funding as and when needed for our cash requirements would have a negative impact on our business, financial condition and prospects and on our ability to execute and achieve our business plan.

If adequate funds are not available for our liquidity needs and cash requirements as and when needed, or at all, we may be required to reduce staff, significantly delay, significantly scale back or even discontinue some or all of our research and development programs and clinical and other product development activities, reduce our planned commercialization efforts, enter into potential funding arrangements on unattractive terms, and otherwise significantly reduce our cash spend and adjust our operating plan, and we would need to seek to take other steps intended to improve our liquidity, any of 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. We also may be required to evaluate additional licensing opportunities, if any become available, of our proprietary products and product candidate programs that we currently plan to self-commercialize

or explore other potential liquidity opportunities or other alternatives or options or strategic alternatives, including the sale of assets, although we cannot be assured that any of these actions would be available at all or available on reasonable terms. 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 most if not all of their investment in us.

We may sell additional equity, incur debt or raise funds through licensing arrangements to fund our operations, which may result in dilution to our stockholders, impose restrictions on our business or require us to relinquish proprietary rights.

As of December 31, 2020, Aquestive has experienced a history of net losses and the Company's accumulated deficits totaled $186,257 which have been partially funded by gross margins from sales of commercialized licensed and proprietary products, license fees, milestone and royalty payments from our commercial licensees and co-development parties, and with the balance of the related funding requirements met by the Company's equity and debt offerings, including the 12.5% Notes. In 2019, the Company raised funding totaling $52.2 million, consisting of net proceeds of $13.1 million from the refinancing of debt in July 2019, $37.3 million from the public offering of 8,050,000 common shares in December 2019, and $1.8 million from the exercise of warrants in connection with the debt financing.

The Company began utilizing its "At-The-Market" (ATM) facility in November 2020 which has generated net cash of approximately $6.1 million as of December 31, 2020. This facility has approximately $18.5 million available at December 31, 2020.

Until such time, if ever, that we can generate sufficient revenue to fully fund our operations, we would need to seek additional capital and cash resources 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. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the stockholders' existing ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of existing stockholders. 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 additional indebtedness would result in increased fixed payment obligations and could also result in certain increased restrictive covenants (most if not all of which currently exist under our existing debt facilities), such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights or sell assets, and other operating restrictions that could adversely impact our ability to conduct our business and continue to result in liens being placed on all of our assets and intellectual property. If we were to default on such indebtedness, we could lose all such assets and intellectual property and our ability to operate our business.

If we raise additional funds through collaborations, or strategic alliance, marketing, distribution or licensing arrangements with third parties, we may need 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 can generate revenues from our operations in the future, our revenues and operating income is likely to fluctuate significantly from year-to-year or quarter-to-quarter and create volatility in our stock price.

Even if we are able to generate future revenues, our results of operations would likely continue to 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 approval, delay in any FDA or other regulatory approvals, or failure to obtain any such FDA or other regulatory approvals;
- competitor's product candidates obtaining FDA or other regulatory approval, which may include orphan drug market exclusivity for seven years in the U.S., before our product has received any such regulatory approval and/or orphan drug exclusivity;
- the timing of process validation for particular product candidates;
- the timing of product launches and market acceptance of such launched products;
- changes in the timing of and the amount we spend to research, develop, acquire, license or promote new product candidates;
- the timing, amount we spend on, and outcome of our research, development, preclinical studies and clinical trial programs;
- serious or unexpected health or safety concerns related to our products or product candidates;
- the introduction of new branded and generic products by others that render our product candidates obsolete, subject to greater competition or noncompetitive;
- our ability to maintain selling prices and gross margins on our commercial products;
- 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 commercial products and product candidates;
- manufacturing and supply interruptions, including product rejections or recalls due to failure to comply with manufacturing specifications or

current Good Manufacturing Practices;

- timing of revenue recognition related to our collaboration agreements;
- our ability and the significant cost to protect our intellectual property and avoid infringing the intellectual property of others and any adverse developments in any related legal proceeding or in other legal proceeding of any nature; and
- the outcome and cost of existing or possible future 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 substantial debt and substantial debt service obligations. At December 31, 2020, we had an aggregate principal amount of $51.5 million of outstanding indebtedness, represented by the 12.5% Notes. 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 (and we have substantial restrictions on incurring any additional indebtedness under our current debt instruments) 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 and revenues from licensed product or collaborative arrangements are insufficient to satisfy our obligations with respect to our existing indebtedness, we may be forced to seek to sell assets (subject to obtaining consent under the Indenture) 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 at a competitive disadvantage compared to our competitors that have less debt, less debt restriction or less restrictive debt covenants;
- our failure to comply with the financial and other restrictive covenants in our debt instruments which, among other things, limits our ability to incur additional debt and sell or dispose of assets, could result in an event of default that, if not cured or waived, would 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 and potential access to other funding. However, we may not have sufficient funds, and may be unable to arrange for additional financing, to pay the amounts due under the Indenture and 12.5% Notes or any other debt instruments we may enter into. Failure to make required debt service payments or comply with other covenants under our existing debt facilities or such other debt instruments would result in an event of default and acceleration of amounts due, which would have a material adverse effect on our business, financial condition and results of operations.

We are dependent upon the commercial success of our licensed and self-commercialized products 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 Suboxone, Exservan, KYNMOBI® and Sympazan, our ability to license Zuplenz, and our ability to commercialize our product candidate Libervant subject to FDA approval including our ability to demonstrate that Libervant will, if approved by the FDA for U.S. market access, represent a “major contribution to patient care” within the meaning of FDA regulations and guidance, as compared to available treatment options. There is no assurance that we will become commercially successful to the extent necessary to become profitable. If our current products are not commercially successful, our ability to generate manufacturing and sale margins and licensing or royalty revenues will be impaired. Without those revenues, our ability to continue planned development initiatives and commercialization efforts would be limited. Due to our dependence on the commercial success of our products, delays or setbacks in the commercial success of any of these products would likely materially adversely affect our business, prospects, results and operations and financial consideration.

A substantial portion of our revenues is derived from a single customer and license and any loss or material reduction in revenues from such significant customer would adversely affect our business.

Historically, a substantial portion of our revenues in each quarter and year has been derived from a single customer and this trend is expected to continue while we continue to develop, seek regulatory approval of and seek to commercialize our proprietary products and product candidates. If revenues from such key customer were to decline significantly, it would materially adversely affect our business, financial condition and results of operations.

In April 2019, the U.S. Department of Justice announced that a federal grand jury sitting in the Western District of Virginia had criminally indicated Indivior PLC, or Indivior, for which we exclusively manufacture and supply Suboxone film products and license certain of our intellectual property, in connection with Indivior's allegedly deceptive and misleading marketing and distribution practices in its distribution and sale of Suboxone film products, dating back a number of years, and seeking a monetary judgment of not less than $3 billion. Indivior has denied the claims and publicly stated that it intends to contest the allegations vigorously. Indivior accounted for approximately 57% of our revenues for 2020 and approximately 86% of our revenues for 2019 and we believe in the future will continue to account for a substantial part of our revenues. On July 24, 2020, Indivior disclosed a $600 million settlement and disposition of this matter with the U.S. Department of Justice. We cannot assess whether this settlement and disposition will have a material adverse financial impact on our business, prospects, liquidity, financial condition and operating results.

Further, the Indivior License Agreement under which we manufacture and supply Suboxone to Indivior on an exclusive basis, may be terminated should certain causes or events occur. For example, either party may terminate the relationship in connection with a material breach by the other party of its contractual obligations. Indivior may also terminate the Indivior License Agreement 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. In addition, the Indivior Licensing Agreement currently has a one-year term, subject to automatic one-year renewals unless either party provides the other party with twelve months' prior notice of non-renewal. As a result, there can be no assurance that either party will not terminate the Indivior License Agreement either due to any future breach of obligation, other termination cause or event, or notice of non-renewal. Any such termination would have a material adverse impact on our business, results of operations, capital position and prospects.

Indivior has ceased production of the authorized generic product of Suboxone which can be expected to continue to have a material impact on our manufactured product sales and revenues.

In early 2019, certain third-party pharmaceutical companies launched at risk, generic film products for buprenorphine-naloxone. Also, in early 2019 Indivior began to market and sell an authorized generic sublingual film product for Suboxone, which we also exclusively manufactured and supplied. In October 2019, Indivior publicly announced its intention to cease production of the authorized generic sublingual film product.

Indivior accounted for approximately 57% of our annual revenues in fiscal year 2020. As a result of Indivior's decision to cease production of the authorized generic sublingual film product, our manufacturing and supply revenue for that product has ceased, which has and we believe will continue to have a material negative impact on our manufacture and supply revenues and our results of operations. Although branded Suboxone has continued to retain meaningful market share, we have planned for the erosion of this sunsetting branded product over time, which will further affect our total revenues and our results from operations.

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

We are named as a defendant in antitrust litigation brought against us and Indivior. The litigation involves allegations that we have engaged in conduct intended to interfere with the introduction of generic drug products that would compete with our product, Suboxone, in the marketplace. We have denied any wrongdoing and are defending the litigation. However, depending on the outcome of the litigation, including whether or not any judgements are entered against us or Indivior and, if so, the extent of those judgements, our ability to earn revenues from Suboxone may be impaired, which may affect our business, profitability, prospects, financial condition ability to generate sufficient revenues, and our ability to raise additional funding. Moreover, regardless of the merits of any claim, the continued legal and other costs arising from these judicial proceedings may result in substantial additional expenses and divert management's time and attention away from our other business operations, which could also significantly harm our business. For more information, please see Part II Item 8. Financial Statements and Supplementary Data, Note 20. Contingencies.

KYNMOBI® is commercialized by Sunovion Pharmaceuticals, Inc., therefore, there is no assurance that we will receive additional contingent payments pursuant to the Monetization Agreement in the amount or at the time we have planned, or at all, and any failure to receive such payments would have a material adverse impact on our financial position and capital needs.

On November 3, 2020, we entered into a Purchase and Sale Agreement (the "Monetization Agreement") with MAM Pangolin Royalty, LLC, an affiliate of Marathon Asset Management ("Marathon"). Under the terms of the Monetization Agreement, we sold all of our contractual rights to receive royalties and milestone payments due under the Sunovion License Agreement related to Sunovion's apomorphine product, KYNMOBI®. KYNMOBI®, an apomorphine film therapy for the treatment of off episodes in Parkinson's disease patients, received approval from the U.S. Food and Drug Administration (FDA) on May 21, 2020. In exchange for the sale of these rights, we received an upfront payment of $40.0 million and an additional payment of $10.0 million through the achievement of the first milestone. We have received an aggregate amount of $50.0 million through December 31, 2020 under the Monetization Agreement.

Under the Monetization Agreement, additional aggregate contingent payments of up to $75.0 million may be due to us upon the achievement of worldwide royalty and other commercial targets within a specified timeframe, which could result in total

potential proceeds of $125.0 million.

With the upfront proceeds of the monetization, we repaid $22.5 million of the 12.5% Notes, and issued $4.0 million of new 12.5% Notes in lieu of paying a prepayment premium on the early repayment of the 12.5% Notes, reducing the aggregate principal balance of 12.5% Notes outstanding to $51.5 million.

We cannot be assured of receiving any additional contingent payments under the Monetization Agreement.

Risks Related to Development and Commercialization of Our Products and Product Candidates

We will be required to demonstrate to the FDA that our drug candidate Libervant™ provides a "major contribution to patient care" relative to the approved drugs with the same active moiety for the same indication, and there can be no assurance that we will be successful.

We are developing Libervant as an alternative to device-dependent rescue therapies currently available to patients with refractory epilepsy, which are a rectal gel and newly approved nasal sprays. We completed the rolling submission of our NDA filing with the FDA for Libervant on November 27, 2019, our NDA for Libervant was accepted by the FDA on February 10, 2020, and a PDUFA goal date of September 27, 2020 was provided by the FDA. On January 10, 2020 Neurelis, Inc. obtained FDA approval of its drug candidate Valtoco® (diazepam nasal spray). We are seeking to demonstrate that Libervant will, if approved by the FDA for U.S. market access, represent a "major contribution to patient care" within the meaning of FDA regulations and guidance, as compared to available treatment options, as the first, non-device delivered, oral diazepam-based product available to manage seizure clusters in epilepsy patients. However, overcoming the orphan drug marketing exclusivity is difficult to establish, with limited precedent, and there can be no assurance that the FDA will agree with our position seeking to overcome such market exclusivity and approve Libervant for U.S. market access. A company that obtains FDA approval for a designated orphan drug receives market exclusivity for that drug for the designated indication for a period of seven years from the grant date in the United States. This orphan drug exclusivity approval may prevent a subsequent product seeking FDA approval from being marketed in the United States during the exclusivity period for the same active moiety for the same orphan drug indication except in the case where the drug candidate sponsor is able to demonstrate, and the FDA concludes, that the later drug is "clinically superior" to the approved products (*e.g.*, safer, more effective, or providing a major contribution to patient care) within the meaning of FDA regulations and guidance. In assessing whether a drug candidate sponsor has demonstrated that its drug candidate provides a "major contribution to patient care" over and above the currently approved drugs, which is evaluated by the FDA on a case by case basis, there is no one objective standard and the FDA may, in appropriate circumstances, consider such factors as convenience of treatment location, duration of treatment, patient comfort, reduced treatment burden, advances in ease and comfort of drug administration, longer periods between doses, and potential for self-administration.

If the FDA does not approve our NDA for Libervant, or the continued development of Libervant is significantly delayed or terminated, our business and results of operations could be significantly adversely affected.

We completed the rolling submission of our NDA filing with the FDA for Libervant on November 27, 2019, our NDA for Libervant was accepted by the FDA on February 10, 2020, and a PDUFA goal date of September 27, 2020 was provided by the FDA. However, on September 25, 2020, we received a Complete Response Letter (CRL) from the FDA for Libervant. The FDA issues a CRL to indicate that the review cycle for an application is complete but the application cannot be approved in its current form. In the CRL, the FDA cited that, in a study submitted by the Company with the NDA, certain weight groups showed a lower drug exposure level than desired. In a Type A meeting with the FDA in November, the FDA confirmed that these issues may be addressed by utilizing modeling and simulations for an updated dosing regimen. The Company resubmitted a revised weight-based dosing regimen with modeling and simulations in December 2020. As recently announced, the FDA provided guidance on the December submission which clarified the information that the Agency expected to see in the Company's population pharmacokinetic model to be included in the resubmitted NDA. Based upon the FDA's feedback at the Type A meeting as well as further guidance from the Agency, the Company continues to believe that no further clinical studies are necessary. The Company expects to resubmit its NDA late in the second quarter of 2021. Once the NDA is resubmitted, the Company anticipates a six month review process. The FDA did not include in the CRL any indication regarding approval of U.S. market access for Libervant. Any failure to obtain FDA approval of, and to demonstrate clinical superiority for, Libervant would have a material adverse effect on our business, financial condition and results of operations in 2021 and later.

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

Prior to receiving approval to commercialize any of our drug products, we must demonstrate with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA and/or other regulatory authorities in the U.S. and other countries, that our particular product candidates are both safe and effective. For each drug product, we must demonstrate its efficacy and monitor its safety throughout the process. If development within these parameters is unsuccessful, our business could be harmed, and our stock price could be adversely affected.

We currently have multiple product candidates in preclinical and 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 applicable NDA or comparable regulatory submissions. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is very uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. Further,

positive results from earlier stage clinical trials may not be predictive of later clinical trials or other regulatory developments. In addition, many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in later stage clinical trials after achieving positive results in early stage development, and we cannot be certain that we will not face similar setbacks. Also, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain FDA approval. 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. We also face hurdles and setbacks by reason of competitors' drug candidates obtaining FDA or other regulatory approvals, including orphan drug market exclusivity, prior to our obtaining FDA or other regulatory approval of our similar drug candidate. Even if the FDA approves our NDA, we may be unable to successfully commercialize our products and product candidates.

In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to the numerous factors, including changes in clinical trial procedures set forth in protocols, differences in the size and type of the patient populations, adherence to the dosing regimen, and other clinical trial protocols, and the rate of dropout among clinical participants. If we fail to produce positive results in our planned preclinical studies or clinical trials of any of our product candidates, the development timeline and regulatory approval and commercialization prospects for our product candidates and, correspondingly, our business and financial prospects, would be materially adversely affected.

It is also possible that the FDA will not approve an 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 from development to commercialization can take many years and will likely require the expenditure of substantial resources beyond the proceeds we currently have on hand, without any guarantee or assurance that we will be successful with regulatory approval, or commercial success, of such product candidate.

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.

If we do not obtain market exclusivity for our certain of our products, including orphan drug exclusivity, our business may be harmed.

We intend to seek exclusivity for certain of our product candidates, including orphan drug exclusivity for Libervant. 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 market 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.

A company that first obtains FDA approval for a designated orphan drug for the designated rare disease or condition receives orphan drug market 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 within the meaning of FDA regulations and guidance. 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 if we receive orphan drug designation for one or more of our drug candidates, we may not be the first to obtain marketing approval for the orphan-designated indication due to the uncertainties associated with developing product candidates. If any of these other pharmaceutical companies obtains approval of an NDA before we are able to receive approval for one or more of our drug candidates with the same active moiety for the same indication, we would be barred from marketing that product in the United States during the seven-year orphan drug exclusivity period, unless we could demonstrate that such drug candidate is clinically superior to the approved products or satisfies one of the other limited exceptions to such orphan drug exclusivity.

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 any of our product candidates or indications, we may never receive such designations or obtain orphan drug exclusivity.

Also, overcoming the orphan drug marketing exclusivity is difficult to establish, with limited precedent, and there can be no assurance that the FDA will agree with our position seeking to overcome such marking exclusivity and approve Libervant for U.S. market access with orphan drug exclusivity. If we fail to receive such extensions or exclusive rights, our ability to prevent competitors from manufacturing, marketing and selling competing products will be materially impaired, and our results of operations and financial condition may be significantly adversely affected.

Clinical trials may be delayed, suspended or terminated for many reasons, which will increase our expenses and delay the time it takes to develop our product candidates.

We may experience delays in our ongoing or future preclinical trials, and we do not know whether future preclinical studies or clinical trials will begin on time, need to be redesigned, enroll an adequate number of patients on time or be completed on schedule. The commencement and completion of clinical trials for our clinical product candidates may be delayed suspended or terminated as a result of many factors, including:

- the FDA disagreeing as to the design, protocol or implementation of our clinical studies;
- the delay or refusal of regulators or institutional review boards, or IRBs, to authorize us to commence a clinical trial at a prospective trial site;
- changes in regulatory requirements, policies and guidelines;
- delays or failure to reach an agreement on acceptable terms with prospective clinical research organizations, or CROs, and clinical trial sites;
- the inability to enroll or delays enrolling a sufficient number of patients in trials, particularly in orphan indications, to observe statistically significant treatment effects in the trial;
- having clinical sites deviate from the trial protocol;
- negative or inconclusive results from ongoing preclinical studies or clinical trials, which may require us to conduct additional preclinical studies or clinical trials or to abandon projects that we had expected to be promising;
- reports from preclinical testing of other similar therapies that raise safety or efficacy concerns;
- regulators or IRBs requiring that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or safety concerns, among others;
- lower than anticipated retention rates of patients and volunteers in clinical trials;
- our CROs or clinical trial sites failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, deviating from the protocol or dropping out of a trial;
- delays in establishing the appropriate dosage levels; and
- exceeding budgeted costs due to difficulty in accurately predicting costs associated with clinical trials.

If we experience delays in the commencement or completion of any clinical trial of our product candidates, or if any clinical trials suspended or terminated, our costs may substantially increase and the commercial prospects of our product candidates may be harmed and our ability to generate revenue from sales of any product candidate will be delayed or not realized at all. Significant preclinical study or clinical trial delays also could shorten the period during which we have exclusive rights to commercialize a product candidate or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize a product candidate.

We have directly marketed just a single product, Sympazan. With this limited experience, we may lack the necessary expertise, personnel and resources to successfully commercialize this product or our other products that must first receive regulatory approval, either on our own or together with collaborators.

We rely on our third-party licensees to commercialize our two licensed products, Suboxone and Exservan, and to date have only marketed, through our own efforts and with the services of third-party outsourcing vendors including contract sales personnel, our first self-developed product, Sympazan, launched in December 2018. Thus, we have a very limited history of direct experience in commercializing product candidates, and we have no long-term experience upon which to measure our ability or success in commercializing a product or our ability to make predictions about financial results or prospects of any product. To achieve commercial success of our existing product as well as our product candidates, if any more are approved, we are in the process of continuing to develop our own sales, marketing and supply capabilities, including through third-party outsourcing and contract sales personnel.

Our ongoing commercial strategy for our products and product candidates involves the development of a commercial infrastructure that spans multiple jurisdictions and is dependent upon our ability to continue to build an infrastructure that is capable of implementing our commercial product launch strategy. The establishment and development of our commercial infrastructure will continue to be expensive and time consuming, and we may not be able to develop our commercial infrastructure successfully or in a timely manner or at all. Doing so will require a high degree of coordination and compliance with laws and regulations in numerous territories, including in the United States, each state, and other countries in which we do business, including restrictions on advertising practices, enforcement of intellectual property rights, restrictions on pricing or discounts, transparency laws and regulations, and unexpected changes in regulatory requirements and tariffs. If we are unable to effectively coordinate such activities or comply with such laws and regulations, our ability to commercialize our products and product candidates in the United States and other jurisdictions in which they are or may be available will be materially adversely affected.

Factors that may affect our ability to commercialize our products and product candidates on our own include: recruiting and retaining adequate numbers of effective sales and marketing personnel, including both internally and through contractual third-party outsourcing arrangements, cultivating effective relationships with third-party physicians and overall pharmaceutical industry payors, 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. Maintaining a sales and marketing organization requires significant investment and resources, is time-consuming and could delay or impair 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 licenses 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 licensees for the commercialization of our products and product candidates, we may have difficulties generating revenue from them and our business, results of operations, financial condition and prospects and the trading price of our stock may be materially adversely affected.

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 for those product candidates. 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, nurses, 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 a period of time after it is launched. If our products or product candidates, if approved, fail to achieve an adequate level of acceptance by patients, physicians, nurses, pharmacists, the medical community or third-party payors, we will be unable to generate significant revenues, and we may not become or remain profitable.

In addition, the potential market opportunities for our product candidates are difficult to estimate. Our estimates of the potential market opportunities are predicated on several key assumptions such as industry knowledge and publications, third-party research reports or analyses and other analytical information. While we believe that our internal assumptions are reasonable, these assumptions may be inaccurate. If any of the assumptions proves to be inaccurate, then the actual market for our product candidates could be smaller than our estimates of the potential market opportunity. If the actual market for our product candidates is smaller than we expect, or if the products fail to achieve an adequate level of acceptance by physicians, health care payors and patients, our revenue from product sales may be limited and we may be unable to achieve or maintain profitability.

Further, we may not be able to hire or contract for a sales force that is sufficient in size or has adequate expertise in the medical markets that we intend to target. Any failure or delay in the development of our sales, marketing and distribution capabilities would adversely impact the commercialization of our products.

Regulatory approval for any approved product is limited by the FDA to those specific indications and conditions for which clinical safety and efficacy have been demonstrated, and any allegations of our failure to comply with such approved indications could limit our sales efforts and have a material adverse effect on our business.

The FDA strictly regulates marketing, labeling, advertising and promotion of prescription drugs. These regulations include standards and restrictions for direct-to-consumer advertising, industry-sponsored scientific and educational activities, promotional activities involving the internet and off-label promotion. Any regulatory approval that the FDA grants is limited to those specific diseases and indications for which a product is deemed to be safe and effective by the FDA. In addition to the FDA approval required for new formulations, any new indication for an approved product also requires FDA approval. If we are not able to obtain FDA approval for any desired future indications for our products and product candidates, our ability to effectively market and sell our products may be reduced and our business may be materially adversely affected.

While physicians in the U.S. may choose and are generally permitted to prescribe drugs for uses that are not described in the product's labeling and for uses that differ from those tested in clinical trials and approved by the regulatory authorities, our ability to promote our products is narrowly limited to those indications that are specifically approved by the FDA. These "off-label" uses are common across medical specialties and may constitute an appropriate treatment for some patients in varied circumstances. Regulatory authorities in the U.S. generally do not regulate the behavior of physicians in their choice of treatments. Regulatory authorities do, however, restrict communications by pharmaceutical companies on the subject of off-label use. If our promotional activities fail to comply with the FDA's regulations or guidelines, we may be subject to warnings from, or enforcement action by, these authorities. In addition, our failure to follow FDA rules and guidelines relating to promotion and advertising may cause the FDA to issue warning letters or untitled letters, bring an enforcement action against us, suspend or withdraw an approved product from the market, require a recall or institute fines, or could result in disgorgement of money, operating restrictions, injunctions or criminal prosecution, any of which could materially harm our reputation and our business 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 action 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, false or disparaging statements about another company's products or product candidates, or other legal theories. To date we have been subject to a number of claims of this nature. In defending such lawsuits, whether or not they are with or without merit or are ultimately determined in our favor, we would continue to 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 the 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 can. 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 product; and to enter into potentially unfavorable royalty or license agreements in order to obtain the rights to use necessary technologies.

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. Regulations and guidelines 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 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 pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.

The 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. 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 companies. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis drug products or drug administration technologies that are more effective than our products or product candidates. In addition, our competitors may file citizen 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. Such actions by our competitors could delay or even prevent the FDA from approving any NDA that we submit under Section 505(b)(2) or other filing pathways.

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

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

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 from third-party payors 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, among other things, 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.

Cost containment is a primary concern of the U.S. healthcare industry and elsewhere as well as for governmental authorities. 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. It is also possible that a third-party payor may consider our products or product candidates as substitutable by less expensive therapies and only offer to reimburse patients for the less expensive product. Even if we show improved efficacy or improved convenience of administration with our products or product candidates, pricing of existing drugs may limit the amount we will be able to charge for our products or product candidates. These payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on investment in product development. Further, 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 challenge the prices charged for medical products and may impose price controls or require that drug companies provide them with predetermined discounts from list prices.

Obtaining and maintaining reimbursement status is time-consuming and costly. No uniform policy for coverage reimbursement for products exists among third-party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is generally a time-consuming and costly process that requires us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases on short notice, and we believe that changes in these rules and regulations are likely.

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 payors are not adequately reimbursed for our product candidates, they may reduce or discontinue purchases of them, 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 our existing proprietary product, any licensed products we are currently marketing and 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 healthcare 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 programs 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 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, 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, healthcare clearinghouses and certain healthcare 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 the 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 policymakers 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 our ability to commercialize and the prices we may obtain for any of our products and product candidates 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 340B drug pricing program, or the 340B program;

- establishment of 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, that 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

- establishment of 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 is required to 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 and their choice of medications to use.

Further, legislative changes to or regulatory changes under the PPACA remain possible in the U.S. Congress and under the Biden 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, including limited coverage for drugs. While Congress has not passed repeal legislation, the Tax Cuts and Jobs Act of 2017, or the TCJA, which was 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, amended the PPACA 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 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 and 2020 contained further drug price control measures that could be enacted during the 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 contain 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 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 indicated that they would continue to pursue 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 we may experience more rigorous coverage criteria and additional downward pricing pressure as the result of these and other healthcare reform measures that may be adopted in the future. 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.

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 visit 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 strive to 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 two third-parties 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 breach or terminate 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 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, or in satisfying our manufacturing and supply commitments and obligations for our licensed products and our commercialized self-developed products, which could harm our financial position, the commercial potential for our products, and our results of operations, as well as to result in a default in our supply commitments and obligations. 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 approved products and 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, we would likely be in default in our supply obligations, which could result in the termination of our supply obligations, our incurring potential default damages and our loss of significant revenues.

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 licensed products, our existing proprietary product and 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 or our obligations under our product supply commitments and obligations. 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 and we would likely be in default in our supply commitments and obligations, which could result in the termination of our supply obligations, our incurring potential default damages and our loss of significant revenues.

Our products and product candidates are highly reliant on very complex sterile techniques and personnel aseptic techniques. The facilities used by us, and 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 we or 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, we or 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 by us or 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 products and 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 would 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 and which could also result in default in our supply commitments and obligations, our incurring potential default damages and our loss of significant revenues.

More generally, we and our API manufacturers of pharmaceutical products, may 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, we and our API manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If we or our manufacturers were to encounter any of these difficulties, or otherwise fail to comply with their contractual obligations, our ability to manufacture our products, or to make our product candidates available for clinical trials and development purposes or to further commercialize any of our products and 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 significant potential revenues and could adversely affect our ability to gain market acceptance for approved products as well as a potential default of our supply commitments or obligations. 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 would likely result in a delay in our desired clinical and commercial timelines and disrupt our supply commitment and obligations.

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 products and 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 products and our 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 us or 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 of our approved products 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 resulting in a significant loss of revenues and results and resulting in a potential default in our supply commitments or obligations, which could lead to termination of our supply obligations our incurrence of default damages and our loss of significant revenues.

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 approvals, establishing manufacturing capabilities and marketing approved products are expensive, we continue to explore collaborations or licensing arrangements with third parties that have available resources and experience both in the United States and in territories outside of the United States. We continue to explore selective collaborations with third parties for development and commercialization of our product candidates both in and outside of the United States. We may, however, be unable to advance the development and/or commercialization of our products and product candidates in territories outside of the United States, which may limit the market potential for certain product candidates outside the U.S.

In situations where we enter into a development and commercial collaborative arrangement for a product or 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 licensees, and we expect to face competition in seeking appropriate licensees. 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 or product candidates and/or effectively market and sell approved products, if any, in all of the territories outside of the United States where it may otherwise be valuable to do so.

Whether we reach an agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the likelihood of approval by the FDA or foreign regulatory authorities, the potential market for the product candidate, the costs and complexities of delivering such product candidate to

patients, competing products, and industry and market conditions generally. Collaborations are complex and time-consuming to negotiate and document.

We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain significant additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

We rely on third parties to perform many essential services for Sympazan and any other products that we commercialize, including services related to sales, marketing, customer service support, warehousing and inventory program services, distribution services, contract administration and chargeback processing services, accounts receivable management and cash application services, and financial management and information technology services. If these third parties fail to perform as expected or to comply with legal and regulatory requirements, our ability to commercialize Sympazan and other products we commercialize will be significantly impacted and we may be subject to regulatory sanctions.

We have entered into agreements with third-party service providers to perform a variety of functions related to the sale and distribution of our self-developed products, including Sympazan, key aspects of which are out of our direct control. These service providers provide key services related to sales, marketing, customer service support, warehousing and inventory program services, distribution services, contract administration and chargeback processing services, accounts receivable management and cash application services, financial management and information technology services. In addition, our inventory is stored at a warehouse maintained by a third party service provider. We substantially rely on the provider as well as other third-party providers that perform services for us. If these third-party service providers fail to comply with applicable laws and regulations, fail to meet expected deadlines or otherwise do not carry out their contractual duties to us, or encounter damage or disruption at their facilities, our ability to deliver product to meet commercial demand would be significantly impaired. In addition, we may engage third parties to perform various other services for us relating to adverse event reporting, safety database management, fulfillment of requests for medical information regarding our product candidates and related services. If the quality or accuracy of the data maintained by these service providers is insufficient, we could be subject to regulatory sanctions.

We may not be successful in maintaining development and commercialization collaborations, and any collaborators 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 and successfully commercialize certain of our products and product candidates and our financial condition and operating results.

When we establish collaborative arrangements, 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 collaborate with a third-party for development and commercialization of a product or 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 third-party collaborator may not devote sufficient resources to the development or commercialization of our product or product candidate or may otherwise fail in development or commercialization efforts, in which event the development and commercialization of such product or 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 or product candidate or research program under a collaboration, and the payment we receive from our licensee 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 commercialization and may substantially increase the cost of developing and commercializing our products and product candidates;
- business combinations of a strategic collaborator 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;
- strategic collaborators could decide to move forward with a competing product or product candidate developed either independently or in collaboration with others, including our competitors;
- collaborators may not perform their obligations as expected;

- clinical trials conducted as part of any of these collaborations may not be successful;
- collaborators may not actively or aggressively pursue development and commercialization of any product candidates that seek to achieve, or that achieves, regulatory approval;
- we may not have access to or may be restricted from disclosing, certain information regarding product candidates being developed or commercialized under a collaboration;
- a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of any such product candidate; and
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability.

If any such collaborations do not result in the successful development and commercialization of product candidates, or if one of our collaborators terminates its agreement with us, the development or commercialization of our product candidates could be delayed and our business and prospects harmed. All of the risks relating to product development, regulatory approval and commercialization apply to the activities of our existing and future collaborators.

Additionally, conflicts may arise between us and our third-party collaborators, 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, our existing revenue streams are largely dependent on Indivior, which holds the global commercialization rights to our approved product, Suboxone. During the years ended December 31, 2020 and 2019, Indivior represented 57% and 86% of our total revenue, respectively. If any such conflicts were to arise with Indivior or any such third party could act in its own self-interest, which may be averse to our interests. Any such disagreement between us and a third-party collaborator could result in one or more of the following, each of which could delay or prevent the development or commercialization of our product or 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 third-party collaborator inside or outside our collaboration which could negatively impact our rights or benefits under our collaboration;
- unwillingness on the part of a third-party collaborator to keep us informed regarding the progress of its development and commercialization activities or to permit public disclosure of the results of those activities; and
- decision by our third-party collaborator to terminate or significantly reduce the relationship.

Risks Related to Our Business Operations and Industry

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 based upon the number of products and product candidates in our pipeline, and we expect to continue to grow over the next number of 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, contractors and contract employees. 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 products and product candidates, if approved, and compete effectively will depend, in part, on our ability to effectively manage any future growth.

In addition, our expected continuing growth in our management team adds increased expense which we must absorb, without necessarily having commensurate growth in our revenues. Also, to date, we have only directly marketed one product in the market. If we commercialize and directly market Libervant, this could require a significant upfront expense and create a rapid growth in our workforce. This increase in expense may negatively impact our results of operations and may add to our need for additional funds.

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 pharmaceutical company, we operate in a market that is subject to significant risk of liability. The sales of our approved products and of 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;
- substantial costs due to litigation;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants;
- the inability to commercialize our products or product candidates; and
- decreased demand for our products or 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 may 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, sale 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 procured product liability insurance with respect to the sale of our approved products and all clinical 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 for our approved products and our marketing and commercialization of such products as well as any future approved products as well as other risks related to our business.

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 materially 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. We have previously been the target of a phishing attack that resulted in unauthorized access to email. While our systems have been secured and strengthened, there can be no assurance that we will not experience cyber-attacks in the future, suffer indirect consequences from cyber-attack on a third-party, or fail to anticipate, identify or offset such threats of potential cyber-attacks or security breaches in a timely manner. This is especially so considering the nature of cyber-attack techniques, which change frequently, can be difficult to detect for extended periods of time and often are not recognized until they succeed. 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 at our manufacturing facilities 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 for any unexpected events 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 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 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 maintain environmental liability insurance coverage to mitigate our exposure in the event of an accident or environmental discharge. In the event that we may be held liable for any consequential damage and any resulting claims for damages, which may exceed our insured limits and financial resources, we may incur costs that may materially adversely affect our business, results of operations and prospects, and the value of our shares.

Risks Related to Government Regulation

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 report. 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 permitted 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 could 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).

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, cause us to suspend or discontinue clinical trials, abandon product candidates, 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 substantial damages for harm caused to patients; and
- our reputation may suffer.

Any of the above described events could prevent us from achieving or maintaining market acceptance of the affected product or product candidate, significantly affect our revenues and profitability from such products, and could substantially increase the costs of commercializing our products and product candidates.

Our business is subject to extensive regulatory requirements and our approved products 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 market our products or commercialize our product candidates 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 materially 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 products and 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, 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 significant 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.

Public concern regarding the safety of any of our drug products could result in the inclusion of unfavorable information in our labeling or require us to undertake other activities that may entail additional costs.

Considering widely publicized events concerning the safety risk of certain drug products, the FDA, members of Congress, the Government Accountability Office, medical professionals and the general public have raised concerns about potential drug safety issues. These events have resulted in the withdrawal of drug products, revisions to drug labeling that further limit use of the drug products and the establishment of risk management programs that may, for example, restrict distribution of drug products after approval. The Food and Drug Administration Amendments Act of 2007, or FDAAA, grants significant expanded authority to the FDA, much of which is aimed at improving the safety of drug products before and after approval. In particular, the FDAAA authorizes the FDA to, among other things, require post-approval studies and clinical trials, mandate changes to drug labeling to reflect new safety information and require risk evaluation and mitigation strategies for certain drugs, including certain currently approved drugs. The FDAAA also significantly expands the federal government's clinical trial registry and results databank, which we expect will result in significantly increased government oversight of clinical trials. Under the FDAAA, companies that violate these and other provisions of the new law are subject to substantial civil monetary penalties, among other regulatory, civil and criminal penalties. The increased attention to drug safety issues may result in a more cautious approach by

the FDA in its review of data from our clinical trials. Data from clinical trials may receive greater scrutiny, particularly with respect to safety, which may make the FDA or other regulatory authorities more likely to require additional preclinical studies or clinical trials. If the FDA requires us to provide additional clinical or preclinical data for any of our approved drug products, the indications for which that product candidate was approved may be limited or there may be specific warnings or limitations on dosing, and our efforts to commercialize any approved product may be otherwise adversely impacted.

Risks Related to Our Intellectual Property

If we are unable to obtain or protect intellectual property rights of 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 or which we choose not to seek to patent, 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 we generally seek to have 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 or other third parties. 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 those 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.

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 are currently, and in the future will likely continue to be, involved in lawsuits to protect or enforce our patents or the patents of our licensors, which are expensive, require us to expend substantial financial resources, are time consuming, may continue for many years for one or more claims and may be unsuccessful.

Competitors may infringe our patents or the patents of any licensors and potential licensors. To counter infringement or unauthorized use, we have been, and in the future may be, required to file infringement claims, which are 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 three of the six generic companies have been resolved. We are also seeking to enforce our patent rights in multiple cases as further described in Part II Item 8. Financial Statements and Supplementary Data, Note 20. Contingencies.

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 invoked 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 significantly harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our bringing or defending litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees from our core business. 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 Part II Item 8. Financial Statements and Supplementary Data, Note 20. Contingencies to our consolidated financial statements, a number 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. There can be no assurance that all claims of the challenged patents will be upheld or that the patents challenged by us will be found infringed. We may lose any of the challenged patents entirely, or we may have to amend the scope of claims to an 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 Part II Item 8. Financial Statements and Supplementary Data, Note 20. Contingencies to our consolidated financial statements.

Third parties may commence legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a negative impact on the success of our business.

Our commercial success depends, in part, upon our ability, and the ability of our existing and future collaborators, to develop, manufacture, market and sell our product candidates, if approved, and use our proprietary technologies without alleged or actual infringement, misappropriation or other violation of the patents and proprietary rights of third parties. There have been many lawsuits and other proceedings involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing product candidates. In addition, patent holding companies that focus solely on extracting royalties and settlements by enforcing patent rights may target us.

We may have been and in the future may become party to or be threatened with adversarial proceedings or litigation regarding intellectual property rights with respect to our product candidates and technology, which may include interference or derivation proceedings, post grant review and *inter partes* review before the USPTO or similar adversarial proceedings or litigation in any jurisdiction. Similarly, we or our licensors or collaborators have initiated, and in the future may initiate, such proceedings or litigation against third parties, which may include challenging the validity or scope of intellectual property rights controlled by third parties. Third parties have asserted and in the future may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of their merit. There is a risk that additional third parties may choose to engage in litigation with us to enforce or to otherwise assert their patent rights against us. Even if we believe any of those claims are without merit, a court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, and the holders of any such patents may be able to block our ability to commercialize such product or product candidates unless we obtain a license under the applicable patents, or until such patents expire or are finally determined to be invalid or unenforceable. Similarly, if any third-party patents were held by a court of competent jurisdiction to cover aspects of our technology, holders of any such patents may be able to block our ability to develop and commercialize the applicable product or product candidate unless we obtained a license or until such patent expires or is finally determined to be invalid, unenforceable or not infringed by our product or technology. In either case, such a license may not be available on commercially reasonable terms, or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. Furthermore, even in the absence of litigation, we may need or may choose to obtain licenses

from third parties to advance our research 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 such event, we may be unable to further practice our technologies or develop and commercialize any of our product candidates at issue, which could significantly harm our business.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates, if approved. Defense of these claims, regardless of their merit, could involve substantial litigation expense and a substantial diversion of employee resources from our business. Third parties making such claims may have the ability to dedicate substantially greater resources to these legal actions than we or our licensors or collaborators can. 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, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure.

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, Zuplenz, Sympazan and Exservan have been approved by the FDA, and we anticipate that other product candidates may 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.

If we or one of our licensees initiated legal proceedings against a third-party to enforce a patent covering one of our products or product candidates, the defendant could counterclaim, and have in certain existing proceedings counterclaimed, 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 Part II Item 8. Financial Statements and Supplementary Data, Note 20. Contingencies to our consolidated financial statements.

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 licensees to monitor the status of these fees so that we may make required payments of these fees when 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 which 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.

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.

Our success will depend in part on our ability to operate without infringing the intellectual property and proprietary rights of third parties. We cannot assure you that our business, products, product candidates and methods do not or will not infringe the patents or other intellectual property rights of third parties.

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, involves substantial litigation expense and could 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 products or 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 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 generally involves substantial costs and can be a distraction to management and other employees.

If we are not able to obtain adequate trademark protection or regulatory approval for our brand names, we may be required to re-brand affected products, which could cause delays in getting such product to market, substantively impact successful commercialization of any such product and substantially increasing our costs.

To protect our rights in any trademark we use or intend to use for our products or our product candidates, we may seek to register such trademarks. Trademark registration is territory-specific and we must apply for trademark registration in the United States as well as any other country where we intend to commercialize our product or product candidates. Failure to obtain trademark registrations may place our use of the trademarks at risk or make them subject to legal challenges, which could force us to choose alternative names for our product or product candidates. In addition, the FDA and other regulatory authorities outside the United States conduct independent reviews of proposed product names for pharmaceuticals, including an evaluation of the potential for confusion with other pharmaceutical product names for medications. These regulatory authorities may also object to a proposed product name if they believe the name inappropriately makes or implies a therapeutic claim. If the FDA or other regulatory authorities outside the United States object to any of our proposed product names, we may be required to adopt alternative names for our product or product candidates. If we adopt alternative names, either because of our inability to obtain a trademark registration or because of objections from regulatory authorities, we would lose the benefit of our existing trademark applications. As a result, we may be required to expend significant additional resources in an effort to adopt a new product name that would be registrable under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA and other regulatory authorities, which could adversely impact our product brand identity and successful commercialization of any product and increase our costs. Furthermore, we may not be able to build a successful brand identity for a new trademark in a timely manner or at all, which would limit our ability to commercialize our product or our product candidates.

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 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 Ownership of Our Common Stock

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

We expect our operating results to continue to be subject to significant quarterly and 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;
- delays in obtaining, failure to obtain, or adverse developments in obtaining, FDA and other regulatory approval of our product candidates;
- other regulatory developments affecting 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 stockholder and management own a significant percentage of our stock and may have the ability to effectively influence matters subject to stockholder approval.

As of December 31, 2020, our executive officers and directors beneficially owned approximately 10.4% of our outstanding common stock. In addition, Bratton Capital Management L.P. beneficially owned, directly, approximately 33.3% of our outstanding common stock as of December 31, 2020. Therefore, these stockholders may have, through their respective ownership positions, the ability to effectively influence or control matters requiring stockholder approval, including 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.

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 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, in general, 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 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.

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

We have incurred substantial losses since the inception of our company 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 2019 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 have experienced and 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 amended and restated certificate of incorporation and amended and restated bylaws, as well as provisions of Delaware law, could make it more difficult for a third-party to acquire us, or may 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 and of our amended and restated 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 amended and restated certificate of incorporation designates the Court of Chancery of the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation provides 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 amended and restated certificate of incorporation or our amended and restated bylaws, any action to interpret, apply, enforce or determine the validity of our certificate of incorporation or our amended and restated 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 amended and restated 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 amended and restated 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.

General Risk Factors

Our business may be adversely affected by the ongoing coronavirus pandemic.

Beginning in late 2019, the outbreak of COVID-19 has evolved into a global pandemic. Depending upon the length and severity of the pandemic or any resurgence, which cannot be predicted, we may experience disruptions that could materially and adversely impact our business including:

- Various aspects of our clinical trials, including delays or difficulties in enrolling patients in our clinical trials, in clinical trial site initiation, and in recruiting clinical site investigators and clinical site staff; increased rates of patients withdrawing from clinical trials; diversion of healthcare resources away from the conduct of clinical trials; interruption of key clinical trial activities such as clinical trials site data monitoring due to limitations on travel imposed or recommended by federal or state governments; impact on employees and others or interruption of clinical trial visits or study procedures which may impact the integrity of subject data and clinical study endpoints; and interruption or delays in the operations of the U.S. FDA, and comparable foreign regulatory agencies, which may impact regulatory review and approval timelines.

- If any third-party in our supply chain for any materials, including active pharmaceutical ingredients and other raw materials supply, which we need for our product candidates for our clinical trials and for the approved products we manufacture and distribute, are adversely impacted by restrictions resulting from the coronavirus pandemic, including staffing shortages, production slowdowns, or disruptions in freight and other transportation services and delivery distribution systems, our supply chain may be disrupted, limiting our ability to manufacture our product candidates for our clinical trials, conduct our research, development and clinical operations, and manufacture, distribute and sell our approved products.

- We have closed our business office and requested most of our colleagues located there to work from home, restricted full-time on-site staff generally to those colleagues who must perform essential activities on-site and implemented staggered schedules for full-time on-site staff in our research and development laboratory in order to reduce risk of transmission. Our increased reliance on colleagues and other third parties on whom we rely working from home or having health issues may negatively impact productivity and has limited our in-person commercialization activities for our existing approved proprietary product and would limit commercial launch activities for any new approved product, or disrupt, delay, or otherwise adversely impact our business. In addition, this could increase our cybersecurity risk, create data accessibility concerns, and make us more susceptible to communication disruptions, any of which could adversely impact our business operations. Our colleagues conducting research and development activities might not be able to access our laboratory or manufacturing facilities for an extended period of time as a result of any further closure of our facilities as well as the possibility of further governmental restrictions. As a result, this could delay timely completion of preclinical activities, including completing Investigational New Drug (IND)/Clinical Trial Application (CTA) enabling studies or our ability to select future development candidates, and initiation of clinical or other of our development programs and production and delivery of our products.

- The FDA and comparable foreign regulatory agencies may experience disruptions, have slower response times or be under-resourced to continue to monitor our clinical trials or to conduct required activities and review of our product candidates seeking regulatory review and such disruptions could materially affect the development, timing and approval of our product candidates.

- The coronavirus pandemic may impact the requirements of our customers and growth of our approved products. For example, Indivior, our significant customer for Suboxone, had announced that it anticipated coronavirus impact on its product sales. Further, sales force expansion may not be as productive during a time when a significant number of interactions are virtual and such interactions may not be as effective as face-to-face interactions. Additionally, an increasing number of patient visits to their Healthcare Professionals have been virtual during the coronavirus pandemic which may reduce the likelihood that a change in medicine would occur which could impact Sympazan growth. We cannot accurately predict the adverse impact the coronavirus pandemic will have on orders of our approved products Suboxone and Sympazan. We also have experienced in one instance, and could in the future experience, extended customer payment cycles.

- As a result of concerns caused by the continuing effects of the coronavirus, we may face issues and investor concerns in raising capital through sales of our common stock or other securities, or in seeking to monetize any of our licensed royalty and milestone rights. In addition, a recession, depression or other sustained adverse market event could materially and adversely affect the financial markets, our business, the value of our common stock and our ability to obtain on favorable terms, or at all, equity or debt financing or any potential monetization of our royalty streams.

The coronavirus pandemic continues to evolve. The ultimate impact of the coronavirus pandemic on us is highly uncertain and subject to change and will depend on future developments, which cannot be accurately predicted. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, our research programs, the manufacturing, marketing, distribution and sale of our approved products, the healthcare system or the global economy. Given the uncertainties, the Company is unable to provide assurance that operations can be maintained as planned prior to the COVID-19 pandemic.

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 referenced under Part III. Item 10. Directors, Executive Officers and Corporate Governance located elsewhere or incorporated by reference in this Annual Report on Form 10-K, and other key executives, 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. Recruiting and retaining other qualified employees for our business, including scientific and technical personnel, will also be critical to our success. 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 executive officers, 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 our interests would be harmed by such competitive behavior, we may be unable to prevent our competitors from benefiting from the expertise of our former executives and our competitiveness may be diminished.

Any failure to comply with applicable data protection and privacy laws and regulations could lead to significant penalties against us, and adversely impact our operating results.

We are subject to U.S. data protection laws and regulations, including laws and regulations that address privacy and data security. Numerous federal and state laws, including state data breach notification laws and state health information privacy laws, govern the collection, use, and disclosure and protection of health-related and other personal information. Failure to comply with data protection laws and regulations could result in government enforcement actions and create liability for us, which could include civil and/or criminal penalties, private litigation and/or adverse publicity that could negatively affect our operating results and business. EU member states and other countries have also adopted data protection laws and regulations which impose significant compliance obligations. In the European Union, the collection and use of personal health data has been governed by the provisions of the EU Data Protection Directive. The EU General Data Protection Regulation (GDPR) replaced the Data Protection Directive (with an enforcement date of May 25, 2018) and is designed to harmonize data privacy laws across Europe and to protect all EU citizens' data privacy and will have a significant impact on how certain data is processed and handled. The European Union data protection laws and regulations impose strict obligations and restrictions on the ability to collect, analyze and transfer personal data, including health data clinical trials.

Any failure to comply with these laws and regulations or the manner in which they are interpreted or implemented could lead to government enforcement actions and significant penalties against us, and adversely impact our operating results.

Our employees, principal investigators, consultants and agents 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 agents. 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.

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 from our core business.

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.

The market price of our common stock since our IPO has been and 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 your purchase 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 or regulatory approval of competitive drugs or therapies;
- regulatory or legal developments in the United States and other countries, as to both our products and product candidates and those of our competitors;
- 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, clinical trials or regulatory approval 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, or our failure to achieve anticipated financial results or funding;
- 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.

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 relies, in part, on the research and reports that industry and financial analysts publish about us or our business. We currently have limited research coverage by industry and financial analysts. Should any analysts then covering our business downgrade their evaluations of our stock, the price of our stock could decline. If any analysts then covering our business 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 are an "emerging growth company," and in addition, we are also a "smaller reporting company", and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies or smaller reporting companies will make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act, and a "smaller reporting company", as defined in Rule 405 under the Securities 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 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 our IPO, (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 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.

We also qualify as a "smaller reporting company," meaning we are not an investment company, an asset-backed issuer, or a majority-owned subsidiary of a parent company that is not a "smaller reporting company" which allows us to take advantage of many of the same exemptions from disclosure requirements including reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and certain reduced financial disclosures in our periodic reports, including this Annual Report on Form 10-K. In addition, we are eligible to remain a smaller reporting company, for so long as we have a public float (based on our common equity) of less than $250 million measured as of the last business day of our most recently completed second fiscal quarter or a public float (based on our common equity) or less than $700 million as of such date and annual revenues of less than $100 million during the most recently completed fiscal year. 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 of these disclosure exemptions, 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 expect to comply with new or revised accounting standards not later than 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 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.

Sales of a substantial number of shares of our common stock in the public market by our existing stockholders would 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 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.

Certain holders of our securities are entitled to rights with respect to the registration of their shares under the Securities Act. Registration of these shares under the Securities Act have resulted in a substantial amount of these 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.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

We lease our 8,400-square-foot current production facility (Melton) in Portage, Indiana, which houses certain research and development offices and 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 the prior lease.

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.

We lease our headquarters and principal laboratory in Warren, New Jersey. Pursuant to various amendments in February 2011, June 2012, May 2013, June 2018 we have secured additional space to provide growth of our laboratory facilities and to accommodate our corporate and administrative requirements. In July 2019, we entered into an Amended and Restated Lease Agreement. This extends our lease to August 2023 and maintains our space of 23,589 square feet.

Item 3. Legal Proceedings

For more information on Legal Proceedings, see Part II Item 8. Financial Statements and Supplementary Data, Note 20. Contingencies.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

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

Market Information

Our common stock began trading on the NASDAQ Global Select Market on July 24, 2018 under the symbol "AQST". Prior to that date there was no public market for our common stock.

Holders of Record

As of March 5, 2021, we had approximately 100 holders of record of our common stock. Certain shares are held in "street" name and accordingly, the number of beneficial owners of such shares is not known or included in the foregoing number. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividend Policy

We have never declared or paid any cash dividends on our common stock. We currently intend to retain future earnings to fund the development and growth of our business. We do not expect to pay any cash dividends in the foreseeable future. Any future determination to pay dividends will be made at the direction of our board of directors and will depend on then-existing conditions, including our financial conditions, operating results, contractual restrictions, capital requirements, business prospects and other factors our board of directors may deem relevant.

Recent Sale of Unregistered Securities

On November 3, 2020, the Company repurchased $22.5 million of the 12.5% Notes and issued $4.0 million of new 12.5% Notes in lieu of a prepayment premium on the early repayment of the 12.5% Notes. In connection therewith, the Company issued warrants for up to 143,000 shares of common stock, $0.001 par value per share.

The recipients of warrants 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 warrants issued in these transactions. The warrants were, at issuance deemed restricted securities for purposes of the Securities Act. The sale of the warrants was 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.

Item 6. Selected Financial Data

Omitted pursuant to SEC Final Rule Release No. 33-10890, *Management's Discussion and Analysis, Selected Financial Data, and Supplementary Financial Information*, with respect to Item 301, effective February 10, 2021.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion of our financial condition and results of operations should be read in conjunction with our financial statements and the notes to those financial statements appearing elsewhere in the Annual Report on Form 10-K. This discussion contains forward-looking statements that involve significant risks and uncertainties. As a result of many factors, such as those set forth under "Risk Factors" in Part 1 Item 1A of this Annual Report on Form 10-K, our actual results may differ materially from those anticipated in these forward-looking statements. All dollar amounts are stated in thousands.

Overview

We are a pharmaceutical company focused on developing and commercializing differentiated products which leverage our proprietary PharmFilm® technology to meet patients' unmet medical needs and to solve patients' therapeutic problems. We have five products approved by the U.S. Food and Drug Administration (FDA), both proprietary and out-licensed, as well as a late-stage proprietary product pipeline focused on the treatment of central nervous system, or CNS, diseases and an earlier stage pipeline including treatment of anaphylaxis. Our licensees market their products in the US and in some instances outside the US. The company markets its proprietary product in the US. We believe that our proprietary and licensed products address the characteristics of these patient populations and the shortcomings of available treatments create opportunities for the development and commercialization of meaningfully differentiated medicines. For a summary of our product and product candidates, please refer to Item I. Business of this Form 10-K.

Business Update Regarding COVID-19

The current COVID-19 pandemic has continued to present substantial health and economic risks, uncertainties and challenges to our business, the U.S. and global economies and financial markets. It is not currently possible to predict how long the pandemic will last or the time it will take for the economy to return to prior levels. The extent to which COVID-19 impacts our business, operations, clinical trials, regulatory approval process, capital, financial and monetization markets, financial results and financial condition, and those of our suppliers, distributors, customers and other third parties necessary to our business including those involved in the regulatory approval process, will depend on future developments, which are highly uncertain and cannot be predicted with certainty or clarity, including the duration and continuing severity of the outbreak, resurgence of the outbreak, continued or additional government actions to contain COVID-19, timing or efficacy of any vaccine, and new information that will emerge concerning the short-term and long-term impact of COVID-19.

To date, we have been able to continue to manufacture and supply our products and currently do not anticipate any significant interruption in supply, although we continue to monitor this situation closely and there is no assurance that disruptions or delay will not occur as a result of COVID-19. We are also monitoring demand for our products, which could be negatively impacted during the COVID-19 pandemic, as well as the financial condition of our customers and licensees, one of whom delayed remittance of certain payments due the Company for development services provided but ultimately made such payments.

Our office-based colleagues have generally been working from home since March 2020. With additional protections and protocols the Company has maintained appropriate and necessary staffing levels at both our laboratory and manufacturing sites. In Q1 2020 we suspended in-person interactions by our sales and marketing personnel and engaged remotely to support our commercialization efforts. Sales and marketing practices continue to evolve in accordance with changing local rules and regulations with predominantly virtual interactions with healthcare providers. However, the landscape continues to change as localities reestablish and/or ease restrictions, as the case may be, with the rise and fall of new case rates and the rollout of vaccinations.

For additional information on various uncertainties and risks caused by the COVID-19 pandemic, see Item Part I. Item IA. Risk Factors included in this report.

Financial Operations Overview

Revenues

Our revenues to date have been earned from our manufactured products made to order for licensees, including Suboxone and Zuplenz, as well as revenue from our self-developed, self-commercialized proprietary product, Sympazan®. Revenues are also earned from our product development services provided under contracts with customers, and from the licensing of our intellectual property. These activities generate revenues in four primary categories: manufacture and supply revenue, co-development and research fees, license and royalty revenue, and proprietary product sales, net.

Manufacture and Supply Revenue

Currently, we produce two licensed pharmaceutical products: Suboxone® and Zuplenz®. We are the exclusive manufacturer for these products. We manufacture based on receipt of purchase orders from our licensees, and our licensees have an obligation to accept these orders once quality assurance validates the quality of the manufactured product with agreed upon technical specifications. Our licensees are responsible for all other aspects of commercialization of these products and the

Company has no role, either direct or indirect, in our customers' commercialization activities, including those related to marketing, pricing, sales, payor access and regulatory operations.

We expect future manufacture and supply revenue from licensed products to be based on volume demand for existing licensed products, and for manufacturing and supply rights under license and supply agreements for existing or new agreements for successful product development collaborations.

Co-development and Research Fees

We work with our licensees 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 licensee. 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

We realize revenue from licenses of our intellectual property. For licenses that do not require further development or other ongoing activities by us, our licensee has acquired the right to use the licensed intellectual property for self-development of their product candidate, for manufacturing, commercialization or other specified purposes, upon the effective transfer of those rights, and related revenues are generally recorded at a point in time, subject to contingencies or constraints, if any. For licenses that may provide substantial value only in conjunction with other performance obligations to be provided by us, such as development services or the manufacture of specific products, revenues are generally recorded over the term of the license agreement. We also earn royalties based on our licensees' sales of products that use our intellectual property that are marketed and sold in the countries where we have patented technology rights. Royalty revenue related to the sale of future revenue is described further in this section under Critical Accounting Policies and Use of Estimates "Royalty Revenue and Interest Expense related to Sale of Future Revenue".

Proprietary Product Sales, Net

We commercialized our first proprietary CNS product, Sympazan, in December 2018. We currently sell Sympazan through wholesalers for distribution through retail pharmacies. Revenues from sales of proprietary product are recorded net of prompt payment discounts, wholesaler service fees, returns allowances, rebates and co-pay support redemptions, each of which are described in more detail below. These reserves are based on estimates of the amounts earned or to be claimed on the related sales. These amounts are treated as variable consideration, estimated and recognized as a reduction of the transaction price at the time of the sale. The Company includes these estimated amounts in connection with the transaction price to the extent it is probable that a significant reversal of cumulative revenue recognized for such transaction will not occur, or when the uncertainty associated with the variable consideration is resolved. The calculation of some of these items requires management to make estimates based on sales data, historical return data, contracts and other related information that may become known in the future. The adequacy of these provisions is reviewed on a quarterly basis.

Costs and Expenses

Our costs and expenses are primarily the result of the following activities: generation of manufacture and supply revenues; development of our pipeline of proprietary product candidates; and selling, general and administrative expenses, including pre-launch and post-launch commercialization efforts, intellectual property procurement, protection, prosecution and litigation expenses, corporate management functions, medical and clinical affairs administration; public company costs, share-based compensation expenses 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 primarily incurred from the manufacture of our commercialized licensed pharmaceutical products and for our self-developed, self-commercialized, approved proprietary product, including raw materials, direct labor and overhead costs principally in our Portage, Indiana facilities. 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 taxes and benefits) of employees engaged in production activities. Overhead costs principally consist of indirect payroll, facilities rent, utilities and depreciation for leasehold improvements and production machinery and equipment. These costs can increase, or decrease, based on the costs of materials, purchased at market pricing, and the amount of direct labor required to produce a product, along with the allocation of fixed overhead, which is dependent on production volume.

Our manufacture and supply costs and expenses are impacted by our customers' supply requirements. Costs of production reflect the costs of raw materials that are purchased at market prices and production efficiency (measured by the cost of a salable unit). These costs 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 to continue to seek to rationalize and manage costs to reflect the declining production volumes of Suboxone. We reduced the cost of manufacturing and supply in late 2019 and continued throughout 2020 in order to recognize the declining volume of Suboxone that began in 2019 and will continue declining in 2021. We expect our manufacture and supply costs and

expenses to decrease over the next several years due to the decline in Suboxone volumes as the generics in that market continue to take market share, modestly offset by the commercialization of our proprietary products, starting with Sympazan launched in December 2018. In addition to our proprietary products coming online, we may add licensee products which may need additional resources to manufacture. If such growth should occur for higher volume product opportunities such as Suboxone, we would incur increased costs associated with hiring additional personnel to support the increased manufacturing and supply costs arising from higher manufactured volumes from proprietary and licensed products.

Research and Development Expenses

Since our inception, we have focused significant resources on our research and development activities. Research and development expenses primarily consist of:

- employee-related expenses, including compensation, benefits, share-based compensation 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 expect our research and development expenses to continue to be significant over the next several years as we continue to develop existing product candidates such as AQST-108-SF, AQST-305 and others, and we identify and develop or acquire additional product candidates and technologies. We may hire or engage additional skilled colleagues or third parties to perform these activities, conduct clinical trials and ultimately seek regulatory approvals for any product candidate that successfully completes those clinical trials.

Selling, General and Administrative Expenses

Selling, general and administrative expenses consist primarily of salaries, benefits, share-based compensation, commercialization and marketing costs 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 patent-related and other legal expenses, consulting, tax and accounting services; insurance; selling; market research; advisory board and key opinion leaders; depreciation; and general corporate expenses, inclusive of IT systems related costs.

A significant portion of selling, general and administrative expenses relate to the sale and marketing of our proprietary product, Sympazan. Sympazan is the precursor and compliment to the launch of Libervant, assuming that it is approved and granted U.S. market access. We believe there is a very high degree of overlap and correlation between prescribers of Sympazan and the likely prescribers of an approved Libervant®. While Sympazan continues to grow, we will continue to rationalize its contribution to move towards profitability while continuing to introduce epilepsy prescribers and patients to Aquestive and PharmFilm® technology in advance of the anticipated launch of Libervant, assuming FDA approval and market access. The current commercial organization would begin the launch of Libervant, subject to its approval for U.S. market access, which cannot be assured, shortly after its approval. Until a Libervant launch is certain, we do not plan to increase the costs of our commercial organization and expect to continue to improve the efficiency of the Sympazan commercial investments.

Our general and administrative costs include costs related to accounting, audit, legal regulatory, and tax-related services required to maintain compliance with exchange listing and SEC regulations, director and officer insurance costs, and investor and public relations costs. We continue to incur significant costs in seeking to protect our intellectual property rights, including significant litigation costs in connection with seeking to enforce our rights concerning third parties' at-risk launch of generic products.

We will continue to manage business costs to appropriately reflect the declining state of Suboxone revenue, the marketing and sales costs related to Sympazan and other external factors affecting our business, including the continuing impact of the COVID-19 pandemic, as we continue to focus on our core business:

- Seeking to obtain the approval and subsequent launch of Libervant, subject to approval by the FDA for U.S. market access, which cannot be assured;
- Continuing the development of AQST-108-SF along the 505(b)(2) pathway; and
- Growing the revenue contribution from Sympazan as a first step to position Aquestive in the epilepsy community.

Interest Expense

Interest expense consists of interest costs on our 12.5% Notes at a fixed rate of 12.5%, payable quarterly, as well as amortization of loan costs and the debt discount. Interest expense increased in Fiscal Year 2020 as compared to Fiscal Year 2019 as the 12.5% Notes were issued in July 2019. The 12.5% Notes are discussed in Note 12, 12.5% Senior Secured Notes due 2025, to our consolidated financial statements. See Liquidity and Capital Resources below for further detail on our 12.5% Notes.

Royalty Revenue and Interest Expense related to Sale of Future Revenue

On November 3, 2020, we entered into a Purchase and Sale Agreement (the "Monetization Agreement") with MAM Pangolin Royalty, LLC, an affiliate of Marathon Asset Management ("Marathon"). Under the terms of the Monetization Agreement, we sold all of our contractual rights to receive royalties and milestone payments due under the Sunovion License Agreement related to Sunovion's apomorphine product, KYNMOBI®. KYNMOBI®, an apomorphine film therapy for the treatment of off episodes in Parkinson's disease patients, received approval from the U.S. Food and Drug Administration (FDA) on May 21, 2020. In exchange for the sale of these rights, we received an upfront payment of $40,000 and an additional payment of $10,000 through the achievement of the first milestone. We have received an aggregate amount of $50,000 through December 31, 2020 under the Monetization Agreement.

Under the Monetization Agreement, additional aggregate contingent payments of up to $75,000 may be due to us upon the achievement of worldwide royalty and other commercial targets within a specified timeframe, which could result in total potential proceeds of $125,000.

We recorded the upfront proceeds of $40,000 and subsequent first milestone of $10,000, reduced by $2,909 of transaction costs, as a liability related to the sale of future revenue that will be amortized using the effective interest method over the life of the Monetization Agreement. As future contingent payments are received, they will increase the balance of the liability related to the sale of future revenue. Although we sold all of our rights to receive royalties and milestones, as a result of our ongoing obligations related to the generation of these royalties, we will account for these royalties as revenue. Our ongoing obligations include the maintenance and defense of the intellectual property and to provide assistance to Marathon in executing a new license agreement for KYNMOBI® in the event Sunovion terminates the Sunovion License Agreement in one or more jurisdictions of the licensed territory under the Sunovion License Agreement.

During the second quarter of 2020, under the Sunovion License Agreement, the Company recognized $8,000 of royalty revenue and corresponding royalty receivable, related to the $1,000 annual minimum guaranteed royalty that is due in each of the next eight years. In connection with the Monetization Agreement, the Company performed an assessment under ASC 860, *Transfer and Servicing* to determine whether the existing receivable was transferred to Marathon and concluded that the receivable was not transferred.

As royalties are remitted to Marathon from Sunovion, the collection of the royalty receivable and balance of the liability related to the sale of future revenue will be effectively repaid over the life of the agreement. In order to determine the amortization of the liability related to the sale of future revenue, we are required to estimate the total amount of future royalty and milestone payments to Marathon over the life of the Monetization Agreement and contingent milestone payments from Marathon to the Company. The sum of future royalty payments less the $50,000 in proceeds received and future contingent payments will be recorded as interest expense over the life of the Monetization Agreement. At execution, the estimate of this total interest expense resulted in an effective annual interest rate of approximately 24.9%. This estimate contains significant assumptions that impact both the amount recorded at execution and the interest expense that will be recognized over the life of the Monetization Agreement. The Company will periodically assess the estimated royalty and milestone payments to Marathon from Sunovion and contingent milestone payments from Marathon to the Company. To the extent the amount or timing of such payments is materially different from the original estimates, an adjustment will be recorded prospectively to increase or decrease interest expense. There are a number of factors that could materially effect the amount and timing of royalty and milestone payments to Marathon from Sunovion, and correspondingly, the amount of interest expense recorded by the Company, most of which are not under our control. Such factors include, but are not limited to, changing standards of care, the initiation of competing products, manufacturing or other delays, generic competition, intellectual property matters, adverse events that result in government health authority imposed restrictions on the use of products, significant changes in foreign exchange rates as the royalties remitted to Marathon are made in U.S. dollars (USD) while a portion of the underlying sales of KYNMOBI® will be made in currencies other than USD, and other events or circumstances that are not currently foreseen. Changes to any of these factors could result in increases or decreases to both royalty revenue and interest expense related to the sale of future revenue.

Interest Income and other income (expense), net

Interest income and other income (expense), net consists of earnings derived from an interest-bearing account and other miscellaneous income and expense items. The interest-bearing account has no minimum amount to be maintained in the account nor any fixed length of period for which interest is earned.

Results of Operations

Comparison of Years Ended December 31, 2020 and 2019

Management's discussion and analysis of our results of operations for the year ended December 31, 2019 compared to the year ended December 31, 2018 may be found in Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations" of our Form 10-K for the year ended December 31, 2019, filed with the SEC on March 11, 2020.

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.

	2020	2019	Change $	Change %
(In thousands, except %)				
Manufacture and supply revenue	$ 24,881	$ 38,739	$ (13,858)	(36%)
License and royalty revenue	14,055	6,959	7,096	102%
Co-development and research fees	1,264	4,042	(2,778)	(69%)
Proprietary product sales, net	5,649	2,869	2,780	97%
Revenues	$ 45,849	$ 52,609	$ (6,760)	(13%)

Revenues decreased 13% or $6,760 in 2020 to $45,849 compared to $52,609 in 2019. The change is attributable to decreases in manufacture and supply revenue and in co-development and research fees partly offset increases in license and royalty revenue and proprietary product sales, net.

Manufacture and supply revenue decreased approximately 36% or $13,858 in 2020 to $24,881 as compared to $38,739 in 2019. This decrease is attributable to lower Suboxone volume in 2020 due to generic competition.

License and royalty revenue increased 102% or $7,096 in 2020 to $14,055 compared to $6,959 in 2019. The increase was primarily due to the $8,000 of KYNMOBI® royalties recognized upon FDA approval which were partly offset by lower license fees in 2020. License fees in 2020 included a $4,000 milestone payment earned upon the FDA approval of KYNMOBI® in May 2020 and $500 from our 10% share of milestones paid to KemPharm. License fees in 2019 included $1,000 from our 10% share of milestone payments paid to KemPharm and $4,250 in license and new patent fees derived from out licensed product Suboxone. License fees are generally driven by transfer of rights, patent performance contingencies, specific FDA or other regulatory achievements, sales levels achievements or other contingencies and milestones, and will likely fluctuate significantly from quarter-to-quarter. All further license fees due from Indivior related to Suboxone have been suspended pending the outcome of litigation related to infringement claims against the generic products that have launched “at risk.”

Co-development and research fees decreased 69% or $2,778 in 2020 to $1,264 compared to $4,042 during the prior period 2019. The decrease was driven by the timing of the achievement of research and development performance obligations which typically fluctuate significantly one reporting period to the next.

Proprietary product sales, net increased 97%% or $2,780 in 2020 to $5,649 compared to $2,869 during the prior period. Acceptance with the medical and patient communities has steadily continued to improve following Sympazan’s launch in December 2018.

Expenses:

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

	2020	2019	Change $	Change %
(In thousands, except %)				
Manufacture and supply	$ 12,964	$ 20,361	$ (7,397)	(36%)
Research and development	19,886	20,574	(688)	(3%)
Selling, general and administrative	55,892	64,342	(8,450)	(13%)
Interest expense	11,064	9,318	1,746	19%
Interest expense related to the sale of future revenue	1,958	—	1,958	100%
Interest income and other income (expense), net	(132)	(636)	504	(79%)
Loss on extinguishment of debt	—	4,896	(4,896)	(100)%

Manufacture and supply costs and expenses decreased 36% or $7,397 to $12,964 in 2020 compared to $20,361 in 2019. The decrease primarily reflected lower volumes of Suboxone production.

Research and development expenses decreased 3% or $688 to $19,886 in 2020 as compared to $20,574 in 2019. Research and development expenses are driven by the timing of clinical trial and other product development activities associated with the Company’s pipeline.

Below are research and development expenses by type of cost for each period presented:

(In thousands)	Year Ended December 31, 2020	2019
Clinical Trials	$ 6,435	$ 8,742
Labor - R&D staff	4,857	5,177
Development and manufacturing	2,034	577
Preclinical	667	798
All Other R&D	5,893	5,280
Total	$ 19,886	$ 20,574

Selling, general and administrative expenses decreased 13% or $8,450 to $55,892 in 2020 as compared to $64,342 in 2019. The decrease was driven by higher Sympazan sales and marketing costs in 2019 with the product launch.

Interest expense increased 19% or $1,746 to $11,064 in 2020 compared to $9,318 in 2019. This was the result of our issuance of the 12.5% Notes in July 2019, which increased the aggregate principal amount of our outstanding debt and an increase in the borrowing rates on our indebtedness, partially offset by the partial repayment of the 12.5% Notes in November 2020. Prior to July 15, 2019, our interest expense on our previously outstanding term loan was subject to fluctuations based on one-month LIBOR and was approximately 12% to 12.5% during that earlier part of 2019. Our 12.5% Notes carry a 12.5% fixed interest rate per annum.

Interest expense related to the sale of future revenue was $1,958 in 2020. This amount is due to the accounting associated with the sale of future revenue related to KYNMOBI® royalties sold to Marathon on November 3, 2020 and does not represent a monetary obligation or cash output at any time during the life of the transaction. See note 14 for details.

Interest income and other income (expense), net decreased 79% or $504 in 2020 as compared to 2019. This decrease is a result of lower interest rates and investing lower net cash balances during 2020 compared to the same period in 2019.

There was no loss on extinguishment of debt in 2020. Loss on the extinguishment of debt was $4,896 in 2019 which represented the expenses associated with early extinguishment of our loan's payable with Perceptive. The amount consists of $2,944 related to the prepayment premium associated with early payment of our outstanding obligations to Perceptive along with unamortized debt discount and unamortized loan acquisition costs of $1,606 and $346, respectively.

Liquidity and Capital Resources

Sources of Liquidity

As of December 31, 2020, Aquestive has experienced a history of net losses and the Company's accumulated deficits totaled $186,257 which have been partially funded by gross margins from sales of commercialized licensed and proprietary products, license fees, milestone and royalty payments from our commercial partners and co-development licensees, and with the balance of the related funding requirements met by the Company's equity and debt offerings, including the Senior Secured Notes due 2025 (the "12.5% Notes"). In 2019, the Company raised funding totaling $52,226, consisting of net proceeds of $13,110 from the refinancing of debt in July 2019, $37,295 from the public offering of 8,050,000 shares of common stock in December 2019, and $1,821 from the exercise of warrants in connection with the debt financing. We had $31,807 in cash and cash equivalents as of December 31, 2020.

On November 3, 2020, we entered into a Purchase and Sale Agreement (the "Monetization Agreement") with MAM Pangolin Royalty, LLC, an affiliate of Marathon Asset Management ("Marathon"). Under the terms of the Monetization Agreement, we sold all of our contractual rights to receive royalties and milestone payments due under the Sunovion License Agreement related to Sunovion's apomorphine product, KYNMOBI®. KYNMOBI®, an apomorphine film therapy for the treatment of off episodes in Parkinson's disease patients, received approval from the U.S. Food and Drug Administration (FDA) on May 21, 2020. In exchange for the sale of these rights, we received an upfront payment of $40,000 and an additional payment of $10,000 through the achievement of the first milestone. We have received an aggregate amount of $50,000 through December 31, 2020 under the Monetization Agreement.

Under the Monetization Agreement, additional aggregate contingent payments of up to $75,000 may be due to us upon the achievement of worldwide royalty and other commercial targets within a specified timeframe, which could result in total potential proceeds of $125,000.

With the upfront proceeds of the monetization, we repaid $22,500 of the 12.5% Notes, and issued $4,000 of new 12.5% Notes in lieu of paying a prepayment premium on the early repayment of the 12.5% Notes, reducing the aggregate principal balance of 12.5% Notes outstanding to $51,500. In addition, the holders of the 12.5% Notes agreed to extend to December 31, 2021 our ability to access, at our option, and additional $30,000 of 12.5% Notes re-openers under the Indenture. The first $10,000 senior notes re-opener represents a commitment of such amount by current holders of 12.5% Notes, at our option, contingent upon FDA approval of our product candidate Libervant. A second $20,000 senior notes re-opener represents a right, at our option, to market to current holders of our 12.5% Notes, and/or other lenders, additional senior notes up to such amount, contingent upon FDA approval of Libervant for U.S. market access. If and to the extent that we access these re-openers, we will

grant warrants to purchase up to 714,000 shares of common stock, with the strike price calculated based on the 30-day volume weighted average closing price of our common stock at the warrant grant date. In addition, as of the closing of this transaction, we issued to the holders of the 12.5% Notes warrants to purchase 143,000 shares of our common stock.

The Company began utilizing its "At-The-Market" (ATM) facility in November 2020 which has generated net cash of approximately $6,055 as of December 31, 2020. This facility has approximately $18,472 available at December 31, 2020.

Cash Flows

The following table provides information regarding our cash flows for the years ended December 31, 2020 and 2019:

(In thousands)	2020	2019
Net cash used for operating activities	$ (45,459)	$ (60,210)
Net cash used for investing activities	(517)	(663)
Net cash provided by financing activities	28,457	49,600
Net (decrease) increase in cash and cash equivalents	$ (17,519)	$ (11,273)

Net Cash Used for Operating Activities

Net cash used for operating activities for the year ended December 31, 2020 of $45,459 was primarily the result of our net loss of $55,783 partially offset by non-cash operating expenses totaling $14,737 and by use of cash from changes in operating assets and liabilities of $4,413. The non-cash operating expenses of $14,737 primarily resulted from $6,581 of share-based compensation expense and $8,156 related to other non-cash charges such as depreciation, amortization, and amortization of debt issuance costs.

Net cash used for operating activities for the year ended December 31, 2019 of $60,210 was primarily the result of our net loss of $66,246 partially offset by non-cash operating expenses totaling $17,160 and by use of cash from changes in operating assets and liabilities of $11,124. The non-cash operating expenses of $17,160 primarily resulted from $7,071 of share-based compensation expense, the $4,896 loss on the extinguishment of debt and $5,193 related to other non-cash charges such as depreciation, amortization and amortization of debt issuance costs.

Net Cash Used for Investing Activities

Net cash used for investing activities was $517 for the year ended December 31, 2020 compared to $663 for the year ended December 31, 2019. This decrease in net cash used for investing activities was primarily attributable to timing of capital expenditures for plant and equipment purchases.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was $28,457 for the year ended December 31, 2020 compared to $49,600 for the year ended December 31, 2019.

Net cash provided for the year ended December 31, 2020 was primarily from the net proceeds of $50,000 from the KYNMOBI® Monetization Agreement and net proceeds of $6,055 from sale of shares under the ATM facility partly offset by debt repayment including premium of $24,750.

Net cash provided for the year ended December 31, 2019 was primarily from the proceeds derived from our equity offering in December 2019 of $37,295 and the $1,821 of proceeds from the exercise of warrants by our noteholders. Additional proceeds were received from the issuance of the 12.5% Notes of $70,000 in excess of the cash used for the repayment of the $50,000 loan principal repaid to our prior term lender, the early payment premium of $2,944 and $3,946 of loan acquisition costs associated with the 12.5% Notes. We also paid $2,827 for withholding taxes associated with tax reimbursements connected to certain share-based compensation incurred in 2019.

The Company does not have any off-balance sheet arrangements as of December 31, 2020 nor do we have any relationships with any unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities.

Funding Requirements

The Company expects that its existing cash and cash equivalents, as of December 31, 2020, together with anticipated revenues from licensed and proprietary products, ATM activity to date, and expense management activities, will be adequate to fund our expected cash requirements for the next 12 months. In addition, the Company has potential sources of capital under its existing shelf registration statement and re-openers under its 12.5% Notes as it continues to execute its business strategy and has access to appropriate financial markets for debt or equity financings, or a combination of these potential sources of funds, although management can provide no assurance that any of these sources of funding, either individually or in combination, will be available on reasonable terms, if at all. In addition, the Company may be required to utilize available financial resources sooner than expected. Management has based its expectation on assumptions that could change or prove to be inaccurate, either due to the impact of COVID-19 or to unrelated factors including factors arising in the capital markets, asset monetization markets, regulatory approval process, regulatory oversight and other factors. Key factors and assumptions inherent in our planned continued operations and anticipated growth include, without limitation, those related to the following:

- the effects of the COVID-19 pandemic on our operations, operations of our key suppliers and third-party clinical and other service providers, our colleagues and contractors and debt equity and other capital markets;
- continued ability of our customers to pay, in a timely manner, for presently contracted and future anticipated orders for our manufactured goods, Suboxone and Sympazan, including effects of generics and other competitive pressures as currently envisioned;
- continued ability of our customers to pay, in a timely manner, for presently contracted and future anticipated orders for provided co-development and feasibility services, as well as regulatory support services for recently licensed products, such as Exservan;
- access to debt or equity markets if, and at the time, needed for any necessary future funding;
- FDA approval of our key new drug candidate, Libervant, for U.S. market access;
- our ability to issue up to $30,000 in additional 12.5% Notes, which is contingent upon FDA product approval and U.S. market access for Libervant;
- continuing review and appropriate adjustment of our cost structure consistent with our anticipated revenues and funding;
- continued growth and market penetration of Sympazan within expected commercialization cost levels for this product, including anticipated patient and physician acceptance and our ability to obtain adequate price and payment support from government agencies and other private medical insurers;
- effective commercialization of within anticipated cost levels and expected ramp-up timeframes of our product candidate Libervant, if approved for U.S. market access by the FDA;
- infrastructure and administrative costs at expected levels to support operations as an FDA and highly regulated public company;
- a manageable level of costs for ongoing efforts to protect our intellectual property rights, including litigation costs in connection with seeking to enforce our rights concerning third parties' "at-risk" launch of generic products;
- continued compliance with all covenants under our 12.5% Notes; and
- absence of significant unforeseen cash requirements.

We expect to continue to manage business costs to appropriately reflect the potential declining state of Suboxone revenue, the marketing and sales costs related Sympazan, the proceeds from the KYNMOBI® Monetization Agreement, and other external resources or factors affecting our business including, if available, any future potential issuances of additional 12.5% Notes under the Indenture, net proceeds or future equity financing, other future access to the capital markets or other potential available sources of liquidity, as well as the uncertainties associated with the coronavirus pandemic. In doing so, we plan to continue to focus on the core drivers of value for our stockholders, including, more importantly continued investments in our ongoing product development and planned commercialization activities in support of Libervant and AQST-108-SF. Until profitability is achieved, if at all, additional capital and/or other financing or funding will be required, which could be material, to further advance the development and commercialization of Libervant and AQST-108-SF, if approved by the FDA for U.S. market access, both of which are subject to regulatory approval, and to meet our other cash requirements, including debt service. We plan to conservatively manage our pre-launch spending as both timing and level relating to Libervant, including cost rationalization associated with marketing and selling Sympazan. In this regard, absent spending on launch activities for Libervant, we expect to spend less on commercialization in 2021 compared to 2020. Even as such, we expect to incur losses and negative cash flows for the foreseeable future and therefore we expect to be dependent upon external financing and funding to achieve our operating plan.

The sufficiency of our short-term and longer-term liquidity is directly impacted by our level of operating revenues and our ability to achieve our operating plan for revenues, regulatory approval in the time period planned of our late-stage proprietary products and our ability to monetize other royalty streams or other licensed rights within planned timeframes. Although we may also be entitled to further potential milestones, royalty and other payments under our Indivior Supplemental Agreement, which are suspended and may only be reinstated if Indivior successfully adjudicates or settles the related patent infringement litigation, there can be no assurance when, or if, any such payments may be realized. Our operating revenues have fluctuated in the past and can be expected to fluctuate in the future. We expect to incur significant operating losses and negative operating cash flows for the foreseeable future, and we have a significant level of debt on which we have substantial ongoing debt repayment and debt service obligations have principal repayments aggregating $2,575 related to our 12.5% Notes due in the second half of 2021. A substantial portion of our current and past revenues has been dependent upon our licensing, manufacturing and sales with one customer, Indivior, which is expected to continue while we commercialize our own proprietary products and it could take significantly longer than planned to achieve anticipated levels of cash flows to help fund our operations and cash needs from sales of our proprietary products other than Suboxone.

To the extent that we raise additional funds by issuance of equity securities, our stockholders would experience further dilution and the terms of these securities could include liquidation or other preferences (if and to the extent permitted under the Indenture) that would adversely affect our stockholders' rights. Our ability to secure additional equity financing could be significantly impacted by numerous factors including our operating performance and prospects, positive or negative developments in the regulatory approval process for our proprietary products, timely achievement of regulatory approval of our late-stage proprietary products, our existing level of debt which is secured by substantially all of our assets, restriction under the Indenture, and general market conditions, and there can be no assurance that we will continue to be successful in raising capital or that any such needed financing will be available, available on favorable or acceptable terms or at the times, or in the amounts needed. Additionally, while the potential economic impact brought on by and the duration of the coronavirus pandemic is difficult to assess or predict, the significant impact of the coronavirus pandemic on the global financial markets, and on our own stock trading price, may reduce our ability to access additional capital, which would negatively impact our short-term and longer-term liquidity.

If adequate funds are not available for our short-term or longer-term liquidity needs and cash requirements as and when needed, we may be required to reduce staff, further delay, significantly scale back, or even discontinue some or all of our current or planned research and development programs and clinical and other product development activities, or reduce our planned commercialization efforts and otherwise significantly reduce our other spend and adjust our operating plan, and we would need to seek to take other steps intended to improve our liquidity. We also may be required to evaluate additional licensing opportunities, if any become available, of our proprietary product candidate programs that we currently plan to self-commercialize or explore other potential liquidity opportunities or other alternatives or options or strategic alternatives, although we cannot assure that any of these actions would be available or available on reasonable terms.

See also Part I, Item II, Risk Factors concerning the significant risks and uncertainties concerning the Company's business, operations, financial results and capital resources associated with the impact of the global coronavirus pandemic.

Contractual Obligations and Commitments

We have entered into various contractual agreements under which we have long term obligations. For more information regarding our commitments, see Part II, Item 8. Financial Statements and Supplementary Data, Note 20. Contingencies.

For more information regarding our future lease payments, see "Part II, Item 8. Financial Statements and Supplementary Data, Note 9. Right of Use Assets and Lease Liabilities" for our minimum lease payments schedule. The expected timing of our leases may be different if future years, depending on our decision to extend lease terms and/or enter into leases in preceding years.

For more information on our repayments of our 12.5% Notes, see Part II, Item 8. Financial Statements and Supplementary Data, Note 12. 12.5% Senior Secured Notes.

Critical Accounting Policies and Use of Estimates

We have based our Management's Discussion and Analysis of our financial condition and results of operations on our Consolidated Financial Statements, which have been prepared in accordance with generally accepted accounting principles, or GAAP, in the U.S. The preparation of the Consolidated Financial Statements requires us to make estimates and judgments that affect the reported amounts of assets and liabilities at the date of the financial statements as well as the revenues and expenses during the reporting periods. On an ongoing basis, we evaluate our estimates and judgments including those related to revenue recognition, inventory costs, liabilities and accruals, clinical trial expenses, share-based compensation and the valuation of deferred tax assets. We base our estimates on historical experience when available 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.

While significant accounting policies are more fully described in Note 3, Summary of Significant Accounting Policies, of the Notes to our Consolidated Financial Statements included in this filing, we believe that the following accounting policies are those that are most critical to the significant judgements and estimates used in the preparation of our Consolidated Financial Statements.

Revenue Recognition

The Company's revenues include (i) sales of manufactured products pursuant to contracts with commercialization licensees, (ii) sales of its proprietary clobazam-based Sympazan oral film product (iii) license and royalty revenues and (iv) co-development and research fees generally in the form of milestone payments. See Part II Item 8. Financial Statements and Supplementary Data, Note 5 Revenues and Trade Receivables, Net for further details. Having adopted ASC 606, *Revenue from Contracts with Customers*, effective on January 1, 2019 and applying the modified retrospective method which resulted in an adjustment totaling $2,832 to the Company's accumulated deficit, the Company recognizes revenue to reflect the transfer of promised goods or services to customers in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those goods or services. To achieve this core principle, a five-step model is applied that includes (1) identifying

the contract with a customer, (2) identifying the performance obligation in the contract, (3) determining the transaction price, (4) allocating the transaction price to the performance obligations, and (5) recognizing when, or as, an entity satisfies a performance obligation.

Performance Obligations

A performance obligation is a promise in a contract to transfer a distinct good or service to the customer and is the unit of account in the current revenue recognition standard. A contract's transaction price is allocated to each distinct performance obligation and recognized as revenue when, or as, the performance obligation is satisfied. At contract inception, we assess the goods promised in our contracts with customers and identify a performance obligation for each promise to transfer to the customer a distinct good. When identifying our performance obligations, we consider all goods or services promised in a contract regardless of whether explicitly stated in the contract or implied by customary business practice. Our performance obligations consist mainly of transferring of goods and services identified in the contracts, purchase orders or invoices.

Manufacture and supply revenue – this revenue is derived from products manufactured exclusively for specific customers according to their strictly-defined specifications, subject only to specified quality control inspections. Accordingly, at the point in time when quality control requirements are satisfied, revenue net of related discounts is recorded.

Proprietary product sales, net - this net revenue is recognized when product is shipped and title passes to the customer, typically at time of delivery. At the time of sale, estimates for various revenue allowances are recorded based on historical trends and judgmental estimates. For sales of Sympazan, returns allowances and prompt pay discounts are estimated based on contract terms and historical return rates, if available, and these estimates are recorded as a reduction of receivables. Similarly determined estimates are recorded relating to wholesaler service fees, co-pay support redemptions, Medicare, Medicaid and other rebates, and these estimates are reflected as a component of accrued liabilities. Once all related variable considerations are resolved and uncertainties as to collectable amounts are eliminated, estimates are adjusted to actual allowance amounts. Provisions for these estimated amounts are reviewed and adjusted on no less than a quarterly basis.

License and Royalty Revenue – license revenues are determined based on an assessment of whether the license is distinct from any other performance obligations that may be included in the underlying licensing arrangement. If the customer is able to benefit from the license without provision of any other performance obligations by the Company and the license is thereby viewed as a distinct or functional license, the Company then determines whether the customer has acquired a right to use the license or a right to access the license. For functional licenses that do not require further development or other ongoing activities by the Company, the customer is viewed as acquiring the right to use the license as, and when, transferred and revenues are generally recorded at a point in time, subject to contingencies or constraints. For symbolic licenses providing substantial value only in conjunction with other performance obligations to be provided by the Company, revenues are generally recorded over the term of the license agreement. Such other obligations provided by the Company generally include manufactured products, additional development services or other deliverables that are contracted to be provided during the license term. Payments received in excess of amounts ratably or otherwise earned are deferred and recognized over the term of the license or as contingencies or other performance obligations are met.

Royalty revenue is estimated and recognized when sales under supply agreements with commercial licensees are recorded, absent any contractual constraints or collectability uncertainties. Royalties based on sales of Suboxone and Zuplenz have been recorded in this manner.

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 development or feasibility study agreement 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.

Revenue recognition arising from milestone payments is dependent upon the facts and circumstances surrounding the milestone payments. Milestone payments based on a non-sales metric such as a development-based milestone (*e.g.*, an NDA filing or obtaining regulatory approval) represent variable consideration and are included in the transaction price subject to any constraints. If the milestone payments relate to future development, the timing of recognition depends upon historical experience and the significance a third party has on the outcome. For milestone payments to be received upon the achievement of a sales threshold, the revenue from the milestone payments is recognized at the later of when the actual sales are incurred or the performance obligation to which the sales relate to has been satisfied.

Contract Assets - in certain situations, customer contractual payment terms provide for invoicing in arrears. Accordingly, some, or all performance obligations may be completely satisfied before the customer may be invoiced under such agreements. In these situations, billing occurs after revenue recognition, which results in a contract asset supported by the estimated value of the completed portion of the performance obligation. These contract assets are reflected as a component of other receivables within Trade and other receivables within the Consolidated Balance Sheet.

Contract Liabilities - in certain situations, customer contractual payment terms are structured to permit invoicing in advance of delivery of a good or service. In such instances, the customer's cash payment may be received before satisfaction of some, or any, performance obligations that are specified. In these situations, billing occurs in advance of revenue recognition, which results in contract liabilities. These contract liabilities are reflected as deferred revenue within the Consolidated Balance Sheet. As remaining performance obligations are satisfied, an appropriate portion of the deferred revenue balance is credited to earnings.

Liability related to sale of future revenue, royalty revenue, and interest expense

The Company treated the sale of future revenue related to KYNMOBI® as debt financing in accordance with ASC 470 Debt, amortized under the effective interest rate method over the estimated life of the related expected royalty stream. The liability related to the sale of future revenue has been initially recorded at its proceeds, net of deferred cost. The liability related to the sale of future revenue and the related interest expense are based on our current estimates of future royalties expected to be paid over the life of the arrangement. The Company will periodically assess the expected royalty payments using a combination of internal projections and forecasts from external resources. To the extent our future estimates of royalty payments are greater or less than previous estimates or the interest timing of such payments is materially different than its previous estimates, the Company will prospectively recognize related interest expense. Royalty revenue related to the sale of future revenue is reflected in license fees and royalties, and amortization of debt is reflected as interest expense related to the sale of future revenue in the Consolidated Statement of Operations and Comprehensive Loss. For further discussion of the sale of the future revenue, refer to Part II Item 8. Financial Statements and Supplementary Data, Note 14, Sale of Future Revenue.

Warrants

We have issued warrants to purchase up to 2,143,000 shares of our common stock (the "Warrants"): warrants to purchase up to 2,000,000 shares of our common stock, with an exercise price of $4.25 per share (the "Initial Warrants"), and warrants to purchase up to 143,000 shares of our common stock, with an exercise price of $5.55 per share (the "Additional Warrants"). The Warrants expire on June 30, 2025 and included specified registration rights. Management estimated the fair value of the Initial Warrants to be $6,800, and the Additional Warrants to be $735 assisted by an independent third-party appraiser. Additional Warrants were issued as part of the partial repayment of the Initial Notes which also expire on June 30, 2025 and entitle the holders thereof to purchase 143,000 of the Company's common stock at $5.55 and include specified registration rights. The fair value of these Warrants is treated as a debt discount, amortizable over the term of the Warrants, with the unamortized portion applied to reduce the face amount of the 12.5% Notes in the Company's balance sheet. Additionally, since the Warrants issued do not provide warrant redemption or put rights within the control of the holders that could require the Company to make a payment of cash or other assets to satisfy the obligations under the Warrants, except in the case of a "cash change in control", the fair value attributed to these Warrants was presented in additional-paid in capital in the accompanying Consolidated Balance Sheets.

Recent Accounting Pronouncements

Refer to Part II Item 8. Financial Statements and Supplementary Data, Note 3 "Summary of Significant Accounting Policies" in the accompanying Notes to our Consolidated Financial Statements for a discussion of recent accounting pronouncements.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

Item 7A is not applicable to us as a smaller reporting company and has been omitted.

Item 8. Financial Statements and Supplementary Data

Our financial statements, together with the report of our independent registered public accounting firm, appear in this Annual Report on Form 10-K beginning on page F-1.

Item 9. Change in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures.

Management's Evaluation of our Disclosure Controls and Procedures

We maintain disclosure controls that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Securities Exchange Act of 1934, as amended (the "Exchange Act") is (1) recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and (2) accumulated and communicated to our management, including our principal executive officer and principal financial officer, to allow timely decisions regarding our required disclosures.

As of December 31, 2020, our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our principal executive officer and principal financial officer have concluded based upon the evaluation described above that, as of December 31, 2020, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate controls over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Our internal control over financial reporting includes those policies and procedures that: (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of Aquestive Therapeutics, Inc,; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and our directors; and (iii) provide reasonable assurance regarding the prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Because of inherent limitations, internal control over financial reporting may not prevent misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies and procedures may deteriorate.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2020. In making this assessment, management used the criteria set forth in the *Internal Control-Integrated Framework (2013*) issued by the Committee of Sponsoring Organization of the Treadway Commission ("COSO"). Based upon its assessment and those criteria, our management has concluded that our internal control over financial reporting was effective as of December 31, 2020.

Attestation Report of the Registered Public Accounting Firm

This Annual Report on Form 10-K does not include an attestation of our registered public accounting firm due to an exemption established by the JOBS Act for "emerging growth companies".

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act), identified in connection with the evaluation of such internal control that occurred during our last fiscal quarter, that have materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers, and Corporate Governance

DIRECTORS

Board Composition and Structure

Our business and affairs are organized under the direction of our Board of Directors, which currently consists of eight members, seven of whom are independent directors. The primary responsibilities of our Board of Directors are to provide oversight, strategic guidance and direction to our management. Our Board meets on a regular basis and additionally as required.

Our certificate of incorporation provides that our Board is divided into three classes of directors, with the classes as nearly equal in number as possible. Each of our directors identified below serves in the class indicated. Subject to any earlier resignation or removal in accordance with the terms of our certificate of incorporation and bylaws, our current Class I directors will serve until the 2022 Annual Meeting of Stockholders, our current Class II directors will serve until the 2023 Annual Meeting of Stockholders, and our current Class III directors will serve until the 2021 Annual Meeting of Stockholders; and, in each case, until their successors are duly elected and qualified. Any additional directorships resulting from an increase in the number of directors will be apportioned by our Board among the three classes as equally as possible.

Below is a list of the names, ages and class of the individuals who currently serve as our directors.

Name	*Age*	*Position*	*Class*
Keith J. Kendall	63	Chief Executive Officer, President and Director	I
Gregory B. Brown, M.D.	67	Director	II
John Cochran	55	Vice Chairman of the Board	II
Santo J. Costa	75	Chairman of the Board	III
Julie Krop, M.D.	54	Director	III
Nancy S. Lurker	63	Director	I
James S. Scibetta	56	Director	I
Marco Taglietti, M.D.	61	Director	III

The Board has determined that the classified Board structure is appropriate for the Company at this time. A classified board provides for stability, continuity and experience among our Board following our initial public offering. The Board believes that building a cohesive board is an important goal. In our industry in particular, the time horizon required for successful development of pharmaceutical products and product candidates makes it important that we have a Board that understands the implications of this process and has the ability to develop long-term strategies while benefiting from an in-depth knowledge of Aquestive's business, development processes and timetables and operations. A classified board structure helps to provide continuity and stability of leadership while resisting pressure to focus on short-term results at the expense of long-term value.

Director Biographies

Information concerning our directors is set forth below. The biographical description of each director includes the specific experience, qualifications, attributes and skills that led the Board to conclude that each nominee should serve as a director.

Class III Directors (with terms expiring at the 2021 Annual Meeting of Stockholders)

Santo J. Costa

Santo J. Costa has served as our Board Chairman since August 2018 and 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. 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 (then traded on the ASX: ACL), a biopharmaceutical company, from March 2014 to June 2015 and on the board of directors of Metabolon, Inc., a private company, from April 2013 to May 2019. 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 B.S. in Pharmacy and a J.D. from St. John's University. Our Board 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.

Julie Krop, M.D.

Julie Krop, M.D., has served as a member of our Board since February 2021. Since April 2020, Dr. Krop has served as Chief Medical Officer of Freeline Therapeutics Holdings plc (Nasdaq: FRLN), a clinical stage gene therapy company, and has more than 20 years of drug development experience across multiple therapeutic areas including orphan drug indications. Dr. Krop served from 2015 to April 2020 as the Chief Medical Officer and Executive Vice President, Development of AMAG Pharmaceuticals, Inc. (Nasdaq: AMAG), where she oversaw clinical development, medical affairs, program management, and pharmacovigilance and regulatory functions. Prior to joining AMAG, Dr. Krop held leadership positions at Vertex Pharmaceuticals, Inc. from 2012 to 2015, including Internal Medicine Development Lead and Vice President, Clinical Development, and had leadership positions at Pfizer, Inc. from 1999 to 2001, at Millennium Pharmaceuticals, Inc. from 2001 to 2003, at Peptimmune from 2003 to 2006, and at Stryker Regenerative Medicine from 2006 to 2012. Dr. Krop is board certified in Internal Medicine and completed a Robert Wood Johnson Foundation Clinical Scholar Fellowship as well as an Endocrinology fellowship at the Johns Hopkins University School of Medicine. Dr. Krop received both a B.A. and an M.D. from Brown University. Our Board believes that Dr. Krop's extensive healthcare knowledge, her extensive experience in overseeing drug development and clinical research, and her executive leadership success in the healthcare industry qualify her to serve on our Board of Directors.

Marco Taglietti, M.D.

Marco Taglietti, M.D., has served as a member of our Board since February 2021. Since 2015, Dr. Taglietti has been President, Chief Executive Officer and Director of Scynexis, Inc. (Nasdaq: SCYZ), a biotechnology company pioneering innovative medicines to overcome and prevent difficult-to-treat and drug resistant infections. From 2007 to 2014 Dr. Taglietti served in senior leadership positions at Forest Laboratories, Inc., a publicly traded pharmaceutical company, including Executive Vice President, Research and Development, and Chief Medical Officer, and also served as President of Forest Research Institute, a division of Forest Laboratories. Prior to joining Forest Laboratories, Inc. in 2007, Dr. Taglietti held the position of Senior Vice President, Head of Global Research and Development, at Stiefel Laboratories, Inc. for three years. He joined Stiefel Laboratories, Inc. after 12 years at Schering-Plough Corporation where he held positions of increasing responsibilities including as Vice President (Executive Level), Clinical Research for Anti-Infectives, CNS, Endocrinology and Dermatology. Dr. Taglietti began his career at Marion Merrell Dow Research Institute. Dr. Taglietti currently serves on the board of directors of BioNJ, Inc., a life science trade association, and was previously a director of Delcath System, Inc and NephroGenex, Inc. He received his medical degree and board certifications from the University of Pavia in Italy. Our Board believes Dr. Taglietti's broad ranging experience in the pharmaceutical industry, his experience as a chief executive officer, his experience in the development of novel medicines, and his experience at public life sciences companies qualify him to serve on our Board of Directors.

Class II Directors (with Terms expiring at 2023 Annual Meeting)

Gregory B. Brown, M.D.

Gregory B. Brown, M.D., has served as a member of our Board of Directors since March 2007. Dr. Brown is currently Chief Executive Officer of Memgen, Inc., a private development-stage biotechnology company. Dr. Brown is also a co-founder at HealthCare Royalty Partners, or HCR Partners, and is a member of 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 B.A. from Yale University, an M.D. from SUNY Upstate Medical Center and an M.B.A from Harvard University. Dr. Brown currently serves on the boards of the following public pharmaceutical companies: Caladrius Biosciences, Inc. (Nasdaq: CLBS) and Faron Pharmaceuticals Oy (LSN: FARN); and previously served as director of Cambrex Corporation. Our Board 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

John Cochran has served as a member of our Board of Directors since January 2004 and was appointed to serve as Vice Chairman of the Board effective April 22, 2020. 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 Investors, an institutional alternative investment management firm. 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 B.A. in Accounting from Texas Christian University and is also a licensed certified public accountant. Our Board 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.

Class I Directors (with terms expiring at the 2022 Annual Meeting of Stockholders)

Keith J. Kendall

Keith J. Kendall has served as our Chief Executive Officer and President and as a member of our Board since November 2014, after having served as our President and Chief Operating Officer from November 2011 to November 2014 and as our Executive Vice President and Chief Financial Officer from 2006 to 2011. From 1999 to 2006, Mr. Kendall served in various business leadership positions for Hewlett Packard Financial Services, most recently as Vice President and Managing Director of the Americas. From 1985 to 1998, Mr. Kendall held a number of positions with AT&T Capital Corporation, including President of AT&T Credit Corporation and NCR Credit Corporation. Mr. Kendall served on the board of directors of Midatech Pharma Plc (Nasdaq: MTP) from January 2010 to December 2014. Mr. Kendall holds a B.S. from St. John's University and an M.B.A from Pace University. Our Board believes that Mr. Kendall's perspective and experience as our 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.

Nancy S. Lurker

Nancy S. Lurker has served as a member of our Board of Directors since April 2018. Ms. Lurker has served as President, Chief Executive Officer and Director of Eyepoint Pharmaceuticals, Inc. (Nasdaq: EYPT), a specialty biopharmaceutical company committed to developing and commercializing innovative ophthalmic products, 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 Chief Executive Officer and a director of PDI, Inc., a Nasdaq-listed healthcare commercialization company now named Interpace Bioscience, 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, Ms. Lurker 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 to 2006 and ConjuChem Biotechnologies from 2004 to 2006. Ms. Lurker currently serves on the Advisory Board of Novo Holdings A/S, Novo Nordisk Foundation's wholly owned holding company for Novo Nordisk A/S and Novozymes A/S. Ms. Lurker received a B.S. in Biology from Seattle Pacific University and an M.B.A. from the University of Evansville. Our Board believes Ms. Lurker's broad ranging experience in the pharmaceutical industry, her experience on the boards of directors of both public and private companies, 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

James S. Scibetta has served as a member of our Board of Directors since April 2017. Mr. Scibetta currently serves as Chief Executive Officer and a member of the board of directors of Maverick Therapeutics, Inc., 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 2008 to 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, from 2006 to 2007, and Merrimack Pharmaceuticals, an oncology-focused systems biology company, from 2001 to 2006. 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 has also served as a director and chairman of the audit committee of Matinas BioPharma Holdings, Inc. (NYSE: MTNB), a biopharmaceutical company, since 2013. Mr. Scibetta received his B.S. in Physics from Wake Forest University and his M.B.A from the University of Michigan. Our Board 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.

CORPORATE GOVERNANCE

Board Meetings, Attendance and Executive Sessions

The Board held fourteen (14) meetings during the year ended December 31, 2020. All Board members attended at least 75% of the meetings of the Board and the committees of the Board on which he or she served. The composition of, and number of meetings held by, each committee is set forth below under "Board Committees."

The independent directors meet in executive sessions, without management present, periodically and as appropriate.

All directors are expected to attend our annual meetings of stockholders absent extenuating circumstances. All members of the Board who were directors at the time attended the 2020 Annual Meeting.

Board Leadership Structure

Our Board of Directors is currently chaired by Santo J. Costa, one of our independent directors. As a general policy, our Board believes that separation of the positions of Chairman and Chief Executive Officer reinforces the independence of the Board from management, creates an environment that encourages objective oversight of management's performance and enhances the effectiveness of the Board as a whole. Mr. Kendall, our Chief Executive Officer, is also a member of the Board, which we believe promotes strategy development and execution and facilitates information flow between management and the Board. We currently expect the positions of Chairman of the Board and Chief Executive Officer to continue to be held by two individuals.

Board of Directors' Role in Risk Oversight

While senior management has primary responsibility for managing risk, the Board as a whole has responsibility for risk oversight. One of the key functions of our Board is informed oversight of our risk management process. Relevant Board committees review specific risk areas, as discussed below, and report on their deliberations to the Board. The full Board oversees risk in several ways. Through periodic management updates on the financial and operating results of Aquestive, including its annual operating plans and strategic planning, the Board provides input to management on ordinary course, business and

commercial operating risks. In addition, management reports to the Board and each committee periodically on specific material risks as they arise or as requested by individual Board members.

The Board does not have a standing risk management committee, but rather administers this oversight function directly through the Board as a whole, as well as through standing committees of our Board that address risks inherent in their respective areas of oversight. In particular, our Board is responsible for monitoring and assessing strategic risk exposure and our Audit Committee has the responsibility to consider and discuss major financial risk exposures and the steps management has taken to monitor and control these exposures. Our Nominating and Corporate Governance Committee monitors the effectiveness of our corporate governance practices, including whether they are successful in preventing illegal or improper conduct, and generally monitors compliance with applicable law and compliance with our Code of Business Conduct and Ethics. Our Compensation Committee assesses and monitors whether any of our compensation policies and programs has the potential to encourage excessive risk-taking.

EXECUTIVE OFFICERS

Below is a list of the names, ages, positions, and a brief account of the business experience of the individuals who serve as our executive officers.

Name	Age	Position(s)
Keith J. Kendall	63	Chief Executive Officer, President and Director
Daniel Barber	45	Senior Vice President - Chief Operating Officer
Peter Boyd	55	Senior Vice President - Business Process and Information Technology
Lori J. Braender	65	Senior Vice President - General Counsel, Chief Compliance Officer and Corporate Secretary
Kenneth Marshall	60	Senior Vice President - Chief Commercial Officer
A. Mark Schobel	65	Chief Innovation and Technology Officer
Gary H. Slatko	64	Senior Vice President - Chief Medical Officer
A. Ernest Toth, Jr.	62	Interim Chief Financial Officer
Theresa Wood	58	Senior Vice President - Human Resources and Organizational Development

Executive Officer Biographies

Keith J. Kendall | *Chief Executive Officer*

Please see Mr. Kendall's biographical information above in this Annual Report on Form 10-K under "Board of Directors - Director Biographies."

Daniel Barber | *Senior Vice President - Chief Operating Officer*

Mr. Barber joined our team in July 2007 and has been our Chief Operating Officer since May 2019. Mr. Barber 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 B.A. from State University of New York at Geneseo and an M.B.A from Seton Hall University.

Peter Boyd | *Senior Vice President – Business Process and Information Technology*

Mr. Boyd joined our Company in August 2013 and has led our Business Process and Information Technology functions since May 2019. Prior to his current position, Mr. Boyd led our Operations and Value Delivery functions from April 2014 to May 2019. 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 positions in business process improvement and in operations. Mr. Boyd received a B.A. in History from Wittenberg University and an M.B.A in Finance from Seton Hall University. Mr. Boyd also received an M.S. in Management and Urban Policy Analysis from the New School University.

Lori J. Braender | *Senior Vice President - General Counsel, Chief Compliance Officer and Corporate Secretary*

Ms. Braender joined our Company in September 2018 as our Senior Vice President - General Counsel, Chief Compliance Officer and Corporate Secretary. Prior to joining us, Ms. Braender was an attorney at Day Pitney LLP for 35 years, most recently serving as a Partner and Chair of the firm's Life Sciences Practice Group. In that role, she specialized in advising clients in the pharmaceutical and biotechnology industries, as well as medical device companies, hospitals and healthcare institutions, on regulatory requirements, contractual arrangements, and other business considerations connected with life science and healthcare transactions. Ms. Braender received a B.S. in Business Administration from Rider University and a J.D. from Seton Hall University School of Law.

Kenneth Marshall | *Senior Vice President - Chief Commercial Officer*

Mr. 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 that company's U.S. business. From 2008 through 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 B.S.B.A in Marketing and Economics from Western Carolina University and M.B.A from Houston Baptist University.

A. Mark Schobel | *Chief Innovation and Technology Officer*

Mr. 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 from November 2005 through the completion of our initial public offering in July 2018. From 2001 to 2005, he was the Global Head of New Technology and Product Innovation for the Consumer Health Business Unit at Novartis where he pioneered thin film delivery of systemic drugs. Prior to Novartis, Mr. Schobel held various general management positions with Reed & Carnrick Pharmaceuticals, Warner-Lambert and Pharmaceutical Formulations Inc. Mr. Schobel received his B.S. 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.

Gary H. Slatko, M.D. | *Senior Vice President - Chief Medical Officer*

Dr. Slatko has served as our Senior Vice President - Chief Medical Officer since January 2019. From 2012 to 2018, Dr. Slatko served as Office Director/Associate Director of the Office of Medication Error Prevention and Risk Management, CDER at the FDA. Prior to that, Dr. Slatko served as Chief Medical Officer at ParagonRx, an inVentiv Health company, from 2001 to 2012. Dr. Slatko previously served in senior management roles at GlaxoSmithKline, AstraZeneca and DuPont-Merck Pharma. Dr. Slatko received his B.A. in Chemistry and Psychology from Emory University, his M.B.A. from West Chester University of Pennsylvania, and his M.D. from the University of Miami Leonard M. Miller School of Medicine. He completed an Internal Medicine residency program at the University of Pittsburgh School of Medicine and is Board Certified.

A. Ernest Toth, Jr. | *Interim Chief Financial Officer*

Mr. Toth became our Interim Chief Financial Officer upon the departure at 2020 year end of our former chief financial officer. Mr. Toth had joined Danforth Advisors as a consultant in November 2020 to provide finance support and strategic consulting services to life science companies and the healthcare technology industry. Prior to that time, Mr. Toth most recently served as Chief Financial Officer of EHE Health from September 2018 to February 2020. Prior to joining EHE Health, he served as Global Chief Financial Officer of ArisGlobal from January 2016 to December 2016, and Global Chief Financial Officer of Synowledge from January 2015 to December 2015. Prior to Synowledge, Mr. Toth held various senior financial positions at JHP Pharmaceuticals, Valeritas, Pharmaceutical Formulations, World Power Technologies and MacAndrews & Forbes. Mr. Toth also serves as Managing Director of Bellair Advisors, LLC, a consulting and advisory firm that provides financial, strategic, operational, and commercial counsel to high growth entrepreneurial businesses. Mr. Toth received his B.S. in Accounting from Shippensburg University of Pennsylvania and his M.B.A. in Corporate Finance from Pace University.

Theresa Wood | *Senior Vice President - Human Resources and Organizational Development*

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

Delinquent Section 16(a) Reports

Section 16(a) of the Exchange Act requires our executive officers and directors and persons who own more than 10% of a registered class of our equity securities to file initial reports of ownership and reports of changes in ownership with the SEC. Based solely on our review of the copies of such forms with respect to fiscal year 2019, we believe our directors, officers and 10% stockholders complied with all applicable filing requirements during the fiscal year ended December 31, 2020 with the exception of A. Mark Schobel who filed one late Form 4 reporting two transactions.

CODE OF ETHICS

Our Board has adopted a Code of Business Conduct and Ethics ("Code of Ethics") that applies to all of our colleagues, including our executive officers and those colleagues responsible for financial reporting, and our directors.

Our Board has also adopted Corporate Governance Guidelines that, along with our committee charters and our Code of Ethics, provide the framework for our corporate governance policies.

Copies of our Code of Ethics and our Corporate Governance Guidelines may be accessed free of charge by visiting our website at www.aquestive.com under “Investors” at “Corporate Governance: Governance Documents” or by requesting a copy via an e-mail addressed to investorrelations@aquestive.com or by written request addressed to our Corporate Secretary at our principal executive offices. To the extent required by applicable law and regulation, we intend to post on our website any amendment to, or waiver under, a provision of the Code of Ethics that applies to our executive officers and directors within the time period required.

BOARD COMMITTEES

Our Board 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. Members will serve on these committees until their resignation or until otherwise determined by our Board.

From time to time, the Board may establish other committees to facilitate the management of our business. In October 2019, the Board established a Disclosure Committee. The Disclosure Committee provides advice with respect to the public disclosures made by the Company to the SEC and the Company's stockholders. Members of the Disclosure Committee include Mr. Kendall, Dr. Brown, Mr. Cochran, Mr. Scibetta and Ms. Lurker.

Each of the Audit, Compensation, and Nominating and Corporate Governance Committees operates pursuant to a written charter, and each committee will review and assess the adequacy of its charter annually, submitting any changes to the Board for approval. Each of the committee charters is available on our website at www.aquestive.com under "Investors" at "Corporate Governance: Governance Documents."

The following table describes which directors serve on each of the below standing Board committees and the number of times each committee met during 2020.

Name:	Nominating and Corporate Governance Committee	Compensation Committee	Audit Committee
Keith J. Kendall			
Gregory B. Brown, M.D.	M	M	
John Cochran	C	M	
Santo J. Costa		C	
Julie Krop, M.D.*	M		
Nancy S. Lurker		M	M
James S. Scibetta			C
Marco Taglietti, M.D.*			M
Number of Meetings Held in 2020	**6**	**6**	**7**
M = Member			
C = Chair			

*****Dr. Krop and Dr. Taglietti were first appointed to the Board in February 2021.

Set forth below are summaries of the responsibilities of each of our standing Board committees.

Audit Committee

Our Audit Committee provides oversight of our accounting and financial reporting processes and the audits of our financial statements. Among other matters, the Audit Committee is responsible for the following:

- reviewing with management and the independent registered public accounting firm the Company's annual audited financial statements, quarterly financial statements and significant financial reporting issues in connection with the preparation of the Company's annual and quarterly financial statements;
- reviewing the Company's major financial risk exposures and the steps management has taken to monitor and control such exposures;
- retention and oversight of the independent registered public accounting firm;
- pre-approving all audit services and permitted non-audit services to be performed for the Company by its independent registered public accounting firm, subject to the de minimis exception for permitted non-audit services;
- establishing procedures for the receipt, retention and treatment of any complaints received by the Company regarding accounting, internal accounting controls or audit matters, including procedures for the confidential and anonymous treatment of submission by colleagues of any such complaints; and
- reviewing, approving or ratifying all related person transactions in accordance with Company policy, applicable law and SEC and Nasdaq rules and regulations.

All members of our Audit Committee meet the requirements for financial literacy under applicable rules of Nasdaq. Our Board has determined that James S. Scibetta is an audit committee financial expert as defined under applicable rules of the SEC. In making this determination, our Board has considered Mr. Scibetta's financial experience and business background. All of the members of our Audit Committee were determined to be independent directors as defined under applicable rules of the SEC and Nasdaq.

Compensation Committee

Our Compensation Committee is responsible for the oversight of our overall compensation structure and establishes the Company's philosophy, objectives, policies and practices in the areas of executive compensation, benefit arrangements, performance evaluations and management development. Among other matters, the Compensation Committee is responsible for the following:

- obtaining the advice of any compensation consultant, legal counsel or other adviser to assist in carrying out its responsibilities and for conducting the related independence assessment;
- approving corporate goals and objectives relating to the compensation of the CEO and other executive officers, evaluating their performance, and making appropriate recommendations for any improvement in performance;
- determining and approving compensation levels of the CEO and other executive officers;
- reviewing compensation provided to our non-employee directors and recommending such compensation and any changes to the Board for approval;
- administering all equity compensation plans and recommending amendments to such plans to the Board for approval;
- administering all cash incentive compensation plans, employee stock purchase plan, bonus plans, any deferred compensation plans, any executive severance plans and other similar programs with respect to the participation of executive officers, and authorizing and approving amendments to such plans; and
- approving employment terms for executive officers, as well as any severance, change in control, indemnification, or other employment or compensation-related agreements or arrangements to be provided to executive officers.

All of the members of our Compensation Committee were determined to be independent under applicable rules of Nasdaq. Our Board has determined that each member of our Compensation Committee is a non-employee director, as defined in Exchange Act Rule 16b-3.

Nominating and Corporate Governance Committee

Our Nominating and Corporate Governance Committee oversees our corporate governance structure. Among other matters, our Nominating and Corporate Governance Committee is responsible for the following:

- identifying and recommending to the Board individuals believed to be qualified to serve as Board members;
- recommending to the Board directors to serve as members and chairpersons of each standing committee and any appropriate changes to the responsibilities, size and membership of such committees;
- determining, on an annual basis, the members of the Board who meet the applicable independence requirements established by the SEC and Nasdaq;
- considering questions of possible conflicts of interest of directors;
- generally reviewing with the Company's chief legal officer and other appropriate legal personnel particular legal matters and compliance with applicable legal requirements and with the Code of Ethics;
- reviewing our Corporate Governance Guidelines and our Code of Ethics on an annual basis and recommending amendments when appropriate;
- periodically reviewing management succession plans and related procedures, including for the CEO; and
- overseeing the annual self-evaluation of the Board and committees.

All members of our Nominating and Corporate Governance Committee were determined to be independent under the applicable rules of Nasdaq.

Policies Governing Director Nominations

Director Nomination Process

Our Board is responsible for determining candidates for nomination to our Board. The Board delegates the selection and nomination process to the Nominating and Corporate Governance Committee, with the expectation that other members of the Board and management will be requested to take part in the process as appropriate. The Nominating and Corporate Governance Committee is responsible for making recommendations to the Board regarding the size and composition of the Board. The Nominating and Corporate Governance Committee will review annually with the Board the composition of the Board as a whole and will recommend, if necessary, measures so that the Board reflects the appropriate balance of knowledge, experience, skills, expertise and diversity required for the Board as a whole. The Nominating and Corporate Governance Committee is responsible

for ensuring that the composition of the Board accurately reflects the needs of our business and, in furtherance of this goal, for proposing the addition of members and the necessary resignation of members for purposes of obtaining the appropriate members, skills and perspectives. The Nominating and Corporate Governance Committee recommends, and the Board nominates, candidates to stand for election as directors.

Generally, our Nominating and Corporate Governance Committee will identify candidates for director nominees in consultation with management as well as through the use of search firms or other advisors, the recommendations submitted by stockholders, and such other methods as the Nominating and Corporate Governance Committee deems appropriate. Once candidates have been identified, our Nominating and Corporate Governance Committee will confirm that the candidates meet the minimum qualifications for director nominees. The Nominating and Corporate Governance Committee may gather information about the candidates through interviews, detailed questionnaires, background checks or any other means that it deems to be appropriate in the evaluation process. The Nominating and Corporate Governance Committee will evaluate the qualifications and skills of director candidates, both on an individual basis and taking into account the overall composition and needs of the Board. Based on the results of the evaluation process, the Nominating and Corporate Governance Committee will recommend candidates as director nominees for the Board's approval. Each of Dr. Krop and Dr. Taglietti were recommended for consideration by the Nominating and Corporate Governance Committee and approved by the Board following a review of candidates identified by a third-party search firm, which presented these director candidates for consideration following review of the backgrounds and qualifications of these and other potential candidates.

The Nominating and Corporate Governance Committee will consider director candidates recommended by our stockholders. Recommendations should be submitted to the Nominating and Corporate Governance Committee, c/o the Corporate Secretary, and include at least the following information: name of the stockholder and evidence of the person's ownership of our common stock, number of shares owned and the length of time of ownership, name of the candidate, the candidate's employment history or a listing of his or her qualifications to be a director and the person's written consent to be named as a director if nominated.

Stockholders may also nominate directors for election at our annual meetings of stockholders in accordance with our bylaws.

Minimum Qualifications

Our Nominating and Corporate Governance Committee will take into consideration all factors it deems relevant and appropriate when recommending candidates for the Board's selection as nominees for the Board. These factors may include judgment, skill, diversity, experience with business and other organizations of a comparable size, the interplay of the candidate's experience with that of the other Board members, and the extent to which a candidate would be a desirable addition to the Board and any committees of the Board. We have no formal policy regarding Board diversity; however, the Board and the Nominating and Corporate Governance Committee believe that it is essential that Board members represent diverse viewpoints. In considering candidates for the Board, the Nominating and Corporate Governance Committee considers gender and ethnicity as well as a diversity of perspectives, experience and skills such that the Board as a whole represents diverse viewpoints, backgrounds and experience.

Item 11. Executive Compensation

EXECUTIVE COMPENSATION

Narrative Discussion of Summary Compensation Table

We are currently an "emerging growth company" and also qualify as a "smaller reporting company" under SEC rules. The following section describes the compensation we paid to our named executive officers ("NEOs") for our fiscal years ended December 31, 2020. and 2019. Our NEOs for 2020 are:

Name:	Title:
Keith J. Kendall	Chief Executive Officer (CEO)
Daniel Barber	Chief Operating Officer (COO)
John T. Maxwell*	Former Chief Financial Officer (CFO)

* John Maxwell separated from the Company at year end 2020.

Compensation Philosophy and Process

Aquestive operates in a highly competitive and continually changing market. Attracting, developing and retaining qualified executives who increase stockholder value by achieving our financial and strategic growth plans and objectives remain key to our success. Our goal is to provide compensation that emphasizes pay-for-performance, rewarding those who achieve or exceed their goals, and seeking to drive long-term value for our stockholders through the use of both short-term and long-term incentive programs.

Our compensation program is designed to:

- Attract, retain and motivate superior executive talent

- Provide incentives that award the achievement of performance goals that directly correlate to the enhancement of stockholder value, as well as to facilitate executive retention
- Align executive interests with those of stockholders through short-term and long-term incentives linked to performance

Role of the Compensation Committee. Pursuant to its charter, our Compensation Committee is charged with determining and approving the compensation and benefits of each executive officer, including our NEOs, on an annual basis, with the goal of achieving a compensation program and total compensation paid to our NEOs and other executives in line with our compensation philosophy. In determining compensation for our executive officers, the Compensation Committee considers compensation for comparable positions in the market and the historical compensation levels of our executives, each NEO's performance as compared to our expectations and objectives, and our desire to motivate our executives to achieve short- and long-term results that are consistent with our business strategies and objectives.

As part of its review, the Compensation Committee works with its independent compensation consultant, Radford, an Aon Hewitt company ("Radford"), as well as management, to ensure the compensation program aligns with market practice and Company strategy and has a balance designed to achieve Aquestive's business objectives. Based on the Committee's review, as well as input and recommendations received from Radford, the Compensation Committee is responsible for approving the compensation of each NEO.

For 2020, our Compensation Committee consisted of Mr. Costa (Chair), Mr. Bratton, Mr. Cochran, and Ms. Lurker. Each member of the Compensation Committee was determined to meet the applicable independence standards of both Nasdaq and the SEC. Mr. Bratton and Mr. Cochran also brought the added perspective of representing the views of a significant stockholder with respect to our executive compensation program. As of February 2021 Dr. Julie Krop, one of our newly appointed independent directors, replaced Mr. Bratton on the Compensation Committee.

Role of Independent Compensation Consultant. In 2018, prior to our initial public offering, our Compensation Committee engaged Radford as its independent compensation consultant to provide the Committee with guidance in connection with developing and implementing Aquestive's executive compensation program following the initial public offering.

In its role, Radford regularly attends meetings of the Compensation Committee to advise on compensation matters. Radford provides the Compensation Committee with information and advice on the design, structure and level of executive compensation, external market factors and evolving compensation trends.

Our Compensation Committee is directly responsible for the engagement and oversight of Radford. While Radford works with our management on various matters for which the Compensation Committee is responsible, our management does not direct or oversee the retention of Radford.

Role of Management. Management regularly assists the Compensation Committee by preparing information and materials for matters under consideration by the Committee. The CEO and our Senior Vice President, Human Resources are also asked to regularly attend Compensation Committee meetings to participate in discussions and provide information regarding executive performance and compensation matters. In addition, as part of its review process, the Compensation Committee meets with the CEO to discuss his recommendations regarding the compensation of each NEO (other than himself).

Annual Base Salary

Our Compensation Committee uses base salaries to recognize the experience, skills, knowledge and responsibilities required of our executive officers. The base salaries for our executive officers were initially established through review and negotiation at the time of hiring, and thereafter are periodically reviewed for possible increase, in each case taking into account the executive officer's qualifications, experience, scope of responsibilities and competitive market compensation paid by other companies for similar positions within the industry. The chart below reflects the annual base salary rates that were in effect during 2020 approved by our Compensation Committee for each NEO. The base salary rates are based upon the recommendations and competitive analysis provided by Radford and are generally consistent with the market 50th percentile, although compensation for individual NEOs may be above or below the median based on experience, scope of position and individual performance. Base salaries are reviewed by the Compensation Committee annually based on performance and other factors.

	Base Salary
Keith J. Kendall	$ 550,000
Daniel Barber	$ 410,000
John T. Maxwell	$ 395,000

Annual Incentive Compensation

We have an annual goal-setting and review process for our executive officers that is the basis for determining potential annual bonuses for our NEOs. Our Compensation Committee sets our annual financial objectives for the year as well as strategic and operational goals which are aligned with our strategic plan and operating budget approved by the Board.

Our employment agreements with our executive officers provide that they will be eligible for annual performance-based bonuses based on achievement of the financial, strategic and operational objectives established by the Compensation Committee. Pursuant

to the terms of their employment agreements, the target bonus opportunities for our NEOs expressed as a percentage of annual base salary are: Mr. Kendall, 75% and Mr. Barber, 50%. Mr. Maxwell's target bonus opportunity was 50%. Each NEO's annual bonus is capped at a maximum of 200% of his target bonus opportunity.

The Compensation Committee assessed Company performance for 2020 with respect to each of the strategic and operational metrics and determined achievement against those metrics. The Compensation Committee determined to award the bonus amounts to our NEOs for 2020 set forth in the Summary Compensation Table below under "Non-Equity Incentive Plan Compensation."

Equity-Based Incentive Awards

Our equity-based awards are designed to provide our NEOs with a strong link to our long-term performance, create an ownership culture and help align the interests of our executive officers and our stockholders. Prior to the closing of our initial public offering, we adopted our 2018 Equity Incentive Plan.

2020 Long-Term Incentive Awards. The Compensation Committee determined to award long-term incentive awards in the form of stock options in order to demonstrate the Company's pay-for-performance philosophy. Stock options are designed to motivate our NEOs to increase stockholder value as the NEO will only realize value if our stock price increases above the exercise price, which is equal to the fair market value of our common stock on the date of grant. In addition, these stock options are subject to time-based vesting restrictions generally requiring our NEOs to remain in our employment during the vesting period.

Equity Grant Policy. The Compensation Committee has adopted an equity grant policy with respect to the issuance of equity awards under our 2018 Equity Incentive Plan. Among other provisions, the equity grant policy establishes parameters for the grant date of equity awards made to officers, employees and non-employee directors. Under the policy, the grant date for annual long-term incentive awards to officers and other employees is the date of the Compensation Committee's regularly scheduled meeting in January or February each year, but if the date of such meeting is not in an open trading window, the awards will be granted effective on the second full trading date following the next public release of earnings. Pursuant to the policy, annual equity awards to our non-employee directors are granted on the date of the Company's annual meeting of stockholders. Additionally, "off-cycle" equity awards may be granted at other times during the year for circumstances such as new hires, promotions and director appointments, during open trading windows, or if the date the Compensation Committee takes action to approve such an award is not in an open trading window, then the awards will be granted effective on the second full trading date following the next public release of earnings.

Perquisites, Health, Welfare and Retirement Benefits

All of our executive officers, including our NEOs, 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 colleagues. We also provide enhanced life insurance and disability benefits to our executive officers.

We maintain a 401(k) retirement savings plan that provides eligible U.S. colleagues with an opportunity to save for retirement on a tax advantaged basis. Eligible colleagues 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 2020, we made 100% matching contributions on up to 6% of an employee's eligible compensation deferred, subject to IRS limitations. These matching contributions vest in 20% increments and vest in full after an employee has attained five years of service.

We do not maintain any non-qualified deferred compensation plans at this time. We also do not maintain, and do not plan to establish, any defined benefit pension plan.

Summary Compensation Table

The following table provides information regarding the compensation provided to our NEOs during the fiscal year ended December 31, 2020 and 2019:

Name & Principal Position	Year	Salary ($)	Bonus ($)	Stock Awards ($) (1)	Option Awards ($) (1)	Non-Equity Incentive Plan Compensation ($) (2)	All Other Compensation ($) (3)	Total ($)
Keith J. Kendall	2020	**550,000**	—	—	**259,364**	**450,368**	**30,686**	**1,290,418**
Chief Executive Officer	2019	540,385	—	—	1,768,598	288,924	30,669	2,628,576
Daniel Barber	2020	**410,000**	—	—	**126,800**	**279,774**	**23,509**	**840,083**
Chief Operating Officer	2019	388,846	—	—	555,257	227,780	23,345	1,195,228
John T. Maxwell	2020	**395,000**	—	—	**69,164**		**847,106**	**1,311,270**
*Chief Financial Officer**	2019	391,154	—	—	516,975	119,490	26,504	1,054,123

* Mr. Maxwell separated from the Company effective December 31, 2020.

(1) Represents the aggregate grant date fair value of equity awards computed in accordance with FASB ASC 718. A discussion of the assumptions used in calculating the fair value of such awards may be found in Note 17.

(2) Represents annual incentive compensation for 2020 and 2019, paid in the first quarter of the following year.

(3) For 2020, this column includes the following:

	Mr. Kendall ($)	Mr. Barber ($)	Mr. Maxwell ($)
401(k) Company match	**17,100**	**17,100**	**17,100**
Disability insurance premiums	**8,569**	**2,778**	**4,656**
Life insurance premiums	**5,017**	**3,631**	**4,468**
Severance+	—	—	**820,882**
Total	**30,686**	**23,509**	**847,106**

+Severance consists of $592,500 of severance covering annual base salary for twelve months and target annual bonus payable in 12 equal installments, $197,500 payable for 2020 year target bonus, and $30,882 representing contribution of medical benefits for up to twelve months. The amount in the “All Other Compensation” column above does not include an amount $228,600 which is the difference between the option exercise price and the market value of the shares underlying the stock options granted to Mr. Maxwell in 2020 (the fair value of which stock options grant is included in the above Table under “Options Awards”), the vesting of which 2020 stock options was accelerated on separation from employment under Mr. Maxwell’s employment agreement; other stock options which accelerated upon separation from employment were not in that money upon the separation date.

Outstanding Equity Awards at Fiscal Year End Table

The following table sets forth certain information regarding equity awards granted to our NEOs that remain outstanding as of December 31, 2020:

Name	Option Awards				Stock Awards			
	Number of Securities Underlying Unexercised Options (#)		Option Exercise Price	Option Expiration	Number of Shares or Units of Stock That Have Not Vested	Market Value of Shares or Units of Stock That Have Not Vested (1)	Equity Incentive Plan Awards: Number of Unearned Shares That Have Not Vested	Equity Incentive Plan Awards: Market Value of Unearned Shares, or Units That Have Not Vested
	Exercisable	Unexercisable	($)	Date	(#)	($)	(#)	($)
Mr. Kendall	193,459	46,706(2)	15.00	7/24/2028		—	—	—
	21,784	6,259(3)	16.46	8/15/2028	—	—	—	—
	81,250	243,750(4)	8.05	2/28/2029	—	—	—	—
	—	225,000(8)	1.54	3/16/2030	—	—	—	—
Mr. Barber	12,998	12,999(6)	6.54	4/18/2028	—	—	—	—
	48,254	48,253(5)	15.00	7/24/2028	—	—	—	—
	17,500	52,500(4)	8.05	2/28/2029	—	—	—	—
	12,500	37,500(7)	4.83	5/9/2029	—	—	—	—
	—	110,000(8)	1.54	3/16/2030	—	—	—	—
Mr. Maxwell(9)	36,120	0	15.00	12/31/2021	—	—	—	—
	95,000	0	8.05	12/31/2021	—	—	—	—
	60,000	0	1.54	12/31/2021	—	—	—	—

(1) Calculated using closing price of our common stock on Nasdaq on December 31, 2020 of $5.35.

(2) Options granted on July 24, 2018. These options vest in 36 equal monthly installments beginning on August 31, 2018.

(3) Options granted on August 15, 2018. These options vest in 36 equal monthly installments beginning on September 30, 2018.

(4) Options granted on February 28, 2019. These options vest as follows: 25% on each of the first and second anniversaries of the grant date and 50% on the third anniversary of the grant date.

(5) Options granted on July 24, 2018. These options vests as follows: 25% on each of the first and second anniversaries of the grant date and 50% on the third anniversary of the grant date.

(6) Options granted on April 18, 2018. These options vests as follows: 25% on the first and second anniversaries of the grant date and 50% on the third anniversary of the grant date.

(7) Options granted on May 9, 2019. These options vest as follows: 25% on each of the first and second anniversaries of the grant date and 50% on the third anniversary of the grant date.

(8) Options granted March 16, 2020. These options vest as follows: 25% on each of the first and second anniversaries of the grant date and 50% on the third anniversary of the grant date.

(9) In connection with John Maxwell’s separation from the Company, all stock options held by Mr. Maxwell vested.

Employment Agreements with our Named Executive Officers

In June and July 2019, we entered into amended and restated employment agreements with Mr. Kendall, our Chief Executive Officer, and Mr. Maxwell, our then Chief Financial Officer, and an employment agreement with Mr. Barber, our Chief Operating 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 employee benefit plan participation. These employment agreements provide for "at will" employment. The material terms of these employment agreements with our NEOs are described below and are qualified in all respects by the full terms of such agreements.

Glossary of Terms . The following terms referred to in the narrative below are generally defined in each NEO's employment agreement as follows:

- "*Cause*" means generally conviction or plea of nolo contendere to a felony; commission of fraud or material act of dishonesty with respect to the Company or its colleagues, customers or affiliates; failure to carry out material responsibilities of employment; material misconduct or similar behavior; a material violation of Company policy; or material breach of the executive's obligations under his employment agreement.

- "*Change in Control*" means generally any person or group becomes the beneficial owner of 40% or more of the Company's outstanding voting securities; completion of a merger, consolidation or reorganization of the Company unless the stockholders before such transaction own at least a majority of the outstanding voting securities of the outstanding securities or at least a majority of the fair market value of the successor company; or a sale, transfer, liquidation or other disposition of all or substantially all of the Company's assets.

- "*Change in Control Period*" means generally, for Mr. Kendall, the period beginning 180 days before and ending 24 months following the effective date of a Change in Control, and for Mr. Maxwell and Mr. Barber, the period beginning 180 days before and ending 12 months following the effective date of a Change in Control.

- "*Good Reason*" means generally a material diminution in the executive's position or duties; a material breach by the Company of the executive's employment agreement, including any reduction of base salary or target bonus percentage; or relocation of more than 50 miles from the Company's headquarters.

- "*Permanent Disability*" means generally the executive's inability to perform the essential functions of his job with or without reasonable accommodation for a period of 150 consecutive days or an aggregate of 180 days in any 12 month period due to illness, accident or other physical or mental incapacity, as determined by a duly licensed physician.

- "*Severance Period*" means generally, for Mr. Kendall, 18 months following termination of employment (or until the end of the initial employment term, if longer), and for Mr. Maxwell and Mr. Barber, 12 months following termination of employment.

Terms of Employment

Keith J. Kendall . The initial term of Mr. Kendall's employment agreement was 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. Non-renewal of his employment agreement by the Company would constitute a termination without Cause. Mr. Kendall's base salary is subject to annual review for possible increase. Mr. Kendall's target award opportunity under any annual incentive program that may be established by the Compensation Committee is equal to 75% of his base salary, and he is eligible to participate in our incentive plans and benefit plans as may be established or in effect from time to time.

Prior to the initial public offering, in April 2018 Mr. Kendall was issued shares of our non-voting common stock in connection with the termination of our PUP Plans equal to 5% of the issued and outstanding capital securities of the Company at the time of issue, and under the terms of his employment agreement, each share of non-voting common stock automatically became one share of voting common stock upon completion of the initial public offering. Under his employment agreement, Mr. Kendall also received stock options covering a number of shares equal to the difference between 5% of the total number of shares of our common stock outstanding following the initial public offering on a fully diluted basis, less the aggregate number of any shares of non-voting common stock and shares covered by stock options that he held immediately prior to the initial public offering, such that the total number of all of the shares of common stock and shares underlying stock options held by Mr. Kendall immediately following the initial public offering represented 5% of our shares of common stock on a fully diluted basis. In addition, upon the completion of the initial public offering, Mr. Kendall received a grant of RSUs equal to 0.47% of our total common stock outstanding following the initial public offering on a fully diluted basis, or 116,576 RSUs. The stock options vest in 36 equal monthly installments and the RSUs vest in eight equal quarterly installments, subject to accelerated vesting if his employment terminates for any reason other than a termination by the Company for Cause or a resignation by Mr. Kendall without Good Reason.

***Daniel Barber*.** The term of Mr. Barber's employment agreement commenced on June 26, 2018 and will continue until terminated in accordance with its terms. Mr. Barber's base salary is subject to annual review for possible increase. For purposes of any annual incentive program established by the Compensation Committee, Mr. Barber's target award opportunity under any annual incentive program that may be established by the Compensation Committee is equal to 50% of his base salary, and he is eligible to participate in our incentive plans and benefit plans as may be established or in effect from time to time. Prior to the initial public offering, in April 2018, Mr. Barber had been awarded shares of our non-voting common stock in connection with the termination of our PUP Plans and under the terms of his agreement, each share of non-voting common stock automatically became one share of voting common stock upon completion of the initial public offering. Mr. Barber was also granted registration rights with respect to the shares of common stock he received at the time of the initial public offering in exchange for his non-voting common stock.

***John T. Maxwell*.** The term of Mr. Maxwell's employment agreement commenced on June 26, 2018. Mr. Maxwell's base salary was subject to annual review for possible increase. Mr. Maxwell's target award opportunity under any annual incentive program that may be established by the Compensation Committee was equal to 50% of his base salary, and he was eligible to participate in our incentive plans and benefit plans. Prior to the initial public offering, in April 2018, Mr. Maxwell had been issued shares of our non-voting common stock in connection with the termination of our PUP Plans and under the terms of his agreement, each share of non-voting common stock automatically became one share of voting common stock upon completion of the initial public offering. Mr. Maxwell was also granted registration rights with respect to the shares of common stock he received at the time of the initial public offering in exchange for his non-voting common stock. Mr. Maxwell separated from employment with the Company effective December 13, 2020.

Severance Arrangements

Each of the employment agreements of our NEOs contains provisions providing for payments and benefits in the event of certain termination events, including employment termination in connection with a Change in Control. The material terms of our NEOs' severance protection are summarized below.

***For Cause Termination or Voluntary Resignation* .** In the event an NEO's employment is terminated by the Company for Cause, or if an NEO voluntarily resigns from employment without Good Reason, he will be entitled to receive 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 the NEO participates consistent with his rights under such plans ("Accrued Payments").

***Death or Permanent Disability* .** In the event that an NEO's employment is terminated by reason of death or Permanent Disability, in addition to the Accrued Payments, he will be entitled to:

- any accrued and unused vacation pay for the year in which employment terminates;
- a pro-rata portion of the NEO's target annual bonus for the year in which employment terminates, pro-rated for the number of days the NEO was employed during the year prior to termination;
- accelerated vesting of outstanding equity awards subject to time-based vesting as if the NEO had continued being employed through the end of the year in which employment terminates, 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 termination date (and stock options and stock appreciation rights will remain exercisable for one year following termination, subject to any earlier expiration date); and pro-rata accelerated vesting of outstanding equity awards subject to performance-based vesting conditions for which the performance period ends at or after the time of termination, with performance goals assumed to have been achieved at target and with pro-ration based on the percentage of the performance period that had elapsed as of the termination date.

Termination Without Cause or for Good Reason - Unrelated to a Change in Control. In the event that an NEO's employment is terminated by us without Cause or the NEO terminates his employment for Good Reason (other than in connection with a Change in Control, as described below), in addition to the Accrued Payments, the NEO will be entitled to receive, subject to the delivery of a fully effective release of claims and continued compliance with restrictive covenant obligations, the following payments and benefits:

- any accrued and unused vacation pay for the year in which his employment terminated;
- a pro-rata portion of the NEO's target annual bonus for the year in which employment terminates, pro-rated for the number of days the NEO was employed during the year prior to termination;
- monthly payments during the NEO's Severance Period (as defined above), with each monthly payment equal to 1/12 th of the sum of his annual base salary and target annual bonus;

- continuing coverage during the NEO's Severance Period (as defined above) under our group health and life insurance plans in which the NEO was a participant prior to termination; and

- immediate vesting of all unvested equity awards (and stock options and stock appreciation rights will remain exercisable for one year following termination, subject to any earlier expiration date), with performance conditions deemed achieved at target for unvested performance-based equity awards.

Termination Without Cause or For Good Reason - During the Change in Control Period. If an NEO's employment is terminated by us without Cause or the NEO terminates his employment for Good Reason, in each case, during the Change in Control Period, then subject to the delivery of a fully effective release of claims and continued compliance with respective restrictive covenant obligations, the NEO will be entitled to receive the following payments and benefits:

- any accrued and unused vacation pay for the year in which his employment terminated;

- a pro-rata portion of his target annual bonus for the year in which his employment terminated, pro-rated for the number of days the NEO was employed during the year prior to termination;

- an immediate lump sum cash payment of an amount equal to, for Mr. Kendall, 2.75 times the sum of his base salary and target annual bonus, and for Mr. Barber, 1.0 times the sum of his base salary and target annual bonus;

- continuing coverage under our group health and life insurance plans in which the NEO was a participant, for Mr. Kendall, for 33 months following termination of employment, and for Mr. Barber, for 12 months following termination of employment; and

- immediate vesting of all unvested equity awards (and stock options and stock appreciation rights will remain exercisable for one year following termination, subject to any earlier expiration date), with performance conditions deemed achieved at target for unvested performance-based equity awards.

In the event that these employment termination payments and benefits in connection with a Change in Control would subject Mr. Kendall to the excise tax imposed by Section 4999 of the Code, he would be entitled to an additional payment such 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. The employment agreement of Mr. Kendall provides that, prior to the third anniversary of the agreement, the executive agrees to discuss a provision to replace this tax gross-up provision on terms and conditions mutually acceptable to the Board and the executive which discussion will take into account then current public market conditions.

In the event that these termination payments and benefits in connection with a Change in Control would subject Mr. Barber to the Code Section 4999 excise tax, he would be entitled to the greater after-tax benefit of either (i) the full Change in Control payment and benefits minus any 280G excise tax, the payment of which would be the NEO's responsibility, or (ii) the NEO's Change in Control payment and benefits cut back to the amount that would not trigger the excise tax.

For each of our NEOs, in the event that the continued coverage under our health plans triggers taxable income to the NEO, the NEO would also receive an additional cash payment such that each NEO would receive the same net after-tax benefits that the NEO would have received under such plans had the NEO continued to be employed and receive such plan benefits.

Each NEO's employment agreement also provides that each NEO agrees to grant us certain intellectual property rights and includes additional provisions that require the NEO 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 the NEO's employment and for his respective Severance Period as defined above.

John Maxwell Separation. John Maxwell separated from the Company effective at year end 2020. In connection with his departure, Mr. Maxwell and the Company entered into a separation and release agreement providing for severance payments and benefits generally consistent with his employment agreement dated June 26, 2018, including a severance payment equal to the sum of his annual base salary and target annual bonus payable in 12 equal monthly installments, a target bonus for 2020, coverage under group health and life insurance plans for up to 12 months and immediate vesting of all unvested stock options which will remain exercisable for one year following his separation from employment.

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.

Under our non-employee director compensation program, we pay each of our non-employee directors a cash retainer for service on the Board and for service on each committee on which the director serves. The chair of each committee other than the Disclosure Committee receives an additional retainer for such service. These retainers will be payable in arrears in 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 paid to non-employee directors for service on the Board and our Board committees are 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
Disclosure Committee	5,000	--

Additionally, each non-employee director receives an annual equity grant in the form of stock options, with terms and conditions determined by the Board. In 2020, each non-employee director was granted an award of 14,000 stock options. This annual equity grant is awarded each year on the date of the Annual Meeting of Stockholders in accordance with the Company's equity grant policy. The stock options vest one year from the date of grant, subject to the director's continued service on the Board.

This program 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.

The following table sets forth information concerning the compensation that we paid or awarded to our non-employee directors during the fiscal year ended December 31, 2020. For more information on the compensation of Keith J. Kendall, our director who is also our CEO, see below under "Executive Compensation."

Name	Fees Earned or Paid in Cash ($)	Option Awards (2) ($)	All Other Compensation ($)	Total ($)
Douglas K. Bratton (1)	57,000	56,522	--	113,522
Gregory B. Brown, M.D.	60,000	56,522	--	116,522
John Cochran	62,000	56,522	--	118,522
Santo J. Costa	92,000	56,522	--	148,522
Nancy S. Lurker	62,000	56,522	--	118,522
James S. Scibetta	75,000	56,522	--	131,522

(1) Julie Krop, M.D. and Marco Taglietti, M.D. were first appointed to the Board in February 2021. Douglas Bratton resigned from the Board in February 2021.

(2) Represents the aggregate grant date fair value of stock option awards computed in accordance with Financial Accounting Standards Board Accounting Standards Codification Topic 718 ("FASB ASC 718"). A discussion of the assumptions used in calculating the fair value of such awards may be found in Note 17. Amounts reflect, for each director, a stock option grant awarded on June 16, 2020 with a grant date fair value of $56,522. As of December 31, 2020, each director other than Ms. Lurker held 54,050 outstanding stock options and Ms. Lurker held 59,128 outstanding stock options.

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

EQUITY COMPENSATION PLAN INFORMATION

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (1)(a)	Weighted-average exercise price of outstanding options, warrants and rights (2) (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (3) (c)
Equity compensation plans approved by security holders	3,190,615	$ 8.18	820,446
Equity compensation plans not approved by security holders	81,068(4)	$ 6.54	--
Total	3,271,683	$ 8.14	820,446

(1) Includes 13,491 RSUs and 3,258,192 stock options outstanding under our 2018 Equity Incentive Plan as of December 31, 2020.

(2) Reflects the weighted average exercise price of outstanding stock options reported in column (a). No exercise price is attributable to outstanding RSUs.

(3) Includes 659,810 shares remaining available for issuance under our 2018 Equity Incentive Plan and 160,636 shares remaining available for issuance under our Employee Stock Purchase Plan as of December 31, 2020. The 2018 Equity Incentive Plan and Employee Stock Purchase Plan each have an evergreen provision whereby, unless the Board determines otherwise, the share reserve is increased automatically by a specified percentage or number of shares on January 1 of each year. The Board determined that effective as of 2021 the number of shares of common stock available for award to eligible participants under the 2018 Equity Incentive Plan would be increased by 4% of the number of shares of common stock outstanding at December 31, 2020. The Board determined that the share reserves under the ESPP would not be increased pursuant to the evergreen provision as of 2021.

(4) In April 2018, the Company granted stock options to purchase an aggregate of 81,068 shares of our common stock each with an exercise price of $6.54 per share, to certain of the Company's employees, consultants and directors in connection with services provided by such parties to the Company.

BENEFICIAL OWNERSHIP OF COMMON STOCK

The following table sets forth certain information as of December 31, 2020 (unless otherwise specified), with respect to the beneficial ownership of our common stock by each person who is known to own beneficially more than 5% of the outstanding shares of common stock, each person currently serving as a director, each nominee for director, each named executive officer (as set forth in the Summary Compensation Table), and all directors and executive officers as a group.

Shares of common stock subject to options or other rights to purchase which are now exercisable or are exercisable within 60 days after December 31, 2020, are to be considered outstanding for purposes of computing the number of shares beneficially owned and the percentage ownership of the persons holding these options or other rights, but are not to be considered outstanding for the purpose of computing the number of shares beneficially owned or the percentage ownership of any other person. As of December 31, 2020, there were 34,569,254 shares of common stock outstanding. Unless otherwise indicated, the address for each beneficial owner is c/o Aquestive Therapeutics Inc., 30 Technology Drive, Warren, NJ 07059.

Name and Address of Beneficial Owner	Number of Shares Beneficially Owned†	Percentage of Shares Beneficially Owned
5% Stockholders:		
MonoLine RX II, L.P. (1)	4,032,907	**11.67%**
MonoLine RX III, L.P. (1)	2,755,541	**7.97%**
MRX Partners, LLC (1)	2,249,077	**6.51%**
MonoLine Rx, L.P. (1)	2,213,314	**6.40%**
MonoLine Partners, L.P. (1)	165,000	*****
MonoSol Rx Genpar, L.P. (1)	87,455	*****
Directors and Named Executive Officers:		
Keith J. Kendall	1,031,790	2.95%
Daniel Barber	210,711	*
John T. Maxwell	341,734	*
Douglas K. Bratton (2)	11,613,979	33.56%
Gregory B. Brown, M.D	110,685	*
John Cochran	110,685	*
Santo J. Costa	52,927	*
Julie Krop, M.C.	--	*
Nancy S. Lurker	40,254	*
James S. Scibetta	67,235	*
Marco Taglietti, M.D.	--	*
All executive officers and directors as a group (17 persons)	15,129,217	43.69%

* Represents beneficial ownership of less than 1%.
† None of the shares are pledged as security.

(1) Information reported as of December 31, 2020 in a Schedule 13G/A filed on February 9, 2021 by MonoLine Rx II, L.P., MonoLine Rx III, L.P., MRX Partners, LLC, MonoLine Rx, L.P., MonoLine Partners, L.P. and MonoSol Rx Genpar, L.P. (collectively, the "MonoSol Entities") and Douglas K. Bratton. Bratton Capital Management L.P. ("Bratton Capital Management") is the general partner or manager of each of the MonoSol Entities, except for MonoSol Rx Genpar, L.P., the general partner of which is Bratton Capital Inc., which, in turn, is the general partner of Bratton Capital Management. Douglas K. Bratton is the sole director and President of Bratton Capital Inc. The MonoSol Entities are each ultimately controlled by Mr. Bratton, who has voting and investment power over all shares held by the Monosol Entities. Bratton Capital Management, Bratton Capital Inc., 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 disclaim beneficial ownership of the reported securities except to the extent of its or his respective pecuniary interest therein. The principal business address for the MonoSol Entities and Mr. Bratton is 201 Main Street, Suite 1900, Fort Worth, Texas 76102.

(2) Includes 2,249,077 shares of common stock owned of record by MRX Partners, LLC, 2,213,314 shares of common stock owned of record by MonoLine Rx, L.P., 4,032,097 shares of common stock owned of record by MonoLine Rx II, L.P. and 2,755,541 shares of common stock owned of record by MonoLine Rx III, L.P. 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, and Mr. Bratton may be deemed to beneficially own all shares held of record by the MonoSol Entities. Mr. Bratton disclaims beneficial ownership of such reported securities except to the extent of his pecuniary interest therein.

Amounts reported for our directors and executive officers include the following number of securities with respect to which the individual has the right to acquire beneficial ownership as of December 31, 2020 or within 60 days thereafter: Mr. Kendall, 392,641; Mr. Maxwell, 191,120 Mr. Barber, 108,752; Mr. Bratton, 35,600 Dr. Brown, 35,600 Mr. Cochran, 35,600; Mr. Costa, 35,600; Ms. Lurker, 40,254 Dr. Krop, 0; Mr. Scibetta, 35,600 Dr. Taglietti, 0 and all directors and executive officers as a group, 1,387,743.

Item 13. Certain Relationships and Related Party Transactions and Director Independence

Related Person Transaction Policy

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 became effective upon the consummation of our initial public offering in July 2018. For purposes of our policy only, a “related person transaction” is 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.

A related person is 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) for review. The presentation is to 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 will take into account the relevant available facts and circumstances which may include:

- 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, if applicable; and
- the terms available to or from, as the case may be, unrelated third parties or to or from our colleagues 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, is to 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.

Registration Rights to Directors and Officers

In connection with our initial public offering, we granted certain registration rights to Mr. Maxwell and Mr. Barber pursuant to their employment agreements and to MRX Partners LLC, Monoline RX L.P., Monoline Rx II, L.P., Monoline Rx III, L.P., Monoline Rx Genpar, MonoSol Investors L.P., Douglas K. Bratton, Gregory B. Brown, M.D., John Cochran, Santo J. Costa, Keith J. Kendall, Nancy S. Lurker, James S. Scibetta and A. Mark Schobel. Pursuant to the terms of the registration rights agreement, if, following the completion of our initial public offering, we were to register any of our securities for public sale in another offering, these related parties would have the right to include their shares in the registration statement, subject to reduction provisions whereby the Company and the underwriters of any underwritten offering would have the right to limit the number of shares registered by these holders if they were to determine that marketing factors require limitation. In such a case the number of shares to be registered would be apportioned pro rata among these holders, according to the total amount of registrable securities entitled to be included by each holder.

Indemnification Agreements

We have entered 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 certain contractual rights to indemnification and 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.

DIRECTOR INDEPENDENCE

Under Nasdaq rules, a majority of a listed company’s board of directors must be comprised of independent directors. In addition, Nasdaq rules require that, subject to specified exceptions, each member of a listed company’s audit committee and compensation committee be independent and satisfy additional independence criteria set forth in Rules 10A-3 and 10C-1, respectively, under the Securities Exchange Act of 1934, as amended (the “Exchange Act”). Under Nasdaq rules, a director will only qualify as an “independent director” if the director meets certain objective independence tests and does not have a relationship that, in the opinion of the Board, would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

In accordance with these standards and criteria, the Board undertook its annual review of the independence of our directors. During this review the Board considered whether there were any relationships or related party transactions between each director, any member of his or her immediate family or other affiliated entities and the Company. The purpose of this review is to determine whether any such relationships or transactions existed that were inconsistent with a determination that the director is independent.

The Board follows a number of procedures to review related party transactions, as described in more detail below under "Related Person Transaction Policy." Each director also answers a questionnaire designed to disclose information concerning conflicts and transactions which may impact independence, and we also review our internal records for any such transactions.

Based on a review of these standards and materials, our Board determined that none of our independent directors had or has any relationship with us other than as a director, with the exception of Mr. Cochran who is affiliated with significant stockholders of the Company. See above under "Beneficial Ownership of Common Stock" for more information.

As a result of its review, our Board has determined, upon the recommendation of our Nominating and Corporate Governance Committee, that each of our directors other than Keith J. Kendall, our Chief Executive Officer, is independent within the meaning of the director independence standards of Nasdaq and the SEC and has no relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. Our Board has also determined that each of the current members of our Audit Committee and our Compensation Committee satisfies the heightened independence standards for such committee members.

Item 14. Principal Accountant Fees and Services

Policy on Audit Committee Pre-Approval of Audit and Permissible Non-Audit Services of Independent Registered Public Accounting Firm

The Audit Committee pre-approves all auditing services and permitted non-audit services to be performed by KPMG, subject to the de minimis exception for non-audit services that are approved by the Audit Committee prior to the completion of an audit. The Audit Committee may delegate pre-approval authority to one or more members of the Audit Committee consistent with applicable law and listing standards, provided that the decisions of such Audit Committee member or members are to be presented to the full Audit Committee at its next scheduled meeting.

Principal Accountant Fees and Services

We regularly review the services and fees of our independent accountants. These services and fees are also reviewed by the Audit Committee on an annual basis. The aggregate fees billed for the fiscal years ended December 31, 2020 and 2019 for each of the following categories of services are as follows:

Fee Category	2020	2019
Audit Fees	$ 786,300	$ 640,000
Audit-Related Fees	—	—
Tax Fees	—	—
All Other Fees	—	—
Total Fees	$ 786,300	$ 640,000

Audit Fees. Consist of aggregate fees for professional services provided in connection with the annual audit of our consolidated financial statements, the review of our quarterly condensed consolidated financial statements, review of registration statements on Forms S-3 and S-8, comfort letters, consents and review of documents filed with the SEC.

Audit-Related Fees. Consist of aggregate fees for accounting consultations and other services that were reasonably related to the performance of audits or reviews of our consolidated financial statements and were not reported above under "Audit Fees."

Tax Fees. Consist of aggregate fees for tax compliance, tax advice and tax planning services including the review and preparation of our federal and state income tax returns.

All Other Fees. Consist of aggregate fees billed for products and services provided by the independent registered public accounting firm other than those fees disclosed above.

The Audit Committee pre-approved all services reflected in the above table performed since the pre-approval policy was adopted.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a)(1) Financial Statements.

The response to this portion of Item 15 is set forth under Item 8 hereof.

(a)(2) Financial Statement Schedules.

All financial statement schedules have been omitted because they are not applicable, not required or the required information is given in the Consolidated Financial Statements or Notes thereto.

(a)(3) Exhibits.

The exhibits below are filed as part of this Form 10-K other than Exhibit 32.1 and Exhibit 32.2, which shall be deemed furnished.

Number	Description
3.1	Amended and Restated Certificate of Incorporation of Aquestive Therapeutics, Inc., dated as of July 27, 2018 (filed as Exhibit 3.1 to the Current Report on Form 8-K of the Company, as filed on July 27, 2018, and incorporated by reference herein).
3.2	Amended and Restated Bylaws of Aquestive Therapeutics, Inc. (filed as Exhibit 3.6 to the Registration Statement on Form S-1 of the Company (File No. 333-225924), as filed on June 27, 2018, and incorporated by reference herein).
4.1	Form of Common Stock Certificate of Aquestive Therapeutics, Inc. (filed as Exhibit 4.1 to the Registration Statement on Form S-1 of the Company (File No. 333-225924), as filed on June 27, 2018, and incorporated by reference herein).
4.2	Indenture dated July 15, 2019, among Aquestive Therapeutics, Inc., as Issuer, any Guarantor that becomes party thereto and U.S. Bank National Association, as Trustee and Collateral Agent (filed as Exhibit 4.1 to the Current Report on Form 8-K filed on July 16, 2019, and incorporated by reference herein).
4.3	First Supplemental Indenture dated November 3, 2020, among Aquestive Therapeutics, Inc., as Issuer, any Guarantor that becomes party thereto and U.S. Bank National Association, as Trustee and Collateral Agent (filed herewith)
4.4	Second Supplemental Indenture dated November 20, 2020, among Aquestive Therapeutics, Inc., as Issuer, any Guarantor that becomes party thereto and U.S. Bank National Association, as Trustee and Collateral Agent (filed herewith)
4.5	Form of 2019 Warrant (filed as Exhibit 4.2 to the Current Report on Form 8-K filed on July 16, 2019 and incorporated by reference herein).
4.6	Form of 2020 Warrant (incorporated by reference herein)
4.7	Registration Rights Agreement, dated as of June 24, 2018, by and between Aquestive Partners, LLC and certain of the holders of its membership interests (filed as Exhibit 4.3 to the Registration Statement on Form S-1 of the Company (File No. 333-225924), as filed on June 27, 2018, and incorporated by reference herein).
4.8	Description of Securities Registered under Section 12 of the Exchange Act (incorporated by reference herein).
10.1	Form of Indemnification Agreement, by and between Aquestive Therapeutics, Inc and its directors and officers (filed as Exhibit 10.1 to the Registration Statement on Form S-1 of the Company (File No. 333-225924), as filed on June 27, 2018, and incorporated by reference herein).
10.2	Form of Purchase Agreement in connection with the 2019 issuance of 12.5% Senior Secured Notes (filed as Exhibit 10.1 to the Current Report on Form 8-K filed on July 16, 2019).
10.3	Form of 2020 Purchase Agreement in connection with the 2020 issuance of 12.5% Senior Secured Notes (filed herewith).
10.4	Collateral Agreement in connection with issuance of 12.5% Senior Secured Notes, dated as of July 15, 2019, among Aquestive Therapeutics, Inc., as Issuer, the Other Grantors from time to time party thereto, U.S. Bank National Association, as Trustee, and U.S. Bank National Association, as Collateral Agent (filed as Exhibit 10.2 to the Current Report on Form 8-K filed on July 16, 2019).
10.5+	Executive Employment Agreement, dated as of June 30, 2018, by and between Aquestive Therapeutics, Inc. and Keith J. Kendall (filed as Exhibit 10.5 to the Pre-Effective Amendment No. 1, as filed on July 16, 2018, to the Registration Statement on Form S-1 of the Company (File No. 333-225924), and incorporated by reference herein).
10.6+	Executive Employment Agreement, dated as of June 26, 2018, by and between Aquestive Therapeutics, Inc. and Daniel Barber (filed as Exhibit 10.6 to the Registration Statement on Form S-1 of the Company (File No. 333-225924), as filed on June 27, 2018, and incorporated by reference herein).
10.7+	Executive Employment Agreement, dated as of June 26, 2018, by and between Aquestive Therapeutics, Inc. and John T. Maxwell (filed as Exhibit 10.7 to the Registration Statement on Form S-1 of the Company (File No. 333-225924), as filed on June 27, 2018, and incorporated by reference herein).
10.8+	Separation Agreement, dated as of December 16, 2020, by and between Aquestive Therapeutics, Inc. and John T. Maxwell (filed herewith).
10.9+	Executive Employment Agreement, dated as of July 9, 2018, by and between Aquestive Therapeutics, Inc. and A. Mark Schobel (filed as Exhibit 10.8 to the Pre-Effective Amendment No. 1, as filed on July 16, 2018, to the Registration Statement on Form S-1 of the Company (File No. 333-225924), and incorporated by reference herein).
10.10†	Commercial Exploitation Agreement, by and between MonoSol Rx, LLC (now Aquestive Therapeutics, Inc.) and Reckitt Benckiser Pharmaceuticals Inc., dated as of 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) (filed as Exhibit 10.9 to the Registration Statement on Form S-1 of the Company (File No. 333-225924), as filed on June 27, 2018, and incorporated by reference herein).
10.11†	Agreement, by and between MonoSol Rx, LLC (now Aquestive Therapeutics, Inc.) and Indivior UK Limited, dated as of September 24, 2017 (filed as Exhibit 10.10 to the Registration Statement on Form S-1 of the Company (File No. 333-225924), as filed on June 27, 2018, and incorporated by reference herein).
10.12†	Agreement to Terminate CLA, by and between MonoSol Rx, LLC (now Aquestive Therapeutics, Inc.) and KemPharm, Inc., dated as of March 20, 2012 (filed as Exhibit 10.11 to the Registration Statement on Form S-1 of the Company (File No. 333-225924), as filed on June 27, 2018, and incorporated by reference herein).
10.13†	License Agreement, by and between MonoSol Rx, LLC (now Aquestive Therapeutics, Inc.) and Cynapsus Therapeutics Inc., dated as of April 1, 2016 (filed as Exhibit 10.12 to the Registration Statement on Form S-1 of the Company (File No. 333-225924), as filed on June 27, 2018, and incorporated by reference herein).
10.14†	First Amendment to License Agreement, by and between Aquestive Therapeutics, Inc. and Sunovion Pharmaceuticals, Inc., dated as of March 16, 2020 (incorporated by reference herein).
10.15†	Second Amendment to License Agreement, by and between Aquestive Therapeutics, Inc. and Sunovion Pharmaceuticals, Inc., dated as of October 23, 2020 (filed herewith).

10.16	Industrial Lease Agreement, by and between Ashland Northwest Partners, L.P. and MonoSol Rx, LLC (now Aquestive Therapeutics, Inc.), dated as of October 24, 2006 (as amended on October 24, 2011 and February 8, 2018) (filed as Exhibit 10.13 to the Registration Statement on Form S-1 of the Company (File No. 333-225924), as filed on June 27, 2018, and incorporated by reference herein).
10.17+	Aquestive Therapeutics, Inc. 2018 Equity Incentive Plan (filed as Exhibit 10.14 to the Pre-Effective Amendment No. 1, as filed on July 16, 2018, to the Registration Statement on Form S-1 of the Company (File No. 333-225924) and incorporated by reference herein).
10.18+	Aquestive Therapeutics, Inc. Employee Stock Purchase Plan as Amended (incorporated by reference herein).
10.19+	Form of Stock Option Agreement (filed as Exhibit 10.16 to the Registration Statement on Form S-1 of the Company (File No. 333-225924), as filed on June 27, 2018, and incorporated by reference herein).
10.20+	Form of Stock Option Agreement under the Aquestive Therapeutics, Inc. 2018 Equity Incentive Plan (filed as Exhibit 10.17 to the Pre-Effective Amendment No. 1, as filed on July 16, 2018, to the Registration Statement on Form S-1 of the Company (File No. 333-225924) and incorporated by reference herein).
10.21+	Form of Restricted Stock Unit Agreement under the Aquestive Therapeutics, Inc. 2018 Equity Incentive Plan (filed as Exhibit 10.18 to the Pre-Effective Amendment No. 1, as filed on July 16, 2018, to the Registration Statement on Form S-1 of the Company (File No. 333-225924) and incorporated by reference herein).
10.22+	Executive Employment Agreement, dated as of September 10, 2018, by and between Aquestive Therapeutics, Inc. and Lori J. Braender (filed as Exhibit 10.4 to the Quarterly Report on Form 10-Q of the Company, as filed on November 6, 2018, and incorporated by reference herein).
10.23	Purchase and Sale Agreement, dated as of November 3, 2020, by and between Aquestive Therapeutics, Inc. and MAM Pangolin Royalty, LLC (filed herewith).
23.1	Consent of KPMG LLP, Independent Registered Public Accounting Firm (filed herewith).
31.1	Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith).
31.2	Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith).
32.1*	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (furnished herewith).
32.2*	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (furnished herewith).
101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document

† Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment that has been granted by the Securities and Exchange Commission.

∗ Furnished herewith and not deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and shall not be deemed to be incorporated by reference to any filing under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.

\+ Indicates a management contract or compensatory plan.

Item 16. Form 10-K Summary

Not applicable.

SIGNATURES

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

AQUESTIVE THERAPEUTICS, INC.

Date: March 9, 2021

By: /s/ Keith J. Kendall

Keith J. Kendall
Chief Executive Officer
(Principal Executive Officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capabilities 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)	March 9, 2021
/s/ A. Ernest Toth, Jr. A.Ernest Toth, Jr.	Interim Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 9, 2021
/s/ Gregory B. Brown Gregory B. Brown	Member of the Board of Directors	March 9, 2021
/s/ John Cochran John Cochran	Member of the Board of Directors	March 9, 2021
/s/ Santo J. Costa Santo J. Costa	Chairman of the Board of Directors	March 9, 2021
/s/ Julie Krop Dr. Julie Krop, M.D.	Member of the Board of Directors	March 9, 2021
/s/ Nancy S. Lurker Nancy S. Lurker	Member of the Board of Directors	March 9, 2021
/s/ James S. Scibetta James S. Scibetta	Member of the Board of Directors	March 9, 2021
/s/ Marco Taglietti Dr. Marco Taglietti, M.D.	Member of the Board of Directors	March 9, 2021

Index to Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors

Aquestive Therapeutics, Inc.:

Opinion on the Consolidated *Financial Statements*

We have audited the accompanying consolidated balance sheets of Aquestive Therapeutics, Inc. and subsidiaries (the Company) as of December 31, 2020 and 2019, the related consolidated statements of operations and comprehensive loss, changes in stockholders' deficit, and cash flows for each of the years in the two-year period ended December 31, 2020, 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, 2020 and 2019, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2020, in conformity with U.S. generally accepted accounting principles.

Change in Accounting Principle

As discussed in Note 3 to the consolidated financial statements, the Company has changed its method of accounting for leases as of January 1, 2020 due to the adoption of Accounting Standards Codification 842, *Leases*.

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. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

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
March 9, 2021

AQUESTIVE THERAPEUTICS, INC.
Consolidated Balance Sheets
(In thousands, except per share/unit amounts)

	December 31, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 31,807	$ 49,326
Trade and other receivables, net	6,955	13,130
Inventories, net	2,461	2,859
Prepaid expenses and other current assets	3,402	2,999
Total current assets	44,625	68,314
Property and equipment, net	6,873	9,726
Right-of-use assets, net	3,448	—
Intangible assets, net	102	153
Other non-current assets	7,836	286
Total assets	$ 62,884	$ 78,479
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 7,089	$ 12,274
Accrued expenses	8,569	5,475
Lease liabilities, current	728	—
Deferred revenue	693	806
Liability related to the sale of future revenue, current	1,450	—
Loans payable, current	2,575	—
Total current liabilities	21,104	18,555
Loans payable, net	34,329	60,338
Liability related to the sale of future revenue, net	47,524	—
Lease liabilities	2,846	—
Deferred revenue, net of current portion	3,633	4,348
Other non-current liabilities	1,945	1,360
Total liabilities	111,381	84,601
Contingencies (note 20)		
Stockholders' deficit:		
Common stock, $0.001 par value. Authorized 250,000,000 shares; 34,569,254 and 33,562,885 shares issued and outstanding at December 31 2020 and 2019, respectively	35	34
Additional paid-in capital	137,725	124,318
Accumulated deficit	(186,257)	(130,474)
Total stockholders' deficit	(48,497)	(6,122)
Total liabilities and stockholders' deficit	$ 62,884	$ 78,479

See accompanying notes to the consolidated financial statements.

AQUESTIVE THERAPEUTICS, INC.
Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except per share data amounts)

	Year Ended December 31,	
	2020	**2019**
Revenues	$ 45,849	$ 52,609
Costs and expenses:		
Manufacture and supply	12,964	20,361
Research and development	19,886	20,574
Selling, general and administrative	55,892	64,342
Total costs and expenses	88,742	105,277
Loss from operations	(42,893)	(52,668)
Other income (expenses):		
Interest expense	(11,064)	(9,318)
Interest expense related to the sale of future revenue	(1,958)	—
Interest income and other income (expense), net	132	636
Loss on the extinguishment of debt	—	(4,896)
Net loss before income taxes	(55,783)	(66,246)
Income taxes	—	—
Net loss	$ (55,783)	$ (66,246)
Comprehensive loss	$ (55,783)	$ (66,246)
Net loss per share – basic and diluted	$ (1.66)	$ (2.61)
Weighted-average number of common shares outstanding - basic and diluted	33,651,127	25,356,098

See accompanying notes to the consolidated financial statements.

AQUESTIVE THERAPEUTICS, INC.
Consolidated Statements of Changes in Stockholders' Deficit
(In thousands, except per share amounts)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity/(Deficit)
	Shares	Amount			
Balance at December 31, 2018	24,957,309	$ 25	$ 71,431	$ (61,376)	$ 10,080
Adoption of ASU 2104-09, ASU 2018-09	—	—	20	(2,852)	(2,832)
Fair value of warrants issued	—	—	6,800	—	6,800
Common Stock issued upon warrant exercises	428,571	1	1,820	—	1,821
Common Stock issued upon public equity offering	8,050,000	8	37,827	—	37,835
Costs of public equity offering	—	—	(540)	—	(540)
Shares issued under employee stock purchase plan	56,378	—	237	—	237
Vested restricted stock units	70,627	—	(313)	—	(313)
Share-based compensation expense	—	—	7,036	—	7,036
Net loss	—	—	—	(66,246)	(66,246)
Balance at Balance at December 31, 2019	33,562,885	$ 34	$ 124,318	$ (130,474)	$ (6,122)
Fair value of warrants issued	—	—	735	—	735
Common Stock issued under public equity offering	930,933	1	6,527	—	6,528
Costs of common stock issuance under public equity offering	—	—	(473)	—	(473)
Shares issued under employee stock purchase plan	32,986	—	158	—	158
Exercise of stock options	500	—	2	—	2
Vested restricted stock units	41,950	—	(99)	—	(99)
Share-based compensation expense	—	—	6,557	—	6,557
Net loss	—	—	—	(55,783)	(55,783)
Balance at Balance at December 31, 2020	34,569,254	$ 35	$ 137,725	$ (186,257)	$ (48,497)

See accompanying notes to the consolidated financial statements.

AQUESTIVE THERAPEUTICS, INC.
Consolidated Statements of Cash Flows
(In thousands)

	Year Ended December 31,	
	2020	2019
Cash flows from operating activities:		
Net loss	$ (55,783)	$ (66,246)
Adjustments to reconcile net loss to net cash (used for) operating activities:		
Depreciation, amortization, and impairment	3,443	2,905
Share-based compensation	6,581	7,071
Amortization of debt issuance costs and discounts	2,587	1,929
Interest expense related to the sale of future revenue	1,938	—
Loss on the extinguishment of debt	—	4,896
All other non-cash expenses	188	359
Changes in operating assets and liabilities:		
Trade receivables and other receivables, net	6,175	(6,815)
Inventories	398	2,582
Prepaid expenses and other assets	(7,953)	(1,366)
Accounts payable	(5,185)	(7,872)
Accrued expenses and other liabilities	2,980	746
Deferred revenue	(828)	1,601
Net cash used for operating activities	(45,459)	(60,210)
Cash flows from investing activities:		
Capital expenditures	(517)	(663)
Net cash used for investing activities	(517)	(663)
Cash flows from financing activities:		
Proceeds from issuance of common stock and warrant exercises	6,215	39,317
Proceeds from sale of future revenue	50,000	—
Proceeds from issuance of debt	—	70,000
Debt repayment	(22,500)	(50,000)
Payments for financing costs	(2,909)	(3,946)
Premium paid to retire debt	(2,250)	(2,944)
Payments for taxes on share-based compensation	(99)	(2,827)
Net cash provided by financing activities	28,457	49,600
Net decrease in cash and cash equivalents	(17,519)	(11,273)
Cash and cash equivalents:		
Beginning of period	49,326	60,599
End of period	$ 31,807	$ 49,326
Supplemental disclosures of cash flow information:		
Cash payments for interest	$ 8,491	$ 7,340
Net increase (decrease) in capital expenditures included in accounts payable and accrued expenses:	(77)	104
Deferred financing costs charged to additional paid in capital	473	540
Warrants issued in connection with long-term debt	735	6,800
Debt issued in lieu of prepayment penalty	4,000	—

See accompanying notes to the consolidated financial statements.

AQUESTIVE THERAPEUTICS, INC.
Notes to Consolidated Financial Statements
(In thousands, except share and per share information)

Note 1. Company Overview and Equity Transactions

Company Overview

Aquestive Therapeutics, Inc. ("Aquestive" or "the Company") is a pharmaceutical company focused on identifying, developing and commercializing differentiated products to address unmet medical needs and solve therapeutic problems. The Company has commercialized one internally-developed proprietary product to date, has a commercial proprietary product pipeline focused on the treatment of diseases of the central nervous system, or CNS, and other unmet needs, and is developing orally administered complex molecules as alternatives to more invasive therapies. The Company is pursuing its business objectives through both in-licensing and out licensing arrangements, as well as the commercialization of its own products. Production facilities are located in Portage, Indiana, and corporate headquarters, sales and commercialization operations and primary research laboratory facilities are based in Warren, New Jersey. The Company's major customer and primary commercialization licensee 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 is subject to risks common to companies in similar industries and stages of development, including, but not limited to, competition from larger companies, reliance on revenue from a limited number of products and customers, adequacy of existing and availability of additional operating and growth capital as and when required, uncertainty of regulatory approval for marketing its product candidates, reliance on a single manufacturing site, new technological innovations, dependence on key personnel, reliance on third-party service providers and sole source suppliers, dependence on patent-protected proprietary technology, ongoing government regulatory compliance requirements, dependence on the clinical and commercial success of its drug candidates, uncertainty of regulatory approval of its drug candidates, and uncertainty of broad adoption of its approved products, if any, by physicians and consumers. Aquestive is also subject to risks and uncertainties related to COVID-19 pandemic.

Equity Transactions

On September 11, 2019, the Company entered into an equity distribution agreement to offer shares of our common stock from time to time in an "at-the-market" offering. We may offer and sell shares of common stock for an aggregate offering price of up to $25,000. Beginning on November 20, 2020 through the year ended December 31, 2020, The Company sold 930,993 shares which provided net proceeds of approximately $6,055 after deducting commissions and other transaction costs of $473. No shares were sold pursuant to this "at-the-market" offering during 2019.

On December 17, 2019, the Company received net proceeds of $37,835 after deducting underwriting discounts of $2,415 for the sale of 8,050,000 shares of common stock in a public offering. Professional fees and other costs of this offering totaled $540, in addition to the underwriting discounts.

Note 2. Basis of Presentation and Principles of Consolidation

These consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America, or GAAP, and in accordance with the rules and regulations of the Securities and Exchange Commission, or SEC. The accounts of wholly owned subsidiaries are included in the consolidated financial statements. Other than corporate formation activities, no such subsidiaries have conducted any commercial, developmental or operational activities and none have customers or vendors. Certain reclassifications were made to conform to the current presentation.

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").

Note 3. Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires the use of estimates and assumptions that affect the reported amounts of assets and liabilities, including disclosure of contingent assets and contingent liabilities, at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. These estimates and assumptions often involve assessments of matters that are inherently uncertain and accordingly actual results could differ from those estimates. Significant items subject to estimates and assumptions include those related to revenue recognition, inventory costs, allowances for rebates from proprietary product sales, allowances for sales returns, the useful lives of fixed assets, the valuations of warrants issued and of share-based compensation, and contingencies.

Cash and Cash Equivalents

The Company considers all short-term, highly liquid investments purchased with original maturities of three months or less to be cash equivalents. At December 31, 2020 and 2019, cash and cash equivalents consisted of cash in bank accounts and money market funds.

Concentration of Credit Risk

Cash and cash equivalents are maintained are held by federally insured financial institutions that management believes are of high credit quality. The Company has not experienced any losses in such accounts and such amounts may exceed federally-insured limits.

Indivior, Sunovion, and three of the largest regional wholesalers represent our most significant customers and details on these relationships are outlined in Note 5.

Trade Accounts Receivable

Trade accounts receivable are recorded at the invoiced amount and do not bear interest. The Company grants credit to customers in the normal course of business, but generally does not require collateral or any other security to support its receivables. The Company's credit terms generally range from 30 to 60 days, depending on the customer and type of invoice. We perform a regular review of our customers' credit risk and payment histories, including payments made subsequent to year-end.

The Company evaluates the collectability of accounts receivable based on a combination of factors. In situations where changing circumstances indicate that a specific customer is unable to meet its financial obligations to the Company, a provision to the allowances for doubtful accounts is recorded against amounts due in order to reduce the net recognized receivable to the amount that is reasonably expected to be collected. For all other customers, a provision to the allowances for doubtful accounts is recorded based on factors including the length of time the receivables are past due, the current business environment and the Company's historical experience. Provisions to the allowances for doubtful accounts are recorded to selling, general and administrative expenses. Account balances are charged off against the allowance when it is probable that the receivable will not be recovered. The allowance for doubtful accounts, associated with recoverability of accounts receivable, was $40 and $124 as of December 31, 2020 and 2019, respectively.

Inventories

Inventories, consisting of purchased materials, direct labor and manufacturing overhead, are stated at the lower of cost, determined by the first-in, first-out method, or net realizable value. The Company regularly reviews its inventories for impairment and reserves are established when necessary.

At each balance sheet date, the Company evaluates inventories for excess quantities, obsolescence and shelf life expiration. This evaluation includes analysis of historical sales levels by product, projections of future demand, the risk of competitive obsolescence for products, general market conditions, and a review of the shelf life expiration dates for products. To the extent that management determines there are excess or obsolete inventory or quantities with a shelf life that is too near its expiration for the Company to reasonably expect that it can sell those products, or use them in production, prior to their expiration, the Company records allowances to adjust the carrying value to estimated net realizable value as necessary. The Company expenses inventory related to our research and development activities when we purchase or manufacture it. Before the regulatory approval of our product candidates, we recognize research and development expense for the manufacture of drug products that could potentially be available to support the commercial launch of our drug candidates, if approved.

Property and Equipment

Property and equipment are stated at cost net of accumulated depreciation and amortization, which is computed by the straight-line method based on the estimated useful lives of the respective assets, as discussed below. Leasehold improvements are amortized over the shorter of the lease terms or the estimated useful lives of the leased assets. Maintenance and repair costs are charged to expense as incurred, and expenditures for major renewals and improvements are capitalized. Upon disposition of property and equipment, the related cost and accumulated depreciation and amortization are removed from the accounts, and any gain or loss is reflected in the accompanying Consolidated Statements of Operations and Comprehensive Loss. The Company assesses the net book value of its property and equipment for impairment at least annually or when events or circumstances indicate that carrying amounts may not be recoverable in the ordinary course of its business.

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.

Impairment of Long-Lived Assets

Long lived assets, such as property, plant, and equipment, are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. In these circumstances, the Company compares undiscounted cash flows expected to be generated by that asset or asset group to the corresponding carrying amounts. If this comparison is indicative of impairment, an impairment charge is recognized to the extent that the carrying amount exceeds its fair value. Fair value is determined through various valuation techniques including discounted cash flow models, quoted market values and third-party independent appraisals, as considered most appropriate.

Leases

Determination if an arrangement is a lease is made at inception. An arrangement is determined to contain a lease if the contract conveys the right to control the use of an identified property and equipment for a period of time in exchange for consideration. If we can benefit from the various underlying assets of a lease on their own or together with other resources that are readably available, or if the various underlying assets are neither highly dependent or highly interrelated with underlying assets in the arrangements, they are considered to be a separate lease component. In the event multiple underlying assets are identified, the lease consideration is allocated to the various components based on each on the component's relative fair value.

Operating lease assets represent our right to use an underlying asset for the lease term and operating lease liabilities represent an obligation to make lease payments arising from the lease arrangement. Operating lease assets and operating lease liabilities are recognized at commencement date based on the present value of lease payments over the lease term. As most of our leases do not provide an implicit rate, in determining the operating lease liability, we use an estimate of our incremental borrowing rate. The calculation of the operating lease assets includes any lease payments made and excludes any lease incentives. Our lease terms may include options to extend or terminate the lease and are included when it is reasonably certain that we will exercise the option.

We record operating lease assets and lease liabilities in our consolidated balance sheets. Lease expenses for lease payments is recognized on a straight-line bases over the lease term. Short-term leases, or leases that have a lease term of 12 months or less at consummation date, are excluded from this treatment and are recognized on a straight-line basis over the term of the lease. We have not entered into any material short-term lease or financing leases as of December 31, 2020.

Liability Related to the Sale of Future Revenue

The Company treats the liability related to the sale of future revenue as debt financing, amortized under the effective interest rate method over the estimated life of the related expected royalty stream. The liability related to the sale of future revenue and the related interest expense are based on our current estimates of future royalties expected to be paid over the life of the arrangement. The Company will periodically assess the expected royalty payments using a combination of internal projections and forecasts from external resources. To the extent our future estimates of royalty payments are greater or less than previous estimates or the interest timing of such payments is materially different than its previous estimates, the Company will prospectively recognize related interest expense. Royalty revenue related to the sale of future revenue is reflected as royalty revenue, and amortization of debt is reflected as interest expense related to the sale of future revenue in the Consolidated Statement of Operations and Comprehensive Loss. For further discussion of the sale of the future revenue, refer to Note 14, *Sale of Future Revenue.*

Revenue Recognition

The Company's revenues include (i) sales of manufactured products pursuant to contracts with commercialization licensees, (ii) sales of its proprietary clobazam-based Sympazan oral film product used as a treatment for LGS-related seizures, (iii) license and royalty revenues and (iv) co-development and research fees generally in the form of milestone payments. See Note 5 for further details. Having adopted ASC 606, *Revenue from Contracts with Customers,* effective on January 1, 2019 and applying the modified retrospective method which resulted in an adjustment totaling $2,832 to the Company's accumulated deficit, the Company recognizes revenue to reflect the transfer of promised goods or services to customers in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those goods or services. To achieve this core principle, a five-step model is applied that includes (1) identifying the contract with a customer, (2) identifying the performance obligation in the contract, (3) determining the transaction price, (4) allocating the transaction price to the performance obligations, and (5) recognizing when, or as, an entity satisfies a performance obligation.

Manufacture and supply revenue – this revenue is derived from products manufactured exclusively for specific customers according to their strictly-defined specifications, subject only to specified quality control inspections. Accordingly, at the point in time when quality control requirements are satisfied, revenue net of related discounts is recorded.

Proprietary product sales, net – this net revenue is recognized when product is shipped and title passes to the customer, typically at time of delivery. At the time of sale, estimates for various revenue allowances are recorded based on historical trends and judgmental estimates. For sales of Sympazan, returns allowances and prompt pay discounts are estimated based on contract terms and historical return rates, if available, and these estimates are recorded as a reduction of receivables. Similarly determined estimates are recorded relating to wholesaler service fees, co-pay support redemptions, Medicare, Medicaid and other rebates, and these estimates are reflected as a component of accrued liabilities. Once all related variable considerations are resolved and uncertainties as to collectable amounts are eliminated, estimates are adjusted to actual allowance amounts. Provisions for these estimated amounts are reviewed and adjusted on no less than a quarterly basis.

License and Royalty Revenue – license revenues are determined based on an assessment of whether the license is distinct from any other performance obligations that may be included in the underlying licensing arrangement. If the customer is able to benefit from the license without provision of any other performance obligations by the Company and the license is thereby viewed as a distinct or functional license, the Company then determines whether the customer has acquired a right to use the license or a right to access the license. For functional licenses that do not require further development or other ongoing activities by the Company, the customer is viewed as acquiring the right to use the license as, and when, transferred and revenues are generally recorded at a point in time, subject to contingencies or constraints. For symbolic licenses providing substantial value only in conjunction with other performance obligations to be provided by the Company, revenues are generally recorded over the term of the license agreement. Such other obligations provided by the Company generally include manufactured products, additional development services or other deliverables that are contracted to be provided during the license term. Payments received in excess of amounts ratably or otherwise earned are deferred and recognized over the term of the license or as contingencies or other performance obligations are met.

Royalty revenue is estimated and recognized when sales under supply agreements with commercial licensees are recorded, absent any contractual constraints or collectability uncertainties. Royalties based on sales of Suboxone and Zuplenz have been recorded in this manner.

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 development or feasibility study agreement 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.

Revenue recognition arising from milestone payments is dependent upon the facts and circumstances surrounding the milestone payments. Milestone payments based on a non-sales metric such as a development-based milestone (*e.g.*, an NDA filing or obtaining regulatory approval) represent variable consideration and are included in the transaction price subject to any constraints. If the milestone payments relate to future development, the timing of recognition depends upon historical experience and the significance a third party has on the outcome. For milestone payments to be received upon the achievement of a sales threshold, the revenue from the milestone payments is recognized at the later of when the actual sales are incurred or the performance obligation to which the sales relate to has been satisfied.

Contract Assets - in certain situations, customer contractual payment terms provide for invoicing in arrears. Accordingly, some, or all performance obligations may be completely satisfied before the customer may be invoiced under such agreements. In these situations, billing occurs after revenue recognition, which results in a contract asset supported by the estimated value of the completed portion of the performance obligation. These contract assets are reflected as a component of other receivables within Trade and other receivables within the Consolidated Balance Sheet.

Contract Liabilities - in certain situations, customer contractual payment terms are structured to permit invoicing in advance of delivery of a good or service. In such instances, the customer's cash payment may be received before satisfaction of some, or any, performance obligations that are specified. In these situations, billing occurs in advance of revenue recognition, which results in contract liabilities. These contract liabilities are reflected as deferred revenue within the Consolidated Balance Sheet. As remaining performance obligations are satisfied, an appropriate portion of the deferred revenue balance is credited to earnings.

Research and Development

Research and development, or R&D, expenses are recorded in accordance ASC 730 *Research and Development* and are expensed as incurred. R&D expenses include R&D activities, services of external contract research organizations, or CROs, costs of their clinical research sites, scale-up and validation costs, and other activities. Internal R&D activity expenses include laboratory supplies, salaries, benefits, and non-cash share-based compensation expenses. CRO activities include preclinical laboratory experiments and clinical studies. Other activity expenses include regulatory consulting and other costs. The activities undertaken by a regulatory consultants that were classified as R&D expense include assisting, communicating with, and advise our in-house staff with respect to various FDA submission processes, clinical trial processes and scientific writing matters, including preparing protocols and FDA submissions. These consulting expenses were direct costs associated with preparing, receiving and understanding work for our clinical trials and investigative drugs. The Company charges internal R&D activities and other activity expenses to operation as incurred. Payments made to CROs based on agreed-upon terms, which may include payments in advance of a study start date. The Company expenses non-refundable advance payments for goods and services that will be used in future R&D activities when the activity has been performed or when goods or services have been received rather than when payment was made. The Company reviews and accrues CRO expenses and clinical trial study expenses based on services performed and rely on estimates of those costs applicable to the completion state of study as provided by CRO's. Estimated CRO costs subject to revisions as such studies progress to completion. The Company charges revisions to expense in the period when the facts that give rise to the revision become known.

Income Taxes

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. 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.

Uncertain tax positions are accounted for in accordance with the provision of ASC 740. When uncertain tax positions exist, the tax benefit is recognized 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, the Company has not had any significant uncertain tax positions.

Share-Based Compensation

The Company records share-based compensation expenses for awards of stock options and restricted stock units (RSUs) under ASC 718, *Compensation — Stock Compensation*. For awards to non-employees for periods prior to the adoption of ASU 2018-07, *Compensation-Stock Compensation: Improvements to Non-employee Share-Based Payment Accounting*, on January 1, 2019, the Company had applied ASC 505-50, *Equity-based Payments to Non-Employees*. ASC 718 establishes guidance for the recognition of expenses arising from the issuance of stock-based compensation awards at their fair value at the grant date.

The Company's stock-based compensation includes grants of stock options and restricted stock units (RSUs) to employees, consultants and non-employee directors. Beginning in 2019, the Company also offered employees an opportunity to participate in an employee stock purchase plan. Expenses arising from these grants are recorded in the accompanying financial statements based on their grant date fair values as ratably earned during their respective vesting periods. The Company's estimates of the fair value of options at their grant dates is based on the Black-Scholes option valuation model and considers various variables and assumptions, including:

- the stock price at the grant date,
- exercise price,
- both the contractual and estimated expected term of the option,
- an estimate of stock price volatility based on that of an industry peer group,
- expected dividends,
- no dividends for the foreseeable future, and
- risk-free interest rate.

These assumptions require estimates and judgements and changes in those inputs could impact the amount of expenses that are charged to earnings. The Company recognizes compensation expense for the fair value of restricted stock unit and stock option awards over the requisite service period of the award. All excess tax benefits, taxes and tax deficiencies from stock-based compensation are included in the provision for income taxes in the Consolidated Statement of Operations.

Per Share Data

Basic net loss per common share is computed by dividing the net loss attributable to common stockholders by the weighted average number of shares of common stock outstanding during the period.

Diluted net income per common share is calculated by dividing net income available to common stockholders as adjusted for the effect of dilutive securities, if any, by the weighted average number of shares of common stock and dilutive common stock outstanding during the period. Potentially dilutive common shares include the shares of common stock issuable upon the exercise of outstanding stock options and warrants, the shares of issued but unvested RSUs and the purchase of shares from the Company's employee stock purchase plan (using the treasury stock method). For all periods presented, potential common shares have been excluded from the calculation of EPS because their effect would be anti-dilutive.

Comprehensive Loss

Comprehensive loss includes net loss as well as other changes in stockholders' equity that may result from transactions and economic events other than those with stockholders, such as unrealized gains or losses on investments. For the periods ending on December 31, 2020 and 2019, the Company's comprehensive loss included only its net loss.

Fair Value Measurements

Certain assets and liabilities are reported on a recurring basis at fair value. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1 — Quoted prices in active markets for identical assets or liabilities. Cash and cash equivalents consisted of cash in bank checking accounts and money market funds which are all Level 1 assets.

- Level 2 — Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data. The Company currently has no Level 2 assets or liabilities.

- Level 3 — Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

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 assets and liabilities.

The Company granted warrants to certain Note Holders in connection with its debt repayment and debt refinancing during 2020 and 2019, respectively. Those warrants were valued based on Level 3 inputs and their fair value was based primarily on an independent third-party appraisal prepared as of the grant date consistent with generally-accepted valuation methods of the Uniform Standards of Professional Appraisal Practice, the American Society of Appraisers and the American Institute of Certified Public Accountants' Accounting and Valuation Guide, *Valuation of Privately-Held Company Equity Securities Issued as Compensation.* See Note 13 Warrants for further information on these warrants.

The Company's 12.5% Senior Secured Notes contain a repurchase offer or put option which gives holders of the option the right, but not the obligation, to receive a specified amount of future royalties up to a capped amount. This put option was valued based on Level 3 inputs and its fair value was based primarily on an independent third-party appraisal consistent with generally-accepted valuation methods of the Uniform Standards of Professional Appraisal Practice, the American Society of Appraisers and the American Institute of Certified Public Accountants Accounting and Valuation Guide. See Note 12 12.5% Senior Notes and Loans Payable for further discussion.

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.

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 by 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.

Recently Adopted Accounting Pronouncements:

In February 2016, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, 2016-02, *Leases (Topic 842),* and issued amendments in July 2018 provided by ASU 2018-10. This ASU, as amended, requires lessees to recognize lease assets, termed "right-of-use assets" and related liabilities on the balance sheet that had previously been classified as operating leases under prior authoritative guidance. For income statement purposes, leases are now required to be classified as either operating or financing leases under a dual model similar to that specified by ASC 840. Operating leases continue to result in straight-line expense while financing leases result in a front-loaded expense pattern in a manner similar to recognition of capital lease expenses under ASC 840.

The Company adopted and applied ASU 2016-02 on January 1, 2020 using the modified retrospective transition provisions of ASC 842 to leases in effect as of that date of adoption and recorded right-of-use assets totaling $4,048 and lease liabilities as adjusted for accrued lease payments, in the amount $4,224 based on an estimated incremental borrowing rate of 16.9%, representing the present value of remaining minimum lease payments. The assets and liabilities thus recorded were primarily those related to the Company's leased plant, laboratory and corporate administrative facilities. The Company elected to apply the ASU-specified practical expedients and accordingly did not re-assess (i) whether its contracts contained a lease under the new definition of a lease, (ii) the classification of those leases, and (iii) initial direct costs of existing leases. In addition, the Company elected not to apply the hindsight expedient in the assessment of lease renewals and resultant term of leases. The Company also elected not to recognize a right-of-use asset and lease liability for those leases with a remaining lease term of 12 months or less. The adoption of ASU 2016-02 did not require a cumulative-effect adjustment to the opening balance of the accumulated deficit at the time of adoption.

In August 2016, the FASB issued ASU 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts from 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, including cash flows related to debt prepayment or extinguishment costs and contingent consideration that may be paid following a business combination. The Company adopted this new guidance on January 1, 2020 without material impact on it consolidated financial position or result of operations.

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework.* The purpose of the update is to improve the effectiveness of the fair value measurement disclosures that allows for clear communication of information that is most important in the users of financial statements. There were certain required disclosures that have been removed or modified. In addition, the update added the following disclosure: (i) changes in unrealized gains and losses for the period included in other comprehensive income (loss) for recurring Level 3 fair value measurements held at the end of the reporting period and (ii) the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements. The Company adopted this new guidance on January 1, 2020 without material impact on its consolidated financial position or results of operations.

In January 2016, the FASB issued revised guidance governing accounting and reporting of financial instruments (ASU 2016-01) and in 2018 issued technical corrections (ASU 2018-03). 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 were effective for the Company on January 1, 2019. Adoption of this standard did not have a material impact on the financial statements.

In November 2018, the FASB issued ASU 2018-18, *Collaborative Arrangements (Topic 808): Clarifying the Interaction Between Topic 808 and 606*, which clarifies that certain transactions between collaborative arrangement participants should be accounted for as revenue under ASC 606 when the collaborative arrangement participant is a customer for a promised good or service that is distinct within the collaborative arrangement. The guidance also precludes entities from presenting amounts related to transactions with a collaborative arrangement participant that is not a customer as revenue, unless these transactions are directly related to third-party sales. The Company adopted this new guidance on January 1, 2020 without material impact on its consolidated financial position or results of operations.

Recent Accounting Pronouncements Not Adopted as of December 31, 2020:

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, 2022. The Company is currently evaluating the impact of adoption on its consolidated financial statements.

In December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740), Simplifying the Accounting for Income Taxes*, which amends accounting for income taxes during interim periods and makes changes to certain income tax classifications. The new standard allows exceptions to the use of the incremental approach for intra-period tax allocation, when there is a loss from continuing operations and income or a gain from other items, and to the general methodology for calculating income taxes in an interim period, when a year-to-date loss exceeds the anticipated loss for the year. The standard also requires franchise or similar taxes partially based on income to be reported as income tax and the effects of enacted changes in tax laws or rates to be included in the annual effective tax rate computation from the date of enactment. The standard will be effective for the Company beginning January 1, 2022, with early adoption of the amendments permitted. The Company is currently evaluating the impact from the adoption of ASU 2019-12 on its consolidated financial statements.

In August 2020, the FASB issued ASU 2020-06, *Debt-Debt with Conversion and Other Options (Subtopic 470-20) and Derivative and Hedging-Contracts in Entity's Own Equity (Subtopic 815-40)*: Accounting for Convertible Instruments and Contracts in an Entity's Own Equity. This Accounting Standards Update was issued to address the complexity in accounting for certain financial instruments with characteristics of liabilities and equity. Among other provisions, the amendments in this ASU significantly change the guidance on the issuer's accounting for convertible instruments and the guidance on the derivative scope exception for contracts in an entity's own equity such that fewer conversion features will require separate recognition, and fewer freestanding instruments, like warrants, will require liability treatment. More specifically, the ASU reduces the number of models that may be used to account for convertible instruments from five to three, amends diluted EPS calculations for convertible instruments, modifies the requirements for a contact that may be settled in an entity's own shares to be classified in equity and requires expanded disclosures intended to increase transparency. These amendments will be effective for the Company beginning January 1, 2024, with early adoption of the amendments permitted. The Company is currently evaluating the impact from the adoption of ASU 2020-06 on its consolidated financial statements.

Other pronouncements issued by the FASB or other authoritative accounting standards groups with future effective dates are either not applicable or not significant to the consolidated financial statements of the Company.

Note 4. Risks and Uncertainties

The Company's cash requirements for 2021 and beyond include expenses related to continuing development and clinical evaluation of its products, manufacture and supply costs, costs of regulatory filings, patent prosecution expenses and litigation expenses, expenses related to commercialization of our products, as well as costs to comply with the requirements of being a public company operating in a highly regulated industry. As of December 31, 2020, we had $31,807 of cash and cash equivalents.

As of December 31, 2020, Aquestive has experienced a history of net losses and the Company's accumulated deficits totaled $186,257 which have been partially funded by gross margins from sales of commercialized licensed and proprietary products, license fees, milestone and royalty payments from our commercial licensees and co-development parties, and with the balance of the related funding requirements met by the Company's equity and debt offerings, including the Senior Secured Notes due 2025 (the "12.5% Notes"). In 2019, the Company raised funding totaling $52,226, consisting of net proceeds of $13,110 from the refinancing of debt in July 2019, $37,295 from the public offering of 8,050,000 common shares in December 2019, and $1,821 from the exercise of warrants in connection with the debt financing.

On November 3, 2020, we entered into a Purchase and Sale Agreement (the "Monetization Agreement") with MAM Pangolin Royalty, LLC, an affiliate of Marathon Asset Management ("Marathon"). Under the terms of the Monetization Agreement, we sold all of our contractual rights to receive royalties and milestone payments due under the Sunovion License Agreement related to Sunovion's apomorphine product, KYNMOBI®. KYNMOBI®, an apomorphine film therapy for the treatment of off episodes in Parkinson's disease patients, received approval from the U.S. Food and Drug Administration (FDA) on May 21, 2020. In exchange for the sale of these rights, we received an upfront payment of $40,000 and an additional payment of $10,000 through the achievement of the first milestone. We have received an aggregate amount of $50,000 through December 31, 2020 under the Monetization Agreement.

Under the Monetization Agreement, additional aggregate contingent payments of up to $75,000 may be due to us upon the achievement of worldwide royalty and other commercial targets within a specified timeframe, which could result in total potential proceeds of $125,000.

With the upfront proceeds of the monetization, we repaid $22,500 of the 12.5% Notes, and issued $4,000 of new 12.5% Notes in lieu of paying a prepayment premium on the early repayment of the 12.5% Notes, reducing the aggregate principal balance of 12.5% Notes outstanding to $51,500. In addition, the holders of the 12.5% Notes agreed to extend to December 31, 2021 our ability to access, at our option, and additional $30,000 of 12.5% Notes re-openers under the Indenture. The first $10,000 senior notes re-opener represents a commitment of such amount by current holders of 12.5% Notes, at our option, contingent upon FDA approval of our product candidate Libervant. A second $20,000 senior notes re-opener represents a right, at our option, to market to current holders of our 12.5% Notes, and/or other lenders, additional senior notes up to such amount, contingent upon FDA approval of Libervant for U.S. market access. If and to the extent that we access these re-openers, we will grant warrants to purchase up to 714,000 shares of common stock, with the strike price calculated based on the 30-day volume weighted average closing price of our common stock at the warrant grant date. In addition, as of the closing of this transaction, we issued to the holders of the 12.5% Notes warrants to purchase 143,000 shares of our common stock.

The Company began utilizing its "At-The-Market" (ATM) facility in November 2020 which has generated net cash of approximately $6,055 as of December 31, 2020. This facility has approximately $18,472 available at December 31, 2020. For further discussion see Note 22 Subsequent Events (B) Continued Utilization of the "At-The-Market" Facility.

The characteristics described above provide indications that the Company's ability to execute its near-term business objectives and achieve profitability over the longer term cannot be assured. Further, management views the impact of COVID-19 on the economy, its industry, its customers and suppliers and its own operations as constantly evolving, the future effects of which continue to be highly uncertain and unpredictable. Due to current or future interruptions and possible disruptions in health services, operations of the United States Food and Drug Administration ("FDA"), freight and other transportation services, supply, manufacturing, workforce health, availability of acceptable capital, financial and asset monetization markets, and availability of essential human and business requirements, and unforeseeable financial difficulties of the Company's customers or vendors, the severity, rapidity of the spread, and duration of the COVID-19 pandemic may be expected to negatively affect a great number of businesses across the various industries, including Aquestive. The Company may experience financial and operational adversity in such areas as preclinical, clinical trials, regulatory review and approval of various product candidates, customer demand for products and services, customers', ability to pay for goods and services, supply of pharmaceutical ingredients and other raw materials from approved vendors, ongoing availability of an appropriate labor force and skilled professionals, and additional capital, financial or monetization markets.

Subject to and absent any material adverse effect of these and other possible COVID-19 effects, the Company expects that its anticipated revenues from licensed and proprietary products, cash on hand, expense management initiatives, milestone payments under the Monetization Agreement, and access to equity markets, including its ATM facility and shelf registration statement would be adequate to meet expected operating needs as the Company continues to execute its business strategy, and access to appropriate financial markets for debt or equity financings, or a combination of these potential sources of funds, although management can provide no assurance that any of these sources of funding, either individually or in combination, will be available on reasonable terms, if at all. In addition, the Company may be required to utilize available financial resources sooner than expected. Management has based its expectation on assumptions that could change or prove to be inaccurate, either due to the impact of COVID-19 or to unrelated factors including factors arising in the capital markets, asset monetization markets, regulatory approval process, regulatory oversight and other factors.

Note 5. Revenues and Trade Receivables, Net

The Company's revenue was comprised of the following:

	Year Ended December 31,	
	2020	2019
Manufacture and supply revenue	$ 24,881	$ 38,739
License and royalty revenue	14,055	6,959
Co-development and research fees	1,264	4,042
Proprietary product sales, net	5,649	2,869
Revenues	$ 45,849	$ 52,609

Disaggregation of Revenue

The following table provides disaggregated net revenue by geographic area:

	Year Ended December 31,	
	2020	2019
United States	$ 40,956	$ 48,293
Ex-United States	4,893	4,316
Revenues	$ 45,849	$ 52,609

Ex-United States revenues are derived primarily from Indivior for product manufactured for markets outside of the United States.

Accounts receivable, net consist of the following:

	December 31,	
	2020	2019
Accounts receivable	$ 4,330	$ 9,094
Contract and other receivables	3,081	4,363
Less: allowance for bad debt	(40)	(124)
Less: sales-related allowances	(416)	(203)
Trade and other receivables, net	$ 6,955	$ 13,130

Other receivables totaled $3,081 and $4,363 as of December 31, 2020 and 2019, respectively, consisting primarily of contract assets and reimbursable costs incurred on behalf of customers. Contract assets consist of products and services provided under specific contracts to customers for which earnings processes have been met prior to shipment of goods or full delivery of completed services. Sales-related allowances for both periods presented are estimated in relation to revenues recognized for sales of Sympazan.

The following table presents the changes in the allowance for bad debt:

	December 31,	
	2020	2019
Allowance for doubtful accounts at beginning of year	$ 124	$ 58
Additions charged to bad debt expense	198	66
Write-downs charged against the allowance	(282)	—
Allowance for doubtful accounts at end of year	$ 40	$ 124

The following table presents the changes in sales-related allowances:

	December 31,	
	2020	2019
Balance at December 31, 2019	$ 203	$ 104
Provision related to sales in 2020	731	244
Credits and payments	(518)	(145)
Balance at December 31, 2020	$ 416	$ 203

Concentration of Major Customers

Customers are considered major customers net revenue exceed 10% of total revenue for the period or outstanding receivable balances exceed 10% of total receivables. For the year ended December 31, 2020, two customers exceeded the 10% threshold for revenue which were Indivior, Inc. (“Indivior”) and Sunovion Pharmaceuticals Inc. (“Sunovion”) that represented 57% and 26%, respectively. As of December 31, 2020, four customers exceeded the 10% threshold for outstanding receivables which were Indivior, AmerisourceBergen, Sunovion, and Cardinal represented 53%, 14%, 13%, and 10%, respectively. Revenues provided by Indivior represented approximately 86% for the year ended December 31, 2019 and outstanding accounts receivable due from Indivior was approximately 80%.

Note 6. Material Agreements

Commercial Exploitation Agreement with Indivior

In August 2008, the Company entered into a Commercial Exploitation Agreement with Reckitt Benckiser Pharmaceuticals, Inc. (with subsequent amendments collectively, the “Indivior License Agreement”). Reckitt Benckiser Pharmaceuticals, Inc. was later succeeded to in interest by Indivior, Inc. Pursuant to the Indivior License Agreement, the Company agreed to manufacture and supply Indivior’s requirements for 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.

The Indivior License Agreement provides for payment by Indivior of a purchase price per unit that is subject to adjustment based on the Company’s 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 scaled rebates on its purchases.

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 and limited to the life of the related United States or international patents. In 2012, Indivior exercised its right to buy out its future royalty obligations in the United States under the Indivior License Agreement. Indivior remains obligated to pay royalties for all sales outside the United States.

The Indivior License Agreement contains customary contractual termination provisions, including with respect to a filing for bankruptcy or corporate dissolution, an invalidation of the intellectual property surrounding Suboxone, and commission of a material breach of the Indivior License Agreement by either party. Additionally, Indivior may terminate the Indivior License Agreement if the 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 either party provides the other 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, or the Indivior Supplemental Agreement. Pursuant to the Indivior Supplemental Agreement, the Company conveyed to Indivior all existing and future rights in the settlement of various ongoing patent enforcement legal actions and disputes related to the Suboxone product. The Company also conveyed to Indivior the right to sublicense manufacturing and marketing capabilities to enable an Indivior licensed generic buprenorphine product to be produced and sold by parties unrelated to Indivior or Aquestive. 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. Through February 20, 2019, the at-risk launch date of the competing generic products of Dr. Reddy’s Labs and Alvogen, the Company received an aggregate of $40,750 from Indivior under the Indivior Supplemental Agreement. Further payments under this agreement were suspended until adjudication of related patent infringement litigation is finalized. If such litigation is successful,

in addition to the amounts already received as described in the foregoing, the Company may receive up to an additional $34,250, consisting of (i) up to $33,000 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 $1,250 that was earned through the issuance of additional process patent rights to the Company. The aggregate payments under this Indivior Supplemental Agreement are capped at $75,000.

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

License Agreement with Sunovion Pharmaceuticals, Inc.

On April 1, 2016, the Company entered into a license agreement with Cynapsus Therapeutics Inc. (which was later succeeded to in interest by Sunovion Pharmaceuticals, Inc.), referred to as the Sunovion License Agreement, pursuant to which Sunovion obtained 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 apomorphine for the treatment of off episodes in Parkinson's disease patients. Sunovion used this intellectual property to develop its apomorphine product KYNMOBI®, which was approved by the FDA on May 21, 2020. This approval triggered Sunovion's obligation to remit a payment of $4,000 (the "FDA Approval Milestone Payment") due on the earlier of: (a) the first day of product availability at a pharmacy in the United States; or (b) with six months of the FDA approval. This amount was received as of September 30, 2020 and is included in License and royalty revenues for the twelve months ended December 31, 2020.

In consideration of the rights granted to Sunovion under the Sunovion License Agreement, the Company received aggregate payments totaling $22,000 to date. In addition to the upfront payment of $5,000, the Company has also earned an aggregate of $17,000 in connection with specified regulatory and development milestones in the United States and Europe (the "Initial Milestone Payments"), all of which of which has been received to date. With the Monetization Agreement, we are no longer entitled to receive certain contingent one-time milestone payments of $23,000 related to product availability and regulatory approval in Europe, certain one-time milestone payments based on the achievement of specific annual net sales thresholds of KYNMOBI®, and ongoing mid-single digit percentage royalty payments related to the net sales of KYNMOBI® (subject to reduction to low-single digit percentage royalty payments in certain circumstances), subject to certain minimum payments. There are minimum annual guaranteed royalty payments under the contract and during the second quarter of 2020, the Company recorded minimum royalty revenue of $8,000 for minimum royalties, reflected in License and royalty revenues for the twelve months ended December 31, 2020.

Effective March 16, 2020, the Company entered into a first amendment (the "First Amendment") to the Sunovion License Agreement. The Amendment was entered into for the primary purpose of amending the Sunovion License Agreement as follows: (i) including the United Kingdom and any other country currently in the European Union (EU) which later withdraws as a member country in the EU for purpose of determining the satisfaction of the condition triggering the obligation to pay the third milestone due under the Sunovion License Agreement, (ii) extending the date after which Sunovion has the right to terminate the Sunovion License Agreement for convenience form December 31 2024 to March 31, 2028, (iii) modifying the effective inception date of the first minimum annual royalty due from Sunovion to the Company form January 1, 2020 to April 1, 2020, and (iv) modifying the termination provision to reflect the Company's waiver of the right to terminate the Sunovion License Agreement in the event that KYNMOBI® was not commercialized by January 1, 2020. This Sunovion License Agreement will continue until terminated by Sunovion in accordance with the termination provisions of the Amendment to the Sunovion License Agreement. The Sunovion License Agreement continues (on a country-by-country basis) until the expiration of all applicable licensed patents. Upon termination of the Sonovion License Agreement, all rights to intellectual property granted to Sunovion to develop and commercialize apomorphine-based products will revert to the Company.

On October 23, 2020, the Company amended the Sunovion License Agreement to clarify the parties' agreement with respect to certain provisions in the License Agreement, specifically the date after which Sunovion has the right to terminate the License Agreement and the License Agreement and the rights and obligations of the parties regarding the prosecution and maintenance of the Company's patents covered under the License Agreement.

Purchase and Sale Agreement with an affiliate of Marathon Asset Management ("Marathon")

On November 3, 2020, we entered into a Purchase and Sale Agreement (the "Monetization Agreement") with MAM Pangolin Royalty, LLC, an affiliate of Marathon Asset Management ("Marathon"). Under the terms of the Monetization Agreement, we sold all of our contractual rights to receive royalties and milestone payments due under the Sunovion License Agreement related to Sunovion's apomorphine product, KYNMOBI®. KYNMOBI®, an apomorphine film therapy for the treatment of off episodes in Parkinson's disease patients, received approval from the U.S. Food and Drug Administration (FDA) on May 21, 2020. In exchange for the sale of these rights, we received an upfront payment of $40,000 and an additional payment of $10,000 through the achievement of the first milestone. We have received an aggregate amount of $50,000 through December 31, 2020 under the Monetization Agreement.

Under the Monetization Agreement, additional aggregate contingent payments of up to $75,000 may be due to us upon the achievement of worldwide royalty and other commercial targets within a specified timeframe, which could result in total potential proceeds of $125,000. See Note 14 Sale of Future Revenue for further details on the accounting for the Monetization Agreement.

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 by the Company and KemPharm in April 2011. Under this termination arrangement, the Company has the right to participate in any and all value that KemPharm may derive from the commercialization or any other monetization of KP-415 and KP-484 compounds or their derivatives. Among these monetization transactions are those related to any business combinations involving KemPharm and collaborations, royalty arrangements, or other transactions from which KemPharm may realize value from these compounds. During September 2019, the Company received $1,000 from its 10% share of milestone payments paid to KemPharm, under its licensing of KP-415 and KP-484 to a third party. The Company has also received payment of $500 under this arrangement during June 2020, which is included in in License and royalty revenues for the twelve-months period ended December 31, 2020, in connection with the FDA's acceptance of a New Drug Application ("NDA") filing for KP-415. On March 2, 2021, KemPharm announced FDA approval of KP 415 (AZTARYS™) a new once-daily treatment for ADHD. The Company's share of the milestone payments associated with KP 415 approval and the achievement of certain targeted labeling goals may reach $4,800.

Note 7. Inventory

Inventory consists of the following:

	December 31,	
	2020	**2019**
Raw material	$ 789	$ 1,244
Packaging material	1,128	1,096
Finished goods	544	519
Total inventory	$ 2,461	$ 2,859

Note 8. Property and Equipment, Net

		December 31,	
	Useful Lives	**2020**	**2019**
Machinery	3-15 years	$ 21,333	$ 21,088
Furniture and fixtures	3-15 years	1,209	1,150
Leasehold improvements	(a)	21,333	21,333
Computer, network equipment and software	3-7 years	2,999	2,787
Construction in progress		877	1,412
		47,751	47,770
Less: accumulated depreciation and amortization		(40,878)	(38,044)
Total property and equipment, net		$ 6,873	$ 9,726

(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 $3,392 and $2,854 for the years ended December 31, 2020 and 2019, respectively.

Note 9. Right-of-Use Assets and Lease Obligations

The Company leases all realty used as its production and warehouse facilities, corporate headquarters, commercialization operations center and research and laboratory facilities. The Company identifies a contract that contains a lease as one which conveys a right, either explicitly or implicitly, to control the use of an identified asset in exchange for consideration. None of these three leases include the characteristics specified in ASC 842, *Leases*, that require classification as financing leases and, accordingly, these leases are accounted for as operating leases. These leases provide remaining terms between 2.25 years and 5.75 years, including renewal options expected to be exercised to extend the lease periods.

The Company does not recognize a right-to use asses and lease liability for short-term leases, which have terms of 12 months or less, on its consolidated balance sheet. For longer-term lease arrangements that are recognized on the Company's consolidated balance sheet, the right-of-use asset and lease liability is initially measured at the commencement date based upon the present value of the lease payments due under the lease. These payments represent the combination of the fixed lease and fixed non-lease components that are due under the arrangement. The costs of associated with the Company's short-term leases, as well as variable costs relating to the Company's lease arrangements, are not material to the consolidated financial results.

The implicit interest rates of the Company's lease arrangements are generally not readily determinable and as such, the Company applies an incremental borrowing rate, which is established based upon the information available at the lease commencement date, to determine the present value of lease payments due under an arrangement. Measurement of the operating lease liability reflects an estimated discount rate of 16.9% applied to minimum lease payments, including expected renewals, based on the incremental borrowing rate experienced in the Company's latest collateralized debt refinancing.

Right-of-use assets recorded upon adoption of ASC 842 totaled $4,048. The Company's lease costs recorded in manufacture and supply, research and development and selling, general and administrative expenses in its consolidated statements of income for the year-end December 31, 2020 was $1,671 including variable lease expenses such as common area maintenance and operating costs of $379 under the new lease accounting standard. Rental expense for all operating leases amounted to $1,613 in 2019. Cash payments arising from the Company's lease arrangements are reflected on its consolidated statement of cash flows as outflows for operating activities.

The Company's payments due under its operating leases are as follow:

	Amount
2021	$ 1,287
2022	1,295
2023	944
2024	565
2025	565
2026	424
Total lease payments	5,080
Less: imputed interest	(1,506)
Total operating lease liabilities	$ 3,574

The following schedule presents future minimum lease payments under operating leases as of December 31, 2019, including those derived from renewal options that are deemed noncancelable under FASB ASC Section 840-10-35, *Leases - Subsequent Measurement*:

	Amount
2020	$ 1,274
2021	1,287
2022	1,153
2023	380
Thereafter	—
Total	$ 4,094

Note 10. Intangible Assets, Net and Other non-current assets

The following table provides the components of identifiable intangible assets, all of which are finite lived and other non-current assets:

	December 31,	
	2020	2019
Purchase technology-based intangible	$ 2,358	$ 2,358
Purchased patent	509	509
	2,867	2,867
Less: accumulated amortization	(2,765)	(2,714)
Intangible assets, net	102	153
Royalty receivable	7,000	—
Other	836	286
Total other non-current assets	$ 7,836	$ 286

Amortization expense was $51 and $50 for each of the years ended December 31, 2020 and 2019, respectively. During the remaining life of the purchased patent, estimated annual amortization expense is $51 for each of the years from 2021 to 2022.

During the second quarter of 2020, under the Sunovion License Agreement, the Company recognized $8,000 of royalty revenue and corresponding royalty receivable, related to the $1,000 annual minimum guaranteed royalty that is due in each of the next eight years. In connection with the Monetization Agreement, the Company performed an assessment under ASC 860 Transfer and Servicing to determine whether the existing receivable was to transferred to Marathon and concluded it was not transferred. Royalty receivable consists of seven annual minimum payments due from Sunovion, the last of which is due in March 2028. The current portion of the royalty receivable is included in Trade and other receivables, net. See Note 14 Sale of Future Revenue for further details on how this receivable relates to the Monetization transaction.

Note 11. Accrued Expenses

Accrued expenses consisted of the following:

	December 31,	
	2020	2019
Accrued compensation	$ 6,330	$ 3,758
Real estate and personal property taxes	316	300
Accrued distribution expenses	1,722	1,174
Other	201	243
Total accrued expenses	$ 8,569	$ 5,475

Note 12. 12.5% Senior Secured Notes and Loans Payable

12.5% Senior Secured Notes - First Supplemental Indenture

On November 3, 2020, the Company entered into the First Supplemental Indenture (the "Supplemental Indenture") by and among the Company and U.S. Bank National Association, as Trustee (the "Trustee") and Collateral Agent thereunder to the Indenture, dated as of July 15, 2019 (the "Base Indenture" and, as supplemented by the Supplemental Indenture, the "Indenture"), by and between the Company and the Trustee. Under the Supplemental Indenture, the Company repaid $22,500 of its $70,000 outstanding 12.5% Notes from the $40,000 upfront proceeds received from its Monetization of Future Revenue Stream associated with Sunovion's KYNMOBI® (apomorphine) product. Further, the Company entered into an additional Purchase Agreement with its lenders whereby the Company issued in aggregate $4,000 of additional 12.5% senior notes (the "2020 Additional Notes") in lieu of paying a prepayment premium to two lenders on the early repayment of the 12.5% Notes discussed above. The result of these two transactions reduced the net balance of the Company's 12.5% Senior Notes outstanding in the aggregate to $51,500 at December 31, 2020. The $4,000 principal issuance is to be repaid proportionally over the same maturities as the remaining outstanding Initial Notes. The Company also paid to one its lenders a $2,250 premium as result of the early retirement of debt.

The Company accounted for the $22,500 debt repayment as a debt modification. The fees paid to lenders inclusive of (i) $2,250 early premium prepayment and (ii) $4,000 issuance of additional debt in lieu of paying a prepayment penalty have been recorded as additional debt discount, amortized over the remaining life of the Notes using the effective interest method. Loan origination costs of $220 associated with the new debt of were expensed as incurred. Existing deferred discounts and loan origination fees are amortized as an adjustment of interest expense over the remaining term of modified debt using the effective interest method.

The Amendment contains a provision whereby as the Company receives any cash proceeds from the Permitted Apomorphine Monetization (the Monetization Proceeds), each Noteholder has the right to require the Company to repay all or any part of such Noteholder's outstanding 12.5% Notes at a repurchase price in cash equal to 112.5% of the principle amount, plus accrued and unpaid interest. This repurchase offer is capped at 30% of the cash proceeds received by the Company as the contingent milestones are attained, if any, up through June 30, 2025. This repurchase offer or put option gives holders of the option the right, but not the obligation, to receive a specified amount of the future royalties up to the capped amount. A valuation study was performed by an independent third party appraiser. Based on the valuation study, the put option was valued at $535, of which $115 has been recorded in Accrued expenses and $420 has been recorded in Other non-current liabilities. The embedded put option is deemed to be a derivative under *ASC 815 Derivatives and Hedging*, which requires the recording of the embedded put option at fair value and subject to remeasurement at each reporting period.

In addition, the holders of the 12.5% Notes have extended to December 31, 2021 from March 31, 2021, the Company's ability to access, at the Company's option, $30,000 of senior notes re-openers under the Indenture. The first $10,000 senior notes re-opener represents a commitment of such amount by current holders of 12.5% Notes, at the option of the Company, contingent upon FDA approval of the Company's product candidate Libervant (diazepam) Bucca Film for the management of seizure clusters. A second $20,000 senior notes re-opener represents a right, at the Company's option, to market to current holders of the Company's 12.5% Notes, and/or other lenders, additional senior notes up to such amount, contingent upon FDA approval of Libervant for U.S. market access.

The 12.5% Notes provide a stated fixed rate of 12.5%, payable quarterly in arrears, with the initial quarterly principal repayment of the Initial Notes due on September 30, 2021 and the final quarterly payment due at maturity on June 30, 2025. The Company has recorded $2,575 as Loan Payable, Current to reflect this obligation in its Consolidated Balance Sheet. Principal payments are scheduled to increase annually from 10% of the face amount of the debt then outstanding during the first four quarters to 40% of the initial loan principal during the final four quarters.

A debt maturity table is presented below:

2021	$ 2,575
2022	7,725
2023	12,875
2024	18,025
2025	10,300
Total	$ 51,500

The Company may elect, at its option, to prepay the 12.5% Notes at any time at premiums that range from 101.56% of outstanding principal if prepayment occurs on or after the fifth anniversary of the issue date of the Initial Notes to 112.50% if payment occurs during the third year after the issuance of the Notes. In the event that redemption occurs within the two years after the issuance of the 12.5% Notes, a make-whole fee is required, based on the present value of remaining interest payments using an agreed-upon discount rate linked to the then-current U.S. Treasury rate. The Indenture also includes change of control provisions under which the Company may be required to repurchase the 12.5% Notes at 101% of the remaining principal plus accrued interest at the election of the Lenders.

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 2015-3, *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 related to the 12.5% Notes and the Perceptive loan for the years ended December 31, 2020 and 2019 were $2,587 and $1,929, respectively. Unamortized deferred debt issuance costs and deferred debt discounts totaled $14,596 and $9,662 as of December 31, 2020 and 2019, respectively.

Collateral for the loan under the 12.5% Notes consists of a first priority lien on substantially all property and assets, including intellectual property, of the Company. This secured obligation provides payment rights that are senior to all existing and future subordinated indebtedness of the Company and provides Lenders with perfected security interests in substantially all of the Company's assets.

12.5% Senior Secured Notes

On July 15, 2019, the Company completed the private placement of up to $100,000 aggregate principal of its 12.5% Senior Secured Notes due 2025 (the "Notes") and issued warrants for 2,000,000 shares of common stock (the "Warrants"), $0.001 per value per share, through its structuring agent, Morgan Stanley & Co., LLC, and entered into a purchase agreement and related indenture (the "Purchase Agreement" or "Indenture") governing these Notes. The Company simultaneously entered into related agreements including a Collateral Agreement with U.S. Bank National Association, as trustee and collateral agent, and a Lien Subordination and Intercreditor Agreement for the benefit of Madryn Health Partners, other institutional noteholders (the "Noteholders") and U.S. Bank National Association in dual roles providing terms governing an asset-based loan facility.

Upon closing of the Indenture for the 12.5% Notes (“Indenture”), the Company issued $70,000 of the principal of the 12.5% Notes (the “Initial Notes”) along with the Warrants and rights of first offer (the “First Offer Rights”) to the lenders participating in this transaction for Notes and Warrants (the “Lenders”). Issuance of the Initial Notes and Warrants provided net proceeds of $66,082.

Proceeds from issuance of the Initial Notes and Warrants were used to fully repay the Company’s $56,340 outstanding indebtedness to Perceptive Credit Holdings, LP, (the “Perceptive Loan”) related early repayment fees and legal and other fees incurred in obtaining this loan and executing this Indenture.

Loans Payable - Perceptive

In August 2016, the Company entered into a Loan Agreement and Guaranty with Perceptive Credit Opportunities Fund, LP (“Perceptive”) under which the total available facility of $50,000` had been borrowed as of March 2017. 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, which was automatically exercised in full at the time of the IPO (see also Note 13). In July 2019, the Perceptive Loan was paid in full in connection with the completion of the sale of the Initial Notes and Warrants described above. The early extinguishment of this debt resulted in a charge to 2019 earnings in the amount of $4,896, including an early retirement premium of $2,944 and the remaining balances of the unamortized loan discount and loan acquisition costs.

Note 13. Warrants

Warrants Issued to 12.5% Senior Secured Noteholders

Warrants were issued in conjunction with the First Supplemental Indenture to Noteholders as part of the 2020 Additional Notes described above expire on June 30, 2025 and entitle the Lenders to purchase 143,000 shares of the Company's common stock at $0.001 per share and include specified registration rights. Management estimated the fair value of the Warrants to be $735, assisted by the an independent third-party appraiser.

Warrants were issued in conjunction with the Initial Notes described above expire on June 30, 2025 and entitle the Lenders to purchase 2,000,000 shares of the Company's common stock at $0.001 per share and include specified registration rights. Management estimated the fair value of the Warrants to be $6,800, assisted by an independent third-party appraiser.

The fair value of these respective Warrants is treated as a debt discount, amortizable over the term of the Warrants, with the unamortized loan portion applied to reduce the face amount of the loan in the Company's balance sheet. Additionally, since the Warrants issued do not provide warrant redemption or put rights within the control of the holders that could require the Company to make a payment of cash or other assets to satisfy the obligations under the Warrants, except in the case of a "cash change in control", the fair value attributed to the Warrants is presented in additional-paid in capital in the accompanying Consolidated Balance Sheets. There were no Warrants exercised by either the holders of the 2020 Additional Notes nor the Initial Noteholders during the year ended December 31, 2020.

Certain 12.5% Noteholders exercised warrants for the purchase of 428,571 shares of common stock, and proceeds totaling $1,821 were received on December 16, 2019.

Note 14. Sale of Future Revenue

On November 3, 2020, we entered into a Purchase and Sale Agreement (the "Monetization Agreement") with MAM Pangolin Royalty, LLC, an affiliate of Marathon Asset Management ("Marathon"). Under the terms of the Monetization Agreement, we sold all of our contractual rights to receive royalties and milestone payments due under the Sunovion License Agreement related to Sunovion's apomorphine product, KYNMOBI®. KYNMOBI®, an apomorphine film therapy for the treatment of off episodes in Parkinson's disease patients, received approval from the U.S. Food and Drug Administration (FDA) on May 21, 2020. In exchange for the sale of these rights, we received an upfront payment of $40,000 and an additional payment of $10,000 through the achievement of the first milestone. We have received an aggregate amount of $50,000 through December 31, 2020 under the Monetization Agreement.

Under the Monetization Agreement, additional aggregate contingent payments of up to $75,000 may be due to us upon the achievement of worldwide royalty and other commercial targets within a specified timeframe, which could result in total potential proceeds of $125,000.

We recorded the upfront proceeds of $40,000 and subsequent first milestone of $10,000, reduced by $2,909 of transaction costs, as a liability related to the sale of future revenue that will be amortized using the effective interest method over the life of the Monetization Agreement. As future contingent payments are received, they will increase the balance of the liability related to the sale of future revenue. Although we sold all of our rights to receive royalties and milestones, as a result of our ongoing obligations related to the generation of these royalties, we will account for these royalties as revenue. Our ongoing obligations include the maintenance and defense of the intellectual property and to provide assistance to Marathon in executing a new license agreement for KYNMOBI® in the event Sunovion terminates the Sunovion License Agreement in one or more jurisdictions of the licensed territory under the Sunovion License Agreement.

During the second quarter of 2020, under the Sunovion License Agreement, the Company recognized $8,000 of royalty revenue and corresponding royalty receivable, related to the $1,000 annual minimum guaranteed royalty that is due in each of the next eight years. In connection with the Monetization Agreement, the Company performed an assessment under ASC 860, *Transfer and Servicing* to determine whether the existing receivable was transferred to Marathon and concluded that the receivable was not transferred.

As royalties are remitted to Marathon from Sunovion, the collection of the royalty receivable and balance of the liability related to the sale of future revenue will be effectively repaid over the life of the agreement. In order to determine the amortization of the liability related to the sale of future revenue, we are required to estimate the total amount of future royalty and milestone payments to Marathon over the life of the Monetization Agreement and contingent milestone payments from Marathon to the Company. The sum of future royalty payments less the $50,000 in proceeds received and future contingent payments will be recorded as interest expense over the life of the Monetization Agreement. At execution, the estimate of this total interest expense resulted in an effective annual interest rate of approximately 24.9%. This estimate contains significant assumptions that impact both the amount recorded at execution and the interest expense that will be recognized over the life of the Monetization Agreement. The Company will periodically assess the estimated royalty and milestone payments to Marathon from Sunovion and contingent milestone payments from Marathon to the Company. To the extent the amount or timing of such payments is materially different from the original estimates, an adjustment will be recorded prospectively to increase or decrease interest expense. There are a number of factors that could materially effect the amount and timing of royalty and milestone payments to Marathon from Sunovion, and correspondingly, the amount of interest expense recorded by the Company, most of which are not under our control. Such factors include, but are not limited to, changing standards of care, the initiation of competing products, manufacturing or other delays, generic competition, intellectual property matters, adverse events that result in government health authority imposed restrictions on the use of products, significant changes in foreign exchange rates as the royalties remitted to Marathon are made in U.S. dollars (USD) while a portion of the underlying sales of KYNMOBI® will be made in currencies other than USD, and other events or circumstances that are not currently foreseen. Changes to any of these factors could result in increases or decreases to both royalty revenue and interest expense related to the sale of future revenue.

The following table shows the activity of the Royalty Obligation since the transaction inception through December 31, 2020:

Upfront proceeds from the sale of future revenue	$ 40,000
Contingent payment from the sale of future revenue	10,000
Issuance costs	(2,909)
Amortization of issuance costs	20
Royalties related to the sale of future revenue	(75)
Interest expense related to the sale of future revenue	1,938
Liability related to the sale of future revenue, net (includes current portion of $1,450)	$ 48,974

Note 15. Other Non-Current Liabilities

The Company's other non-current liabilities at December 31, 2020 of $1,945 consist of asset retirement obligations ("AROs") of $1,525 and the fair value of the put option on the 12.5% Notes of $420. At December 31, 2019, the balance consisted of asset retirement obligations.

AROs 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. Depreciation expense related to the ARO assets included in overall depreciation expense for the periods ended December 31, 2020 and 2019 were $24 and $24, respectively.

Below is a schedule of activity in the Company's liability for AROs for the year ended December 31, 2020 and 2019.

Balance at December 31, 2018	$ 1,216
Additions	—
Accretion	144
Balance at December 31, 2019	1,360
Additions	—
Accretion	165
Balance at December 31, 2020	$ 1,525

Note 16. Net Loss Per Share

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

As a result of the Company's net loss incurred for the year ended December 31, 2020 and 2019, all potentially dilutive instruments outstanding would have anti-dilutive effects on per-share calculations for this period. Therefore, basic and diluted net loss per share were the same for all periods presented as reflected below.

	Year Ended December 31, 2020	Year Ended December 31, 2019
Numerator:		
Net loss	$ (55,783)	$ (66,246)
Denominator:		
Weighted-average number of common shares – basic and diluted	33,651,127	25,356,098
Loss per common share – basic and diluted	$ (1.66)	$ (2.61)

As of December 31, 2020 and 2019, respectively, the Company's potentially dilutive instruments included 3,258,192 and 2,231,092 options to purchase common shares and 13,491 and 73,839 unvested RSUs that were excluded from the computation of diluted weighted average shares outstanding because these securities had an antidilutive impact due to the losses reported. Similarly excluded as of December 31, 2020 and 2019 were potentially dilutive warrants for the purchase of 1,714,429 and 1,571,429 common shares, respectively.

Note 17. Share-Based Compensation

The Company provides certain employees, non-employee directors and consultants with performance incentives under the Aquestive Therapeutics, Inc. Equity Incentive Plan (the Plan), adopted by the Board of Directors on June 15, 2018. Under this Plan, the Company may grant restricted stock units, stock options, or other stock-based awards in order to align the long-term financial interests of selected participants with those of its stockholders, strengthen the commitment of such persons to the Company, and attract and retain competent and dedicated persons whose efforts will enhance long-term growth, profitability and share value.

Restricted stock units and options that have been awarded are subject to graded vesting over a service period, which is typically three years. Compensation cost is recognized for these awards on a pro-rata basis over the requisite service period for each award granted.

At December 31, 2020, there were approximately 0.7 million shares available for grant.

The Company recognized share-based compensation in its Consolidated Statements of Operations during the periods presented as follows:

Expense classification:	Year Ended December 31, 2020	Year Ended December 31, 2019
Manufacture and supply	$ 275	$ 231
Research and development	729	720
Selling, general and administrative	5,577	6,120
Total share-based compensation expenses	$ 6,581	$ 7,071
Share-based compensation from:		
Restricted Stock Units (A)	806	1,863
Stock Options (B)	5,751	5,173
Employee Stock Purchase Plan (C)	24	35
Total share-based compensation expenses	$ 6,581	$ 7,071

(A) Restricted Stock Units

The following table summarizes the Company's awards of restricted stock units for the year ended December 31, 2019 and 2020:

	Number of Units	Weighted Average Grant Date Fair Value Per Share
	(In thousands)	
Unvested, December 31, 2018	205	$ 14.77
Granted	—	—
Forfeited	(6)	—
Vested	(125)	14.94
Unvested, December 31, 2019	74	$ 14.64
Granted	4	7.54
Forfeited	—	—
Vested	(64)	14.88
Unvested, December 31, 2020	14	$ 11.38

The total grant date fair market value of shares vested in 2020 and 2019 was $958 and $1,863, respectively.

As of December 31, 2020, there was approximately $122 of unrecognized compensation costs related to restricted stock units awarded and is expected to be recognized during 2021. The RSUs granted to employees are subject to a three-year graduated vesting schedule. These RSUs are not subject to performance-based criteria other than continued employment.

(B) Stock option awards

The following table summarizes the Company's stock option activity for the period from December 31, 2018 through December 31, 2020:

(in 000s, except share price data)	Number of Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term in Years	Aggregate Intrinsic Value
Outstanding at December 31, 2018	1,033	$ 14.72	9.55	$ —
Granted	1,258	$ 6.66		
Forfeited	(60)	$ 5.78		
Exercised	—			
Outstanding at December 31, 2019	2,231	$ 10.42	8.94	$ 689
Granted	1,168	3.32		
Forfeited	(140)	$ 4.36		
Exercised	—			$ —
Outstanding at December 31, 2020	3,259	$ 8.14	8.42	$ 2,978
Vested and expected to vest at December 31, 2020	3,035	$ 8.14	8.42	$ 2,758
Exercisable at December 31, 2020	1,235	$ 11.26	7.89	$ 403

The weighted average grant date fair value of stock options granted during 2020 and 2019 was $2.61 and $4.95, respectively. The fair values of stock options granted were estimated using the Black-Scholes model based on the following assumptions:

	Year Ended December 31,	
	2020	2019
Expected dividend yield	0%	0%
Expected volatility	100%	85% — 106%
Expected term (years)	5.50 — 6.10	5.50 — 6.10
Risk-free interest rate	0.33% — 1.69%	1.5% — 2.6%
Exercise prices	$ 1.54 — 7.86	$ 3.36 — 8.05

We anticipate reinvesting earnings for the foreseeable future in product development and other avenues of share-value growth and therefore used a dividend yield of zero. The estimate of volatility was determined based on the historical trading data of comparable public companies at the time of grant given the lack of sufficient history for our own publicly-traded common stock. The expected term of the award was calculated using the simplified method and weighted average was utilized taking into account the vesting periods and contractual life. The risk-free interest rates are derived from the U.S. Treasury yield curve in effect on the date of grant for instruments with a remaining term similar to the expected term of the options.

As of December 31, 2020, $5,653 of total unrecognized compensation expenses related to non-vested stock options is expected to be recognized over a weighted average period of 1.3 years from the date of grant. These option grants provided a maximum contract term of 10 years from grant date, with a weighted average remaining contract life of 8.0 years. Options granted to senior management and key employees are subject to a three-year graded vesting schedule while options granted to the board of directors are subject to a one year cliff vesting schedule. These stock options are not subject to performance-based criteria other than continued employment.

(C) Employee Stock Purchase Plan

The Company's Board of Directors adopted the Aquestive Therapeutics, Inc. Employee Stock Purchase Plan (ESPP) in June 2018, plan rollout began in late 2018, and initial employee purchases were made in 2019.

The purpose of the ESPP is to help retain and motivate current employees, to attract new talent, and to provide eligible employees of the Company a convenient manner of purchasing shares of common stock at a discounted price at periodic intervals by means of accumulated payroll deductions. The Company may offer common stock purchase rights biannually under offerings that allow for the purchase of common stock at the lower of 85% of the fair value of shares on either the first or last day of the offering period. The offerings may, or may not, also provide tax advantages. Purchases made via a tax-advantaged offering are intended to qualify as purchases made within the meaning of Section 423 of the Internal Revenue Code. Offerings may run concurrently, or serially, and each offering will be treated as separate and distinct. Under the ESPP, a total of 250,000 shares of common stock were initially reserved for issuance. During 2020 and 2019, employees purchased 32,986 and 56,378 shares, respectively, through this plan.

Note 18. 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 year ended December 31, 2020 and 2019 were $673 and $819, respectively.

Note 19. Income Taxes

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 as of December 31, 2020 and 2019 are as follows:

	December 31, 2020	December 31, 2019
Deferred tax assets:		
Accounts receivable	$ 112	$ 126
Inventory	4	69
Accrued expenses	353	835
NOL carryforwards	22,569	23,687
Interest limitation imposed by the TJCA	7,235	5,748
Stock Compensation	4,051	2,505
Other	1,229	783
Sale of Future Revenue	14,444	—
Property and equipment	2,380	1,741
Orphan Drug and R&D Tax Credits	5,851	4,621
	58,228	40,115
Deferred tax liabilities:		
Intangible assets	(551)	(58)
Prepaid expenses	(908)	—
	(1,459)	(58)
Valuation Allowance	(56,769)	(40,057)
Net deferred tax asset/(liability)	$ —	$ —

At December 31, 2020 and 2019, the Company had federal net operating loss carryforwards of $81,566 and $85,905, respectively, a significant portion of which carryforward for an indefinite period. At December 31, 2020 and 2019, the Company also had state net operating loss carryforwards of $74,379 and $80,266, respectively. These state net operating losses carry forwards begin expiring in 2039 and 2038, respectively. As a result of the December 2017 U.S. Tax Cuts and Jobs Act (“TCJA”), updated regulations under section 163(j) create new limitations on deductible interest expense. The Company’s interest expense deduction under 163(j) will be limited for tax purposes based on a calculation of 30% of its EBITDA on a tax basis. On March 27, 2020, the Coronavirus Aid, Relief and Economic Security Act, which we refer to as the “U.S. CARES Act,” was signed into law. The U.S. CARES Act, among other things, includes provisions related to net operating loss carryback periods, modifications to the interest deduction limitation. The U.S. CARES Act increased the adjusted taxable income limitation from 30% to 50% for business interest deductions for tax years beginning in 2019 and 2020. This modification increased the allowable interest expense deduction and resulted in additional net operating loss (NOL) for the year 2019 and lower current taxable income (before NOL utilization) for the Company. Additionally, the U.S. CARES Act allowed us to fully offset the 2020 taxable income with prior years’ NOL carried forward. 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 $56,769, and $40,057 have been established at December 31, 2020 and 2019, respectively. The Company may also be subject to the net operating loss utilization provisions of Section 382 of the Internal Revenue Code due to ownership changes. As a result, the use of NOL carry forwards from the current and prior periods are subject to annual limitations.

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 there were no uncertain positions as of December 31, 2020 and 2019. The Company did not have any unrecognized tax benefits and has not accrued any interest or penalties for the years ended December 31, 2020 and 2019. The Company’s U.S. federal and state net operating losses have occurred since its election to treat as a C Corporation in 2017 and as such, tax years subject to potential tax examination could apply from that date because the utilization of net operating losses from prior years opens the relevant year to audit by the IRS and/or state taxing authorities. In early 2020, the U.S. Internal Revenue Service began an examination of the Company’s federal income tax return for 2018. The Company does not expect to recognize a significant amount of additional tax expense as a result of concluding this examination.

A reconciliation of income tax benefit and the amount computed by applying the statutory federal income tax rates of 21% to loss before taxes for the year ended December 31, 2020 and 2019, respectively, as follows:

	Year Ended December 31, 2020	Year Ended December 31, 2019
Income taxes at statutory rate	21.00%	21.00%
Increase (decrease) resulting from:		
State income tax	6.81	6.76
Permanent differences	(0.12)	(0.04)
Research & development credit	2.35	2.32
Return to provision	—	0.98
Valuation allowance	(30.04)	(31.02)
Effective tax rate	0.00%	0.00%

On July 1, 2018, the New Jersey governor signed into law a bill which included significant changes to the New Jersey taxation of corporations. Chiefly, this legislation imposes a 2.5% surtax on taxpayers with allocated net income over $1 million for 2018 and 2019, and a 1.5% surtax for taxpayers with allocated net income over $1 million for 2020 and 2021. Subsequently, on September 29,2020, Assembly Bill 4721 extended the additional corporation business tax surtax of 2.5% for the tax years 2020 through 2023. In addition, the state is changing its filing requirements from separate entity reporting to combined reporting on a water's edge basis. Further, there are changes to the state's computation of its dividend received deduction and application of IRC section 163(j). The Company has considered these changes and does not believe this change in law will have a material impact due to availability of significant New Jersey NOL carryforwards to set off against future taxable income and a full valuation allowance against the net deferred tax assets.

Note 20. Contingencies

Litigation and Contingencies

From time to time, we have been and may again become involved in legal proceedings arising in the course of our business, including product liability, intellectual property, commercial litigation, or environmental or other regulatory matters.

Patent-Related Litigation

Indivior Inc., Indivior UK Ltd., and Aquestive Therapeutics, Inc. v. Dr. Reddy's Labs. S.A. and Dr. Reddy's Labs., Inc.,

On February 7, 2018, we and Indivior Inc. and Indivior UK Ltd. (collectively, "Indivior") initiated a lawsuit against Dr. Reddy's Laboratories S.A. and Dr. Reddy's Laboratories, Inc. (collectively, "Dr. Reddy's") asserting infringement of U.S. Patent No. 9,855,221 (the "221 patent"). On April 3, 2018, we and Indivior initiated a separate lawsuit against Dr. Reddy's asserting infringement of U.S. Patent No. 9,931,305 (the "'305 patent"). On May 29, 2018, the lawsuits regarding the '221 and '305 patents were consolidated which was originally initiated by Indivior against Dr. Reddy's asserting infringement of U.S. Patent No. 9,687,454 (he "'454 patent"). On February 19, 2019, the Court granted the parties' agreed stipulation to drop the '221 patent from the case. On January 8, 2020, the Court entered a stipulated order of non-infringement of the '305 patent based on the Court's claim construction ruling, and we and Indivior preserved our rights to appeal the claim construction ruling.

On November 22, 2019, Dr. Reddy's filed an amended answer and counterclaims asserting conspiracy to monopolize against us and monopolization, attempted monopolization, and conspiracy to monopolize against Indivior under federal and New Jersey antitrust laws. The Court denied our motion to dismiss Dr. Reddy's counterclaims on August 24, 2020. Fact discovery on Dr. Reddy's antitrust counterclaims concluded on January 29, 2021. Expert discovery is ongoing and is scheduled to continue through the end of July 2021. Dispositive motions are currently due August 27, 2021. There is no trial date set. We are not able to determine or predict the ultimate outcome of this proceeding or provide a reasonable estimate or range of estimates of the possible outcome or losses, if any, in this matter.

Indivior Inc., Indivior UK Ltd., and Aquestive Therapeutics, Inc. v. Teva Pharmaceuticals USA, Inc.,

On February 7, 2018, we and Indivior initiated a lawsuit against Teva Pharmaceuticals USA, Inc. ("Teva") asserting infringement of the '221 patent. On April 3, 2018, we and Indivior initiated a separate lawsuit against Teva asserting infringement of the '305 patent. On May 29, 2018, the lawsuits regarding the '221 and '305 patents were consolidated which was originally initiated by Indivior against Teva asserting infringement of the '454 patent. The parties agreed that the case would be governed by the final judgment against Dr. Reddy's (described above). We are not able to determine or predict the ultimate outcome of this proceeding or provide a reasonable estimate or range of estimates of the possible outcome or losses, if any, in this matter.

Indivior Inc., Indivior UK Ltd., and Aquestive Therapeutics, Inc. v. Alvogen Pine Brook LLC,

On September 14, 2017, Indivior initiated a lawsuit against Alvogen Pine Brook LLC ("Alvogen") asserting infringement of the '454 patent. On February 7, 2018, we and Indivior filed an Amended Complaint, adding us as a plaintiff and asserting infringement of U.S. Patent No. 9,855,221 (the "'221 patent"). On April 3, 2018, we and Indivior initiated a separate lawsuit against Alvogen asserting infringement of the '305 patent. On May 29, 2018, the cases were consolidated. On February 26, 2019, the Court granted the parties' agreed stipulation to drop the '221 patent from the case. On January 9, 2020, the Court entered a stipulated order of non-infringement of the '305 patent based on the Court's claim construction ruling, and we and Indivior preserved our rights to appeal the claim construction ruling.

On November 21, 2019, Alvogen filed an amended answer and counterclaims asserting monopolization, attempted monopolization, and conspiracy to monopolize against us and Indivior under federal and New Jersey antitrust laws. The court denied our motion to dismiss Alvogen's counterclaims on August 24, 2020. On November 2, 2020, Alvogen filed a second amended answer and counterclaims, removing its allegations of monopolization and attempted monopolization against us and asserting only conspiracy to monopolize against us. Fact discovery on Alvogen's antitrust counterclaims concluded on January 29, 2021. Expert discovery is ongoing and is scheduled to continue through the end of July 2021. Dispositive motions are currently due August 27, 2021. There is no trial date set. We are not able to determine or predict the ultimate outcome of this proceeding or provide a reasonable estimate or range of estimates of the possible outcome or losses, if any, in this matter.

BioDelivery Sciences International, Inc. v. Reckitt Benckiser Pharmaceuticals, Inc., RB Pharmaceuticals Limited and MonoSol Rx, LLC,

On September 20, 2014, BioDelivery Sciences International, Inc. ("BDSI") initiated a lawsuit against us and RB seeking a declaratory judgment of non-infringement and invalidity of U.S. Patent No. 8,475,832 (the "'832 patent"), U.S. Patent No. 7,897,080 (the "'080 patent"), and U.S. Patent No. 8,652,378 (the "'378 patent"). On December 12, 2014, BDSI voluntarily dismissed the '378 patent from the case. On December 12, 2015, the parties jointly moved the Court for a stay of the case pending *inter partes* review of the '832 patent and reexamination of the '080 patent. On February 10, 2021, the parties submitted a covenant not to sue regarding the '378 patent, as well as a joint status report notifying the court that BDSI will file a notice of dismissal of the case. We are not able to determine or predict the ultimate outcome of this proceeding or provide a reasonable estimate or range of estimates of the possible outcome or losses, if any, in this matter.

Reckitt Benckiser Pharmaceuticals, Inc. and MonoSol Rx, LLC v. BioDelivery Sciences International, Inc. and Quintiles Commercials US, Inc.,

On September 22, 2014, we and RB initiated a lawsuit against BDSI and Quintiles Commercial US, Inc. ("Quintiles") asserting infringement of U.S. Patent No. 8,765,167 (the "'167 patent") in the District of New Jersey (Civil Action No. 3:14-cv-5892). On July 22, 2015, the case was transferred to the Eastern District of North Carolina. BDSI filed requests for *inter partes* review ("IPR") of the '167 patent before the Patent Trial and Appeal Board ("PTAB"), and on May 6, 2016, the Court stayed the case pending the outcome and final determination of the IPR proceedings. On March 24, 2016, the PTAB issued final written decisions finding the '167 patent was not unpatentable, and the United States Court of Appeals for the Federal Circuit ("Federal Circuit") remanded those decisions for further proceedings before the PTAB. Following the PTAB's February 7, 2019 decision on remand denying institution, BDSI appealed that decision to the Federal Circuit. The Federal Circuit granted our motion to dismiss the appeal, and denied BDSI's request for rehearing *en banc*. BDSI filed a petition for writ of certiorari to the Supreme Court of the United States ("Supreme Court"), which the Supreme Court denied on October 5, 2020. On January 4, 2021, the parties submitted a joint status report to the Eastern District of North Carolina stating their agreement that all proceedings and appeals of the IPR on the '167 patent are complete and that, as a result, the stay of the matter may be lifted. The parties are awaiting further action from the Court. We are not able to determine or predict the ultimate outcome of this proceeding or provide a reasonable estimate or range of estimates of the possible outcome or losses, if any, in this matter.

Aquestive Therapeutics, Inc. v. BioDelivery Sciences International, Inc.,

On November 11, 2019, we initiated a lawsuit against BDSI asserting infringement of the '167 patent in the Eastern District of North Carolina. On April 1, 2020, the Court denied BDSI's motion to stay and its motion to dismiss the complaint. On April 16, 2020, BDSI filed its Answer and Counterclaims to the complaint, including counterclaims for non-infringement, invalidity, and unenforceability of the '167 patent. On May 7, 2020, we filed a Motion to Dismiss BDSI's unenforceability counterclaim and a Motion to Strike BDSI's corresponding affirmative defenses. On May 28, 2020, BDSI amended its counterclaims and filed an Answer and Amended Counterclaims, which included additional allegations in support of BDSI's unenforceability counterclaim. On June 25, 2020, we filed a Motion to Dismiss BDSI's Amended Counterclaim for unenforceability and a Motion to Strike BDSI's corresponding affirmative defense of unenforceability. BDSI filed its opposition to our Motion to Dismiss and Strike on July 16, 2020, and we filed our Reply on July 30, 2020. The parties are awaiting further action from the Court on our motion. We are not able to determine or predict the ultimate outcome of this proceeding or provide a reasonable estimate or range of estimates of the possible outcome or losses, if any, in this matter.

Antitrust Litigation

State of Wisconsin, et al. v. Indivior Inc., Reckitt Benckiser Healthcare (UK) Ltd., Indivior PLC, and MonoSol Rx, LLC,

On September 22, 2016, forty-one states and the District of Columbia, or the States, brought a lawsuit 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 and seeking an injunction, civil penalties, and disgorgement. After filing the lawsuit, 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' conspiracy claims, but 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. Daubert motions were filed on September 28, 2020, and oppositions were filed on October 19, 2020. There is no date set for an oral argument on the motions. Opening summary judgment briefs are due March 8, 2021, and responses to summary judgment motions are due April 8, 2021. No trial date has yet been set. We are not able to determine or predict the ultimate outcome of this proceeding or provide a reasonable estimate or range of estimates of the possible outcome or loss, if any, in this matter.

Humana and Centene Actions

Humana Inc. v. Indivior Inc, Indivior Solutions Inc., Indivior PLC, Reckitt Benckiser Healthcare (UK) Ltd., and Aquestive Therapeutics, Inc.,

Centene Corporation, Wellcare Health Plans, Inc., New York Quality Healthcare Corporation d/b/a Fidelis Care, and Health Net, LLC v. Indivior Inc, Indivior Solutions Inc., Indivior PLC, Reckitt Benckiser Healthcare (UK) Ltd., and Aquestive Therapeutics, Inc.,

On September 18, 2020, Humana, Inc. ("Humana"), a health insurance payor, filed a lawsuit against us and Indivior in the Eastern District of Pennsylvania alleging facts similar to those at issue in the Antitrust Case and the Suboxone MDL described above, which lawsuit was assigned to the same judge that is presiding over Antitrust Case and Suboxone MDL. Humana's Complaint alleges five causes of action against us, including conspiracy to violate the RICO Act, fraud under state law, unfair and deceptive trade practices under state law, insurance fraud, and unjust enrichment.

On September 21, 2020, Centene Corporation ("Centene") and other related insurance payors filed a similar lawsuit against us and Indivior in the Eastern District of Missouri. The counsel representing Humana is also representing Centene. On September 21, 2020, the Centene action was provisionally transferred to the Eastern District of Pennsylvania by the United States Judicial Panel on Multidistrict Litigation. On January 15, 2021, we filed a motion to dismiss the Centene and Humana complaints. The other defendants in the actions also filed motions to dismiss on the same date. Briefing on the motions to dismiss is currently scheduled to end on March 16, 2021. We are not able to determine or predict the ultimate outcome of this proceeding or provide a reasonable estimate or range of estimates of the possible outcome or loss, if any, in this matter.

California Litgation

Neurelis, Inc. v. Aquestive Therapeutics, Inc.,

On December 5, 2019, Neurelis filed a lawsuit against us in the Superior Court of California, County of San Diego alleging the following three causes of action: (1) Unfair Competition under California Business and Professional Code § 17200; (2) Defamation; and (3) Malicious Prosecution. Neurelis filed a First Amended Complaint on December 9, 2019, alleging the same three causes of action. We filed a Motion to Strike Neurelis's Complaint under California's anti-SLAPP ("strategic lawsuit against public participation") statute on January 31, 2020, which Neurelis opposed. On August 6, 2020, the Court issued an order granting in part and denying in part our anti-SLAPP motion. We filed a notice of appeal to the California Court of Appeal on September 1, 2020, and Neurelis filed a notice of cross-appeal on October 5, 2020. We filed our opening appeal brief on January 27, 2021. Briefing on the appeal is currently scheduled to end on July 2, 2021, and there is no date yet set for a hearing on the appeal. The trial court proceedings remain stayed while the appeal is pending. We are not able to determine or predict the ultimate outcome of this proceeding or provide a reasonable estimate or range of estimates of the possible outcome or loss, if any, in this matter.

Note 21. Quarterly Financial Data (unaudited)

The following tables contain selected quarterly financial information from 2020 and 2019 (in thousands, except per share amounts). The Company believes that this information reflects all normal recurring adjustments necessary for a fair statement of the information for the periods presented. The operating results for any quarter are not necessarily indicative of results for any future period.

	Three Months Ended			
	March 31, 2020	June 30, 2020	September 30, 2020	December 31, 2020
Revenues	$ 8,765	$ 21,675	$ 8,260	$ 7,149
Manufacture and supply	3,659	3,539	2,978	2,788
Total costs and expenses	22,626	21,280	22,041	22,795
Net loss	(16,530)	(2,334)	(16,551)	(20,368)
Basic and diluted net loss per common share	$ (0.49)	$ (0.07)	$ (0.49)	$ (0.60)

	Three Months Ended			
	March 31, 2019	June 30, 2019	September 30, 2019	December 31, 2019
Revenues	$ 12,643	$ 11,129	$ 12,418	$ 16,419
Manufacture and supply	3,506	5,420	4,643	6,792
Total costs and expenses	25,717	29,817	23,420	26,323
Net loss	(14,726)	(20,472)	(18,412)	(12,636)
Basic and diluted net loss per common share	$ (0.59)	$ (0.82)	$ (0.74)	$ (0.48)

For periods in which the Company reported a net loss, potentially dilutive securities were excluded from the computation of per share amounts.

Note 22. Subsequent Events

(A) License Agreement with Mitsubishi Tanabe

On January 21, 2021, the Company entered into an exclusive license agreement with Mitsubishi Tanabe Pharma America, Inc. for the commercialization in the United States of Exservan® (riluzole), an oral film formulation of riluzole for treatment of amyotrophic lateral sclerosis (ALS).

(B) Continued Utilization of the At-The-Market Facility

The Company continued utilization of its At-The-Market facility from January 1 through March 5, 2021 and sold 1,644,715 shares which generated net proceeds of approximately $9,749.

(C) Stockholder Class Action

On March 1, 2021, a securities class action lawsuit was filed in the United States District Court of the District of New Jersey alleging that the Company and certain of its officers engaged in violations of the federal securities laws relating to public statements made by the Company relating to the approval of Libervant. We are not able to determine or predict the ultimate outcome of this proceeding or provide a reasonable estimate or range of estimates of the possible outcome or loss, if any, in this matter.

EXHIBIT 4.3

FIRST SUPPLEMENTAL INDENTURE

This First Supplemental Indenture, made as of November 3, 2020 (the "Supplemental Indenture"), to that certain Indenture (as such indenture has been supplemented and amended to date, the "Existing Indenture" and the Existing Indenture, as it may from time to time be supplemented or amended by one or more additional indentures supplemental thereto entered into pursuant to the applicable provisions thereof, being hereinafter called the "Indenture") dated as of July 15, 2019 among Aquestive Therapeutics, Inc., a Delaware corporation with an address at 30 Technology Drive, Warren, New Jersey 07059 (the "Issuer"), any Guarantor that becomes party thereto pursuant to Section 4.10 of the Existing Indenture, and U.S. Bank National Association, as trustee (the "Trustee") and as collateral agent (the "Collateral Agent").

WHEREAS, the Issuer has heretofore executed and delivered to the Trustee the Existing Indenture, providing for the issuance of an aggregate principal amount of up to $100.0 million of 12.5% Senior Secured Notes due 2025 (the "Notes");

WHEREAS, the Issuer proposes to amend the Existing Indenture and the Notes (the "Proposed Amendments"), which amendments, pursuant to Section 9.02 of the Indenture, must be approved with the written consent of the Holders of all of the aggregate principal amount of the outstanding Notes (the "Required Holders");

WHEREAS, the Issuer has received and delivered to the Trustee and to the Collateral Agent the consent of the Required Holders to the Proposed Amendments (the "Holder Consent");

WHEREAS, the Required Holders also consented to the Repurchase, in the Holder Consent;

WHEREAS, the Holder Consent also authorizes the issuance of an additional $4.0 million of Notes (the "2020 Additional Securities');

WHEREAS, the Issuer has been authorized by a resolution of its board of directors to enter into this Supplemental Indenture, to complete the Repurchase and to issue the 2020 Additional Securities;

WHEREAS, all other acts and proceedings required by law, by the Existing Indenture and by the certificate of incorporation and bylaws of the Issuer to make this Supplemental Indenture a valid and binding agreement for the purposes expressed herein, in accordance with its terms, have been duly done and performed;

WHEREAS, pursuant to Section 9.02, the Trustee and the Collateral Agent are authorized to execute and deliver this Supplemental Indenture;

WHEREAS, following the execution of this Supplemental Indenture, the terms hereof will become operative on the date hereof.

NOW, THEREFORE, THIS SUPPLEMENTAL INDENTURE WITNESSETH:

That, for and in consideration of the premises herein contained and in order to effect the Proposed Amendments contained herein, pursuant to Section 9.02 of the Existing Indenture, the Issuer agrees with the Trustee and the Collateral Agent as follows:

ARTICLE 1

Amendment of Existing Indenture

Section 1.01. Amendment of Existing Indenture. Effective as of the Supplement Effective Date, this Supplemental Indenture amends the Existing Indenture as provided for herein.

Section 1.02. Amendment of Section 1.01. Pursuant to Section 9.02 of the Existing Indenture, Section 1.01 of the Existing Indenture is hereby amended:

By deleting in their entirety the definitions of "Apomorphine Disposition", "Apomorphine License Transaction" and "Apomorphine Royalty Disposition";

By amending and restating the definition of "First Additional Securities Triggering Event" in its entirety to read as follows:

""First Additional Securities Triggering Event" means the approval of Libervant by the FDA; *provided*, *however,* that such approval shall not require any market access or a waiver of orphan drug exclusivity."

By amending and restating the definition of "Non-Recourse Debt" in its entirety to read as follows:

""Non-Recourse Debt" means Indebtedness as to which (i) neither the Issuer nor any of its Subsidiaries (other than any Royalty Subsidiary) (a) provides credit support of any kind (other than unsecured undertakings in respect of representations and warranties and covenants in connection with the Permitted Apomorphine Monetization that are usual and customary in transactions of that kind) or collateral security to secure such Indebtedness, (b) is directly or indirectly liable as an obligor, guarantor or otherwise or (c) constitutes the lender or counterparty thereto, (ii) no default with respect to such Indebtedness (including any rights that the holders of the Indebtedness may have to take enforcement action against a Royalty Subsidiary) would permit, upon notice, lapse of time or both, any holder of any other Indebtedness (other than the Securities) of the Issuer or its Subsidiaries to declare a default on such other Indebtedness or cause the payment of the Indebtedness to be accelerated or payable prior to its stated maturity date and (iii) the lenders have been notified in writing that they will not have any recourse to the stock or assets of the Issuer or any of its Subsidiaries (other than such Royalty Subsidiary)."

By amending and restating the definition of "Notes Collateral" in its entirety to read as follows:

""Notes Collateral" means all property subject, or purported to be subject from time to time, to a Lien under any Security Documents, including all Intellectual Property of the Issuer and the Collateral Account; *provided*, *however*, that the Notes Collateral does not include the Excluded Assets."

By amending and restating the definition of Clause (31) of the definition of "Permitted Liens" as follows:

"(31) the Permitted Apomorphine Monetization;"

By amending and restating the definition of "Royalty Subsidiary" in its entirety to read as follows:

""Royalty Subsidiary" means any Subsidiary of the Issuer that is designated by the Board of Directors of the Issuer as a Royalty Subsidiary pursuant to a resolution of such Board of Directors, but only to the extent that such Subsidiary (i) has no Indebtedness other than Non-Recourse Debt, (ii) has no assets other than the assets that are the subject of the Permitted Apomorphine Monetization and is not engaged in any activities other than those related or incidental to the Permitted Apomorphine Monetization, (iii) is a Person with respect to which neither the Issuer nor any of its other Subsidiaries has any direct or indirect obligation (a) to subscribe for additional Equity Interests or (b) to maintain or preserve such Person's financial condition or to cause such Person to achieve any specified levels of operating results and (iv) has not guaranteed or otherwise directly or indirectly provided credit support for any Indebtedness of the Issuer or any of its other Subsidiaries."

By amending and restating the definition of "Royalty Subsidiary Liens" in its entirety to read as follows:

""Royalty Subsidiary Liens" means Liens (i) solely on assets owned by a Royalty Subsidiary that are the subject of the Permitted Apomorphine Monetization securing the Non-Recourse Debt of such Royalty Subsidiary in connection with the Permitted Apomorphine Monetization and (ii) solely on the Equity Interests of a Royalty Subsidiary securing the Non-Recourse Debt of such Royalty Subsidiary in connection with the Permitted Apomorphine Monetization; *provided* that there is no recourse (whether as an obligor, guarantor or otherwise) to, or other credit support provided by, the Issuer or any other Subsidiary (other than unsecured undertakings in respect of representations and warranties and covenants in connection with such Permitted Apomorphine Monetization that are usual and customary in transactions of that kind)."

By amending and restating the definition of "Second Additional Securities Triggering Event" in its entirety to read as follows:

"Second Additional Securities Triggering Event" means the full approval of Libervant by the FDA for sale in the United States, which full approval shall include market access.

By amending and restating the definition of "Securities" in its entirety to read as follows:

""Securities" means the Issuer's 12.5% Senior Secured Notes due 2025 and shall include, for the avoidance of doubt, the Original Securities issued on the Issue Date, the 2020 Additional Securities issued on the 2020 Additional Securities Issuance Date, the First Additional Securities and the Second Additional Securities that may be issued after the Issue Date, in each case, as and to the extent issued pursuant to the terms and conditions of this Indenture."

By adding the following definitions:

““2020 Additional Securities” means the Issuer’s 12.5% Senior Secured Notes due 2025 that shall be issued on the 2020 Additional Securities Issuance Date pursuant to Section 2.01(f).”

““2020 Additional Securities Issuance Date” shall be the tenth Business Day following the funding of the Permitted Apomorphine Monetization.”

“”Initial Permitted Apomorphine Monetization” means the $40,000,000 upfront payment referenced in clause (i) of the definition of “Permitted Apomorphine Monetization.””

““November 2020 Purchase Agreements” means each Purchase Agreement dated November 3, 2020, between the Issuer and the purchaser(s) party thereto.”

““Permitted Apomorphine Monetization” means that certain sale, dated as of November 3, 2020, by the Issuer to MAM Pangolin Royalty, LLC of all of the Issuer’s rights to receive royalties and milestone payments under its license agreement with Sunovion Pharmaceuticals Inc. in consideration of payment by MAM Pangolin Royalty, LLC to the Issuer of (i) an up-front purchase price of $40,000,000 received substantially concurrently with the closing of such sale and (ii) additional contingent payments of up to $85,000,000 in the aggregate due upon the attainment of certain specified royalty and commercial targets.”

 ““Repurchase” means the repurchase on the tenth Business Day following the funding of the Permitted Apomorphine Monetization of $22,500,000 aggregate principal amount of Original Securities, for 100.000% of the principal amount thereof plus accrued and unpaid interest, if any, thereon to the date of repurchase, pursuant to the October 2020 Purchase Agreements.”

““Upfront Apomorphine Monetization Payment” means the initial cash amount of $40,000,000 received pursuant to the Permitted Apomorphine Monetization.”

Section 1.03. Amendment of Section 1.02. Pursuant to Section 9.02 of the Existing Indenture, Section 1.02 of the Existing Indenture is hereby amended to (i) add “30% Limitation” and “4.06(b)(ii)” to the chart and (ii) remove the reference to “Apomorphine Asset Sale Offer” and “4.06(b)(ii)” in its entirety.

Section 1.04. Amendment of Section 2.01. Pursuant to Section 9.02 of the Existing Indenture:

Section 2.01(a), (c) and (d) of the Existing Indenture are hereby amended and restated in their entirety as follows:

“(a) The aggregate principal amount of Securities that may be authenticated and delivered under this Indenture is limited to $104,000,000.”

"(c) On any Business Day on or prior to December 31, 2021 that does not fall between a Record Date and its related Payment Date (but, for the avoidance of doubt, only one Business Day, but not more than one Business Day), the Issuer may issue and deliver, in accordance with this Article 2, and pursuant to and in accordance with the terms and conditions of the October 2020 Purchase Agreements, without the consent of any Holder of or any holder of beneficial interests in the Securities, upon five Business Days' written notice to the Trustee, First Additional Securities in an aggregate principal amount of $10,000,000; *provided*, that, as of such Business Day, as conditions to the issuance of such First Additional Securities, (i) no Event of Default has occurred and is continuing, (ii) the First Additional Securities Triggering Event has occurred and (iii) the Issuer shall deliver to the Trustee, in addition to the written order of the Issuer pursuant to Section 2.03, Officers' Certificates of the Issuer (A) certifying as to the satisfaction of the foregoing clause (i) and clause (ii) and (B) stating that the representations and warranties of the Issuer in the October 2020 Purchase Agreements are true and correct in all material respects on and as of such Business Day with the same force and effect as if expressly made on and as of such Business Day (except for such representations and warranties qualified by materiality or material adverse effect, which are true and correct in all respects). Such First Additional Securities shall have the same terms as the Original Securities and any 2020 Additional Securities, except that the issue date, the issue price, the initial Payment Date and the initial date from which interest shall accrue may vary. If the Issuer determines that such First Additional Securities are issued as part of a "qualified reopening" for U.S. federal income tax purposes, such First Additional Securities will have the same CUSIP number as the Original Securities or any 2020 Additional Securities, as the case may be, and for U.S. federal income tax purposes will have the same issue date and issue price as the Original Securities or such 2020 Additional Securities, as the case may be. If the Issuer determines that such First Additional Securities are not issued as part of a "qualified reopening" for U.S. federal income tax purposes, such First Additional Securities will be required to have a CUSIP number that is different than the CUSIP number of the Original Securities and any 2020 Additional Securities.

(d) On any Business Day on or prior to December 31, 2021 that does not fall between a Record Date and its related Payment Date (but, for the avoidance of doubt, only one Business Day, but not more than one Business Day), the Issuer may issue and deliver, in accordance with this Article 2, without the consent of any Holder of or any holder of beneficial interests in the Securities, upon five Business Days' written notice to the Trustee, Second Additional Securities in an aggregate principal amount of up to $30,000,000; *provided*, that, as of such Business Day, if the Issuer has issued the First Additional Securities, the Issuer may only issue and deliver such Second Additional Securities in an aggregate principal amount of up to $20,000,000; *provided, further*, that, as of such Business Day, as conditions to the issuance of such Second Additional Securities, (i) no Event of Default has occurred and is continuing, (ii) the Second Additional Securities Triggering Event has occurred and (iii) the Issuer shall deliver to the Trustee, in addition to the written order of the Issuer pursuant to Section 2.03, Officers' Certificates of the Issuer (A) certifying as to the satisfaction of the foregoing clause (i) and clause (ii) (the "Second Additional Securities Triggering Event Officers' Certificate") and (B) stating that the representations and warranties of the Issuer in the October 2020 Purchase Agreements are true and correct in all material respects on and as of such Business Day with the same force and effect as if expressly made on and as of such Business Day (except for such representations and warranties qualified by materiality or material adverse effect, which are true and correct in all respects). Such Second Additional Securities shall have the same terms as the Original Securities and any First Additional Securities, 2020 Additional Securities, except that the issue date, the issue price, the initial Payment Date and the initial date from which interest shall accrue may vary. If the Issuer determines that such Second Additional Securities are issued as part of a "qualified reopening" for U.S. federal income tax purposes, such Second Additional Securities will have the same CUSIP number as the Original Securities or any First Additional Securities or 2020 Additional Securities, as the case may be, and for U.S. federal income tax purposes will have the same issue date and issue price as the Original Securities or such First Additional Securities, 2020 Additional Securities, as the case may be. If the Issuer determines that such Second Additional Securities are not issued as part of a "qualified reopening" for U.S. federal income tax purposes, such Second Additional Securities will be required to have a CUSIP number that is different than the CUSIP number of the Original Securities and any First Additional Securities, 2020 Additional Securities."

Section 2.01 of the Existing Indenture is hereby amended to add the following subsections:

"(f) On the 2020 Additional Securities Issuance Date, the Issuer shall issue and deliver, without the consent of any Holder of or any holder of beneficial interests in the Original Securities, in accordance with this Article 2, 2020 Additional Securities in an aggregate principal amount of $4,000,000 *provided*, that, as of such Business Day, as conditions to the issuance of such 2020 Additional Securities, the Issuer shall deliver to the Trustee, in addition to the written order of the Issuer pursuant to Section 2.03, Officers' Certificates of the Issuer stating that the representations and warranties of the Issuer in the purchase agreements governing the issuance of the 2020 Additional Securities are true and correct in all material respects on and as of such Business Day with the same force and effect as if expressly made on and as of such Business Day (except for such representations and warranties qualified by materiality or material adverse effect, which are true and correct in all respects). Such 2020 Additional Securities shall have the same terms as the Original Securities, except that the issue date, the issue price, the initial Payment Date and the initial date from which interest shall accrue may vary. If the Issuer determines that such 2020 Additional Securities are issued as part of a "qualified reopening" for U.S. federal income tax purposes, such 2020 Additional Securities will have the same CUSIP number as the Original Securities, and for U.S. federal income tax purposes will have the same issue date and issue price as the Original Securities. If the Issuer determines that such 2020 Additional Securities are not issued as part of a "qualified reopening" for U.S. federal income tax purposes, such 2020 Additional Securities will be required to have a CUSIP number that is different than the CUSIP number of the Original Securities.

Section 1.05. Amendment of Section 2.03. Pursuant to Section 9.02 of the Existing Indenture, the first paragraph of Section 2.03 of the Existing Indenture shall be amended and restated in its entirety as follows:

"Execution and Authentication. The Trustee shall authenticate and make available for delivery upon a written order of the Issuer signed by one Officer (i) Original Securities for original issue on the Issue Date in an aggregate principal amount of $70,000,000, (ii) First Additional Securities for original issue pursuant to Section 2.01(c), (iii) Second Additional Securities for original issue pursuant to Section 2.01(d), and (iv) 2020 Additional Securities for original issue pursuant to Section 2.01(f). Such order shall specify the amount of the Securities to be authenticated, the form in which the Securities are to be authenticated and the date on which the original issue of Securities is to be authenticated."

Section 1.06. Amendment of Section 4.01(b). Pursuant to Section 9.02 of the Existing Indenture, the first paragraph of Section 4.01 of the Existing Indenture shall be amended and restated in its entirety as follows:

"On each Payment Date, commencing on September 30, 2021, or on the succeeding Business Day if any such date is not a Business Day, the Issuer shall pay to the Holders an installment of principal of the Securities in accordance with the table below corresponding to the applicable Payment Date, where the applicable percentage is the percentage of (i) the initial aggregate principal amount of Original Securities issued on the Issue Date plus (ii) the initial aggregate principal amount of any First Additional Securities issued on their date of issuance plus (iii) the initial aggregate principal amount of any Second Additional Securities issued on their date of issuance plus (iv) the initial aggregate principal amount of any 2020 Additional Securities issued on their date of issuance minus (v) the aggregate principal amount of Securities redeemed or repurchased pursuant to this Indenture prior to such Payment Date:"

Section 1.07. Amendment of Section 4.05(c). Pursuant to Section 9.02 of the Existing Indenture, clause (15) of Section 4.05(c) of the Existing Indenture shall be amended and restated in its entirety as follows:

"(15) the Permitted Apomorphine Monetization to a Royalty Subsidiary;"

Section 1.08. Amendment of Section 4.06. Pursuant to Section 9.02 of the Existing Indenture, Section 4.06 of the Existing Indenture shall be amended and restated in its entirety as follows:

"Section 4.06. Asset Sales.

(a) General. The Issuer shall not, and shall not permit any of its Restricted Subsidiaries to, directly or indirectly, (i) make a Disposition or (ii) issue or sell Equity Interests (other than directors' qualifying shares and shares issued to foreign nationals or other third parties to the extent required by applicable law) of any Restricted Subsidiary (other than to the Issuer or another Restricted Subsidiary of the Issuer) (whether in a single transaction or a series of related transactions), in each case except for (A) the Permitted Apomorphine Monetization, and (B) Permitted Asset Sales.

(b) Permitted Apomorphine Monetization.

(i) Upon the receipt of any cash proceeds by the Issuer from the Permitted Apomorphine Monetization (other than the Upfront Apomorphine Monetization Payment), each Holder shall have the right to require the Issuer to repurchase all or any part of such Holder's then outstanding Securities at a repurchase price in cash equal to 112.5000% of the principal amount thereof, plus accrued and unpaid interest, if any, thereon to the repurchase date (subject to the right of the Holders of record on the relevant Record Date to receive interest due on the related Payment Date), in accordance with the terms contemplated in this Section 4.06(b); *provided, however*, that notwithstanding the occurrence of the Permitted Apomorphine Monetization, the Issuer shall not be obligated to repurchase any Securities pursuant to this Section 4.06(b) in the event that it has exercised (x) its unconditional right to redeem such Securities in accordance with Article 3 or (y) its legal defeasance option or covenant defeasance option in accordance with Article 8; (i) such repurchase offer shall be for 30% of the cash proceeds received by the Issuer in such Permitted Apomorphine Monetization (the "30% Limitation"), (ii) the Issuer shall not be obligated to repurchase Securities from any Holder with the proceeds of the Upfront Apomorphine Monetization Payment, except for the Repurchase; and (iii) that the Issuer shall not repurchase more than $40,000,000 in aggregate principal amount of Securities from the cash proceeds from the Permitted Apomorphine Monetization (or $50,000,000 in aggregate principal amount of Securities if the First Additional Securities have been issued) (and, in the event that the aggregate principal amount of Securities so requested to be repurchased pursuant to this Section 4.06(b) would otherwise exceed $40,000,000 (or $50,000,000 if the First Additional Securities have been issued), then the Issuer shall repurchase the Securities from such Holders on a pro rata basis); provided, such $40,000,000 (or $50,000,000 if the First Additional Securities have been issued) in aggregate principal amount of Securities to be repurchased with cash proceeds from the Permitted Apomorphine Monetization shall be reduced by the aggregate principal amount of Original Securities purchased by the Issuer in the Repurchase.

(ii) Within 30 days following the receipt of cash proceeds from the Permitted Apomorphine Monetization, except to the extent that the Issuer has exercised (x) its unconditional right to redeem the Securities by delivery of a notice of redemption in accordance with Article 3 or (y) its legal defeasance option or covenant defeasance option in accordance with Article 8, the Issuer shall provide a written notice (an "Apomorphine Asset Sale Offer") to each Holder with a copy to the Trustee stating:

(A) the Issuer has received cash proceeds from the Permitted Apomorphine Monetization and that such Holder has the right to require the Issuer to repurchase (subject to the second proviso of Section 4.06(b)(i)) all or any part of such Holder's then outstanding Securities at a repurchase price in cash equal to 112.5000% of the principal amount thereof, plus accrued and unpaid interest, if any, thereon to the repurchase date (subject to the right of the Holders of record on the relevant Record Date to receive interest due on the related Payment Date), subject to the 30% Limitation;

(B) the amount of cash proceeds received by the Issuer from such Permitted Apomorphine Monetization that triggered delivery of the Apomorphine Asset Sale Offer, including a calculation of the 30% Limitation;

(C) the aggregate amount of cash proceeds received by the Issuer in the Permitted Apomorphine Monetization, through the date of such Apomorphine Asset Sale Offer;

(D) the repurchase date (which shall be no earlier than 30 days nor later than 60 days from the date such written notice is provided); and

(E) the instructions determined by the Issuer, consistent with this Section 4.06(b), that a Holder must follow in order to have its Securities repurchased.

(iii) At any time prior to the Libervant Approval, to the extent that the aggregate principal amount of Securities repurchased by the Issuer pursuant to this Section 4.06(b), taken together with any prior repurchases by the Issuer pursuant to this Section 4.06(b) including the amounts repurchased in the Repurchase, is less than $40,000,000 (or $50,000,000 if the First Additional Securities have been issued), the difference between (x) the cash proceeds received by the Issuer in the Permitted Apomorphine Monetization (excluding the Upfront Apomorphine Monetization Payment) limited to the first $40,000,000 of all such cash proceeds (or $50,000,000 if the First Additional Securities have been issued) and (y) the aggregate principal amount of Securities so repurchased shall be deposited into the Collateral Account; provided, for the avoidance of doubt, all amounts received by the Issuer in the Upfront Apomorphine Monetization Payment not used to repurchase Securities in the Repurchase shall be retained by the Issuer and shall not be deposited in the Collateral Account.

(iv) Holders electing to have a Security repurchased pursuant to this Section 4.06(b) shall be required to surrender the Security, with an appropriate form duly completed, to the Issuer at the address specified in the Apomorphine Asset Sale Offer (or otherwise in accordance with the applicable procedures of the Depository) at least three Business Days prior to the repurchase date. The Holders shall be entitled to withdraw their election if the Issuer receives not later than one Business Day prior to the repurchase date a letter setting forth the name of the Holder, the principal amount of the Security that was delivered for repurchase by the Holder and a statement that such Holder is withdrawing its election to have such Security repurchased. Holders whose Securities are repurchased only in part shall be issued new Securities equal in principal amount to the portion of the Securities surrendered but not repurchased. If the Securities are Global Securities held by the Depository, then the applicable operational procedures of the Depository for tendering and withdrawing securities will apply.

(v) On the repurchase date, all Securities repurchased by the Issuer under this Section 4.06(b) shall be delivered to the Trustee for cancellation, and the Issuer shall pay the repurchase price plus accrued and unpaid interest, if any, thereon to the date of repurchase, to the Holders entitled thereto.

(vi) Securities repurchased by the Issuer pursuant to this Section 4.06(b) will have the status of Securities issued but not outstanding or will be retired and canceled at the option of the Issuer.

(vii) At the time the Issuer delivers (or causes to be delivered) Securities to the Trustee that are to be accepted for repurchase, the Issuer shall also deliver an Officers' Certificate stating that such Securities are to be accepted by the Issuer pursuant to and in accordance with the terms of this Section 4.06(b) and confirming whether the Securities will be considered issued but not outstanding or including orders to cancel the repurchased Securities. A Security shall be deemed to have been accepted for repurchase at the time the Trustee, directly or through an agent, provides payment therefor to the surrendering Holder.

(viii) Prior to providing written notice to the Holders of any Apomorphine Asset Sale Offer pursuant to Section 4.06(b)(ii), the Issuer shall deliver to the Trustee an Officers' Certificate stating that all conditions precedent contained herein to the right of the Issuer to make such offer have been complied with.

(ix) The Issuer shall comply, to the extent applicable, with the requirements of Section 14(e) of the Exchange Act and any other securities laws or regulations in connection with the repurchase of Securities pursuant to this Section 4.06(b). To the extent that the provisions of any securities laws or regulations conflict with provisions of this Section 4.06(b), the Issuer shall comply with the applicable securities laws and regulations and shall not be deemed to have breached its obligations under this Section 4.06(b) by virtue thereof.

(c) Administration of Collateral Account.

(i) The Issuer shall establish and maintain a segregated account held with U.S. Bank National Association (or another segregated account in replacement thereof held with another U.S. federally insured depositary financial institution that is acting as the Trustee or other Paying Agent) in the name of the Trustee or other Paying Agent (acting in either case as an agent for or representative of the Collateral Agent), or in the name of the Issuer, in each case, subject to the Liens established under the Collateral Agreement and the other Security Documents (such account, the "Collateral Account"). The Collateral Account shall be established and maintained so as to create, perfect and establish the priority of the Liens established under the Collateral Agreement and the other Security Documents in such Collateral Account and all funds and other assets or property from time to time deposited therein or credited thereto and otherwise to effectuate the Liens under the Security Documents. The Collateral Account shall bear a designation clearly indicating that the funds and other assets or property deposited therein or credited thereto are held for the benefit of the Holders and the Trustee.

(ii) The Trustee or other Paying Agent, as applicable, shall have sole dominion and control over the Collateral Account (including, among other things, the sole power to direct withdrawals or transfers from the Collateral Account). The Trustee or other Paying Agent, as applicable, shall make withdrawals and transfers from the Collateral Account in accordance with the terms of this Indenture. Each of the Issuer and the Trustee, any other Paying Agent and the Collateral Agent acknowledges and agrees that the Collateral Account is a "securities account" within the meaning of Section 8-501 of the Uniform Commercial Code and that the Trustee or other Paying Agent, as applicable, has "control", for purposes of Section 9-314 of the Uniform Commercial Code, of the Collateral Account that is maintained with the Trustee or other Paying Agent. The Trustee hereby confirms that it has established account number 217428010 in the name of the Issuer for the benefit of the Holders and the Trustee as the Collateral Account. The Issuer and the Trustee, any other Paying Agent and the Collateral Agent further agree that the jurisdiction of the Trustee, such other Paying Agent or the Collateral Agent, as applicable, for purposes of the Uniform Commercial Code shall be the State of New York. The crediting by the Trustee or other Paying Agent, as applicable, to the Collateral Account of any asset or property that is not otherwise a financial asset by virtue of Section 8-102(a)(9)(i) of the Uniform Commercial Code or Section 8-102(a)(9)(ii) of the Uniform Commercial Code, including cash, shall constitute the "express agreement" of the Trustee or such other Paying Agent, as applicable, under Section 8-102(a)(9)(iii) of the Uniform Commercial Code that such property is a financial asset under Section 8-102(a)(9)(iii) of the Uniform Commercial Code.

(iii) The funds in the Collateral Account shall be released to the Issuer in whole or in part (free and clear of any Liens established under the Collateral Agreement and any other applicable Security Document) only upon (A) the occurrence of the Second Additional Securities Triggering Event and receipt by the Trustee or other applicable Paying Agent of the Second Additional Securities Triggering Event Officers' Certificate or (B) the written consent of the Holders of a majority in principal amount of the Securities. The funds in the Collateral Account may not otherwise be withdrawn except (x) upon the occurrence and during the continuance of an Event of Default at the direction of the Holders of a majority in principal amount of the Securities as further described in Article 6, (y) to the Issuer following the discharge of this Indenture or (z) solely to be used in connection with the Issuer's (A) unconditional right to redeem the Securities in whole in accordance with Article 3 or (B) legal defeasance option or covenant defeasance option in accordance with Article 8. Funds in the Collateral Account may be invested by the Trustee or such Paying Agent in Cash Equivalents available to the Trustee or other Paying Agent, as applicable, at the written direction of the Issuer absent the occurrence and continuance of an Event of Default. Promptly following the occurrence of an Event of Default and during the continuation thereof, the Trustee or other Paying Agent, as applicable (acting as an agent for or representative of the Collateral Agent), shall direct the funds in the Collateral Account to be invested pursuant to the direction of the Holders of a majority in principal amount of the Securities that are available to the Trustee or other Paying Agent, as applicable. In the absence of written instructions, no investments shall be made using the funds in the Collateral Account.

(iv) The cash proceeds in respect of the Permitted Apomorphine Monetization in excess of the first $40,000,000 of cash proceeds from the Permitted Apomorphine Monetization (or $50,000,000 if the First Additional Securities have been issued) may be used by the Issuer for any purpose that is not prohibited by this Indenture. At any time following the Second Additional Securities Triggering Event, after any repurchase of Securities by the Issuer pursuant to Section 4.06(b), any cash proceeds in respect of the Permitted Apomorphine Monetization not used for such repurchase may be used by the Issuer for any purpose that is not prohibited by this Indenture. Notwithstanding anything to the contrary in this Indenture, all amounts received by the Issuer in the Upfront Apomorphine Monetization Payment not used to repurchase Securities in the Repurchase shall be retained by the Issuer free and clear of this Section 4.06(c) and shall not be deposited in the Collateral Account."

Section 1.09. Amendment of Section 4.07(a). Pursuant to Section 9.02 of the Existing Indenture, clause (xvi) of Section 4.05(c) of the Existing Indenture shall be amended and restated in its entirety as follows:

"(xvi) the Permitted Apomorphine Monetization to a Royalty Subsidiary;"

Section 1.09 Amendment of Section 4.19. Pursuant to Section 9.02 of the Existing Indenture, Section 4.19 of the Existing Indenture shall be amended and restated in its entirety as follows:

"Section 4.19. Right of First Offer. Upon each proposed issuance, if any, of First Additional Securities or Second Additional Securities, the Issuer will grant to the initial purchasers of the Original Securities (or, in the case of the First Additional Securities, their permitted transferees in accordance with the terms hereof) the right to purchase an aggregate amount of such First Additional Securities or Second Additional Securities, as applicable, in an amount equal to the same proportion that the principal amount of Original Securities each such purchaser initially purchased bears to the aggregate principal amount of Original Securities issued on the Issue Date and at a purchase price specified by the Issuer (which purchase price shall not be more than the purchase price being offered to other investors), with such right to purchase being exercised by each such purchaser by written notice to the Issuer no later than 15 days after being notified of such proposed issuance by the Issuer. To the extent that any of the initial purchasers of the Original Securities (or, in the case of the First Additional Securities, their permitted transferees in accordance with the terms hereof) decline to exercise their right to purchase any First Additional Securities or Second Additional Securities, as applicable (in whole or in part), the Issuer will promptly notify the other initial purchasers of the Original Securities (or, in the case of the First Additional Securities, their permitted transferees in accordance with the terms hereof) that have exercised such right in full, in which case such other initial purchasers will have the right to purchase such remaining First Additional Securities or Second Additional Securities, as applicable (subject to proportional reduction to the extent of the relative initial principal amount of First Additional Securities or Second Additional Securities, as applicable, purchased by other initial purchasers exercising the same right), on the same terms as any First Additional Securities or Second Additional Securities, as applicable, it previously exercised the right to purchase pursuant to the preceding sentence, with such right to purchase being exercised by each such purchaser by written notice to the Issuer no later than two days after being notified of the opportunity to purchase such remaining First Additional Securities or Second Additional Securities, as applicable, by the Issuer.

If, and solely to the extent that, the initial purchasers of the Original Securities (or their permitted transferees in accordance with the terms hereof) purchase the First Additional Notes in accordance with Section 2.01(c) at the request of the Company, the Issuer will grant to the initial purchasers of the Original Securities (or their or their permitted transferees in accordance with the terms hereof), for no additional consideration, warrants to purchase shares of common stock of the Issuer equal to 14.3 shares of common stock per $1,000 aggregate principal amount of First Additional Securities purchased by the initial purchasers of the Original Securities, at an exercise price per share of common stock equal to the volume weighted average price of a single share of the Issuer's common stock in composite trading for the principal exchange on which such securities are listed for the thirty (30) trading days ending on, but excluding, the date of issuance, and otherwise substantially in accordance with the terms of those certain common stock purchase warrants issued by the Issuer to the initial purchasers of the Original Securities on July 15, 2019; *provided*, in no event shall the Issuer issue warrants to purchase fractional shares of common stock, and the Issuer shall round the amount of common stock each such warrant is exercisable for to the nearest whole share of common stock.

If, and solely to the extent that, the initial purchasers of the Original Securities elect to exercise the Right of First Offer described above and purchase the Second Additional Securities in connection with the issuance and sale of the Second Additional Securities, the Issuer will grant to such initial purchasers of the Original Securities, for no additional consideration, warrants to purchase shares of common stock of the Issuer equal to (i) if the First Additional Securities have not been issued, 14.3 shares of common stock per $1,000 aggregate principal amount of Second Additional Securities purchased by such initial purchasers of the Original Securities until an aggregate of $10.0 million of Second Additional Securities have been issued, and, (ii) thereafter, 28.5 shares of common stock per $1,000 aggregate principal amount of Second Additional Securities purchased by such initial purchasers of the Original Securities, in each case, at an exercise price per share of common stock equal to the volume weighted average price of a single share of the Issuer's common stock in composite trading for the principal exchange on which such securities are listed for the thirty (30) trading days ending on, but excluding, the date of issuance, and otherwise substantially in accordance with the terms of those certain common stock purchase warrants issued by the Issuer to the initial purchasers of the Original Securities on July 15, 2019; *provided*, in no event shall the Issuer issue warrants to purchase fractional shares of common stock, and the Issuer shall round the amount of common stock each such warrant is exercisable for to the nearest whole share of common stock. For the avoidance of doubt, if the First Additional Notes have not been issued, any warrants issued to the initial purchasers of the Original Securities in connection with the Second Additional Notes pursuant to each of clauses (i) and (ii) in this paragraph above shall be allocated to such purchasers on a pro rata basis."

Section 1.10. Amendment of Section 11.03(a). Pursuant to Section 9.02 of the Existing Indenture, the lead-in of Section 11.03(a) of the Existing Indenture shall be amended and restated in its entirety as follows:

"(a) Subject to Sections 11.03(b) and 11.04, the Notes Collateral may be released from the Lien and security interest created by the Security Documents at any time or from time to time in accordance with the provisions of the Security Documents or the Intercreditor Agreements or as provided hereby. The Issuer and the Guarantors will be entitled to a release of assets included in the Notes Collateral from the Liens securing the Securities, and the Trustee shall release, or instruct the Collateral Agent to release, as applicable, the same from such Liens at the Issuer's sole cost and expense, under one or more of the following circumstances:"

Section 1.11. Amendment of Section 11.03(a). Pursuant to Section 9.02 of the Existing Indenture, clause (1) of Section 11.03(a) of the Existing Indenture shall be amended and restated in its entirety as follows:

"(1) to enable the Issuer or any Restricted Subsidiary to exchange or Dispose of any of the Notes Collateral to any Person other than the Issuer or any Guarantor (but excluding any transaction subject to Article 5 where the recipient is required to become the obligor on the Securities or a Guarantee) to the extent not prohibited by this Indenture, including Section 4.06, and only to the extent that such exchange or Disposal results in a legal transfer of title of such Notes Collateral (except in connection with the Permitted Apomorphine Monetization);"

ARTICLE 2

Amendment to Notes

Effective as of the Supplement Effective Date, this Supplemental Indenture amends the Notes as provided for herein:

Section 2.01. Amendment of Section 8. Pursuant to Section 9.02 of the Existing Indenture and Section 15 of the Notes, Section 8 of the Notes shall be amended and restated in its entirety as follows:

"Upon the receipt of any cash proceeds by the Issuer in the Permitted Apomorphine Monetization (other than the Upfront Apomorphine Monetization Payment), each Holder shall have the right, subject to certain conditions specified in the Indenture, to require the Issuer to repurchase all or any part of such Holder's then outstanding Securities at a repurchase price in cash equal to 112.5000% of the principal amount thereof, plus accrued and unpaid interest, if any, thereon to the repurchase date (subject to the right of the Holders of record on the relevant Record Date to receive interest due on the related Payment Date), as provided in, and subject to the terms of, the Indenture."

ARTICLE 3

Conditions Precedent

This Supplement shall be deemed to be effective on the tenth business day following the funding of the Initial Permitted Apomorphine Monetization, assuming each of the following conditions is satisfied as of such tenth business day (the "Supplement Effective Date"):

Section 3.01. Executed Supplement. The Trustee and Collateral Agent shall have received from the Company and each Guarantor, counterparts of this Supplement signed on behalf of each of the parties hereto.

Section 3.02. Further Assurances. The Collateral Agent and Trustee shall have received such documents as the Collateral Agent and Trustee or special counsel to the Collateral Agent and Trustee may reasonably request.

Section 3.03. Representatives and Warranties. Each of the representations and warranties contained in the Purchase Agreements shall be true and correct in all material respects (except that any representation and warranty that is qualified as to "materiality" or "Material Adverse Effect" shall be true and correct in all respects) on and as of the Supplement Effective Date, except to the extent such representations and warranties expressly related to any earlier date.

Section 3.04. Issuance of New Notes. Substantially concurrently with the Supplement Effective Date, the 2020 Additional Securities Issuance Date shall have occurred and the 2020 Additional Securities shall have been issued.

Section 3.05. Repurchase. Substantially concurrently with the Supplement Effective Date, the Repurchase shall have been consummated.

Section 3.06. No Default. No Default or Event of Default has occurred and is then continuing.

ARTICLE 4

Miscellaneous Provisions

Section 4.01. Ratification of Indenture; Supplemental Indentures Part of Indenture. Except as expressly amended and supplemented hereby, the Indenture is in all respects ratified and confirmed and all the terms, conditions and provisions thereof shall remain in full force and effect. This Supplemental Indenture shall form a part of the Indenture for all purposes, and every Holder shall be bound hereby.

Section 4.02. Defined Terms. As used in this Supplemental Indenture, terms defined in the Indenture or in the preamble or recitals hereto are used herein as therein defined, except that the term "Holders" in this Supplemental Indenture shall refer to the term "Holders" as defined in the Indenture and the Trustee and the Collateral Agent acting on behalf of and for the benefit of such Holders. The words "herein", "hereof" and "hereby" and other words of similar import used in this Supplemental Indenture refer to this Supplemental Indenture as a whole and not to any particular section hereof.

Section 4.03. Counterparts. The parties may sign any number of copies of this Supplemental Indenture. Each signed copy shall be an original, but all of them together represent the same agreement. The exchange of copies of this Supplemental Indenture and of signature pages by facsimile or PDF transmission shall constitute effective execution and delivery of this Supplemental Indenture as to the parties hereto and may be used in lieu of the original Supplemental Indenture for all purposes. Signatures of the parties hereto transmitted by facsimile or PDF shall be deemed to be their original signatures for all purposes.

Section 4.04. Effect of Headings. The Section headings herein are for convenience of reference only and shall not affect the construction thereof.

Section 4.05. Effectiveness. The provisions of this Supplemental Indenture will take effect immediately upon execution thereof by the parties hereto.

Section 4.06. Governing Law. THIS SUPPLEMENTAL INDENTURE SHALL BE GOVERNED BY, AND CONSTRUED IN ACCORDANCE WITH THE LAWS OF THE STATE OF NEW YORK WITHOUT REGARD TO PRINCIPLES OF CONFLICTS OF LAW (OTHER THAN SECTIONS 5-1401 AND 5-1402 OF THE NEW YORK GENERAL OBLIGATIONS LAW).

Section 4.07. No Representation. Neither the Trustee nor the Collateral Agent makes any representation as to the validity or sufficiency of this Supplemental Indenture.

{Remainder of page intentionally left blank}

IN WITNESS WHEREOF, the parties have caused this Supplemental Indenture to be duly executed as of the date first written above.

AQUESTIVE THERAPEUTICS, INC.

By: /s/ Keith J. Kendall
Name: Keith J. Kendall
Title: Chief Executive Officer

Signature Page to the First Supplemental Indenture

U.S. BANK NATIONAL ASSOCIATION,
as Trustee

By: /s/ Allison D.B. Nadeau
Name: Allison D.B. Nadeau
Title: Vice President

U.S. BANK NATIONAL ASSOCIATION,
as Collateral Agent

By: /s/ Allison D.B. Nadeau
Name: Allison D.B. Nadeau
Title: Vice President

Signature Page to the First Supplemental Indenture

EXHIBIT 4.4

SECOND SUPPLEMENTAL INDENTURE

This Second Supplemental Indenture, made as of November 19, 2020 (the "Supplemental Indenture"), to that certain Indenture (as such indenture has been supplemented and amended by the First Supplemental Indenture, dated November 3, 2020 (the "First Supplemental Indenture"), the "Existing Indenture" and the Existing Indenture, as it may from time to time be supplemented or amended by one or more additional indentures supplemental thereto entered into pursuant to the applicable provisions thereof, being hereinafter called the "Indenture") dated as of July 15, 2019 among Aquestive Therapeutics, Inc., a Delaware corporation with an address at 30 Technology Drive, Warren, New Jersey 07059 (the "Issuer"), any Guarantor that becomes party thereto pursuant to Section 4.10 of the Existing Indenture, and U.S. Bank National Association, as trustee (the "Trustee") and as collateral agent (the "Collateral Agent").

WHEREAS, the Issuer has heretofore executed and delivered to the Trustee the Existing Indenture, providing for the issuance of an aggregate principal amount of up to $104.0 million of 12.5% Senior Secured Notes due 2025 (the "Notes");

WHEREAS, the Existing Indenture provides for certain exceptions to the Note repurchase requirements otherwise applicable to the Issuer in connection with the Issuer's receipt of the initial cash amount of $40,000,000 pursuant to the sale by the Issuer of certain rights to receive royalties and milestone payments under its license agreement with Sunovion Pharmaceuticals Inc.;

WHEREAS, the Issuer proposes to amend the Existing Indenture, the First Supplemental Indenture and the Notes (the "Proposed Amendments"), which amendments, pursuant to Section 9.02 of the Indenture, must be approved with the written consent of the Holders of all of the aggregate principal amount of the outstanding Notes (the "Required Holders");

WHEREAS, the Issuer has received and delivered to the Trustee and to the Collateral Agent the consent of the Required Holders to the Proposed Amendments (the "Holder Consent");

WHEREAS, the Issuer has been authorized by a resolution of its board of directors to enter into this Supplemental Indenture;

WHEREAS, all other acts and proceedings required by law, by the Existing Indenture and by the certificate of incorporation and bylaws of the Issuer to make this Supplemental Indenture a valid and binding agreement for the purposes expressed herein, in accordance with its terms, have been duly done and performed;

WHEREAS, pursuant to Section 9.02, the Trustee and the Collateral Agent are authorized to execute and deliver this Supplemental Indenture;

WHEREAS, following the execution of this Supplemental Indenture, the terms hereof will become operative on the date hereof.

NOW, THEREFORE, THIS SUPPLEMENTAL INDENTURE WITNESSETH:

That, for and in consideration of the premises herein contained and in order to effect the Proposed Amendments contained herein, pursuant to Section 9.02 of the Existing Indenture, the Issuer agrees with the Trustee and the Collateral Agent as follows:

ARTICLE 1

Amendment of Existing Indenture

Section 1.01. Amendment of Existing Indenture. Effective as of the Supplement Effective Date, this Supplemental Indenture amends the Existing Indenture as provided for herein.

Section 1.02. Amendment of Section 1.01. Pursuant to Section 9.02 of the Existing Indenture, Section 1.01 of the Existing Indenture is hereby amended:

By amending and restating the definition of "2020 Additional Securities Issuance Date" in its entirety to read as follows:

""2020 Additional Securities Issuance Date" shall be November 19, 2020."

By amending and restating the definition of "Repurchase" in its entirety to read as follows:

""Repurchase" means the repurchase on November 19, 2020 of the $22,500,000 aggregate principal amount of Original Securities, for 100.000% of the principal amount thereof plus accrued and unpaid interest, if any, thereon to the date of repurchase, pursuant to the October 2020 Purchase Agreements."

By adding the following definitions:

""Permitted Apomorphine Monetization Agreement" means that certain Purchase and Sale Agreement, dated as of November 3, 2020, between the Issuer and MAM Pangolin Royalty, LLC."

""Second Apomorphine Monetization Payment" means the cash amount of $10,000,000 that may be received by the Company pursuant to Section 2.2(b) of the Permitted Apomorphine Monetization Agreement."

Section 1.03. Amendment of Section 4.06. Pursuant to Section 9.02 of the Existing Indenture, Section 4.06 of the Existing Indenture shall be amended and restated in its entirety as follows:

"Section 4.06. Asset Sales.

(a) General. The Issuer shall not, and shall not permit any of its Restricted Subsidiaries to, directly or indirectly, (i) make a Disposition or (ii) issue or sell Equity Interests (other than directors' qualifying shares and shares issued to foreign nationals or other third parties to the extent required by applicable law) of any Restricted Subsidiary (other than to the Issuer or another Restricted Subsidiary of the Issuer) (whether in a single transaction or a series of related transactions), in each case except for (A) the Permitted Apomorphine Monetization, and (B) Permitted Asset Sales.

(b) Permitted Apomorphine Monetization.

(i) Upon the receipt of any cash proceeds by the Issuer from the Permitted Apomorphine Monetization (other than the Upfront Apomorphine Monetization Payment and Second Apomorphine Monetization Payment), each Holder shall have the right to require the Issuer to repurchase all or any part of such Holder's then outstanding Securities at a repurchase price in cash equal to 112.5000% of the principal amount thereof, plus accrued and unpaid interest, if any, thereon to the repurchase date (subject to the right of the Holders of record on the relevant Record Date to receive interest due on the related Payment Date), in accordance with the terms contemplated in this Section 4.06(b); *provided*, *however*, that notwithstanding the occurrence of the Permitted Apomorphine Monetization, the Issuer shall not be obligated to repurchase any Securities pursuant to this Section 4.06(b) in the event that it has exercised (x) its unconditional right to redeem such Securities in accordance with Article 3 or (y) its legal defeasance option or covenant defeasance option in accordance with Article 8; (i) such repurchase offer shall be for 30% of the cash proceeds received by the Issuer in such Permitted Apomorphine Monetization (the "30% Limitation"), (ii) the Issuer shall not be obligated to repurchase Securities from any Holder with the proceeds of the Upfront Apomorphine Monetization Payment, except for the Repurchase, or the Second Apomorphine Monetization Payment; and (iii) that the Issuer shall not repurchase more than $40,000,000 in aggregate principal amount of Securities from the cash proceeds from the Permitted Apomorphine Monetization (or $50,000,000 in aggregate principal amount of Securities if the First Additional Securities have been issued) (and, in the event that the aggregate principal amount of Securities so requested to be repurchased pursuant to this Section 4.06(b) would otherwise exceed $40,000,000 (or $50,000,000 if the First Additional Securities have been issued), then the Issuer shall repurchase the Securities from such Holders on a pro rata basis); provided, such $40,000,000 (or $50,000,000 if the First Additional Securities have been issued) in aggregate principal amount of Securities to be repurchased with cash proceeds from the Permitted Apomorphine Monetization shall be reduced by the aggregate principal amount of Original Securities purchased by the Issuer in the Repurchase.

(ii) Within 30 days following the receipt of cash proceeds from the Permitted Apomorphine Monetization (other than the Upfront Apomorphine Monetization Payment and Second Apomorphine Monetization Payment), except to the extent that the Issuer has exercised (x) its unconditional right to redeem the Securities by delivery of a notice of redemption in accordance with Article 3 or (y) its legal defeasance option or covenant defeasance option in accordance with Article 8, the Issuer shall provide a written notice (an "Apomorphine Asset Sale Offer") to each Holder with a copy to the Trustee stating:

(A) the Issuer has received cash proceeds from the Permitted Apomorphine Monetization and that such Holder has the right to require the Issuer to repurchase (subject to the second proviso of Section 4.06(b)(i)) all or any part of such Holder's then outstanding Securities at a repurchase price in cash equal to 112.5000% of the principal amount thereof, plus accrued and unpaid interest, if any, thereon to the repurchase date (subject to the right of the Holders of record on the relevant Record Date to receive interest due on the related Payment Date), subject to the 30% Limitation;

(B) the amount of cash proceeds received by the Issuer from such Permitted Apomorphine Monetization that triggered delivery of the Apomorphine Asset Sale Offer, including a calculation of the 30% Limitation;

(C) the aggregate amount of cash proceeds received by the Issuer in the Permitted Apomorphine Monetization, through the date of such Apomorphine Asset Sale Offer;

(D) the repurchase date (which shall be no earlier than 30 days nor later than 60 days from the date such written notice is provided); and

(E) the instructions determined by the Issuer, consistent with this Section 4.06(b), that a Holder must follow in order to have its Securities repurchased.

(iii) At any time prior to the Libervant Approval, to the extent that the aggregate principal amount of Securities repurchased by the Issuer pursuant to this Section 4.06(b), taken together with any prior repurchases by the Issuer pursuant to this Section 4.06(b) including the amounts repurchased in the Repurchase, is less than $40,000,000 (or $50,000,000 if the First Additional Securities have been issued), the difference between (x) the cash proceeds received by the Issuer in the Permitted Apomorphine Monetization (excluding the Upfront Apomorphine Monetization Payment and the Second Apomorphine Monetization Payment) limited to the first $40,000,000 of all such cash proceeds (or $50,000,000 if the First Additional Securities have been issued) and (y) the aggregate principal amount of Securities so repurchased shall be deposited into the Collateral Account; provided, for the avoidance of doubt, all amounts received by the Issuer in the Upfront Apomorphine Monetization Payment and the Second Apomorphine Monetization Payment not used to repurchase Securities in the Repurchase shall be retained by the Issuer and shall not be deposited in the Collateral Account.

(iv) Holders electing to have a Security repurchased pursuant to this Section 4.06(b) shall be required to surrender the Security, with an appropriate form duly completed, to the Issuer at the address specified in the Apomorphine Asset Sale Offer (or otherwise in accordance with the applicable procedures of the Depository) at least three Business Days prior to the repurchase date. The Holders shall be entitled to withdraw their election if the Issuer receives not later than one Business Day prior to the repurchase date a letter setting forth the name of the Holder, the principal amount of the Security that was delivered for repurchase by the Holder and a statement that such Holder is withdrawing its election to have such Security repurchased. Holders whose Securities are repurchased only in part shall be issued new Securities equal in principal amount to the portion of the Securities surrendered but not repurchased. If the Securities are Global Securities held by the Depository, then the applicable operational procedures of the Depository for tendering and withdrawing securities will apply.

(v) On the repurchase date, all Securities repurchased by the Issuer under this Section 4.06(b) shall be delivered to the Trustee for cancellation, and the Issuer shall pay the repurchase price plus accrued and unpaid interest, if any, thereon to the date of repurchase, to the Holders entitled thereto.

(vi) Securities repurchased by the Issuer pursuant to this Section 4.06(b) will have the status of Securities issued but not outstanding or will be retired and canceled at the option of the Issuer.

(vii) At the time the Issuer delivers (or causes to be delivered) Securities to the Trustee that are to be accepted for repurchase, the Issuer shall also deliver an Officers' Certificate stating that such Securities are to be accepted by the Issuer pursuant to and in accordance with the terms of this Section 4.06(b) and confirming whether the Securities will be considered issued but not outstanding or including orders to cancel the repurchased Securities. A Security shall be deemed to have been accepted for repurchase at the time the Trustee, directly or through an agent, provides payment therefor to the surrendering Holder.

(viii) Prior to providing written notice to the Holders of any Apomorphine Asset Sale Offer pursuant to Section 4.06(b)(ii), the Issuer shall deliver to the Trustee an Officers' Certificate stating that all conditions precedent contained herein to the right of the Issuer to make such offer have been complied with.

(ix) The Issuer shall comply, to the extent applicable, with the requirements of Section 14(e) of the Exchange Act and any other securities laws or regulations in connection with the repurchase of Securities pursuant to this Section 4.06(b). To the extent that the provisions of any securities laws or regulations conflict with provisions of this Section 4.06(b), the Issuer shall comply with the applicable securities laws and regulations and shall not be deemed to have breached its obligations under this Section 4.06(b) by virtue thereof.

(c) Administration of Collateral Account.

(i) The Issuer shall establish and maintain a segregated account held with U.S. Bank National Association (or another segregated account in replacement thereof held with another U.S. federally insured depositary financial institution that is acting as the Trustee or other Paying Agent) in the name of the Trustee or other Paying Agent (acting in either case as an agent for or representative of the Collateral Agent), or in the name of the Issuer, in each case, subject to the Liens established under the Collateral Agreement and the other Security Documents (such account, the "Collateral Account"). The Collateral Account shall be established and maintained so as to create, perfect and establish the priority of the Liens established under the Collateral Agreement and the other Security Documents in such Collateral Account and all funds and other assets or property from time to time deposited therein or credited thereto and otherwise to effectuate the Liens under the Security Documents. The Collateral Account shall bear a designation clearly indicating that the funds and other assets or property deposited therein or credited thereto are held for the benefit of the Holders and the Trustee.

(ii) The Trustee or other Paying Agent, as applicable, shall have sole dominion and control over the Collateral Account (including, among other things, the sole power to direct withdrawals or transfers from the Collateral Account). The Trustee or other Paying Agent, as applicable, shall make withdrawals and transfers from the Collateral Account in accordance with the terms of this Indenture. Each of the Issuer and the Trustee, any other Paying Agent and the Collateral Agent acknowledges and agrees that the Collateral Account is a "securities account" within the meaning of Section 8-501 of the Uniform Commercial Code and that the Trustee or other Paying Agent, as applicable, has "control", for purposes of Section 9-314 of the Uniform Commercial Code, of the Collateral Account that is maintained with the Trustee or other Paying Agent. The Trustee hereby confirms that it has established account number 217428010 in the name of the Issuer for the benefit of the Holders and the Trustee as the Collateral Account. The Issuer and the Trustee, any other Paying Agent and the Collateral Agent further agree that the jurisdiction of the Trustee, such other Paying Agent or the Collateral Agent, as applicable, for purposes of the Uniform Commercial Code shall be the State of New York. The crediting by the Trustee or other Paying Agent, as applicable, to the Collateral Account of any asset or property that is not otherwise a financial asset by virtue of Section 8-102(a)(9)(i) of the Uniform Commercial Code or Section 8-102(a)(9)(ii) of the Uniform Commercial Code, including cash, shall constitute the "express agreement" of the Trustee or such other Paying Agent, as applicable, under Section 8-102(a)(9)(iii) of the Uniform Commercial Code that such property is a financial asset under Section 8-102(a)(9)(iii) of the Uniform Commercial Code.

(iii) The funds in the Collateral Account shall be released to the Issuer in whole or in part (free and clear of any Liens established under the Collateral Agreement and any other applicable Security Document) only upon (A) the occurrence of the Second Additional Securities Triggering Event and receipt by the Trustee or other applicable Paying Agent of the Second Additional Securities Triggering Event Officers' Certificate or (B) the written consent of the Holders of a majority in principal amount of the Securities. The funds in the Collateral Account may not otherwise be withdrawn except (x) upon the occurrence and during the continuance of an Event of Default at the direction of the Holders of a majority in principal amount of the Securities as further described in Article 6, (y) to the Issuer following the discharge of this Indenture or (z) solely to be used in connection with the Issuer's (A) unconditional right to redeem the Securities in whole in accordance with Article 3 or (B) legal defeasance option or covenant defeasance option in accordance with Article 8. Funds in the Collateral Account may be invested by the Trustee or such Paying Agent in Cash Equivalents available to the Trustee or other Paying Agent, as applicable, at the written direction of the Issuer absent the occurrence and continuance of an Event of Default. Promptly following the occurrence of an Event of Default and during the continuation thereof, the Trustee or other Paying Agent, as applicable (acting as an agent for or representative of the Collateral Agent), shall direct the funds in the Collateral Account to be invested pursuant to the direction of the Holders of a majority in principal amount of the Securities that are available to the Trustee or other Paying Agent, as applicable. In the absence of written instructions, no investments shall be made using the funds in the Collateral Account.

(iv) The cash proceeds in respect of the Permitted Apomorphine Monetization in excess of the first $40,000,000 of cash proceeds from the Permitted Apomorphine Monetization (or $50,000,000 if the First Additional Securities have been issued) may be used by the Issuer for any purpose that is not prohibited by this Indenture. At any time following the Second Additional Securities Triggering Event, after any repurchase of Securities by the Issuer pursuant to Section 4.06(b), any cash proceeds in respect of the Permitted Apomorphine Monetization not used for such repurchase may be used by the Issuer for any purpose that is not prohibited by this Indenture. Notwithstanding anything to the contrary in this Indenture, all amounts received by the Issuer in the Upfront Apomorphine Monetization Payment not used to repurchase Securities in the Repurchase and the Second Apomorphine Monetization Payment shall be retained by the Issuer free and clear of this Section 4.06(c) and shall not be deposited in the Collateral Account."

ARTICLE 2

Amendment to First Supplemental Indenture

Effective as of the Supplement Effective Date, this Supplemental Indenture amends the First Supplemental Indenture as provided for herein:

Section 2.01. Amendment of Article 3. Pursuant to Section 9.02 of the Existing Indenture, the lead in of Article 3 of the First Supplemental Indenture shall be amended and restated in its entirety as follows:

"This Supplement shall be deemed to be effective on November 19, 2020, assuming each of the following conditions is satisfied as of such date (the "Supplemental Effective Date"):"

ARTICLE 3

Amendment to Notes

Effective as of the Supplement Effective Date, this Supplemental Indenture amends the Notes as provided for herein:

Section 3.01. Amendment of Section 8. Pursuant to Section 9.02 of the Existing Indenture and Section 15 of the Notes, Section 8 of the Notes shall be amended and restated in its entirety as follows:

"Upon the receipt of any cash proceeds by the Issuer in the Permitted Apomorphine Monetization (other than the Upfront Apomorphine Monetization Payment and the Second Apomorphine Monetization Payment), each Holder shall have the right, subject to certain conditions specified in the Indenture, to require the Issuer to repurchase all or any part of such Holder's then outstanding Securities at a repurchase price in cash equal to 112.5000% of the principal amount thereof, plus accrued and unpaid interest, if any, thereon to the repurchase date (subject to the right of the Holders of record on the relevant Record Date to receive interest due on the related Payment Date), as provided in, and subject to the terms of, the Indenture."

ARTICLE 4

Conditions Precedent

This Supplement shall be deemed to be effective on November 19, 2020, assuming each of the following conditions is satisfied as of such date (the "Supplemental Effective Date"):

Section 4.01. Executed Supplement. The Trustee and Collateral Agent shall have received from the Company and each Guarantor, counterparts of this Supplement signed on behalf of each of the parties hereto.

Section 4.02. Further Assurances. The Collateral Agent and Trustee shall have received such documents as the Collateral Agent and Trustee or special counsel to the Collateral Agent and Trustee may reasonably request.

Section 4.03. Representatives and Warranties. Each of the representations and warranties contained in the Purchase Agreements shall be true and correct in all material respects (except that any representation and warranty that is qualified as to "materiality" or "Material Adverse Effect" shall be true and correct in all respects) on and as of the Supplement Effective Date, except to the extent such representations and warranties expressly related to any earlier date.

Section 4.04. No Default. No Default or Event of Default has occurred and is then continuing.

ARTICLE 5

Miscellaneous Provisions

Section 5.01. Ratification of Indenture; Supplemental Indentures Part of Indenture. Except as expressly amended and supplemented hereby, the Indenture is in all respects ratified and confirmed and all the terms, conditions and provisions thereof shall remain in full force and effect. This Supplemental Indenture shall form a part of the Indenture for all purposes, and every Holder shall be bound hereby.

Section 5.02. Defined Terms. As used in this Supplemental Indenture, terms defined in the Indenture or in the preamble or recitals hereto are used herein as therein defined, except that the term "Holders" in this Supplemental Indenture shall refer to the term "Holders" as defined in the Indenture and the Trustee and the Collateral Agent acting on behalf of and for the benefit of such Holders. The words "herein", "hereof" and "hereby" and other words of similar import used in this Supplemental Indenture refer to this Supplemental Indenture as a whole and not to any particular section hereof.

Section 5.03. Counterparts. The parties may sign any number of copies of this Supplemental Indenture. Each signed copy shall be an original, but all of them together represent the same agreement. The exchange of copies of this Supplemental Indenture and of signature pages by facsimile or PDF transmission shall constitute effective execution and delivery of this Supplemental Indenture as to the parties hereto and may be used in lieu of the original Supplemental Indenture for all purposes. Signatures of the parties hereto transmitted by facsimile or PDF shall be deemed to be their original signatures for all purposes.

Section 5.04. Effect of Headings. The Section headings herein are for convenience of reference only and shall not affect the construction thereof.

Section 5.05. Effectiveness. The provisions of this Supplemental Indenture will take effect immediately upon execution thereof by the parties hereto.

Section 5.06. Governing Law. THIS SUPPLEMENTAL INDENTURE SHALL BE GOVERNED BY, AND CONSTRUED IN ACCORDANCE WITH THE LAWS OF THE STATE OF NEW YORK WITHOUT REGARD TO PRINCIPLES OF CONFLICTS OF LAW (OTHER THAN SECTIONS 5-1401 AND 5-1402 OF THE NEW YORK GENERAL OBLIGATIONS LAW).

Section 5.07. No Representation. Neither the Trustee nor the Collateral Agent makes any representation as to the validity or sufficiency of this Supplemental Indenture.

{Remainder of page intentionally left blank}

IN WITNESS WHEREOF, the parties have caused this Supplemental Indenture to be duly executed as of the date first written above.

AQUESTIVE THERAPEUTICS, INC.

By: /s/ John T. Maxwell
Name: John T. Maxwell
Title: Senior Vice President – Chief Financial Officer

Signature Page to the Second Supplemental Indenture

U.S. BANK NATIONAL ASSOCIATION,
as Trustee

By: /s/ Allison D.B. Nadeau
Name: Allison D.B. Nadeau
Title: Vice President

U.S. BANK NATIONAL ASSOCIATION,
as Collateral Agent

By: /s/ Allison D.B. Nadeau
Name: Allison D.B. Nadeau
Title: Vice President

Signature Page to the Second Supplemental Indenture

Exhibit 10.3

PURCHASE AGREEMENT

dated November 3, 2020

between

AQUESTIVE THERAPEUTICS, INC.

and

THE PURCHASER NAMED HEREIN

$4,000,000 12.5% SENIOR SECURED NOTES DUE 2025

and

UP TO AN ADDITIONAL $10,000,000 12.5% SENIOR SECURED NOTES DUE 2025

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PURCHASE AGREEMENT

November 3, 2020

To the Purchaser named in Schedule 1

Ladies and Gentlemen:

Aquestive Therapeutics, Inc., a Delaware corporation (the "Issuer"), hereby covenants and agrees with you as follows:

ARTICLE I

INTRODUCTORY

Section 1.1 Introductory. The Issuer proposes, subject to the terms and conditions stated herein, to issue to the purchaser named in Schedule 1 (the "Purchaser") and to the Other Purchasers an additional $4,000,000 in aggregate principal amount of the Issuer's 12.5% Senior Secured Notes due 2025, if applicable (the "November 2020 Notes"), up to an additional $10,000,000 in aggregate principal amount of the Issuer's 12.5% Senior Secured Notes due 2025 (the "First Additional Notes"), and up to an aggregate principal amount equal to the difference of (x) $30,000,000 *minus* (y) the aggregate principal amount of any First Additional Notes actually issued, of the Issuer's 12.5% Senior Secured Notes due 2025 (the "Second Additional Notes" and, together with the November 2020 Notes and the First Additional Notes, the "Notes"). The Issuer previously issued $70,000,000 aggregate principal amount of the 12.5% Senior Secured Notes due 2025 on July 15, 2019 (the "Existing Notes"). The principal amount of Notes to be issued to the Purchaser pursuant to this Purchase Agreement is set forth opposite the Purchaser's name in Schedule 1. [The Closing Payment owing to each Purchaser pursuant to this Purchase Agreement is set forth opposite the Purchaser's name in Schedule 1.][1] The Notes to be issued to the Purchaser and the Other Purchasers, as applicable, are to be issued on the Applicable Closing Date (as defined below) pursuant to, and subject to the terms and conditions of, the Indenture.

The Notes will be offered and sold to the Purchaser and the Other Purchasers (collectively, the "Purchasers") in transactions exempt from the registration requirements of the Securities Act.

ARTICLE II

RULES OF CONSTRUCTION AND DEFINED TERMS

Section 2.1 Rules of Construction and Defined Terms. The rules of construction set forth in Annex A shall apply to this Purchase Agreement and are hereby incorporated by reference into this Purchase Agreement as if set forth fully in this Purchase Agreement. Capitalized terms used but not otherwise defined in this Purchase Agreement shall have the respective meanings given to such terms in Annex A, which is hereby incorporated by reference into this Purchase Agreement as if set forth fully in this Purchase Agreement.

[1] Included in certain purchasers' agreements.

ARTICLE III

SALE AND PURCHASE OF NOTES; CLOSING; FIRST ADDITIONAL SECURITIES AND WARRANTS

Section 3.1 Sale and Purchase of Notes; Closing.

(a) On the basis of the representations and warranties contained in, and subject to the terms and conditions of, this Purchase Agreement and the Indenture, the Issuer will issue to the Purchaser, and the Purchaser will be issued at an issue price of 100% of the aggregate principal amount thereof, on the Closing Date, the principal amount of November 2020 Notes set forth opposite the Purchaser's name in Schedule 1.

(b) The Purchaser will receive the principal amount of November 2020 Notes set forth in Schedule 1 on the Closing Date [or the Closing Payment, as the case may be], in consideration of the Repurchase described in Section 3.2 below (if applicable) and the Purchaser's agreement to execute and deliver to the Issuer that certain written consent, substantially in the form attached hereto as Exhibit A (the "Consent"), which includes a consent to the execution and delivery of the Supplemental Indenture, and the consummation of the transactions contemplated hereby and thereby (collectively, the "Consideration"). The November 2020 Notes will be issued solely in exchange for the Consideration and the Purchasers shall be under no obligation to pay any cash consideration. Contemporaneously with entering into this Purchase Agreement, the Issuer is entering into separate purchase agreements (the "Other Agreements") with other purchasers (the "Other Purchasers"), providing for the issuance on the Closing Date to each of the Other Purchasers of the November 2020 Notes in the principal amount specified opposite its name in Schedule 1 to such Other Agreement. The Issuer shall not be obligated to deliver, and the Purchaser shall not be required to purchase, any of the November 2020 Notes except upon (i) delivery of all the Notes to be purchased by the Other Purchasers under the Purchase Agreements on the Closing Date, (ii) the execution and delivery of the Consent by all holders of the 2019 Notes, and (iii) the effectiveness of the Supplemental Indenture on the Closing Date, and in each case subject to the satisfaction or waiver of the respective terms and conditions hereunder and thereunder.

(c) On the Closing Date, simultaneously with the issuance of the November 2020 Notes, the Issuer will issue one or more Global Securities for the account of DTC, evidencing the aggregate principal amount of Notes to be acquired by all Purchasers pursuant to the Purchase Agreements as of the Closing Date.

(d) For U.S. federal income (and other applicable) tax purposes, each of the Issuer and the Purchaser acknowledge and agree that the transfer by the Issuer to the Purchaser of the November 2020 Notes pursuant to Section 3.1(b) is intended to be treated as a fee paid to the Purchaser for the Consent (the "Consent Fee") and not as consideration for the purchase of the Notes. For U.S. federal income (and other applicable) tax purposes the Issuer and the Purchaser agree to treat the Consent Fee, and shall file all tax returns, consistently with such treatment unless otherwise required by applicable law.

Section 3.2 Repurchase of 2019 Notes.

(a) [On the Closing Date, simultaneously with the issuance of the November 2020 Notes, the Issuer will redeem, by wire transfer, the aggregate principal amount of the 2019 Notes held by the Purchaser set forth opposite the Purchaser's name on Schedule 1 hereto (the "Repurchased Notes") for cash proceeds equal to 100.000% of the principal amount of the Repurchased Notes plus accrued and unpaid interest, if any, thereon to the Closing Date (the "Repurchase").][2]

Section 3.3 Additional Securities and Warrants.

(a) Following the occurrence of the First Additional Securities Triggering Event (as defined in the Indenture) on or prior to December 31, 2021 and otherwise in accordance with Section 2.01(c) of the Indenture, the Purchaser agrees, at the election of the Issuer in its sole discretion and upon at least twenty (20) Business Days' prior written notice by the Issuer to the Purchaser, to acquire the principal amount of First Additional Notes set forth opposite the Purchaser's name in Schedule 1 hereto at an issue price of 100% of the aggregate principal amount thereof (such date, the "First Additional Notes Closing Date" and, together with the Closing Date, the "Applicable Closing Date") for a cash payment on the First Additional Notes Closing Date in an amount equal to 100.000% of the principal amount of the First Additional Notes, delivered to the Issuer by wire transfer to an account designated by the Issuer not less than three (3) Business Days prior to the First Additional Notes Closing Date. The First Additional Notes shall be issued upon the terms and conditions set forth herein. If the Issuer elects to issue less than $10,000,000 of First Additional Notes, the Purchasers shall participate in such issuance on a pro rata basis (determined on the basis of the principal amount of First Additional Notes set forth opposite the Purchaser's name in Schedule 1 hereto).

(b) The Purchaser shall have the right, upon prior written notice to the Issuer, to assign its rights and obligations to purchase First Additional Notes pursuant to the terms hereof; *provided* that the Purchaser shall not be released from its funding obligations so assigned to the extent such assignee fails to fund any portion of the obligations assigned to it on the First Additional Notes Closing Date.

(c) On the First Additional Notes Closing Date, the Issuer shall certify that, as of such date, each of the representations and warranties contained in the Purchase Agreement shall be true and correct in all material respects (except that any representation and warranty that is qualified as to "materiality" or "Material Adverse Effect" shall be true and correct in all respects) on and as of the First Additional Notes Closing Date, except to the extent such representations and warranties expressly related to any earlier date in which case such representations and warranties were true and correct as of such earlier date. Purchaser shall have no obligation to purchase the First Additional Notes if a certificate certifying to the foregoing is not delivered to the Purchaser on the First Additional Notes Closing Date.

[2] Included in certain purchasers' agreements.

(d) Upon the occurrence of the Closing Date, the Issuer shall grant and issue to the Purchaser, for no additional consideration, warrants to purchase shares of common stock of the Issuer equal to the amount set forth opposite the Purchaser's name on Schedule 1 hereto (collectively, the "Warrants") at an exercise price per share of common stock equal to the volume weighted average price of a single share of the Issuer's common stock in composite trading for the principal exchange on which such securities are listed for the thirty (30) trading days ending on, but excluding, the date of issuance, and otherwise substantially in accordance with the terms of those certain common stock purchase warrants issued by the Issuer to the initial purchasers of the Original Securities (as defined in the Indenture) on July 15, 2019.

(e) If, and solely to the extent that, the initial purchasers of the Original Securities (or their permitted transferees in accordance with the terms of the Indenture) purchase the First Additional Notes in accordance with Section 2.01(c) at the request of the Company following the occurrence of the First Additional Securities Triggering Event, if the First Additional Securities Triggering Event occurs on or prior to December 31, 2021, the Issuer shall, on or before the tenth (10th) Business Day following the date of such issuance of the First Additional Notes, grant and issue to the Purchaser, for no additional consideration, warrants to purchase shares of common stock of the Issuer equal to 14.3 shares of common stock per $1,000 aggregate principal amount of First Additional Notes purchased by the initial purchasers of the Original Securities (or their permitted transferees in accordance with the terms of the Indenture), at an exercise price per share of common stock equal to the volume weighted average price of a single share of the Issuer's common stock in composite trading for the principal exchange on which such securities are listed for the thirty (30) trading days ending on, but excluding, the date of issuance, and otherwise substantially in accordance with the terms of those certain common stock purchase warrants issued by the Issuer to the initial purchasers of the Original Securities on July 15, 2019.

(f) If, and solely to the extent that, the initial purchasers of the Original Securities elect to exercise the Right of First Offer (as defined in the Indenture) and purchase the Second Additional Notes following the occurrence of the Second Additional Securities Triggering Event (as defined in the Indenture), if the Second Additional Securities Triggering Event occurs on or prior to December 31, 2021, the Issuer shall, on or before the tenth (10th) Business Day following the date of such issuance of the Second Additional Notes, grant and issue to the Purchaser, for no additional consideration, warrants to purchase shares of common stock of the Issuer equal to (i) if the First Additional Notes have not been issued, 14.3 shares of common stock per $1,000 aggregate principal amount of Second Additional Notes purchased by the initial purchasers of the Original Securities until an aggregate of $10.0 million of Second Additional Notes have been issued, and, (ii) thereafter, 28.5 shares of common stock per $1,000 aggregate principal amount of Second Additional Notes purchased by the initial purchasers of the Original Securities, in each case, at an exercise price per share of common stock equal to the volume weighted average price of a single share of the Issuer's common stock in composite trading for the principal exchange on which such securities are listed for the thirty (30) trading days ending on, but excluding, the date of issuance, and otherwise substantially in accordance with the terms of those certain common stock purchase warrants issued by the Issuer to the initial purchasers of the Original Securities on July 15, 2019. For the avoidance of doubt, if the First Additional Notes have not been issued, the warrants issued to the Purchasers in connection with the Second Additional Notes pursuant to each of clauses (f)(i) and (f)(ii) above shall be allocated to such Purchasers on a pro rata basis.

Section 3.4 [Closing Payment.

(a) On the Closing Date, the Issuer shall wire, in immediately available funds, to the Purchaser, at an account to be designated by the Purchaser, the Closing Payment in the amounts set forth opposite the Purchaser's name in Schedule I.] [3]

ARTICLE IV

REPRESENTATIONS, WARRANTIES AND AGREEMENTS OF PURCHASER

The Purchaser agrees and acknowledges that the Issuer and counsel to the Issuer may rely upon the accuracy of and performance of obligations under the representations, warranties and agreements of the Purchaser contained in this Article IV.

Section 4.1 Purchase for Investment and Restrictions on Resales. The Purchaser:

(a) acknowledges that (i) neither the offer and sale of the Notes nor the issuance of the Warrants have been nor will be registered under the Securities Act or the Laws of any U.S. state or other jurisdiction relating to securities matters and (ii) neither the Notes nor the Warrants may be offered, sold, pledged or otherwise transferred except as set forth in the Transaction Documents and the legend regarding transfers on the Notes;

(b) agrees that, if it should resell or otherwise transfer the Notes or the Warrants, in whole or in part, it will do so only pursuant to an exemption from, or in a transaction not subject to, registration under the Securities Act, the Laws of any applicable state or other jurisdiction relating to securities matters and in accordance with the restrictions and requirements of the provisions of the Transaction Documents and the legend regarding transfers on the Notes and only to a Person whom it reasonably believes, at the time any buy order for such Notes or Warrants is originated, is (i) the Issuer or a Subsidiary of the Issuer, (ii) for so long as such Notes or Warrants are eligible for resale pursuant to Rule 144A, a QIB that purchases for its own account or for the account of a QIB, to which notice is given that the transfer is being made in reliance on Rule 144A, (iii) a Person outside the United States in an offshore transaction in compliance with Rule 903 or 904 of Regulation S (if available) or (iv) an Accredited Investor that is purchasing such Notes or Warrants for its own account or for the account of such an Accredited Investor for investment purposes and not with a view to, or for offer or sale in connection with, any distribution in violation of the Securities Act, in each case unless consented to by the Issuer in writing;

(c) acknowledges and agrees that, as a condition to the transfer of any Notes or the Warrants, each transferee of such Notes or Warrants shall be deemed to have given, and may be required expressly to give, the assurances set forth in Section 4.3 as to itself;

(d) acknowledges the restrictions and requirements contained in the Transaction Documents applicable to transfers of the Notes and the Warrants and the legend regarding transfers on the Notes and agrees that it will only offer or sell the Notes and the Warrants in accordance with such restrictions and requirements; and

(e) represents that it is purchasing the Notes for investment purposes and not with a view toward resale or distribution thereof in contravention of the requirements of the Securities Act; provided, however, that the Purchaser reserves the right to resell or otherwise transfer the Notes at any time in compliance with this Section 4.1 and in accordance with its investment objectives.

[3] Included in certain purchasers' agreements.

Section 4.2 Purchaser Status. The Purchaser represents and warrants that, as of the date hereof, (a) if it is purchasing a Rule 144A Global Security or would purchase a Rule 144A Global Security except that it cannot or opts not to hold a beneficial interest in a Global Security, it is a QIB and is purchasing the Notes for its own account or for the account of a QIB, (b) if it is purchasing a Regulation S Global Security or would purchase a Regulation S Global Security except that it cannot or opts not to hold a beneficial interest in a Global Security, it is a Person outside the United States purchasing the Notes in an offshore transaction in compliance with Regulation S or (c) if neither clause (a) nor clause (b) is applicable, it is an Accredited Investor.

Section 4.3 [Reserved].

Section 4.4 Due Diligence. The Purchaser acknowledges that, prior to the date of this Purchase Agreement, (a) it has made, either alone or together with its advisors, such separate and independent investigation of the Issuer and its business, financial condition, prospects and management as the Purchaser deems to be, or such advisors have advised to be, necessary or advisable in connection with the purchase of the Notes pursuant to the transactions contemplated by this Purchase Agreement, (b) it and its advisors have received all information and data that it and such advisors believe to be necessary in order to reach an informed decision as to the advisability of the purchase of the Notes pursuant to the transactions contemplated by this Purchase Agreement, (c) it understands the nature of the potential risks and potential rewards of the purchase of the Notes, (d) it is a sophisticated investor with investment experience and has the ability to bear complete loss of its investment, whether as a result of an Event of Default on the Notes or any insolvency, liquidation or winding up of the Issuer or otherwise, and (e) it has such knowledge and experience in financial and business matters that it is capable of evaluating the merits and risks of purchasing the Notes and can bear the economic risks of investing in the Notes for an indefinite period of time, including the complete loss of its investment. The Purchaser acknowledges that it has obtained its own attorneys, business advisors and tax advisors as to legal, business and tax advice (or has decided not to obtain such advice) and has not relied in any respect on the Issuer for such advice. The Purchaser has had a reasonable time prior to the date of this Purchase Agreement to ask questions and receive answers concerning the Issuer and its business and the terms and conditions of the offering of the Notes and the transactions contemplated hereby and to obtain any additional information that the Issuer possesses or could acquire without unreasonable effort or expense, and has generally such knowledge and experience in business and financial matters and with respect to investments in securities as to enable the Purchaser to understand and evaluate the risks of such investment and form an investment decision with respect thereto. Except for (i) the representations, warranties and covenants made by the Issuer in the Transaction Documents and (ii) the legal opinions provided to the Purchaser in connection with the transactions contemplated by the Transaction Documents, the Purchaser is relying on its own investigation and analysis in entering into the transactions contemplated hereby.

Section 4.5 Enforceability of this Purchase Agreement. This Purchase Agreement has been duly authorized, executed and delivered by the Purchaser and constitutes the valid, legally binding and enforceable obligation of the Purchaser, except as enforceability may be limited by applicable bankruptcy, insolvency, reorganization, moratorium or similar Laws affecting creditors' rights generally and by general principles of equity.

Section 4.6 Tax Matters.

(a) Except as otherwise required by Law, the Purchaser agrees to treat, and shall treat, the Notes as indebtedness of the Issuer for U.S. federal income tax purposes.

(b) The Purchaser understands and acknowledges that, if Definitive Securities are issued, the Purchaser must provide the Issuer, the Trustee or any Paying Agent with the applicable U.S. federal income tax certifications (generally, on IRS Form W-9 (or successor applicable form) in the case of a Person that is a United States person (for purposes of this Section 4.6(b), within the meaning of Section 7701(a)(30) of the Code) or on an appropriate IRS Form W-8 (or successor applicable form) in the case of a Person that is not a United States person).

(c) The Purchaser represents and warrants that (i) it has not relied upon the Issuer for any tax advice or disclosure of tax consequences arising from the purchase, ownership or disposition of the Notes or the Warrants and (ii) it has relied upon its own tax counsel or advisors with respect to any tax consequences arising from the purchase, ownership or disposition of the Notes or the Warrants.

Section 4.7 Reliance for Opinions. The Purchaser acknowledges and agrees that the Issuer and, for purposes of the opinions to be delivered to the Purchaser pursuant to Section 6.1, counsel for the Issuer may rely, without any independent verification thereof, upon the accuracy of the representations and warranties of the Purchaser, and compliance by the Purchaser with its agreements, contained in Sections 4.1 and 4.2, and the Purchaser hereby consents to such reliance.

Section 4.8 2019 Notes. The Purchaser has good and marketable title to the Repurchased Notes, free and clear of all Liens or restrictions.

ARTICLE V

REPRESENTATIONS AND WARRANTIES OF THE ISSUER

The Issuer represents and warrants to the Purchaser as of the date hereof as follows:

Section 5.1 Securities Laws.

(a) No securities of the same class (within the meaning of Rule 144A(d)(3)(i) under the Securities Act) as the Notes or the Warrants have been issued and sold by the Issuer within the six-month period immediately prior to the date hereof.

(b) Assuming the accuracy of the representations and warranties of the Purchasers in each of the Purchase Agreements, neither the Issuer nor any affiliate (as defined in Rule 144 under the Securities Act) of the Issuer has directly, or through any agent, (i) sold, offered for sale, solicited offers to buy or otherwise negotiated in respect of any security (as defined in the Securities Act) that is or will be integrated with the sale of the Notes or the Warrants in a manner that would require the registration under the Securities Act of the Notes or the Warrants, (ii) engaged in any form of general solicitation or general advertising in connection with the offering of the Notes or the Warrants (as those terms are used in Regulation D under the Securities Act), or in any manner involving a public offering within the meaning of Section 4(a)(2) of the Securities Act, including publication or release of articles, notices or other communications published in any newspaper, magazine or similar medium or broadcast over television, radio or internet, or any seminar or meeting whose attendees have been invited by any general solicitation or general advertising, or (iii) engaged in any directed selling efforts within the meaning of Rule 902(c) of Regulation S.

(c) Assuming the accuracy of the representations and warranties of the Purchasers in each of the Purchase Agreements, (i) the Indenture is not required to be qualified under the U.S. Trust Indenture Act of 1939, as amended, and (ii) no registration under the Securities Act of the Notes or the Warrants is required in connection with the sale thereof to the Purchasers as contemplated by the Transaction Documents.

Section 5.2 Investment Company Act Matters. After giving effect to the offering and sale of the Notes and the issuance of the Warrants, the Issuer will not be required to register as an "investment company" or "controlled" by an "investment company" within the meaning of the U.S. Investment Company Act of 1940, as amended.

Section 5.3 Apomorphine Purchase Agreement.

(a) The Apomorphine Purchase Agreement has been duly executed and delivered by the Company and constitutes a legal, valid and binding obligation of the Company and is enforceable against the Company.

(b) Pursuant to the Apomorphine Purchase Agreement, the Company shall receive (i) an up-front purchase price of $40,000,000 received substantially concurrently with the closing of such sale and (ii) additional contingent payments of up to $85,000,000 in the aggregate due upon the attainment of certain specified royalty and commercial targets.

Section 5.4 Exchange Act Documents. The documents filed by the Issuer with the Commission pursuant to the Exchange Act since December 31, 2019 (excluding any documents or portions thereof furnished to, rather than filed with, the Commission) (such documents, the "Exchange Act Documents"), when they were filed with the Commission, conformed as to form in all material respects with the requirements of the Exchange Act, and none of such documents contained any untrue statement of a material fact or omitted to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading.

Section 5.5 Financial Statements. The financial statements included in the Exchange Act Documents, together with the related notes and schedules, present fairly in all material respects the consolidated financial position of the Issuer as of the respective dates indicated and the consolidated results of operations, cash flows and changes in shareholders' equity of the Issuer for the respective periods specified and have been prepared in all material respects in compliance with the requirements of the Exchange Act and in conformity with GAAP applied on a consistent basis during the periods covered thereby, except as may be expressly stated in the related notes thereto and, in the case of unaudited financial statements, subject to normal and recurring year-end adjustments that, if presented, would not differ materially from that included in the audited financial statements. The other financial and accounting data of the Issuer contained in the Exchange Act Documents are accurately and fairly presented and prepared on a basis consistent with the financial statements or the books and records of the Issuer in all material respects.

Section 5.6 Organization; Power; Authorization; Enforceability. The Issuer has been duly organized, is legally existing and is in good standing under the Laws of the State of Delaware. The Issuer does not have any Subsidiaries except the following Immaterial Subsidiaries: Midasol Therapeutics, GP; and Midasol Therapeutics, LP. MSRX US, LLC has had its existence as a Delaware limited liability company canceled, and such entity did not at any point have any material assets, liabilities or operations. The Issuer is duly qualified as a foreign corporation (or other equivalent entity) in all jurisdictions in which the nature of its business or location of its properties require such qualifications, except where the failure to be so qualified would not reasonably be expected to have a Material Adverse Effect. The Issuer has the requisite corporate power and authority to own, lease or operate the properties and assets it purports to own, lease or operate, to carry on its business as presently conducted and to execute, deliver and perform its obligations under each Transaction Document except where the failure to have such power and authority to own, lease or operate such properties and assets and carry on such business would not reasonably be expected to have a Material Adverse Effect. Each Transaction Document entered into as of the date hereof has been duly authorized, executed and delivered by the Issuer and constitutes the valid, legally binding and, assuming due authorization, execution and delivery by all other parties thereto, enforceable obligation of the Issuer (subject, in each case, to general equitable principles, insolvency, liquidation, reorganization and other Laws of general application relating to creditors' rights). Each Transaction Document to be entered into after the date hereof will be duly authorized, executed and delivered by the Issuer and will constitute the valid, legally binding and, assuming due authorization, execution and delivery by all other parties thereto, enforceable obligation of the Issuer (subject, in each case, to general equitable principles, insolvency, liquidation, reorganization and other Laws of general application relating to creditors' rights).

Section 5.7 Organizational Information. The Issuer's principal place of business is Warren, New Jersey. The Issuer's U.S. taxpayer identification number is 82-3827296.

Section 5.8 Common Stock. The shares of Common Stock of the Issuer to be issued upon the exercise of the Warrants have been reserved by the Issuer and, upon exercise of the Warrants in accordance with their terms, will be validly issued, fully paid and non-assessable.

Section 5.9 [Reserved].

Section 5.10 Governmental and Third Party Authorizations. No consent, approval, authorization, license, registration, qualification or order of, or filing or declaration with, any Governmental Authority, any self-regulatory organization or any other non-governmental regulatory authority (including the Nasdaq Stock Market LLC) or approval of the shareholders of the Issuer or any other Person is required in connection with (a) the execution or delivery by the Issuer of any Transaction Document or the performance of obligations by the Issuer under any Transaction Document (including the issuance and sale of the Notes and the issuance of the Warrants), (b) the transactions contemplated by the Transaction Documents, (c) the grant by the Issuer of the Liens granted or purported to be granted by it pursuant to the Security Documents or (d) the perfection of the Liens created under the Security Documents, other than (i) such consents, approvals, authorizations, licenses, registrations, qualifications, orders, filings, declarations and other actions as shall have been taken, given, made or obtained and are in full force and effect as of the Applicable Closing Date, in each case, as set forth in Schedule 5.10, (ii) any necessary filings under the securities or blue sky Laws of the various jurisdictions in which the Notes and the Warrants are being offered, (iii) the filing of financing statements under the UCC and recordings with the PTO and the filing of any other recordings (including in any applicable non-U.S. jurisdiction) required to perfect a security interest in the Notes Collateral and (iv) such consents, approvals, authorizations, licenses, registrations, qualifications, orders, filings, declarations and other actions, the failure of which to take, give, make or obtain would not reasonably be expected to have a Material Adverse Effect.

Section 5.11 No Conflicts. The execution, delivery and performance of each Transaction Document by the Issuer, the issuance and sale of the Notes, the issuance of the Warrants and the consummation of the transactions contemplated by the Transaction Documents will not conflict with, result in any breach or violation of or constitute a default under (nor constitute any event that, with notice, lapse of time or both, would result in any breach or violation of, constitute a default under or give the holder of any indebtedness (or a Person acting on such holder's behalf) the right to require the repurchase, redemption or repayment of all or a part of such indebtedness under) (or result in the creation or imposition of a Lien on any property or assets of the Issuer pursuant to) (a) the certificate of incorporation or bylaws of the Issuer, (b) any indenture, mortgage, deed of trust, bank loan, credit agreement, other evidence of indebtedness, license, lease, contract or other agreement or instrument to which the Issuer is a party or by which it or its properties may be bound or affected, (c) any Law or (d) any rule or regulation of any self-regulatory organization or other non-governmental regulatory authority (including the rules and regulations of the Nasdaq Stock Market LLC), except, in the case of clause (b), (c) or (d), where such conflict, breach, violation, default, event, right or Lien would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect.

Section 5.12 No Violation or Default. The Issuer is not in breach or violation of or in default under (nor has any event occurred that, with notice, lapse of time or both, would result in any breach or violation of, constitute a default under or give the holder of any indebtedness (or a Person acting on such holder's behalf) the right to require the repurchase, redemption or repayment of all or a part of such indebtedness under) (a) its certificate of incorporation or bylaws, (b) any indenture, mortgage, deed of trust, bank loan, credit agreement, other evidence of indebtedness, license, lease, contract or other agreement or instrument to which it is a party or by which it or any of its properties may be bound or affected, (c) any Law or (d) any rule or regulation of any self-regulatory organization or other non-governmental regulatory authority (including the rules and regulations of the Nasdaq Stock Market LLC), except, in the case of clause (b), (c) or (d), where such breach, violation, default, event or right would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect. On the Applicable Closing Date, no Event of Default on the Notes exists.

Section 5.13 No Material Adverse Change. Except as disclosed in the Exchange Act Documents, subsequent to the respective dates as of which information is given in the Exchange Act Documents, (a) there has not been any material change in the Capital Stock or long-term debt of the Issuer or any material adverse change, or any development that would be expected to result in a material adverse change, in or affecting the business, condition (financial or otherwise), results of operations, earnings, properties or prospects of the Issuer and its Subsidiaries taken as a whole, (b) the Issuer has not incurred any material liabilities or obligations, direct or contingent, nor has it entered into any material transactions not in the ordinary course of business, other than pursuant to the Transaction Documents and the transactions referred to herein and therein, (c) the Issuer has not and will not have paid or declared any dividends or other distributions of any kind on any class of its Capital Stock, (d) the Issuer 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 Governmental Authority and (e) the Issuer has not altered its method of accounting.

Section 5.14 Compliance with ERISA. The Issuer has not maintained or contributed to a defined benefit plan as defined in Section 3(35) of ERISA. No plan maintained or contributed to by the Issuer 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 Code that could subject the Issuer 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 that 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 (a) a determination letter has been issued by the IRS stating that such ERISA Plan and the attendant trust are qualified thereunder or (b) 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 Issuer has never completely or partially withdrawn from a "multiemployer plan", as defined in Section 3(37) of ERISA.

Section 5.15 Tax Matters. The Issuer has filed all income and franchise tax returns and all other material tax returns required to be filed by it and has paid all taxes required to be paid by it and, if due and payable, any related or similar assessment, fine or penalty levied against it (except for any such taxes, assessments, fines or penalties currently being contested in good faith and for which adequate reserves in accordance with GAAP are being maintained or in any case in which the failure to file or pay, individually or collectively, would not reasonably be expected to have a Material Adverse Effect). The Issuer has made adequate charges, accruals and reserves in the applicable financial statements referred to in Section 5.5 in respect of all material federal, state and foreign income and franchise taxes for all periods as to which the tax liability of the Issuer has not been finally determined. The Issuer is not aware of any material claims against it by any taxing authority in relation to the filing of tax returns or the payment of required taxes, assessments, fines or penalties.

Section 5.16 Legal Proceedings. Except as disclosed in the Exchange Act Documents, there are no actions, suits or proceedings pending or, to the Issuer's knowledge, threatened against or affecting, the Issuer or any of its officers in their capacity as such before or by any Governmental Authority or the Financial Industry Regulatory Authority, Inc. or the Nasdaq Stock Market LLC, wherein an unfavorable ruling, decision or finding could reasonably be expected to result in a Material Adverse Effect. Except as set forth in the Exchange Act Documents, the Issuer 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 Issuer involving the Issuer by any Governmental Authority having jurisdiction over the Issuer or its business or operations that would reasonably be expected to result in a Material Adverse Effect.

Section 5.17 Solvency. No step has been taken or is currently intended by the Issuer or, to the knowledge of the Issuer, any other Person for the winding-up, liquidation, dissolution or administration or for the appointment of a receiver or administrator of the Issuer for all or any of its properties or assets. Immediately after the issuance and sale of the Notes and the consummation of the other transactions contemplated by the Transaction Documents on the Applicable Closing Date, the Issuer will not be rendered insolvent within the meaning of 11 U.S.C. 101(32) or any other applicable insolvency Laws or, taken as a whole, be unable to pay its debts as they mature.

Section 5.18 Existing Indebtedness. The Exchange Act Documents disclose all of the following types of material third-party outstanding indebtedness of the Issuer as of the Applicable Closing Date: (a) indebtedness in respect of borrowed money; (b) any other obligation of the Issuer to be liable for, or to pay, as obligor, guarantor or otherwise, on the indebtedness for borrowed money of another Person (other than by endorsement of negotiable instruments for collection in the ordinary course of business); and (c) to the extent not otherwise included, indebtedness for borrowed money of another Person secured by a Lien on any asset owned by such Person (whether or not such indebtedness for borrowed money is assumed by such Person).

Section 5.19 Material Contracts. There is no document or agreement of a character required to be described in the Exchange Act Documents or to be filed as an exhibit to the Exchange Act Documents that is not described or filed as required. All Material Contracts are in full force and effect and constitute the valid, legally binding and (subject to general equitable principles and insolvency, liquidation, reorganization and other Laws of general application relating to creditors' rights) enforceable obligation of the Issuer and, to the knowledge of the Issuer, all other parties thereto, except in each case as would not reasonably be expected to have a Material Adverse Effect. To the knowledge of the Issuer, there are no oral waivers or modifications (or pending requests therefor) in respect of any Material Contract except as would not reasonably be expected to have a Material Adverse Effect. The Issuer is not in breach or default under or with respect to any Material Contract binding on it except where such breaches or defaults would not reasonably be expected to have a Material Adverse Effect. To the knowledge of the Issuer, no other Person party to any Material Contract is in default thereunder except where such default would not reasonably be expected to have a Material Adverse Effect. To the knowledge of the Issuer, no party to any Material Contract has given any notice of termination or breach of any Material Contract.

Section 5.20 Properties. The Issuer has good and marketable title to all properties and assets described in the Exchange Act Documents as being owned by it, free and clear of all Liens or restrictions other than Permitted Liens and the Liens created by the Security Documents, except as set forth in the Exchange Act Documents or those where the failure to have such title would not, individually or in the aggregate, have a Material Adverse Effect. To the knowledge of the Issuer, the Issuer has valid, subsisting and (subject to general equitable principles and insolvency, liquidation, reorganization and other Laws of general application relating to creditors' rights) enforceable leases for the properties described in the Exchange Act Documents 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 Issuer.

Section 5.21 Intellectual Property.

(a) Except as disclosed in the Exchange Act Documents, the Issuer owns, has valid and enforceable licenses for or otherwise has adequate rights to use all technology (including 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 material to its business as currently conducted or as proposed to be conducted, including the development, manufacture, operation and sale of any of the Issuer's products or product candidates, as described in the Exchange Act Documents, 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 Exchange Act Documents, the Intellectual Property of the Issuer has not been adjudged by a Governmental Authority 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 Exchange Act Documents: (i) to the knowledge of the Issuer, there are no third parties who have, or will be able to establish, rights to any Intellectual Property owned by or licensed to the Issuer, except for, and to the extent of, the rights of any third parties that are licensors or licensees of such Intellectual Property as set forth in Schedule 5.21; (ii) to the Issuer's knowledge, there is no infringement, misappropriation or other violation by third parties of any Intellectual Property owned by, or licensed to, the Issuer; (iii) there is no pending or, to the knowledge of the Issuer, threatened action, suit, proceeding or claim by others against the Issuer challenging the Issuer's rights in or to any Intellectual Property owned by, or licensed to, the Issuer, and the Issuer is unaware of any facts that could form a reasonable basis for any such action, suit, proceeding or claim; (iv) there is no pending or, to the knowledge of the Issuer, threatened action, suit, proceeding or claim by others against the Issuer challenging the validity, enforceability or scope of any Intellectual Property owned by, or licensed to, the Issuer, and the Issuer is unaware of any facts that could form a reasonable basis for any such action, suit, proceeding or claim; (v) there is no pending or, to the knowledge of the Issuer, threatened action, suit, proceeding or claim by others against the Issuer that (nor has the Issuer received any written claim from a third party that) the Issuer infringed, misappropriated or otherwise violated, or is infringing, misappropriating or otherwise violating, any intellectual property rights of others, and the Issuer is unaware of any facts that could form a reasonable basis for any such action, suit, proceeding or claim; and (vi) the Issuer has complied with and there has been no breach or default by the Issuer under the terms of each agreement pursuant to which Intellectual Property has been licensed to the Issuer, and all such agreements are in full force and effect, except, in each case of clauses (i) through (vi), as would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect. Except as set forth in the Exchange Act Documents, the Issuer 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 in connection with the conduct of its business or otherwise. No Immaterial Subsidiary owns or licenses any material Intellectual Property.

(b) The Issuer 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 Exchange Act Documents, 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 Issuer 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 Issuer's knowledge, the use of such trademarks and trade names in connection with the business and operations of the Issuer does not materially infringe on the rights of any Person. Except as set forth in the Exchange Act Documents, the Issuer 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 in connection with the conduct of its business or otherwise.

(c) The Issuer has taken reasonable security measures to protect the secrecy, confidentiality and value of all its Intellectual Property in all material aspects, including complying with all material duty of disclosure requirements before the PTO and any other non-U.S. patent offices, as appropriate.

(d) Schedule 5.21 contains a complete list of (i) all registered trademarks, copyrights and Patents that are owned by the Issuer, in each case that are reasonably necessary for the operation of the business of the Issuer as presently conducted, and (ii) all Patent license agreements granting exclusive rights to the Issuer to such licensed Patents.

(e) The Issuer is the owner or holder of each new drug application or abbreviated new drug application set forth opposite its name in Schedule 5.21. Except as set forth in Schedule 5.21, the Issuer has not granted, assigned or licensed to any Person, directly or indirectly, any rights under any such new drug application or abbreviated new drug application. Schedule 5.21 sets forth the product that pertains to each such new drug application and abbreviated new drug application (and whether or not approval of any such drug application has been granted in any jurisdiction, and, if so, in which jurisdictions such approvals have been granted).

Section 5.22 Environmental Matters. Except in each case as would not individually or in the aggregate reasonably be expected to result in a Material Adverse Effect, (a) the Issuer is and has been in compliance with, and is not subject to any pending or, to the knowledge of the Issuer, threatened costs or liability under, any and all applicable Laws (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 Issuer, no facts or circumstances currently exist that would reasonably be expected to result in such non-compliance, cost or liability, (b) to the knowledge of the Issuer, the Issuer does not own, occupy, operate, lease or use any real property contaminated with Hazardous Substances in violation of Environmental Laws and that would reasonably be expected to result in the Issuer incurring any liability, (c) the Issuer is not conducting or funding any investigation, remediation, remedial action or monitoring of actual or suspected Hazardous Substances in the environment, (d) to the knowledge of the Issuer, the Issuer 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, (e) the Issuer is not subject to any written claim, action, suit, order, demand or notice by any Governmental Authority or Person alleging liability or violation relating to Environmental Laws or Hazardous Substances, (f) the Issuer 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 (g) to the knowledge of the Issuer, there are no new requirements applicable to the conduct of the Issuer's business, as currently conducted, proposed for adoption or implementation under any Environmental Law. Except as set forth in the Exchange Act Documents, there are no judicial or administrative proceedings that are pending, or known to be contemplated, against the Issuer 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. Except as set forth in the Exchange Act Documents, the Issuer 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 Issuer.

Section 5.23 Labor Matters. The Issuer 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 Issuer, is any such dispute threatened. The Issuer is currently in compliance with all applicable Laws relating to employment and labor, including those related to wages, hours, collective bargaining and the payment and withholding of Taxes.

Section 5.24 Insurance. The Issuer carries, or is covered by, insurance in such amounts and covering such risks as the Issuer 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 Issuer has no reason to believe that it will not be able to (a) renew its existing insurance coverage as and when such policies expire or (b) obtain comparable coverage from similar institutions as may be necessary or appropriate to conduct its 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 Issuer has not been denied any insurance coverage that it has sought or for which it has applied.

Section 5.25 No Unlawful Payments. None of the Issuer, any of its directors or officers or, to the Issuer's knowledge, any agent, employee or representative of the Issuer or its Affiliates or other Person associated with or acting on behalf of the Issuer has (a) used any corporate funds for any unlawful contribution, gift, entertainment or other unlawful expense relating to political activity, (b) 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 government or regulatory official or employee, including 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, (c) taken any action, directly or indirectly, that would result in a violation of any provision of the FCPA, the U.K. Bribery Act 2010, or any applicable Law 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 (d) made, offered, agreed to, requested or taken an act in furtherance of any unlawful bribe or other unlawful benefit, including any rebate, payoff, influence payment, kickback or other unlawful or improper payment or benefit. The Issuer and, to the knowledge of the Issuer, 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.

Section 5.26 Compliance with Anti-Money Laundering Laws. The operations of the Issuer 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 Laws of all jurisdictions in which the Issuer conducts business (collectively, the "Anti-Money Laundering Laws"), and no action, suit or proceeding by or before any Governmental Authority involving the Issuer with respect to the Anti-Money Laundering Laws is pending or, to the knowledge of the Issuer, threatened.

Section 5.27 Sanctions. None of the Issuer or any director or officer of the Issuer or, to the knowledge of the Issuer, any agent, employee or representative of the Issuer or any Affiliate or other Person associated with or acting on behalf of the Issuer is currently the subject or target of any sanctions administered or enforced by the U.S. government (including the Office of Foreign Assets Control of the U.S. Treasury Department or the U.S. Department of State and including 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 Issuer located, organized or resident in a country or territory that is the subject or the target of Sanctions, including Cuba, Iran, North Korea, the Crimean region and Syria (each, a "Sanctioned Country"). The Issuer will not directly or indirectly use the proceeds of the offering of the Notes, or lend, contribute or otherwise make available such proceeds to any Subsidiary, joint venture partner or other Person, (a) 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, (b) to fund or facilitate any activities of or business in any Sanctioned Country or (c) in any other manner that will result in a violation by any Person (including any Person participating in the transaction contemplated hereby, whether as underwriter, advisor, investor or otherwise) of Sanctions. For the past five years, the Issuer 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.

Section 5.28 Disclosure Controls. The Issuer 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 Issuer is made known to the Issuer's principal executive officer and principal financial officer by others within the Issuer, 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 Issuer'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.

Section 5.29 Accounting Controls.

(a) The Issuer maintains a system of internal accounting controls sufficient to provide reasonable assurance that (i) transactions are executed in accordance with management's general or specific authorizations, (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with GAAP and to maintain asset accountability, (iii) access to assets is permitted only in accordance with management's general or specific authorization and (iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences.

(b) Since the end of the Issuer's most recent audited fiscal year, there has been (i) no material weakness (as defined in Rule 1-02 of Regulation S-X of the Commission) in the Issuer's internal control over financial reporting (whether or not remediated) and (ii) no change in the Issuer's internal control over financial reporting that has materially affected, or is reasonably likely to materially affect, the Issuer's internal control over financial reporting. The Issuer is not aware of (x) any significant deficiency in the design or operation of its internal control over financial reporting that is reasonably likely to adversely affect the Issuer's ability to record, process, summarize and report financial data or any material weaknesses in its internal controls, except as disclosed in the Exchange Act Documents, since the end of the Issuer'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 Issuer's internal controls.

Section 5.30 Licenses and Permits. Except as would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect, (a) the Issuer holds, and is operating in compliance with, such permits, licenses, franchises, registrations, exemptions, approvals, authorizations and clearances of any Governmental Authorities (including 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 (b) the Issuer has fulfilled and performed all of its obligations with respect to the Permits, and, to the Issuer's knowledge, no event has occurred that 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, other than, in each case, the Permits set forth in Schedule 5.30. 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 Issuer, its business and its products, when submitted to the FDA or other Governmental Authority by or on behalf of the Issuer, were true, complete and correct in all material respects. Any necessary or required updates, changes, corrections or modifications to such applications, notifications, submissions, information, claims, reports and statistics and other data have been submitted to the FDA or other Governmental Authority, other than, in each case, the Permits set forth in Schedule 5.30. The Issuer has not received any written notification, correspondence or other written communication, including notification of any pending or, to the Issuer's knowledge, threatened claim, suit, proceeding, hearing, enforcement, investigation, arbitration or other action, from any Governmental Authority, including the FDA or the DEA, of potential or actual non-compliance by, or liability of, the Issuer under any Permits except as would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect. To the Issuer's knowledge, no facts or circumstances currently exist that would reasonably be expected to give rise to any liability of the Issuer under any Permits except as would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

Section 5.31 Clinical Trials. The pre-clinical studies and clinical trials conducted by or, to the knowledge of the Issuer, on behalf of or sponsored by the Issuer, or in which the Issuer has participated, that are described in, or the results of which are referred to in, the Exchange Act Documents 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 Laws (including those of 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 such pre-clinical studies and clinical trials in such manner would not have a Material Adverse Effect. Each description of the results of such studies and trials contained in the Exchange Act Documents is accurate and complete in all material respects and fairly presents the data derived from such studies and trials, and the Issuer 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 Exchange Act Documents. The Issuer 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 non-U.S. government or drug or medical device regulatory agency (collectively, the "Regulatory Agencies") requiring or, to the Issuer's knowledge, threatening the termination, suspension or modification of any clinical trials that are described or referred to in the Exchange Act Documents. The Issuer has operated at all times and currently is in compliance with all applicable Laws 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.

Section 5.32 Regulatory Filings. The Issuer 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 Exchange Act Documents or any other material filing required by any other applicable Regulatory Agency or other 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). 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.

Section 5.33 Compliance with Certain Regulatory Matters. The Issuer, its directors and officers and, to the Issuer's knowledge, its employees and agents have operated and currently are in compliance in all material respects with applicable Laws administered or enforced by the FDA, the DEA or any other Governmental Authority, including the Food, Drug and Cosmetic Act (21 U.S.C. § 301 et seq.), the Anti-kickback Statute (42 U.S.C. § 1320a-7b(b)), the civil False Claims Act (31 U.S.C. §3729 et seq.), the 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 18 U.S.C. §§ 286 and 287, the exclusions law (42 U.S.C. § 1320a-7), the Laws 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, and 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.). The Issuer 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 Issuer nor, to the knowledge of the Issuer, any of its directors, officers, employees or agents has been debarred, excluded or suspended from participation in or receiving payment from any U.S. 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.

Section 5.34 Absence of Certain Regulatory Actions. Except as described in the Exchange Act Documents or as would not, individually or in the aggregate, have a Material Adverse Effect, the Issuer has not (a) had any product or manufacturing site (whether Issuer-owned or that of a contract manufacturer for Issuer products or product candidates) subject to a Governmental Authority (including the FDA) shutdown or import or export prohibition or (b) received any FDA Form 483 or other Governmental Authority notice of inspectional observations, "warning letters", "untitled letters", requests to make changes to the Issuer 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 Issuer's knowledge, neither the FDA nor any other Governmental Authority has threatened such action. The Issuer has not received written notice of any claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action from any Regulatory Agency or other Governmental Authority alleging that any product operation or activity is in violation of any health care Laws, and, to the Issuer's knowledge, no such claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action is threatened, except where such claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action would not reasonably be expected, individually or in the aggregate, to result in a Material Adverse Effect.

Section 5.35 Collateral Agreement. The representations and warranties of the Issuer in Article III of that certain collateral agreement, dated July 15, 2019, among the Issuer, the other subsidiary parties from time to time party thereto, the Trustee and the Collateral Agent are true and correct in all material respects (except to the extent qualified by materiality, in which case such representation or warranty shall be true and correct in all respects).

ARTICLE VI

CONDITIONS TO CLOSING

The obligations of the Purchaser hereunder on the Applicable Closing Date are subject to the accuracy in all material respects (except for such representations qualified by materiality or Material Adverse Effect, which shall be accurate in all respects) of the representations and warranties of the Issuer contained herein as of the Applicable Closing Date, to the accuracy of the statements of the Issuer and its officers made in any certificates delivered pursuant hereto on the Applicable Closing Date, to the performance by the Issuer of its obligations hereunder as of the Applicable Closing Date and to the satisfaction or waiver by the Purchaser of each of the following additional terms and conditions applicable on the Applicable Closing Date:

Section 6.1 Issuer's Counsel Opinion. Dechert LLP, counsel to the Issuer, shall have furnished to the Purchasers their opinion, addressed to the Purchasers and dated the Applicable Closing Date, in form and substance reasonably satisfactory to the Purchasers.

Section 6.2 Supplemental Indenture. The Issuer shall have furnished to the Purchasers an executed copy of the Supplemental Indenture by and among the Issuer, the other subsidiary parties from time to time party thereto, the Trustee and the Collateral Agent.

Section 6.3 Certification as to Purchase Agreement. The Issuer shall have furnished to the Purchasers a certificate, dated the Applicable Closing Date, of a Responsible Officer, stating that, as of the Applicable Closing Date, the representations and warranties of the Issuer in this Purchase Agreement are true and correct in all material respects (except for such representations qualified by materiality or Material Adverse Effect, which are true and correct in all respects) and the Issuer has complied in all material respects with all of the agreements and satisfied all of the conditions on its part to be performed or satisfied hereunder on or before the Applicable Closing Date.

Section 6.4 Authorizations. The Issuer shall have furnished to the Purchasers (a) a copy of the resolutions, consents or other documents, certified by a Responsible Officer of the Issuer, as of the Applicable Closing Date, duly authorizing the execution and delivery of, and performance of obligations under, the Transaction Documents and any other documents to be executed on or prior to the Applicable Closing Date by or on behalf of the Issuer in connection with the transactions contemplated hereby and thereby, the issuance and sale of the Notes and the issuance of the Warrants, and a certification that such resolutions, consents or other documents have not been modified, rescinded or amended and are in full force and effect, (b) certified copies of its organizational documents, (c) a certification by a Responsible Officer, as of the Applicable Closing Date, as to the incumbency and specimen signatures of each officer executing any Transaction Document or any other document delivered in connection herewith or therewith on behalf of the Issuer (together with a certification of another Responsible Officer as to incumbency and specimen signature of the first-mentioned Responsible Officer) and (d) a certificate of good standing of the Issuer as of a recent date from the Secretary of State of the State of Delaware.

Section 6.5 [Reserved].

Section 6.6 [Reserved].

Section 6.7 Further Information. On or prior to the Applicable Closing Date, the Issuer shall have furnished to the Purchaser such further information, certificates and documents as the Purchaser may reasonably request in connection with this Purchase Agreement and the other Transaction Documents and the transactions contemplated hereby and thereby.

Section 6.8 Consummation of Transactions. All of the transactions contemplated by the Transaction Documents to be completed on or before the Applicable Closing Date shall have been consummated or shall be consummated concurrently with the transactions contemplated hereby, and the Purchaser shall have received executed copies of the Transaction Documents (which shall be in full force and effect).

Section 6.9 No Actions. No action shall have been taken and no Law shall have been enacted, adopted or issued by any Governmental Authority that would, as of the Closing Date, prevent the issuance or sale of the Notes, and no injunction, restraining order or order of any other nature by any Governmental Authority of competent jurisdiction shall have been issued as of the Closing Date that would prevent the issuance or sale of the Notes.

Section 6.10 Consents. The Purchasers shall have received copies of all consents, approvals, authorizations, orders, registrations and qualifications set forth in Schedule 5.10, if any.

ARTICLE VII

ADDITIONAL COVENANTS

Section 7.1 DTC. The Issuer will use reasonable best efforts to comply with the agreements set forth in the representation letter of the Issuer to DTC relating to the approval of the Notes by DTC for "book-entry" transfer.

Section 7.2 Expenses. The Issuer agrees to pay or cause to be paid all reasonable, documented fees and expenses of Proskauer Rose LLP, acting as special counsel to the Purchasers (the amount of any such payment of the reasonable, documented fees and expenses of Proskauer Rose LLP (excluding such fees and expenses related to intellectual property work and opinions) not to exceed in the aggregate $100,000, it being understood that the Issuer will not reimburse any other expenses of any Purchasers (including expenses of any other counsel).

Section 7.3 Confidentiality; Public Announcement.

(a) Except as otherwise required by Law or judicial or administrative proceedings (by oral questions, interrogatories, requests for information or documents, subpoena, civil investigation demand or similar process) or the rules and regulations of any securities exchange or trading system or any Governmental Authority or pursuant to requests from regulatory agencies having oversight over the Issuer and except as otherwise set forth in this Section 7.3, the Issuer will, and will cause each of its Affiliates, directors, officers, employees, agents, representatives and similarly situated Persons who receive such information to, treat and hold as confidential and not disclose to any Person any and all Confidential Information furnished to it by the Purchaser, as well as the information in Schedule 1, and to use any such Confidential Information and other information only in connection with this Purchase Agreement and any other Transaction Document and the transactions contemplated hereby and thereby. Notwithstanding the foregoing, the Issuer may disclose such information solely on a need-to-know basis and solely to its directors, employees, officers, agents, brokers, advisors, lawyers, bankers, trustees, representatives, investors, co-investors, insurers, insurance brokers, underwriters and financing parties; provided, however, that such Persons shall be informed of the confidential nature of such information and shall be obligated to keep such Confidential Information and other information confidential pursuant to obligations of confidentiality no less onerous than those set forth herein.

(b) The Purchaser acknowledges that it will not, after the execution of this Purchase Agreement, make a public announcement or filing with respect to the transactions contemplated by the Transaction Documents or reference or describe such transactions in a public announcement or filing, without the Issuer's prior written consent (such consent not to be unreasonably withheld, delayed or conditioned). Except as required by applicable Law or judicial or administrative proceedings (by oral questions, interrogatories, requests for information or documents, subpoena, civil investigation demand or similar process) or the rules and regulations of any securities exchange or trading system or any Governmental Authority or pursuant to requests from regulatory agencies having oversight over the Issuer, in no event shall the Purchaser's name (in any variation) be used in any public announcement or filing, or in any type of mail or electronic distribution intended for an audience that is not solely limited to the Affiliates of the Issuer, without the Purchaser's written consent.

(c) Except as required by applicable Law or judicial or administrative proceedings (by oral questions, interrogatories, requests for information or documents, subpoena, civil investigation demand or similar process) or the rules and regulations of any securities exchange or trading system or any Governmental Authority or pursuant to requests from regulatory agencies having oversight over the Issuer, neither the Issuer nor any of its Affiliates shall disclose to any Person, or use or include in any public announcement or any public filing, the identity of any shareholders, members, directors or Affiliates of the Purchaser, without the prior written consent of such shareholder, member, director or Affiliate.

ARTICLE VIII

SURVIVAL OF CERTAIN PROVISIONS

Section 8.1 Survival of Certain Provisions. The representations, warranties, covenants and agreements contained in this Purchase Agreement shall survive (a) the execution and delivery of this Purchase Agreement, the Notes and the Warrant and (b) the sale or transfer by any Purchaser of any Note or any Warrant or portion thereof or interest therein. All such provisions are binding upon and may be relied upon by any subsequent holder or beneficial owner of a Note or a Warrant, regardless of any investigation made at any time by or on behalf of any Purchaser or any other holder or beneficial owner of a Note or a Warrant. All statements contained in any certificate or other instrument delivered by or on behalf of either party hereto pursuant to this Purchase Agreement shall be deemed to have been relied upon by the other party hereto and shall survive the consummation of the transactions contemplated hereby regardless of any investigation made by or on behalf of either such party. The Transaction Documents embody the entire agreement and understanding between the parties hereto and supersede all prior agreements and understandings relating to the subject matter hereof. Notwithstanding anything to the contrary elsewhere in this Purchase Agreement, neither party hereto shall, in any event, be liable to any other Person for any consequential, incidental, indirect, special or punitive damages of such other Person, including loss of revenue, income or profits, diminution of value or loss of business reputation or opportunity relating to the breach or alleged breach hereof (provided, that such limitation with respect to lost profits or otherwise shall not limit the Issuer's right to recover contract damages in connection with the Purchaser's failure to close in violation of this Purchase Agreement).

ARTICLE IX

NOTICES

Section 9.1 Notices

. All statements, requests, notices and agreements hereunder shall be in writing and delivered by hand, mail, overnight courier or telefax as follows:

(a) if to the Purchaser, in accordance with Schedule 1; and

(b) if to the Issuer, in accordance with Section 12.01 of the Indenture.

ARTICLE X

SUCCESSORS AND ASSIGNS

Section 10.1 Successors and Assigns. This Purchase Agreement will inure to the benefit of and be binding upon the parties hereto and their respective successors, permitted assignees and permitted transferees. So long as any of the Notes or the Warrant are outstanding, the Issuer may not assign any of its rights or obligations hereunder or any interest herein without the prior written consent of the Purchaser except as permitted in accordance with the Indenture and the Warrant, as applicable.

ARTICLE XI

SEVERABILITY

Section 11.1 Severability. Any provision of this Purchase Agreement that is prohibited or unenforceable in any jurisdiction shall, as to such jurisdiction, be ineffective to the extent of such prohibition or unenforceability without invalidating the remaining provisions hereof, and any such prohibition or unenforceability in any jurisdiction shall (to the full extent permitted by Law) not invalidate or render unenforceable such provision in any other jurisdiction.

ARTICLE XII

WAIVER OF JURY TRIAL

Section 12.1 WAIVER OF JURY TRIAL. THE PURCHASER AND THE ISSUER HEREBY WAIVE TRIAL BY JURY IN ANY ACTION BROUGHT ON OR WITH RESPECT TO THIS PURCHASE AGREEMENT.

ARTICLE XIII

GOVERNING LAW; CONSENT TO JURISDICTION

Section 13.1 Governing Law; Consent to Jurisdiction. THIS PURCHASE AGREEMENT SHALL BE GOVERNED BY AND CONSTRUED IN ACCORDANCE WITH THE INTERNAL SUBSTANTIVE LAWS OF THE STATE OF NEW YORK WITHOUT REFERENCE TO THE RULES THEREOF RELATING TO CONFLICTS OF LAW OTHER THAN SECTION 5-1401 OF THE GENERAL OBLIGATIONS LAW OF THE STATE OF NEW YORK, AND THE OBLIGATIONS, RIGHTS AND REMEDIES OF THE PARTIES HEREUNDER SHALL BE DETERMINED IN ACCORDANCE WITH SUCH LAWS. The parties hereto hereby submit to the non-exclusive jurisdiction of the U.S. federal and state courts of competent jurisdiction in the Borough of Manhattan in The City of New York in any suit or proceeding arising out of or relating to this Purchase Agreement or the transactions contemplated hereby.

ARTICLE XIV

COUNTERPARTS

Section 14.1 Counterparts. This Purchase Agreement may be executed in any number of counterparts, each of which shall be deemed to be an original, but all such counterparts shall together constitute one and the same Purchase Agreement. Any counterpart may be executed by facsimile or other electronic transmission, and such facsimile or other electronic transmission shall be deemed an original.

ARTICLE XV

TABLE OF CONTENTS AND HEADINGS

Section 15.1 Table of Contents and Headings. The Table of Contents and headings of the Articles and Sections of this Purchase Agreement have been inserted for convenience of reference only, are not to be considered a part hereof and shall in no way modify or restrict any of the terms or provisions hereof.

ARTICLE XVI

TAX DISCLOSURE

Section 16.1 Tax Disclosure. Notwithstanding anything expressed or implied to the contrary herein, the Purchaser, on the one hand, and the Issuer, on the other hand, and its respective employees, representatives and agents may disclose to any and all Persons, without limitation of any kind, the tax treatment and the tax structure of the transactions contemplated by this Purchase Agreement and the agreements and instruments referred to herein and all materials of any kind (including opinions or other tax analyses) that are provided to such Person relating to such tax treatment and tax structure; provided, however, that neither such Person nor any employee, representative or other agent thereof shall disclose any other information that is not relevant to understanding the tax treatment and tax structure of such transactions (including the identity of any party and any information that could lead another to determine the identity of any party) or any other information to the extent that such disclosure could reasonably result in a violation of any Law relating to U.S. federal or state securities matters. For these purposes, the tax treatment of the transactions contemplated by this Purchase Agreement and the agreements and instruments referred to herein means the purported or claimed U.S. federal or state tax treatment of such transactions. Moreover, the tax structure of the transactions contemplated by this Purchase Agreement and the agreements and instruments referred to herein includes any fact that may be relevant to understanding the purported or claimed U.S. federal or state tax treatment of such transactions.

{SIGNATURE PAGE FOLLOWS}

If the foregoing is in accordance with your understanding of this Purchase Agreement, kindly sign and return to us one of the counterparts hereof, whereupon it will become a binding agreement between us and you in accordance with its terms.

Very truly yours,
AQUESTIVE THERAPEUTICS, INC.

By: _____
Name:
Title:

{*Signature Page to the Purchase Agreement*}

[PURCHASER SIGNATURE PAGE]

{*Signature Page to the Purchase Agreement*}

ANNEX A

RULES OF CONSTRUCTION AND DEFINED TERMS

Unless the context otherwise requires, in this Annex A and each Transaction Document (or other document) to which this Annex A is attached:

(a) A term has the meaning assigned to it and an accounting term not otherwise defined has the meaning assigned to it in accordance with GAAP, unless any Transaction Document (or other document) otherwise provides.

(b) Where any payment is to be made, any funds are to be applied or any calculation is to be made under any Transaction Document (or other document) on a day that is not a Business Day, unless any Transaction Document (or other document) otherwise provides, such payment shall be made, such funds shall be applied and such calculation shall be made on the succeeding Business Day, and payments shall be adjusted accordingly, including interest unless otherwise specified.

(c) Words of the masculine, feminine or neuter gender shall mean and include the correlative words of other genders.

(d) The definitions of terms shall apply equally to the singular and plural forms of the terms defined.

(e) The terms “include”, “including” and similar terms shall be construed as if followed by the phrase “without limitation”.

(f) Unless otherwise specified, references to an agreement or other document include references to such agreement or document as from time to time amended, restated, reformed, supplemented or otherwise modified in accordance with the terms thereof (subject to any restrictions on such amendments, restatements, reformations, supplements or modifications set forth in this Annex A or any Transaction Document (or other document)) and include any Annexes, Exhibits and Schedules attached thereto.

(g) References to any Law shall include such Law as from time to time in effect, including any amendment, modification, codification, replacement or reenactment thereof or any substitution therefor.

(h) References to any Person shall be construed to include such Person’s successors and permitted assigns (subject to any restrictions on assignment, transfer or delegation set forth in this Annex A or any Transaction Document (or other document)), and any reference to a Person in a particular capacity excludes such Person in other capacities.

(i) The word “will” shall be construed to have the same meaning and effect as the word “shall”.

(j) The words “hereof”, “herein”, “hereunder” and similar terms when used in this Annex A or any Transaction Document (or other document) shall refer to this Annex A or such Transaction Document (or other document) as a whole and not to any particular provision hereof or thereof, and Article, Section, Annex, Schedule and Exhibit references herein and therein are references to Articles and Sections of, and Annexes, Schedules and Exhibits to, the relevant Transaction Document (or other document) unless otherwise specified.

(k) In the computation of a period of time from a specified date to a later specified date, the word “from” means “from and including” and each of the words “to” and “until” means “to but excluding”.

(l) References to any action, remedy or method of judicial proceeding for the enforcement of the rights of creditors or of security shall be deemed to include, in respect of any jurisdiction other than the State of New York, references to such action, remedy or method of judicial proceeding for the enforcement of the rights of creditors or of security available or appropriate in such jurisdiction as shall most nearly approximate such action, remedy or method of judicial proceeding described or referred to in the relevant Transaction Document (or other document).

"$" means lawful money of the United States.

"2019 Notes" means the 12.5% Senior Secured Notes due 2025 of the Issuer in the initial outstanding principal balance of $70,000,000 that were issued on July 15, 2019 pursuant to Section 2.01(b) of the Indenture and Section 3.1 of the related purchase agreements.

"Accredited Investor" means an "accredited investor" as defined in Rule 501(a)(1), (a)(2), (a)(3) or (a)(7) under the Securities Act that is not (i) a QIB or (ii) a Person other than a U.S. person (as defined in Regulation S) that acquires Notes or Warrants in reliance on Regulation S.

"Affiliate" means, with respect to any specified Person, another Person that directly, or indirectly through one or more intermediaries, controls, is controlled by or is under common control with the specified Person. For purposes of this definition, "control" means the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of a Person, whether through the ownership of the Capital Stock of such Person that is at the time entitled to vote in the election of the board of directors (or equivalent) of such Person, by contract or otherwise, and "controlled" has a meaning correlative thereto.

"Anti-Money Laundering Laws" has the meaning set forth in Section 5.26 of the Purchase Agreements.

"Apomorphine Purchase Agreement" means that certain Purchase and Sale Agreement, dated as of November 3, 2020, between the Issuer and MAM Pangolin Royalty, LLC (the "Royalty Purchaser") regarding, among other things, the assignment to the Royalty Purchaser of the Issuer's rights to receive future royalty and milestone payments under the Sunovion License Agreement.

"Business Day" means any day other than a Saturday, a Sunday or any other day on which banking institutions are authorized or required by Law to close in New York City or the city in which the Trustee's corporate trust office is located.

"Capital Stock" means (a) in the case of a corporation, corporate stock or shares, (b) in the case of an association or business entity, any and all shares, interests, participations, rights or other equivalents (however designated) of corporate stock, (c) in the case of a partnership or limited liability company, partnership or membership interests (whether general or limited) and membership rights, and (d) any other interest or participation that confers on a Person the right to receive a share of the profits and losses of, or distributions of assets of, the issuing Person, in each case to the extent treated as equity in accordance with GAAP, but excluding from all of the foregoing any debt securities convertible into or exchangeable for Capital Stock whether or not such debt securities include any right of participation with Capital Stock.

"Closing Date" means the tenth business day following the date the Initial Permitted Apomorphine Monetization (as defined in the Indenture) is funded.

["Closing Payment" means, in respect of each of [●], the amount of USD cash specified beside such Purchaser's name in the column labeled "Closing Payment Amount" on Schedule 1 attached hereto.]

"Code" means the U.S. Internal Revenue Code of 1986, as amended.

"Collateral Agent" means U.S. Bank National Association in its capacity as "Collateral Agent" under the Indenture and under the Security Documents and any successor thereto in such capacity.

"Commission" means the U.S. Securities and Exchange Commission or any successor thereto.

"Common Stock" means (i) the common stock, par value $0.001 per share, of the Issuer and (ii) any other Capital Stock into which such common stock is reclassified or reconstituted.

"Confidential Information" means, as it relates to the Purchaser (or its Affiliates), all information (whether written or oral, or in electronic or other form) furnished before or after the date of this Purchase Agreement concerning the Purchaser or its Affiliates (including any of its equityholders), including any and all information regarding any aspect of the Purchaser's business, including its owners, funds, strategy, market views, structure, investors or potential investors. Such Confidential Information includes any IRS Form W-9 or W-8BEN (or any similar type of form) provided by the Purchaser (or its Affiliates) to the Issuer or its Affiliates. Notwithstanding the foregoing definition, "Confidential Information" shall not include information that is (v) independently developed or discovered by the Issuer without use of or access to any information described in the second preceding sentence, as demonstrated by documentary evidence, (w) already in the public domain at the time the information is disclosed or has become part of the public domain after such disclosure through no breach of this Purchase Agreement, (x) lawfully obtainable from other sources, (y) required to be disclosed in any document to be filed with any Governmental Authority or otherwise required to be disclosed under applicable Law or judicial or administrative proceedings (by oral questions, interrogatories, requests for information or documents, subpoena, civil investigation demand or similar process) or pursuant to requests from regulatory agencies having oversight over the Issuer or (z) required to be disclosed by court or administrative order or under securities Laws applicable to any party to this Purchase Agreement or pursuant to the rules and regulations of any stock exchange or stock market on which securities of the Issuer or its Affiliates or the Purchaser or its Affiliates may be listed for trading.

"DEA" means the U.S. Drug Enforcement Administration or any successor thereto.

"Definitive Security" has the meaning set forth in Appendix A to the Indenture as of the date of the Purchase Agreements.

"DTC" means The Depository Trust Company (including its nominees).

"Environmental Laws" has the meaning set forth in Section 5.22 of the Purchase Agreements.

"ERISA" means the U.S. Employee Retirement Income Security Act of 1974, as amended.

"ERISA Plan" has the meaning set forth in Section 5.14 of the Purchase Agreements.

"Event of Default" has the meaning set forth in the Indenture as of the date of the Purchase Agreements.

"Exchange Act" means the U.S. Securities Exchange Act of 1934, as amended.

"Exchange Act Documents" has the meaning set forth in Section 5.4 of the Purchase Agreements.

"FCPA" means the U.S. Foreign Corrupt Practices Act of 1977, as amended.

"FDA" means the U.S. Food and Drug Administration or any successor thereto.

"GAAP" means generally accepted accounting principles in effect in the United States from time to time.

"Global Security" has the meaning set forth in Appendix A to the Indenture as of the date of the Purchase Agreements.

"Governmental Authority" means the government of the United States or any other nation, or of any political subdivision thereof, whether state or local, and any agency, authority, instrumentality, regulatory body, court, arbitrator, central bank or other entity exercising executive, legislative, judicial, taxing, regulatory or administrative powers or functions of or pertaining to government (including any supra-national bodies such as the European Union or the European Central Bank).

"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.

"Immaterial Subsidiaries" has the meaning set forth in the Indenture as of the date of the Purchase Agreements.

"Indenture" means that certain indenture for the Notes, dated as of July 15, 2019, as amended by that certain first supplemental indenture, dated as of the Closing Date, by and among the Issuer, the other subsidiary parties from time to time party thereto, the Trustee and the Collateral Agent.

"Intellectual Property" has the meaning set forth in Section 5.21(a) of the Purchase Agreements.

"IRS" means the U.S. Internal Revenue Service.

"Issuer" has the meaning set forth in the preamble to the Purchase Agreements.

"Laws" means, collectively, all applicable international, foreign, federal, state and local laws, statutes, treaties, rules, regulations, ordinances, judgments, orders, writs, injunctions, decrees, codes and administrative or judicial precedents or authorities, including the binding and enforceable interpretation or administration thereof by any Governmental Authority charged with the enforcement, interpretation or administration thereof, and all applicable administrative orders, directed duties, licenses, authorizations and permits of, and binding and enforceable agreements with, any Governmental Authority.

"Lien" means, with respect to any asset, any mortgage, lien, pledge, charge, security interest or encumbrance of any kind in respect of such asset, whether or not filed, recorded or otherwise perfected under applicable Law (including any conditional sale or other title retention agreement, any lease in the nature thereof, any option or other agreement to sell or give a security interest in and any filing of or agreement to give any financing statement under the UCC (or equivalent Laws) of any jurisdiction); provided, that in no event shall an operating lease be deemed to constitute a Lien.

"Material Adverse Effect" means a material adverse effect (a) in or affecting the business, condition (financial or otherwise), results of operations, earnings, properties or prospects of the Issuer and its Subsidiaries taken as a whole or (b) on the ability of the Issuer to perform its obligations under the Transaction Documents.

"Material Contract" means a contract or other agreement that is required to be filed by the Issuer with the Commission pursuant to Item 601(b)(4), Item 601(b)(10) or Item 601(b)(99) of Regulation S-K as an exhibit to the Exchange Act Documents.

"Notes Collateral" means all property subject, or purported to be subject from time to time, to a Lien under any Security Documents.

"Other Agreements" has the meaning set forth in Section 3.1(b) of the Purchase Agreements.

"Other Purchasers" has the meaning set forth in Section 3.1(b) of the Purchase Agreements.

"Patents" means (i) an issued patent or a patent application, (ii) all registrations and recordings thereof, (iii) all continuations and continuations-in-part to an issued patent or patent application, (iv) all divisions, patents of addition, reissues, renewals and extensions of any patent, patent application, continuation or continuation-in-part and (v) all counterparts of any of the above in any jurisdiction.

"Paying Agent" means an office or agency where Notes may be presented for payment, maintained by the Issuer in accordance with Section 2.04(a) of the Indenture.

"Permits" has the meaning set forth in Section 5.30 of the Purchase Agreements.

"Permitted Lien" has the meaning set forth in the Indenture as of the date of the Purchase Agreements.

"Person" means an individual, corporation, partnership, association, limited liability company, unincorporated organization, trust, joint stock company or joint venture, a Governmental Authority or any other entity.

"Plan Assets" has the meaning given to such term by Section 3(42) of ERISA and regulations issued by the U.S. Department of Labor.

"PTE" means the United States Department of Labor Prohibited Transaction Exemption.

"PTO" means the U.S. Patent and Trademark Office or any successor thereto.

"Purchase Agreement" means this purchase agreement.

"Purchase Agreements" means, collectively, each Purchase Agreement and the Other Agreements.

"Purchaser" has the meaning set forth in Section 1.1 of the Purchase Agreements.

"Purchasers" has the meaning set forth in Section 1.1 of the Purchase Agreements.

"QIB" means a qualified institutional buyer within the meaning of Rule 144A.

"QPAM Exemption" means PTE 84-14 (issued December 21, 1982, as subsequently amended).

"Regulation S" means Regulation S under the Securities Act.

"Regulation S Global Security" has the meaning set forth in Appendix A to the Indenture as of the date of the Purchase Agreements.

"Regulatory Agencies" has the meaning set forth in Section 5.31 of the Purchase Agreements.

"Responsible Officer" means, with respect to the Issuer, any director or officer of the Issuer.

"Rule 144A" means Rule 144A under the Securities Act.

"Rule 144A Global Security" has the meaning set forth in Appendix A to the Indenture as of the date of the Purchase Agreements.

"Sanctioned Country" has the meaning set forth in Section 5.27 of the Purchase Agreements.

"Sanctions" has the meaning set forth in Section 5.27 of the Purchase Agreements.

"Securities Act" means the U.S. Securities Act of 1933, as amended.

"Security Documents" means the security agreements, pledge agreements, mortgages, collateral assignments and related agreements, as amended, supplemented, restated, renewed, refunded, replaced, restructured, repaid, refinanced or otherwise modified from time to time, creating, perfecting or otherwise evidencing the security interests in the Notes Collateral as contemplated by the Indenture.

"Similar Law" has the meaning set forth in Section 4.3(b) of the Purchase Agreements.

"Source" has the meaning set forth in Section 4.3(a) of the Purchase Agreements.

"Subsidiary" means, with respect to any Person, (a) any corporation, association or other business entity (other than a partnership, joint venture or limited liability company) of which more than 50% of the total voting power of shares of Capital Stock entitled (without regard to the occurrence of any contingency) to vote in the election of directors, managers or trustees thereof is at the time of determination owned or controlled, directly or indirectly, by such Person or one or more of the other Subsidiaries of that Person or a combination thereof, and (b) any partnership, joint venture or limited liability company of which (x) more than 50% of the capital accounts, distribution rights, total equity and voting interests or general and limited partnership interests, as applicable, are owned or controlled, directly or indirectly, by such Person or one or more of the other Subsidiaries of that Person or a combination thereof, whether in the form of membership, general, special or limited partnership interests or otherwise, or (y) such Person or any Subsidiary of such Person is a controlling general partner or otherwise controls such entity. For purposes of clarity, a Subsidiary of a Person shall not include any Person that is under common control with the first Person solely by virtue of having directors, managers or trustees in common and shall not include any Person that is solely under common control with the first Person (i.e., a sister company with a common parent).

"Sunovion License Agreement" means that certain License Agreement, dated as of April 1, 2016, by and between the Issuer (formerly MonoSol Rx, LLC) and Sunovion Pharmaceuticals Inc., a Delaware corporation (formerly Cynapsus Therapeutics Inc.), as amended from time to time in accordance with the terms thereof.

"Supplemental Indenture" means that certain First Supplemental Indenture to the Indenture, dated on or after the date hereof, by and among the Issuer, the other subsidiary parties from time to time party thereto, the Trustee and the Collateral Agent, substantially in the form attached hereto as Exhibit B.

"Taxes" means any present or future tax, fee, duty, levy, tariff, impost, assessment or other charge imposed by a Governmental Authority (including penalties, interest and additions to tax applicable thereto).

"Transaction Documents" means the Indenture, the Notes, the Warrants, the Security Documents, the Purchase Agreements, any intercreditor agreement in the form of Exhibit D to the Indenture, and each other agreement pursuant to which the Collateral Agent (or its agent) is granted a Lien to secure the obligations under the Indenture or the Notes.

"Trustee" means U.S. Bank National Association, as trustee under the Indenture.

"Trustee Closing Account" means the account maintained with the Trustee at U.S. Bank National Association, ABA No. 091000022, Account No. 1731 0332 1092, Ref. Aquestive Senior Secured Notes, Attention: Alison D.B. Nadeau.

"UCC" means the Uniform Commercial Code as in effect in the State of New York; provided, that, if perfection, the effect of perfection or non-perfection or the priority of any security interest in any Notes Collateral is governed by the Uniform Commercial Code (or equivalent Law) as in effect in a jurisdiction other than the State of New York, then "UCC" means the Uniform Commercial Code (or equivalent Law) as in effect from time to time in such other jurisdiction for purposes of the provisions relating to such perfection, effect of perfection or non-perfection or priority.

"U.S." or "United States" means the United States of America, its 50 states, each territory thereof and the District of Columbia.

Exhibit A

Holder Consent

(see attached)

Exhibit B

Supplemental Indenture

(see attached)

Exhibit 10.8

SEPARATION AGREEMENT AND RELEASE

THIS SEPARATION AGREEMENT AND RELEASE (the "Agreement") is made and entered into as of this 15th day of December, 2020 (the "Effective Date") by and between Aquestive Therapeutics, Inc. (the "Company") and John Maxwell an individual (the "Executive"). The Company and the Executive are collectively referred to in this Agreement as the "Parties" and sometimes individually as a "Party." Capitalized terms not defined in this Agreement shall have the same meanings ascribed to them in the Executive Employment Agreement between the Company and the Executive dated as of June 26, 2018 (the "Employment Agreement").

1. Resignation. The Executive and the Company agree that on December 15, 2020, by and through this Agreement, Executive provided the Company with written notice of his voluntary resignation in satisfaction of the requirements set forth in Section 5(D) of the Employment Agreement. The Parties further agree and recognize that, at the Company's request, the Executive's employment with the Company will end effective December 31, 2020 (the "Separation Date"), and that the Company will have no further obligation to employ or re-employ him as an employee, consultant, agent or otherwise after the Separation Date.

2. Unpaid Base Salary. The Executive will receive any unpaid Base Salary earned by the Executive through the date on which the Executive's employment terminates payable in the Company's regularly scheduled payroll following the date of such termination.

3. Vacation. In the last paycheck, Executive will be paid $13,673.07 for his accrued and unused vacation days up through the Separation Date.

4. Separation Benefits. As consideration for the Executive's promises as set forth in this Agreement, the Company hereby agrees to provide the Executive with the following benefits (the "Separation Benefits"), minus applicable deductions and withholdings:

(i) a cash payment consisting of the Executive's Annual Bonus for the one year period ending December 31, 2020 in the sum of $197,500;

(ii) monthly payments for a period of twelve (12) months (the "Severance Period") following the Effective Date of the termination of Executive's employment 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), at the rate established for the year in which Executive's employment is terminated; for clarity, the amount payable under this Section 4(ii) for the Severance Period is $592,500 in the aggregate and the monthly amount is $49,375 during the Severance Period;

(iii) continuing coverage under the Company's group health and life insurance plans in which the Executive is a participant immediately before the termination of the Executive's 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

(iv) full and immediate vesting of 191,120 options to purchase the Company's common stock, par value $0.001 per share, representing vesting of all outstanding unvested stock options and other equity-based compensation awards granted to the Executive prior to the Separation Date, with such stock options that are or become vested upon the Separation Date remaining exercisable, as applicable, for at least one year after the Separation Date or, if earlier, until the expiration of the stated term of the award.

Notwithstanding anything to the contrary contained in this Agreement or otherwise, the payments and benefits described in parts (i) – (iv) of this Section 4 shall be conditioned upon and subject to the Executive's continuing compliance with the Executive's obligations under this Agreement, and the Executive's voluntary execution and delivery of the Release in the form annexed hereto as Exhibit A on or after the Separation Date, and not revoking his signature.

5. Covenant Not to Sue. The Executive hereby covenants and agrees not to file a lawsuit or initiate any action against the Company or any of its officers, directors, employees, agents or representatives seeking any personal recovery or personal injunctive relief with respect to any matter arising out of or relating in any way to the Executive's employment with the Company and/or the separation of that employment arising prior to the Separation Date. The Executive is barred from asserting any of the claims, rights or causes of action described in Exhibit A of this Agreement against the Company. If Executive does commence, join in, continue or in any other manner attempt to assert a claim, right, complaint or cause of action in violation of the release and covenant not to sue contained in this Agreement, or otherwise breaches any promise made in this Agreement, the Executive agrees to indemnify and hold harmless the Company from and against all losses incurred by the Company, including the Company's costs and attorneys' fees in defending such claim, right, complaint or cause of action. Nothing in this Section 5 precludes the Executive from initiating an action based on conduct which may arise after the Separation Date .

6. Executive's Covenants. The covenants, representations and warranties set forth in Section 8 of the Employment Agreement shall remain in place and enforceable after the termination of the Executive's employment with the Company, with the exception of the covenant not to compete for the 12-month Restrictive Period set forth under Section 8(A) of the Employment Agreement; provided, however, that if the Executive revokes his signature to this Agreement, the covenant not to compete shall be reinstated and continue to apply and the 12-month Restrictive Period shall commence as of the date of revocation by the Executive of his signature to this Agreement. Executive understands and agrees to comply with the Covenants during and after his employment with the Company is terminated.

7. Company's Covenants. The indemnification obligations of the Company set forth in Section 9 of the Employment Agreement shall remain in place and enforceable after the termination of the Executive's employment with the Company. The obligations of the Company set forth in the Indemnification Agreement between the Company and Executive, as the Indemnitee, dated as of June 26, 2018 (the "Indemnification Agreement"), shall remain in place and enforceable for the duration set forth in Paragraph 16 of the Indemnification Agreement. The Covenant Not to Sue set forth in Paragraph 5 of this Agreement shall not preclude Executive from initiating an action to enforce his indemnification rights under the Employment Agreement or his indemnification and advances of expenses rights under the Indemnification Agreement if the claim or proceeding for which Executive is seeking indemnification or advances of expenses is based on any action, inaction, event or occurrence pre-dating the Separation Date.

8. Neutral Reference. The Company will respond to inquiries from the Executive's prospective employers by communicating only the term of employment and position with the Company. The Executive agrees that the Company shall have the right to issue the press release substantially in the form attached hereto as Exhibit B.

9. Non-Disparagement. The Executive shall not defame, demean, criticize, disparage, communicate any negative information about, or denigrate the name or reputation of the Company or any of its officers, directors, employees, agents or representatives. The Company vice presidents, officers and directors shall not defame, demean, criticize, disparage, communicate any negative information about, or denigrate the name or reputation of the Executive.

10. Consideration and Revocation Period. The Executive agrees that he has been given twenty-one (21) calendar days to review and consider this Agreement. The Executive is free to use as much of the 21-day period as he wishes, but understands that the earliest date on which he can sign this Agreement is the Effective Date. The Executive also understands that after signing this Agreement he may revoke his signature within seven (7) calendar days, by delivering written notice of his revocation within the seven- day period to Theresa Wood, Senior Vice President, Human Resources, Aquestive Therapeutics, Inc., 30 Technology Drive, Warren, New Jersey 07059. Notice of revocation must be received by Ms. Wood on or before 5:00 p.m. on the seventh (7th) calendar day in order to be effective. This Agreement will become effective on the eighth (8th) calendar day following the Executive's signature; provided that it is not revoked. The Separation Benefits described in Section 4 of this Agreement will not be paid if the Executive (i) fails to sign the Agreement within twenty-one (21) calendar days of receipt or (ii) revokes the Agreement by giving timely notice as set forth in this Section 10; in which case this Agreement will be null and void and the Executive will not be eligible for, or entitled to, the Separation Benefits.

11. Voluntary Agreement. The Executive states that he has had the opportunity to read, review and consider all of the provisions of this Agreement; that the Executive understands its provisions and its binding effect on him; and that the Executive is accepting the consideration offered to him in this Agreement and is entering into this Agreement freely, voluntarily, and without duress or coercion. The Executive acknowledges that he has not relied upon the Company's or its employees, managers, officers, directors, counsel, agents, accountants or representatives for any legal, tax or other accounting advice, and the Executive has, to the extent the Executive deems necessary, consulted with his own advisors as to these matters.

12. 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 Company 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 is in breach of his covenants or obligations under this Agreement.

13. Cooperation. Executive agrees that, after the termination of the Executive’s employment, the Executive 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 the Executive pursuant to this section.

14. 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 the Executive’s 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 14.

15. 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 Essex County of the State of New Jersey.

16. 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.

17. 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 Employment Agreement and any other employment agreement between Executive and the Company, and any 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.

18. 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.

19. 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.

20. 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.

21. Survival. The provisions of Sections 5 through and including Section 9 and Sections 12 through and including Section 21 of this Agreement shall survive any termination of this Agreement and the termination of Executive's employment by either Party for any reason.

BY SIGNING THIS AGREEMENT THE EXECUTIVE ACKNOWLEGES THAT:

HE HAS READ IT;

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

HE AGREES WITH EVERYTHING IN IT;

HIS ATTORNEY, IF HE USED ONE, NEGOTIATED THIS AGREEMENT WITH HIS KNOWLEDGE AND CONSENT;

HE HAS BEEN ADVISED TO CONSULT WITH HIS ATTORNEY PRIOR TO EXECUTING THIS AGREEMENT; AND

HE HAS SIGNED THIS AGREEMENT KNOWINGLY AND VOLUNTARILY.

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

JOHN MAXWELL

AQUESTIVE THERAPEUTICS, INC.

By:

Name: Keith Kendall

Title: CEO

EXHIBIT A

GENERAL RELEASE

In exchange for certain payments and benefits to be provided to me by Aquestive Therapeutics, Inc. pursuant to the Separation Agreement and Release (the "Agreement") dated as of December 15, 2020, between the undersigned executive (the "Executive") and Aquestive Therapeutics, Inc. (the "Company"), the Executive hereby knowingly and voluntarily waives, releases and discharges the Company, and each of its predecessors, successors, parent corporations, subsidiaries, and affiliates and each of their respective officers, directors, employees, agents, trustees, fiduciaries, and representatives (collectively with the Company, the "Company Parties") from any and all claims, liabilities, demands, and causes of action, which the Executive may have or claim to have against any of the Company Parties, 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 or any rights or claims for indemnification or advances of expenses set forth in the Employment Agreement between the Company and the Executive dated as of June 26, 2018 or in the Indemnification Agreement between the Company and the Executive, as the Indemnitee, dated as of June 26, 2018, for any proceedings or lawsuit based on any action, inaction, event or occurrence pre-dating the date 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 the Executive in writing that the Executive should consult with an attorney prior to executing this General Release. The Executive hereby states that the Executive has had the opportunity to discuss this General Release with whomever the Executive wished, including an attorney of the Executive's own choosing. The Executive further states that the Executive 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 the Executive has not relied upon the Company employees, officers, directors, counsel, agents, accountants or representatives for any legal, tax or other advice, and the Executive has, to the extent the Executive deems necessary, consulted with the Executive's own advisors as to these matters. The Executive represents that the Executive 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, agents, or representatives with respect to any matter, including but not limited to, the Executive's 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 the 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 the Executive has twenty-one (21) calendar days within which to consider this General Release before signing it. The Executive also understands that the Executive is free to use as much of the twenty-one (21) calendar day period as the Executive wishes or considers necessary before deciding to sign this General Release. The Executive may revoke the Executive's signature of this General Release within seven (7) calendar days of signing it by delivering written notice of revocation to Theresa Wood, Senior Vice President, Human Resources, 30 Technology Drive South, Warren, New Jersey 07059. If Executive has not revoked the Executive's 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 the Executive's failure or refusal to execute this General Release or the Executive's timely revocation of this General Release will result in forfeiture of any severance payments and benefits.

BY SIGNING THIS GENERAL RELEASE, THE EXECUTIVE ACKNOWLEDGES THAT:

THE EXECUTIVE HAS READ IT;

THE EXECUTIVE UNDERSTANDS IT AND KNOWS THAT HE/SHE IS GIVING UP IMPORTANT RIGHTS;

THE EXECUTIVE AGREES WITH EVERYTHING IN IT;

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

THE EXECUTIVE HAS SIGNED THIS GENERAL RELEASE KNOWINGLY AND VOLUNTARILY.

EXECUTIVE

JOHN MAXWELL

Date: _____

EXHIBIT B

PRESS RELEASE

Aquestive Therapeutics Announces Departure of Chief Financial Officer and Appointment of Interim Chief Financial Officer

Warren, NJ, December XX, 2020 – Aquestive Therapeutics, Inc. (NASDAQ: AQST), a pharmaceutical company focused on developing and commercializing differentiated products that address patients' unmet needs and solve therapeutic problems, today announced that John Maxwell, Senior Vice President, Chief Financial Officer (CFO) of the Company, has provided his intent to resign his positions with the Company to pursue other interests. Current plans call for Mr. Maxwell to continue to serve as CFO of the Company until his departure, which currently is anticipated at year end. Mr. Ernie Toth, a seasoned financial executive most recently with EHE Health as Chief Financial Officer, will assume the role of CFO on an interim basis upon Mr. Maxwell's departure.

"We have made meaningful progress in our business since John joined the Company in January 2017," said Keith J. Kendall, President and Chief Executive Officer of Aquestive. "John has been a valuable part of the continued development of the Company. We thank him for his contributions, especially in shepherding our efforts to become a public company and close several critical capital markets transactions. The management team and board of directors of Aquestive joins me in wishing him well in his future business pursuits. We anticipate effecting a very smooth transition over the next few weeks and are pleased to welcome Mr. Toth as the new interim CFO to our team," concluded Mr. Kendall.

"I have enjoyed my time with Aquestive Therapeutics," said Mr. Maxwell. "Upon arrival, my immediate objective was to help evolve the capitalization of the Company. Aquestive was in the midst of its transformation into a commercial proprietary pharmaceutical company. Having accomplished this critical goal, I believe the Company is well positioned for future growth and I believe in the strength of the Aquestive business. I wish the team all the best for its continued success."

The Company also reported that Mr. Maxwell's departure is not related to the Company's operations, financial reporting or controls.

2020 Outlook

The Company also announced that there is no change to its full year 2020 financial outlook.

About Aquestive Therapeutics
Aquestive Therapeutics is a pharmaceutical company that applies innovative technology to solve therapeutic problems and improve medicines for patients. The Company has commercialized one internally-developed proprietary product to date, Sympazan, has a commercial proprietary product pipeline focused on the treatment of diseases of the central nervous system, or CNS, and other unmet needs, and is developing orally administered complex molecules to provide alternatives to invasively administered standard of care therapies. The Company also collaborates with other pharmaceutical companies to bring new molecules to market using proprietary, best-in-class technologies, like PharmFilm®, and has proven capabilities for drug development and commercialization.

Forward-Looking Statement

This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as “believe,” “anticipate,” “plan,” “expect,” “estimate,” “intend,” “may,” “will,” or the negative of those terms, and similar expressions, are intended to identify forward-looking statements. These forward-looking statements include, but are not limited to, statements regarding therapeutic benefits and plans and objectives for regulatory approvals of AQST-108 and Libervant; ability to address the concerns identified in the FDA’s Complete Response Letter dated September 25, 2020 regarding the New Drug Application for Libervant and obtain FDA approval of Libervant for U.S. market access; ability to obtain FDA approval and advance AQST-108, Libervant and our other product candidates to the market; about our growth and future financial and operating results and financial position; regulatory approval and pathway; clinical trial timing and plans; our and our competitors’ orphan drug approval and resulting drug exclusivity for our products or products of our competitors; short-term and long-term liquidity and cash requirements, cash funding and cash burn; business strategies, market opportunities, and other statements that are not historical facts. These forward-looking statements are also subject to the uncertain impact of the COVID-19 global pandemic on our business including with respect to our clinical trials including site initiation, patient enrollment and timing and adequacy of clinical trials; on regulatory submissions and regulatory reviews and approvals of our product candidates; pharmaceutical ingredient and other raw materials supply chain, manufacture, and distribution; sale of and demand for our products; our liquidity and availability of capital resources; customer demand for our products and services; customers’ ability to pay for goods and services; and ongoing availability of an appropriate labor force and skilled professionals. Given these uncertainties, the Company is unable to provide assurance that operations can be maintained as planned prior to the COVID- 19 pandemic. These forward-looking statements are based on our current expectations and beliefs and are subject to a number of risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. Such risks and uncertainties include, but are not limited to, risks associated with the Company's development work, including any delays or changes to the timing, cost and success of our product development activities and clinical trials and plans; risk of delays in FDA approval of Libervant and our other drug candidates or failure to receive approval; risk of our ability to demonstrate to the FDA “clinical superiority” within the meaning of the FDA regulations of our drug candidate Libervant relative to FDA-approved diazepam rectal gel and nasal spray products including by establishing a major contribution to patient care within the meaning of FDA regulations relative to the approved products as well as risks related to other potential pathways or positions which are or may in the future be advanced to the FDA to overcome the seven year orphan drug exclusivity granted by the FDA for the approved nasal spray product of a competitor in the U.S. and there can be no assurance that we will be successful; risk that a competitor obtains FDA orphan drug exclusivity for a product with the same active moiety as any of our other drug products for which we are seeking FDA approval and that such earlier approved competitor orphan drug blocks such other product candidates in the U.S. for seven years for the same indication; risk inherent in commercializing a new product (including technology risks, financial risks, market risks and implementation risks and regulatory limitations); risks for consummating the monetization transaction for KYNMOBI and other risks and uncertainties concerning the royalty and other revenue stream of KYNMOBI, achievement of royalty targets worldwide or in any jurisdiction and certain other commercial targets required for contingent payments under the monetization transaction, and of sufficiency of net proceeds of the monetization transaction after satisfaction of and compliance with 12.5% Senior Notes obligations, as applicable, and for funding the Company’s operations; risk of development of our sales and marketing capabilities; risk of legal costs associated with and the outcome of our patent litigation challenging third party at risk generic sale of our proprietary products; risk of sufficient capital and cash resources, including access to available debt and equity financing and revenues from operations, to satisfy all of our short-term and longer term cash requirements and other cash needs, at the times and in the amounts needed; risk of failure to satisfy all financial and other debt covenants and of any default; risk related to government claims against Indivior for which we license, manufacture and sell Suboxone® and which accounts for the substantial part of our current operating revenues; risk associated with Indivior’s cessation of production of its authorized generic buprenorphine naloxone film product, including the impact from loss of orders for the authorized generic product and risk of eroding market share for Suboxone and risk of sunsetting product; risks related to the outsourcing of certain marketing and other operational and staff functions to third parties; risk of the rate and degree of market acceptance of our product and product candidates; the success of any competing products, including generics; risk of the size and growth of our product markets; risks of compliance with all FDA and other governmental and customer requirements for our manufacturing facilities; risks associated with intellectual property rights and infringement claims relating to the Company's products; risk of unexpected patent developments; the impact of existing and future legislation and regulatory provisions on product exclusivity; legislation or regulatory actions affecting pharmaceutical product pricing, reimbursement or access; claims and risks that may arise regarding the safety or efficacy of the Company's products and product candidates; risk of loss of significant customers; risks related to legal proceedings, including patent infringement, investigative and antitrust litigation matters; changes in government laws and regulations; risk of product recalls and withdrawals; uncertainties related to general economic, political, business, industry, regulatory and market conditions and other unusual items; and other uncertainties affecting the Company described in the “Risk Factors” section and in other sections included in our Annual Report on Form 10 K, in our Quarterly Reports on Form 10-Q, and in our Current Reports on Form 8-K filed with the Securities Exchange Commission (SEC). Given those uncertainties, you should not place undue reliance on these forward-looking statements, which speak only as of the date made. All subsequent forward-looking statements attributable to us or any person acting on our behalf are expressly qualified in their entirety by this cautionary statement. The Company assumes no obligation to update forward-looking statements or outlook or guidance after the date of this press release whether as a result of new information, future events or otherwise, except as may be required by applicable law.

Investor Inquiries:

Westwicke, an ICR Company
Stephanie Carrington
stephanie.carington@westwicke.com
646-277-1282

Exhibit 10.15

THE SYMBOL "[****]" DENOTES PLACES WHERE CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH (i) NOT MATERIAL, AND (ii) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF PUBLICLY DISCLOSED

SECOND AMENDMENT

TO

LICENSE AGREEMENT

This amendment ("Second Amendment") to Agreement (defined below) is entered into by and between **Sunovion Pharmaceuticals Inc.** (formerly Cynapsus Therapeutics, Inc.) ("Sunovion") and **Aquestive Therapeutics, Inc. (**formerly MonoSol Rx, LLC) ("Aquestive") and is effective as of October 23, 2020 (the "Second Amendment Effective Date"). Capitalized terms not defined herein shall have the meaning set forth in the Agreement. Except as set forth in this Second Amendment, all other terms and conditions of the Agreement shall remain in full force and effect.

RECITALS

WHEREAS, Cynapsus Therapeutics, Inc. developed and owned patented technology related to the film based drug delivery of the active pharmaceutical ingredient, Apomorphine;

WHEREAS, Aquestive Therapeutics, Inc. owns patented and trade secret proprietary technology related to film-based drug delivery systems which includes orally soluble film strips containing active pharmaceutical ingredients;

WHEREAS, under the Agreement, Cynapsus Therapeutics, Inc. obtained an exclusive right and license from Aquestive Therapeutics, Inc. in connection with the development and commercialization of Apomorphine for oral administration (the "Product");

WHEREAS, Sunovion acquired Cynapsus Therapeutics, Inc. and all rights and licenses to its technology in October of 2016;

WHEREAS, the Parties entered into the First Amendment of the Agreement effective as of March 16, 2020 wherein the Parties agreed, among other things, to amend Section 7.2.2(d) of the Agreement to extend the date by which Sunovion may terminate the Agreement upon 180 days prior written notice to March 31, 2028; and

WHEREAS, the parties to this Second Amendment wish to amend certain terms of that certain License Agreement (as amended) entered into by and between Sunovion and Aquestive effective as of April 1, 2016 (the "Agreement") to clarify certain rights and obligations of the Parties under the Agreement, as outlined below;

NOW, THEREFORE, the parties agree as follows:

1. Section 3.3.2 of the Agreement is deleted in its entirety and replaced with the following:

"3.3.2

Subject to Section 3.4, from January 1, 2025 until the termination of this Agreement, Licensee or its Affiliates, in consideration of the rights granted to Licensee under Section 2.1.1 and/or 2.1.2, as applicable, shall pay Licensor an amount equal to [****] percent ([****]%) of the quarterly Net Sales of the Product in the Territory, provided that on and after March 31, 2028, in respect of any jurisdiction or jurisdictions in the Territory, Licensee may terminate its rights with respect to the Licensed Patents upon one hundred and eighty (180) days prior written notice to Licensor. In such event Licensee or its Affiliates shall cease to be obligated to pay to Licensor an amount equal to [****] percent ([****]%) of the quarterly Net Sales of the Product in such jurisdiction or jurisdictions. Licensor will have no further obligations under this Agreement in such jurisdictions where Licensee is not paying and/or ceases to pay a royalty on or after March 31, 2028."

2. Section 8.1.3 is deleted in its entirety and replaced with the following:

"8.1.3

(a) In the event that Licensor desires to abandon or cease prosecution or maintenance of any Licensor Patent in any country in the Territory, Licensor shall provide reasonable prior written notice to Licensee of such intention to abandon ("Notice to Abandon"), such Notice to Abandon shall be given no later than sixty (60) days prior to the next deadline for any action that must be taken with respect to any such Licensor Patent in the relevant patent office. In such case, upon Licensee's written election ("Step-In Notice"), provided no later than thirty (30) days after Licensee's receipt of the applicable Notice to Abandon, Licensee shall have the right to assume prosecution and maintenance of such Licensor Patent at Licensee's expense ("Step-In Rights").

(b) Licensor shall have the right to rescind a Notice to Abandon upon written notification to Licensee no later than ten (10) days after Licensor's receipt of the applicable Step-In Notice and such rescission shall revoke Licensee's Step-In Rights provided that Licensor within five (5) days of such written notification of rescission shall take all actions necessary to prevent abandonment, cessation of prosecution or maintenance of the applicable Licensor Patent at Licensor's sole expense.

(c) Should Licensee fail to provide Step-In Notice within thirty (30) days after Licensee's receipt of the applicable Notice to Abandon, Licensor may, in its sole discretion, continue prosecution and maintenance of such Licensor Patent or discontinue prosecution and maintenance of such Licensor Patent.

(d) For clarity, with respect to a Licensor Patent in a country in the Territory, "abandon or cease prosecution or maintenance of any Licensor Patent" as used in this section 8.1.3 shall mean (i) if pending, abandon said pending Licensor Patent without having a pending continuing application (e.g., continuation or divisional) on file claiming priority to the pending Licensor Patent to be abandoned in such country, or (ii) if issued, stop maintaining said issued Licensor Patent in such country."

[Signatures to follow on next page.]

IN WITNESS WHEREOF, the parties hereto have caused this Second Amendment to be executed by their duly authorized representatives to be effective as of the Second Amendment Effective Date stated above.

Sunovion Pharmaceuticals Inc.

By: /s/ Yumi Sato

Print Name: Yumi Sato

Title: EVP, Chief Corporate Strategy Officer

Aquestive Therapeutics, Inc.

By: /s/ Daniel Barber

Print Name: Daniel Barber, COO

By: /s/ Lori Braender

Print Name: Lori Braender, SVP, General Counsel

Exhibit 10.23

THE SYMBOL "[*****]" DENOTES PLACES WHERE CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH (i) NOT MATERIAL, AND (ii) WOULD LIKELY CAUSE COMPETITIVE HARM TO THE COMPANY IF PUBLICLY DISCLOSED

PURCHASE AND SALE AGREEMENT

dated as of November 3, 2020

between

AQUESTIVE THERAPEUTICS, INC.

and

MAM PANGOLIN ROYALTY, LLC

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ARTICLE VIII
MISCELLANEOUS

PURCHASE AND SALE AGREEMENT

This PURCHASE AND SALE AGREEMENT (this "Purchase and Sale Agreement") dated as of November 3, 2020 is between AQUESTIVE THERAPEUTICS, INC., a Delaware corporation (the "Seller"), and MAM PANGOLIN ROYALTY, LLC, a Delaware limited liability company (the "Purchaser").

W I T N E S S E T H :

WHEREAS, the Seller has the right to receive royalties based on Net Sales of the Products in the Territory and certain regulatory and commercial milestone payments under the Counterparty License Agreement; and

WHEREAS, the Seller desires to sell, assign, transfer, convey and grant to the Purchaser, and the Purchaser desires to purchase, acquire and accept from the Seller, the Purchased Assets described herein, upon and subject to the terms and conditions set forth in this Purchase and Sale Agreement;

NOW, THEREFORE, in consideration of the premises and the mutual agreements, representations and warranties set forth herein and of other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, the parties hereto covenant and agree as follows:

ARTICLE I
DEFINED TERMS AND RULES OF CONSTRUCTION

Section 1.1 Defined Terms. The following terms, as used herein, shall have the following respective meanings:

"Additional License Agreement" has the meaning set forth in Section 5.6(a).

"Additional Licensee" has the meaning set forth in Section 5.6(a).

"Affiliate" means, with respect to any Person, any other Person that, directly or indirectly, controls, is controlled by or is under common control with such Person. For purposes of this definition, "control" of a Person means the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of such Person, whether through the ownership of Voting Securities, by contract or otherwise, and the terms "controlled" and "controlling" have meanings correlative to the foregoing.

"Applicable Law" means, with respect to any Person, all laws, rules, regulations and orders of Governmental Authorities applicable to such Person or any of its properties or assets.

[*****]

"Bill of Sale" means that certain bill of sale dated as of the Closing Date executed by the Seller and the Purchaser substantially in the form of Exhibit A.

"Business Day" means any day that is not a Saturday, Sunday or other day on which commercial banks in New York City are authorized or required by Applicable Law to remain closed.

"Capital Securities" means, with respect to any Person, all shares, interests, participations or other equivalents (however designated, whether voting or non-voting) of such Person's capital, whether now outstanding or issued after the Closing Date, including common shares, ordinary shares, preferred shares, membership interests or share capital in a limited liability company or other Person, limited or general partnership interests in a partnership, beneficial interests in trusts or any other equivalent of such ownership interest or any options, warrants and other rights to acquire such shares or interests, including rights to allocations and distributions, dividends, redemption payments and liquidation payments.

"Closing" has the meaning set forth in Section 6.1.

"Closing Date" has the meaning set forth in Section 6.1.

"Code" means the U.S. Internal Revenue Code of 1986, as amended, and the regulations thereunder.

"Competitor" shall mean any Person engaged in research, development, manufacturing, marketing, sale, importation or exportation of (i) any product containing the active pharmaceutical ingredient apomorphine, or any salts, prodrugs, derivative and analogues thereof, alone or in combination with any antiemetic, or (ii) any oral film pharmaceutical technologies or products.

"Confidential Information" means, as it relates to the Seller and its Affiliates, the Counterparty, any Additional Licensee, the Products, the Licensed Patents and the related Intellectual Property, all information (whether written or oral, or in electronic or other form) involving or relating in any way, directly or indirectly, to the Products, the Counterparty License Agreement, any Additional License Agreement, the Purchased Assets or the Royalties, including (a) any license, sublicense, assignment, product development, royalty, sale, supply, escrow or other agreements (including the Counterparty License Agreement and any applicable Additional License Agreement) involving or relating in any way, directly or indirectly, to the Purchased Assets, the Royalties, the Licensed Patents or the other related Intellectual Property, compounds or products giving rise to the Purchased Assets, and including all terms and conditions thereof and the identities of the parties thereto, (b) any reports, data, materials or other documents of any kind concerning or relating in any way, directly or indirectly, to the Seller, the Counterparty, any Additional Licensee, the Products, the Counterparty License Agreement, any Additional License Agreement, the Purchased Assets, the Royalties or the Intellectual Property, compounds or products giving rise to the Purchased Assets (including, for the avoidance of doubt, any and all "Confidential Information" as such term is defined in the Counterparty License Agreement any similar concept defined in any Additional License Agreement), and including reports, data, materials or other documents of any kind delivered pursuant to or under any of the agreements referred to in clause (a) above or based on or derived from any such reports, data, materials or other documents of any kind, and (c) any inventions, devices, improvements, formulations, discoveries, compositions, ingredients, patents (including the Licensed Patents), patent applications, know-how, processes, trial results, research, developments or any other intellectual property, trade secrets or information involving or relating in any way, directly or indirectly, to the Purchased Assets or the compounds or products giving rise to the Purchased Assets; provided, however, that Confidential Information shall not include information that is (i) already in the public domain at the time the information is disclosed other than as a result of disclosure in violation of the confidentiality undertakings in this Purchase and Sale Agreement, (ii) lawfully obtainable from other sources without the breach of any such other source's confidentiality obligations to the Seller, the Counterparty or any Additional Licensee, (iii) already known by the Purchaser at the time that such information is disclosed, as demonstrated by documentary evidence (unless such information was disclosed to the Purchaser as a result of disclosure to the Purchaser that was subject to a written confidentiality agreement between the Purchaser and the Seller, the Counterparty or any Additional Licensee) or (iv) independently developed by the Purchaser's directors, officers, managers, members, partners, employees, affiliates, assigns, representatives, agents or similar persons or entities who have not had access to such information, as demonstrated by documentary evidence.

"Contingent Payments" the portions of the Purchase Price payable, if at all, in compliance with clauses (b) through (g) of Section 2.2.

"Counterparty" means Sunovion Pharmaceuticals Inc., a Delaware corporation (formerly Cynapsus Therapeutics Inc.), and any successor thereto.

"Counterparty Confirmation" means written confirmation signed by an authorized officer of the Counterparty, in form and substance as set forth on Exhibit D, with only such changes as are acceptable to the Purchaser in its reasonable discretion.

"Counterparty Instruction" means the irrevocable direction to Counterparty substantially in the form set forth in Exhibit B.

"Counterparty License Agreement" means that certain License Agreement, dated as of April 1, 2016, by and between the Seller (formerly MonoSol Rx, LLC) and the Counterparty, as amended by the First Amendment and the Second Amendment, as further amended in accordance with the provisions of this Purchase and Sale Agreement.

"Defaulting Party" has the meaning set forth in Section 5.5(d).

"Disputes" has the meaning set forth in Section 3.10(e).

"Dollar" or the sign "$" means United States dollars.

"Earned Date" means, with respect to any Contingent Payment described in clauses (c) through (g) of Section 2.2, the date on which the Purchaser has received Royalties Received with respect to the period set forth in the applicable clause sufficient to satisfy the conditions set forth in such clause.

"FDA" means the U.S. Food and Drug Administration and any successor agency thereto.

"Field" has the meaning set forth in Section 1.1.25 of the Counterparty License Agreement.

"First Amendment" means that certain First Amendment to License Agreement, dated as of March 16, 2020, by and between the Seller and the Counterparty.

"GAAP" means generally accepted accounting principles in effect in the United States from time to time (or the applicable accounting standards in any relevant jurisdiction outside of the United States).

"Governmental Authority" means the government of the United States or any other nation or any political subdivision thereof, whether state or local, and any agency, authority (including supranational authority), commission, instrumentality, regulatory body, court, central bank or other Person exercising executive, legislative, judicial, taxing, regulatory or administrative powers or functions of or pertaining to government, including each Patent Office, the FDA and any other governmental authority in any jurisdiction.

"Infringement" has the meaning set forth in Section 5.5(f).

"Initial Contingent Payment" has the meaning set forth in Section 2.3.

"Intellectual Property" has the meaning set forth in Section 1.1.31 of the Counterparty License Agreement.

"Invalidity Claim" has the meaning set forth in Section 5.5(f).

"Involuntary Seller Bankruptcy" means, without the consent or acquiescence of the Seller, the entering of an order for relief or approving a petition for relief or reorganization or any other petition seeking any reorganization, arrangement, composition, readjustment, liquidation, dissolution or other similar relief under any present or future bankruptcy, insolvency or similar Applicable Law, or the filing of any such petition against the Seller or, without the consent or acquiescence of the Seller, the entering of an order appointing a trustee, custodian, receiver or liquidator of the Seller or of all or any substantial part of the property of the Seller, in each case where such petition or order shall remain unstayed or shall not have been stayed or dismissed within 90 days from entry thereof.

"Licensed Patents" has the meaning set forth in Section 1.1.32 of the Counterparty License Agreement; provided, however, that, for purposes of this Purchase and Sale Agreement, as limited to those owned by the Seller that are listed in the Orange Book in the U.S. and their foreign counterparts as set forth on Exhibit C, including any patents owned by Seller that are listed in the Orange book for the Product after the date of this Purchase and Sale Agreement.[1]

[1] Aquestive: Please confirm whether there is any portion of this definition that you'd prefer to redact.

"Lien" means any security interest, mortgage, pledge, hypothecation, assignment, deposit arrangement, encumbrance, lien (statutory or otherwise), charge against or interest in property or other priority or preferential arrangement of any kind or nature whatsoever, in each case to secure payment of a debt or performance of an obligation, including any conditional sale or any sale with recourse.

"Loss" means any loss, assessment, award, cause of action, claim, charge, cost, expense (including expenses of investigation and attorneys' fees), fine, judgment, liability, obligation, penalty or Set-off.

"Material Adverse Change" means any event, circumstance or change that could reasonably be expected to result, individually or in the aggregate, in a material adverse effect, in any respect, on (a) the legality, validity or enforceability of any of the Transaction Documents, the Counterparty License Agreement or any Additional License Agreement or the back-up security interest granted pursuant to Section 2.1(d), (b) the right or ability of the Seller (or any permitted assignee) to perform any of its obligations under any of the Transaction Documents, the Counterparty License Agreement or any Additional License Agreement, or to consummate the transactions contemplated hereunder or thereunder, (c) the rights or remedies of the Purchaser under any of the Transaction Documents, the Counterparty License Agreement or any Additional License Agreement, (d) the timing, amount or duration of the Royalties, taken as a whole, under the Counterparty License Agreement and any Additional License Agreement or the right of the Purchaser to receive the Royalties under this Purchase and Sale Agreement, (e) the Purchased Assets, or (f) the Licensed Patents.

"Net Sales" has the meaning set forth in Section 1.1.41 of the Counterparty License Agreement.

[*****]

"Patent" means any pending or issued patent or continuation, continuation in part, division, extension or reissue thereof.

"Patent Office" means the applicable patent office, including the United States Patent and Trademark Office and any comparable foreign patent office, for any Licensed Patents.

[*****]

"Pending Patent Application" means "U.S. Patent Application No. [*****]" and/or any continuation application thereof.

"Person" means any natural person, firm, corporation, limited liability company, partnership, joint venture, association, joint-stock company, trust, unincorporated organization, Governmental Authority or any other legal entity, including public bodies, whether acting in an individual, fiduciary or other capacity.

"Product" has the meaning set forth in Section 1.1.46 of the Counterparty License Agreement.

"Purchase and Sale Agreement" has the meaning set forth in the preamble.

"Purchased Assets" means, collectively, the Seller's (a) right, title and interest in, to and under the Counterparty License Agreement and any Additional License Agreement to receive all of the Royalties, (b) right to receive the Quarterly Royalty Reports produced by Counterparty pursuant to the Counterparty License Agreement and any comparable reports or information produced by any Additional License pursuant to any applicable Additional License Agreement, and (c) right to transfer, assign or pledge the foregoing, in whole or in part, and the payments, proceeds and income of and the rights to enforce each of the foregoing in accordance with the terms hereof.

"Purchase Price" has the meaning set forth in Section 2.2.

"Purchaser" has the meaning set forth in the preamble.

"Purchaser Indemnified Party" has the meaning set forth in Section 7.1.

"Quarterly Payment Date" means the 30th day following the end of each calendar quarter, beginning with the calendar quarter ending March 31, 2021.

"Quarterly Royalty Reports" has the meaning set forth in Section 1.1.48 of the Counterparty License Agreement.

"Regulatory Agency" means a Governmental Authority with responsibility for the approval of the marketing and sale of pharmaceuticals or other regulation of pharmaceuticals in any jurisdiction.

"Regulatory Approvals" means, collectively, all regulatory approvals, registrations, certificates, authorizations, permits and supplements thereto, as well as associated materials (including the product dossier) pursuant to which the Products may be marketed, sold and distributed in a jurisdiction, issued by the appropriate Regulatory Agency.

"Retained Liabilities" has the meaning set forth in Section 2.4.

[*****]

"Royalties" means, without duplication, (a) all royalties and other amounts or fees paid, owed, accrued or otherwise required to be paid to the Seller pursuant to the Counterparty License Agreement (net of any deduction or withholding from or Set-offs against such amounts made by the Counterparty in accordance with Section 5.4(e) hereof and the terms thereof) arising out of, related to or resulting from the sale by Counterparty or any of its Affiliates, successors, Sublicensees, subcontractors or agents of any and all Products in the Territory and, in each case, attributable to the period commencing on the Royalties Commencement Date, including all amounts due or to be paid to the Seller or any of its Affiliates under Section 3.3 or Section 3.4 of the Counterparty License Agreement (whether based upon Net Sales of the Products in the Territory or otherwise), (b) all milestone payments paid, owed, accrued or otherwise required to be paid to the Seller by the Counterparty or any of its Affiliates or successors pursuant to the Counterparty License Agreement (net of any deduction or withholding from or Set-offs against such amounts made by the Counterparty in accordance with Section 5.4(e) hereof and the terms thereof) and, in each case, attributable to the achievement during the period from and after the date hereof of any regulatory or sales milestones set forth in Sections 3.1.2 and 3.1.3 of the Counterparty License Agreement (but excluding, for the avoidance of doubt, the $4,000,000 milestone payment payable pursuant to section 3.1.2 of the Counterparty License Agreement upon the first day of Product availability at a pharmacy in the United States, which shall remain the property of the Seller), (c) all amounts due or to be paid to the Seller pursuant to Sections 3.5, 3.6 or 3.11 of the Counterparty License Agreement in respect or in lieu of amounts described in clauses (a) and (b) above, (d) all Substitute Amounts paid or payable to the Seller or any of its Affiliates by one or more Additional Licensees under any Additional License Agreement, and (e) all proceeds (as defined under the UCC) of any of the foregoing.

"Royalties Commencement Date" means October 1, 2020.

"Royalties Received" means, with respect to Net Sales during any specified period, the Royalties received with respect to such Net Sales in accordance with the terms of the Counterparty License Agreement; including Royalties received after the end of such specified period with respect to Net Sales made during such period. For the purpose of determining whether or not the Contingent Payments are due to the Seller (or adjustments thereto) or [*****] are due to [*****], as applicable, Royalties as used in the calculation of Royalties Received shall include any Royalties paid pursuant to Section 3.4 of the Counterparty License Agreement but shall not include milestone payments, late payment interest or other penalties.

"Second Amendment" means that certain Second Amendment to License Agreement, dated as of October 23, 2020, by and between the Seller and the Counterparty.

"Seller" has the meaning set forth in the preamble.

"Seller Account" has the meaning set forth in Section 5.4(d).

"Seller Indemnified Party" has the meaning set forth in Section 7.2.

"Set-off" means any set-off, off-set, rescission, counterclaim, reduction, deduction or defense.

"Sublicensee" means any sublicensee of Counterparty under the Counterparty License Agreement.

"Subsidiary" means, with respect to any Person, any other Person of which more than 50% of the outstanding Voting Securities of such other Person (irrespective of whether at the time Capital Securities of any other class or classes of such other Person shall or might have voting power upon the occurrence of any contingency) is at the time directly or indirectly owned or controlled by such Person, by such Person and one or more other Subsidiaries of such Person or by one or more other Subsidiaries of such Person.

"Substitute Amounts" has the meaning set forth in Section 5.6(a).

[*****]

"Territory" has the meaning set forth in Section 1.1.56 of the Counterparty License Agreement.

"Total Net Sales" means, with respect to any period, the sum of the Net Sales of the Product under the Counterparty License Agreement during such period plus total net sales of the Product under any Additional License Agreements during such period; provided that, for purposes of determining Total Net Sales, any Net Sales or net sales in a currency other than Dollars shall be converted to Dollars as provided for in the Counterparty License Agreement or Additional License Agreement, as applicable.

"Transaction Documents" means this Purchase and Sale Agreement, the Bill of Sale and the Counterparty Instruction.

"UCC" means the Uniform Commercial Code as in effect from time to time in Delaware; provided, that, if, with respect to any financing statement or by reason of any provisions of Applicable Law, the perfection or the effect of perfection or non-perfection of the back-up security interest or any portion thereof granted pursuant to Section 2.1(d) is governed by the Uniform Commercial Code as in effect in a jurisdiction of the United States other than Delaware, then "UCC" means the Uniform Commercial Code as in effect from time to time in such other jurisdiction for purposes of the provisions of this Purchase and Sale Agreement and any financing statement relating to such perfection or effect of perfection or non-perfection.

"U.S." or "United States" means the United States of America, its 50 states, each territory thereof and the District of Columbia.

"Voluntary Seller Bankruptcy" means (a) an admission in writing by the Seller of its inability to pay its debts generally or a general assignment by the Seller for the benefit of creditors, (b) the filing of any petition or answer by the Seller seeking to adjudicate itself as bankrupt or insolvent, or seeking for itself any liquidation, winding-up, reorganization, arrangement, adjustment, protection, relief or composition of the Seller or its debts under any Applicable Law relating to bankruptcy, insolvency, receivership, winding-up, liquidation, reorganization, examination, relief of debtors or other similar Applicable Law now or hereafter in effect, or seeking, consenting to or acquiescing in the entry of an order for relief in any case under any such Applicable Law, or the appointment of or taking possession by a receiver, trustee, custodian, liquidator, examiner, assignee, sequestrator or other similar official for the Seller or for any substantial part of its property, or (c) corporate or other action taken by the Seller to authorize any of the actions set forth above.

"Voting Securities" means, with respect to any Person, Capital Securities of any class or kind ordinarily having the power to vote for the election of directors, managers or other voting members of the governing body of such Person.

Section 1.2 Rules of Construction. Unless the context otherwise requires, in this Purchase and Sale Agreement:

(a) A term has the meaning assigned to it and an accounting term not otherwise defined has the meaning assigned to it in accordance with GAAP.

(b) Unless otherwise defined, all terms that are defined in the UCC shall have the meanings stated in the UCC.

(c) Words of the masculine, feminine or neuter gender shall mean and include the correlative words of other genders.

(d) The definitions of terms shall apply equally to the singular and plural forms of the terms defined.

(e) The terms "include," "including" and similar terms shall be construed as if followed by the phrase "without limitation."

(f) The word "or" is not exclusive.

(g) Unless otherwise specified, references to an agreement or other document include references to such agreement or document as from time to time amended, restated, reformed, supplemented or otherwise modified in accordance with the terms thereof (subject to any restrictions on such amendments, restatements, reformations, supplements or modifications set forth herein) and include any annexes, exhibits and schedules attached thereto.

(h) References to any Applicable Law shall include such Applicable Law as from time to time in effect, including any amendment, modification, codification, replacement or reenactment thereof or any substitution therefor.

(i) References to any Person shall be construed to include such Person's successors and permitted assigns (subject to any restrictions on assignment, transfer or delegation set forth herein or in any of the other Transaction Documents), and any reference to a Person in a particular capacity excludes such Person in other capacities.

(j) The word “will” shall be construed to have the same meaning and effect as the word “shall.”

(k) The words “hereof,” “herein,” “hereunder” and similar terms when used in this Purchase and Sale Agreement shall refer to this Purchase and Sale Agreement as a whole and not to any particular provision hereof, and Article, Section and Exhibit references herein are references to Articles and Sections of, and Exhibits to, this Purchase and Sale Agreement unless otherwise specified.

(l) In the computation of a period of time from a specified date to a later specified date, the word “from” means “from and including” and each of the words “to” and “until” means “to but excluding.”

(m) Where any payment is to be made, any funds are to be applied or any calculation is to be made under this Purchase and Sale Agreement on a day that is not a Business Day, unless this Purchase and Sale Agreement otherwise provides, such payment shall be made, such funds shall be applied and such calculation shall be made on the succeeding Business Day, and payments shall be adjusted accordingly.

(n) Any reference herein to a term that is defined by reference to its meaning in the Counterparty License Agreement shall refer to such term’s meaning in the Counterparty License Agreement as in existence on the date hereof (and not to any new, substituted or amended version thereof).

ARTICLE II
PURCHASE AND SALE OF THE PURCHASED ASSETS

Section 2.1 Purchase and Sale.

(a) Subject to the terms and conditions of this Purchase and Sale Agreement, on the Closing Date, the Seller hereby sells, assigns, transfers, conveys and grants to the Purchaser, and the Purchaser hereby purchases, acquires and accepts from the Seller, all of the Seller’s rights, title and interest in and to the Purchased Assets, free and clear of any and all Liens, other than those Liens created in favor of the Purchaser by the Transaction Documents.

(b) The Seller and the Purchaser intend and agree that the sale, assignment, transfer, conveyance and granting of the Purchased Assets under this Purchase and Sale Agreement shall be, and are, a true, complete, absolute and irrevocable assignment and sale by the Seller to the Purchaser of the Purchased Assets and that such assignment and sale shall provide the Purchaser with the full benefits of ownership of the Purchased Assets. Neither the Seller nor the Purchaser intends the transactions contemplated hereby to be, or for any purpose characterized as, a loan from the Purchaser to the Seller or a pledge or assignment or a security agreement. The Seller waives any right to contest or otherwise assert that this Purchase and Sale Agreement does not constitute a true, complete, absolute and irrevocable sale and assignment by the Seller to the Purchaser of the Purchased Assets under Applicable Law in any Voluntary Seller Bankruptcy or Involuntary Seller Bankruptcy. The sale, assignment, transfer, conveyance and granting of the Purchased Assets shall be reflected on the Seller’s financial statements and other records as a sale of assets to the Purchaser (except to the extent GAAP or the rules of the SEC require otherwise with respect to the Seller’s consolidated financial statements).

(c) The Seller hereby authorizes the Purchaser or its designee to execute, record and file, and consents to the Purchaser or its designee executing, recording and filing, at the Purchaser's sole cost and expense, financing statements in the appropriate filing offices under the UCC (and continuation statements with respect to such financing statements when applicable), and amendments thereto or assignments thereof, in such manner and in such jurisdictions as are necessary or appropriate to evidence or perfect the sale, assignment, transfer, conveyance and grant by the Seller to the Purchaser, and the purchase, acquisition and acceptance by the Purchaser from the Seller, of the Purchased Assets and to perfect the security interest in the Purchased Assets granted by the Seller to the Purchaser pursuant to Section 2.1(d).

(d) Notwithstanding that the Seller and the Purchaser expressly intend for the sale, assignment, transfer, conveyance and granting of the Purchased Assets to be a true, complete, absolute and irrevocable sale and assignment, the Seller hereby assigns, conveys, grants and pledges to the Purchaser, as security for its obligations created hereunder in the event that the transfer contemplated by this Purchase and Sale Agreement is held not to be a sale, a security interest of first priority in and to all of the Seller's right, title and interest in, to and under the Purchased Assets, whether now or hereafter acquired or arising, and wherever located, and any and all "proceeds" thereof (as such term is defined in the UCC), to secure payment to Purchaser of amounts equal to the Purchased Assets as they are paid under the Counterparty License Agreement, in such event, this Purchase and Sale Agreement shall constitute a security agreement, and Seller does hereby authorize Purchaser to file such financing statements (and continuation statements with respect to such financing statements when applicable), in form and substance reasonably acceptable to the Seller, as may be necessary to perfect its security interest.

Section 2.2 Purchase Price. In full consideration for the sale, assignment, transfer, conveyance and granting of the Purchased Assets, and subject to the terms and conditions set forth herein, the Purchaser shall pay (or cause to be paid) to the Seller, or the Seller's designee, the following amounts, to the extent earned and payable in accordance with the below (collectively, the "Purchase Price"):

(a) the sum of $40,000,000 on the Closing Date;

(b) the sum of $10,000,000 upon the first to occur of (1) the Counterparty executes and delivers the Counterparty Confirmation, or (2) the patent issued pursuant to the Pending Patent Application is listed in the Orange Book for the Product;

(c) the sum of $[*****] in the event that [*****];

(d) the sum of $[*****] in the event that [*****];

(e) the sum of $[*****] in the event that [*****];

(f) the sum of $[*****] in the event that [*****]; and

(g) the sum of $[*****] in the event that [*****].

Payment of the Purchase Price shall be made in Dollars in immediately available funds by wire transfer to the Seller Account. Payment of the Purchase Price (i) described in clause (a) above shall be made on the Closing Date, (ii) described in clause (b) above shall be made, subject to the limitations set forth in Section 2.3, on the date that is no later than twelve (12) Business Days following the satisfaction of the conditions set forth in clause (b), (iii) described in clauses (c) through (e) above, shall be made on a date that is no later than 30 days following the Earned Date for such clause, (iv) described in clause (f) above, shall be made [*****] following such Earned Date, [*****] and (v) described in clause (g) above, shall be made [*****] following the Earned Date for clause (g), [*****]. [*****]. In the event that the Seller changes the payment instructions set forth in the Counterparty Instruction without the prior written consent of the Purchaser and fails to reverse such payment instruction change within thirty (30) days' written notice from the Purchaser, all further Contingent Payments shall be forfeited, including any quarterly payments that would otherwise have been due and payable. Each Contingent Payment shall only be payable once, if earned in accordance with its terms.

Section 2.3 [*****].

Section 2.4 No Assumed Obligations. Notwithstanding any provision in this Purchase and Sale Agreement or any other writing to the contrary, the Purchaser is purchasing, acquiring and accepting only the Purchased Assets and is not assuming any liability or obligation of the Seller or any of the Seller's Affiliates of whatever nature, whether presently in existence or arising or asserted hereafter (including any liability or obligation of the Seller under the Counterparty License Agreement or any Additional License Agreement) (collectively, the "Retained Liabilities"). All Retained Liabilities shall be retained by and remain liabilities and obligations of the Seller or the Seller's Affiliates, as the case may be.

Section 2.5 Excluded Assets. Except as otherwise explicitly set forth herein, the Purchaser does not, by purchase, acquisition or acceptance of the rights, title or interest granted hereunder or otherwise pursuant to any of the Transaction Documents, purchase, acquire or accept any Intellectual Property or other assets or property of the Seller, or rights, title or interests granted therein, by implication or otherwise, other than the Purchased Assets.

Section 2.6 Payment Default. In addition to the remedies set forth in Article VII or elsewhere herein, if either the Seller or the Purchaser fails to pay any [*****], Contingent Payment or other payment with respect to the Purchased Assets required to be made by the Seller (or any of its Affiliates) or the Purchaser, as applicable, within thirty (30) days after the applicable due date (the "Payment Date"), all such unpaid amounts shall bear interest at a rate of [*****] per annum, compounded monthly ("Default Interest"), commencing on the applicable due date on which such payment was not paid and continuing until such time as the unpaid payment is paid. The receipt by the Purchaser or the Seller, as applicable, of such Default Interest shall not be construed as a waiver by such receiving party of any default or any of the rights or remedies of such receiving party under this Agreement. For the avoidance of doubt, Seller shall not be liable for any Default Interest in respect of an unpaid Royalty payment where a Counterparty has failed to make the corresponding payment under the Counterparty License Agreement.

ARTICLE III
REPRESENTATIONS AND WARRANTIES OF THE SELLER

The Seller hereby represents and warrants to the Purchaser as of the date hereof as follows:

Section 3.1 Organization. The Seller is a corporation duly organized, validly existing and in good standing under the laws of the State of Delaware and has all powers and authority, and all licenses, permits, franchises, authorizations, consents and approvals of all Governmental Authorities, required to own its property and conduct its business as now conducted and to exercise its rights and to perform its obligations under the Counterparty License Agreement. The Seller is duly qualified to transact business and is in good standing in every jurisdiction in which such qualification or good standing is required by Applicable Law (except where the failure to be so qualified or in good standing would not be a Material Adverse Change).

Section 3.2 No Conflicts.

(a) None of the execution and delivery by the Seller of any of the Transaction Documents to which the Seller is party, the performance by the Seller of the obligations contemplated hereby or thereby or the consummation of the transactions contemplated hereby or thereby will: (i) contravene, conflict with, result in a breach, violation, cancellation or termination of, constitute a default (with or without notice or lapse of time, or both) under, require prepayment under, give any Person the right to exercise any remedy or obtain any additional rights under, or accelerate the maturity or performance of or payment under, in any respect, (A) any Applicable Law or any judgment, order, writ, decree, permit or license of any Governmental Authority, to which the Seller or any of its Subsidiaries or any of their respective assets or properties may be subject or bound, (B) any term or provision of any contract, agreement, indenture, lease, license, deed, commitment, obligation or instrument to which the Seller or any of its Subsidiaries is a party or by which the Seller or any of its Subsidiaries or any of their respective assets or properties is bound or committed (including the Counterparty License Agreement) or (C) any term or provision of any of the organizational documents of the Seller or any of its Subsidiaries; (ii) give rise to any additional right of termination, cancellation or acceleration of any right or obligation of the Seller or any of its Subsidiaries; or (iii) except as provided in any of the Transaction Documents to which it is party, result in or require the creation or imposition of any Lien on the Licensed Patents, the Products, the Counterparty License Agreement or the Purchased Assets.

(b) Except for any Lien created or existing under the Counterparty License Agreement, the Seller has not granted, nor does there exist, any Lien on the Transaction Documents, the Counterparty License Agreement or the Purchased Assets. Except for any Lien created under the Counterparty License Agreement or in connection with the Seller's commercial lending arrangements, the Seller has not granted, nor does there exist, any Lien on the Licensed Patents. Except for the license granted by the Seller to Counterparty under the Counterparty License Agreement and any sublicenses granted by the Counterparty pursuant to Section 2.1.3 of the Counterparty License Agreement, there are no licenses, sublicenses or other rights under the Licensed Patents in the Territory that have been granted to any other Person.

Section 3.3 Authorization. The Seller has all powers and authority to execute and deliver, and perform its obligations under, the Transaction Documents to which it is party and to consummate the transactions contemplated hereby and thereby. The execution and delivery of each of the Transaction Documents to which the Seller is party and the performance by the Seller of its obligations hereunder and thereunder have been duly authorized by the Seller. Each of the Transaction Documents to which the Seller is party has been duly executed and delivered by the Seller. Each of the Transaction Documents to which the Seller is party constitutes the legal, valid and binding obligation of the Seller, enforceable against the Seller in accordance with its respective terms, subject to applicable bankruptcy, insolvency, reorganization, moratorium or similar Applicable Laws affecting creditors' rights generally, general equitable principles and principles of public policy.

Section 3.4 Ownership. The Seller is the exclusive owner of the entire right, title (legal and equitable) and interest in, to and under the Purchased Assets and has good and valid title thereto, free and clear of all Liens. The Seller is the exclusive owner of the entire right, title (legal and equitable) and interest in, or has a license, sublicense or otherwise permission to use and license Licensed Patents, free and clear of all Liens except for Liens granted in connection with the Seller's commercial lending arrangements. The Seller has duly and legally filed or applied for registration for its ownership interest in the Licensed Patents in the appropriate agencies and in the jurisdictions set forth on Exhibit C, and the Seller is the exclusive "owner of record" of such Licensed Patents in each such jurisdiction. The Purchased Assets sold, assigned, transferred, conveyed and granted to the Purchaser on the Closing Date have not been pledged, sold, assigned, transferred, conveyed or granted by the Seller to any other Person. The Seller has full right to sell, assign, transfer, convey and grant the Purchased Assets to the Purchaser. Upon the sale, assignment, transfer, conveyance and granting by the Seller of the Purchased Assets to the Purchaser, the Purchaser shall acquire good and marketable title to the Purchased Assets free and clear of all Liens, other than Liens in favor of the Purchaser, and shall be the exclusive owner of the Purchased Assets. The Purchaser shall have the same rights as the Seller would have with respect to the Purchased Assets (if the Seller were still the owner of such Purchased Assets) against any other Person.

Section 3.5 Governmental and Third Party Authorizations. The execution and delivery by the Seller of the Transaction Documents to which the Seller is party, the performance by the Seller of its obligations hereunder and thereunder and the consummation of any of the transactions contemplated hereunder and thereunder (including the sale, assignment, transfer, conveyance and granting of the Purchased Assets to the Purchaser) do not require any consent, approval, license, order, authorization or declaration from, notice to, action or registration by or filing with any Governmental Authority or any other Person, except for the filing of a Current Report on Form 8-K with the Securities and Exchange Commission, the filing of UCC financing statements, the notice to Counterparty contained in the Counterparty Instruction, the notice to the holders of the Seller's debt pursuant to its commercial lending arrangements and those previously obtained.

Section 3.6 No Litigation. There is no (a) action, suit, arbitration proceeding, claim, demand, citation, summons, subpoena, investigation or other proceeding (whether civil, criminal, administrative, regulatory, investigative or informal) pending or, to the knowledge of the Seller, threatened in respect of the Products, the Counterparty License Agreement or the Purchased Assets, at law or in equity, or (b) to the knowledge of the Seller, inquiry or investigation (whether civil, criminal, administrative, regulatory, investigative or informal) by or before a Governmental Authority pending or threatened against the Seller or any of its Subsidiaries in respect of the Products, the Counterparty License Agreement or the Purchased Assets, that, in each case, (i) could reasonably be expected to result in a Material Adverse Change or (ii) challenges or seeks to prevent or delay the consummation of any of the transactions contemplated by any of the Transaction Documents to which the Seller is party. To the knowledge of the Seller, no event has occurred or circumstance exists that may give rise to or serve as a basis for the commencement of any such action, suit, arbitration, claim, investigation, proceeding or inquiry.

Section 3.7 Solvency. The Seller has determined that, and by virtue of its entering into the transactions contemplated by the Transaction Documents to which the Seller is party and its authorization, execution and delivery of the Transaction Documents to which the Seller is party, the Seller's incurrence of any liability hereunder or thereunder or contemplated hereby or thereby is in its own best interests. Upon consummation of the transactions contemplated by the Transaction Documents and the application of the proceeds therefrom, (a) the fair saleable value of the Seller's assets will be greater than the sum of its debts, liabilities and other obligations, including contingent liabilities, (b) the present fair saleable value of the Seller's assets will be greater than the amount that would be required to pay its probable liabilities on its existing debts, liabilities and other obligations, including contingent liabilities, as they become absolute and matured, (c) the Seller will be able to realize upon its assets and pay its debts, liabilities and other obligations, including contingent obligations, as they mature, (d) the Seller will not be rendered insolvent, will not have unreasonably small capital with which to engage in its business and will not be unable to pay its debts as they mature, (e) the Seller has not incurred, will not incur and does not have any present plans or intentions to incur debts or other obligations or liabilities beyond its ability to pay such debts or other obligations or liabilities as they become absolute and matured, (f) the Seller will not have become subject to any Voluntary Seller Bankruptcy or Involuntary Seller Bankruptcy and (g) the Seller will not have been rendered insolvent within the meaning of Section 101(32) of Title 11 of the United States Code. No step has been taken or is intended by the Seller or, so far as it is aware, any other Person to make the Seller subject to a Voluntary Seller Bankruptcy or Involuntary Seller Bankruptcy.

Section 3.8 No Brokers' Fees. The Seller has not taken any action that would entitle any person or entity other than Morgan Stanley & Co. LLC to any commission or broker's fee in connection with the transactions contemplated by this Purchase and Sale Agreement.

Section 3.9 Compliance with Laws. None of the Seller or any of its Subsidiaries (a) has violated or is in violation of, or, to the knowledge of the Seller, is under investigation with respect to or has been threatened to be charged with or been given notice of any violation of, any Applicable Law or any judgment, order, writ, decree, injunction, stipulation, consent order, permit or license granted, issued or entered by any Governmental Authority or (b) is subject to any judgment, order, writ, decree, injunction, stipulation, consent order, permit or license granted, issued or entered by any Governmental Authority, in each case, that would be a Material Adverse Change. Each of the Seller and any Subsidiary of the Seller is in compliance with the requirements of all Applicable Laws, a breach of any of which would be a Material Adverse Change.

Section 3.10 Intellectual Property Matters.

(a) Exhibit C sets forth an accurate and complete list of all Licensed Patents. For each of such Licensed Patents listed on Exhibit C, the Seller has indicated (i) the jurisdictions in which such Licensed Patent is pending, allowed, granted or issued, (ii) the patent number or patent serial number, (iii) the scheduled expiration date of such issued patent, (iv) the scheduled expiration date of each patent issuing from such pending patent application once issued and (v) the owner of such Licensed Patent.

(b) To the knowledge of the Seller, each claim that has been issued or granted by the appropriate Patent Office included in the relevant Licensed Patents is valid and enforceable.

(c) There are no unpaid maintenance or renewal fees payable by the Seller to any third party that currently are overdue for any of the Licensed Patents. No Licensed Patents listed on Exhibit C have lapsed or been abandoned, cancelled or expired. To the knowledge of the Seller, each individual associated with the filing and prosecution of the Licensed Patents, including the named inventors of the Licensed Patents, has complied in all material respects with all applicable duties of candor and good faith in dealing with any Patent Office, including any duty to disclose to any Patent Office all information known by such inventors to be material to the patentability of each of the Licensed Patents (including any relevant prior art), in each case, in those jurisdictions in the Territory where such duties exist.

(d) Subsequent to the issuance of the Licensed Patents, neither the Seller nor, to the knowledge of the Seller, Counterparty has filed any disclaimer or made or permitted any other voluntary reduction in the scope of the Licensed Patents.

(e) To the knowledge of the Seller, there is no pending or threatened opposition, interference, inter partes proceeding, reexamination, injunction, claim, suit, action, citation, summon, subpoena, hearing, inquiry, investigation (by the International Trade Commission or otherwise), complaint, arbitration, mediation, demand, decree or other dispute, disagreement, proceeding or claim (collectively, "Disputes") challenging the validity, enforceability or ownership of any of the Licensed Patents or that could reasonably be expected to give rise to any Set-off against the payments due to the Seller under the Counterparty License Agreement for the use of the related Licensed Patents. To the knowledge of the Seller, there are no Disputes by or with any third party against the Seller involving any of the Products. The Licensed Patents are not subject to any outstanding injunction, judgment, order, decree, settlement or, to the knowledge of the Seller, other disposition of a Dispute.

(f) To the knowledge of the Seller, there is no pending or threatened, and no event has occurred or circumstance exists that (with or without notice or lapse of time, or both) could reasonably be expected to give rise to or serve as a basis for any, action, suit or proceeding, or any investigation or claim, and the Seller has not received any written notice of the foregoing, that claims that the manufacture, use, marketing, sale, offer for sale, importation or distribution of any of the Products infringes on any valid and enforceable patent of any other Person or constitute misappropriation of any other Person's trade secrets or other intellectual property rights.

(g) To the knowledge of the Seller, there is no third party infringing any Licensed Patents in any material respect, nor has the Seller received any notice under the Counterparty License Agreement of infringement of any of the Licensed Patents, except as set forth on Exhibit C.

(h) [*****].

Section 3.11 Regulatory Approval, Manufacturing and Marketing.

(a) To the knowledge of the Seller, Counterparty has complied with its obligations to develop the Products and seek and obtain Regulatory Approval for the Products to the extent required by the Counterparty License Agreement.

(b) To the knowledge of the Seller, the KYNMOBI product received Regulatory Approval for marketing and distribution in the U.S. on May 21, 2020.

Section 3.12 Counterparty License Agreement.

(a) Other than the Transaction Documents, the Counterparty License Agreement and (solely in respect of the creation of Liens) the commercial lending arrangements of the Seller, there is no contract, agreement or other arrangement (whether written or oral) to which the Seller or any of its Subsidiaries is a party or by which any of their respective assets or properties is bound or committed (i) that creates a Lien on, affects or otherwise relates to the Purchased Assets or the Counterparty License Agreement or the Licensed Patents or (ii) for which breach, nonperformance, cancellation or failure to renew would be a Material Adverse Change.

(b) The Seller has provided to the Purchaser a true, correct and complete copy of the Counterparty License Agreement. The Seller has no written agreement with the Counterparty with respect to the Product or the Licensed Patents other than the Counterparty License Agreement.

(c) The Counterparty License Agreement is in full force and effect and is the legal, valid and binding obligation of the Seller, enforceable against the Seller in accordance with its respective terms, subject, as to enforcement of remedies, to bankruptcy, insolvency, reorganization, moratorium or similar Applicable Laws affecting creditors' rights generally, general equitable principles and principles of public policy. The execution and delivery of, and performance of obligations by the Seller under, the Counterparty License Agreement were and are within the powers of the Seller. The Counterparty License Agreement was duly authorized by all necessary action on the part of, and validly executed and delivered by, the Seller. The Seller is not in breach or violation of or in default under the Counterparty License Agreement that would be a Material Adverse Change. The representations and warranties of the Seller in the Counterparty License Agreement were true and correct on the date of the Counterparty License Agreement. To the knowledge of the Seller, there is no event or circumstance that, upon notice or the passage of time, or both, would constitute or give rise to any breach or default in the performance of the Counterparty License Agreement by the Seller that would be a Material Adverse Change.

(d) Except as set forth under the First Amendment, the Seller has not waived any rights or defaults under the Counterparty License Agreement or released Counterparty or any other party thereto, in whole or in part, from any of its obligations under the Counterparty License Agreement the existence of which would have a Material Adverse Change. To the knowledge of the Seller, there are no oral waivers or modifications in respect of the Counterparty License Agreement. Except as set forth under the First Amendment and the Second Amendment, neither the Seller nor Counterparty has agreed to amend or waive any provision of the Counterparty License Agreement, and there is no current proposal to do so.

(e) To the knowledge of the Seller, no event has occurred that would give the Seller or Counterparty or any other party thereto the right to terminate the Counterparty License Agreement or cease paying Royalties thereunder. The Seller has not received any notice of an intention by Counterparty or any other Person to terminate or breach the Counterparty License Agreement, in whole or in part, of force majeure under the Counterparty License Agreement, or challenging the validity or enforceability of the Counterparty License Agreement or the obligation to pay the Royalties under the Counterparty License Agreement, or that the Seller or Counterparty or any other party thereto is in default of its obligations under the Counterparty License Agreement. The Seller is not aware of any default, violation or breach by Counterparty under or of the Counterparty License Agreement. The Seller has no present intention of terminating the Counterparty License Agreement and has not given Counterparty or any other party thereto any notice of termination of the Counterparty License Agreement, in whole or in part, or of force majeure under the Counterparty License Agreement.

(f) Except as provided in the Counterparty License Agreement, the Seller is not a party to any agreement entitling any other Person to any payments, including by way of Set-off, in respect of the Royalties payable under the Counterparty License Agreement to the Seller.

(g) Except for sublicense arrangements pursuant to Section 2.1.3 of the Counterparty License Agreement, the Seller has not consented to an assignment by Counterparty or any other party thereto of any of Counterparty's or such other party's rights or obligations under the Counterparty License Agreement, and the Seller does not have knowledge of any such assignment by Counterparty or any other such party. Except as contemplated by Section 2.1, the Seller has not assigned, in whole or in part, and has not granted, incurred or suffered to exist any Liens (other than Liens created or existing under the Counterparty License Agreement) (i) on the Counterparty License Agreement or the Purchased Assets or (ii) other than Liens granted in connection with the Seller's commercial lending arrangements, on any of the Seller's rights, title or interest in and to the Licensed Patents.

(h) None of the Seller, Counterparty or any other party thereto has made any claim of indemnification under the Counterparty License Agreement.

(i) The Seller has not exercised its rights to conduct an audit under the Counterparty License Agreement.

(j) To the knowledge of the Seller, the Seller has received all amounts owed to it under the Counterparty License Agreement.

(k) The Seller has not granted any Person any rights in the Licensed Patents that conflict with the rights therein granted to the Counterparty under the Counterparty License Agreement.

Section 3.13 UCC Matters. The Seller's exact legal name is, and since January 1, 2018 has been, "Aquestive Therapeutics, Inc." Prior to such date, the Seller's exact legal name was "MonoSol Rx, LLC." The Seller has had no other legal name during the 10 years preceding the date hereof. The Seller's principal place of business is, and for the preceding 10 years has been, located in Warren, New Jersey. The Seller's jurisdiction of organization is, and for the preceding 10 years has been, Delaware. For the preceding 10 years, the Seller has not been the subject of any merger or other corporate or other reorganization in which its identity or status was materially changed, except in each case when it was the surviving or resulting Person.

Section 3.14 Set-off and Other Sources of Royalty Reduction. Except as provided in the Counterparty License Agreement, Counterparty has no right of Set-off under any contract or other agreement against the Royalties or any other amounts payable to the Seller under the Counterparty License Agreement. Counterparty has not exercised, and, to the knowledge of the Seller, Counterparty has not had the right to exercise, and no event or condition exists that, upon notice or passage of time or both, would reasonably be expected to permit Counterparty to exercise, any Set-off against the Royalties or any other amounts payable to the Seller under the Counterparty License Agreement. To the knowledge of the Seller, there are no third party patents that would provide a basis for a reduction in the royalties due to the Seller pursuant to the Counterparty License Agreement. There are no compulsory licenses granted or, to the knowledge of the Seller, threatened to be granted with respect to the Licensed Patents.

Section 3.15 Competing Products. Neither the Seller nor any of its Affiliates is currently involved in the development of another Apomorphine product for the Field that could reasonably be expected to result in a reduction or termination of any Royalties under the Counterparty License Agreement. To the actual knowledge of the Seller, the Counterparty is not currently involved in the development of another Apomorphine product for the Field that could reasonably be expected to result in a reduction or termination of any Royalties under the Counterparty License Agreement.

ARTICLE IV
REPRESENTATIONS AND WARRANTIES OF THE PURCHASER

The Purchaser hereby represents and warrants to the Seller as of the date hereof as follows:

Section 4.1 Organization. The Purchaser is a limited liability company duly organized, validly existing and in good standing under the laws of the State of Delaware and has all powers and authority, and all licenses, permits, franchises, authorizations, consents and approvals of all Governmental Authorities, required to own its property and conduct its business as now conducted.

Section 4.2 No Conflicts. None of the execution and delivery by the Purchaser of any of the Transaction Documents to which the Purchaser is party, the performance by the Purchaser of the obligations contemplated hereby or thereby or the consummation of the transactions contemplated hereby or thereby will contravene, conflict with, result in a breach, violation, cancellation or termination of, constitute a default (with or without notice or lapse of time, or both) under, require prepayment under, give any Person the right to exercise any remedy or obtain any additional rights under, or accelerate the maturity or performance of or payment under, in any respect, (i) any Applicable Law or any judgment, order, writ, decree, permit or license of any Governmental Authority to which the Purchaser or any of its assets or properties may be subject or bound, (ii) any term or provision of any contract, agreement, indenture, lease, license, deed, commitment, obligation or instrument to which the Purchaser is a party or by which the Purchaser or any of its assets or properties is bound or committed or (iii) any term or provision of any of the organizational documents of the Purchaser.

Section 4.3 Authorization. The Purchaser has all powers and authority to execute and deliver, and perform its obligations under, the Transaction Documents to which it is party and to consummate the transactions contemplated hereby and thereby. The execution and delivery of each of the Transaction Documents to which the Purchaser is party and the performance by the Purchaser of its obligations hereunder and thereunder have been duly authorized by the Purchaser. Each of the Transaction Documents to which the Purchaser is party has been duly executed and delivered by the Purchaser. Each of the Transaction Documents to which the Purchaser is party constitutes the legal, valid and binding obligation of the Purchaser, enforceable against the Purchaser in accordance with its respective terms, subject to applicable bankruptcy, insolvency, reorganization, moratorium or similar Applicable Laws affecting creditors' rights generally, general equitable principles and principles of public policy.

Section 4.4 Governmental and Third Party Authorizations. The execution and delivery by the Purchaser of the Transaction Documents to which the Purchaser is party, the performance by the Purchaser of its obligations hereunder and thereunder and the consummation of any of the transactions contemplated hereunder and thereunder do not require any consent, approval, license, order, authorization or declaration from, notice to, action or registration by or filing with any Governmental Authority or any other Person, except as described in Section 3.5.

Section 4.5 No Litigation. There is no (a) action, suit, arbitration proceeding, claim, demand, citation, summons, subpoena, investigation or other proceeding (whether civil, criminal, administrative, regulatory, investigative or informal) pending or, to the knowledge of the Purchaser, threatened by or against the Purchaser, at law or in equity, or (b) inquiry or investigation (whether civil, criminal, administrative, regulatory, investigative or informal) by or before a Governmental Authority pending or, to the knowledge of the Purchaser, threatened against the Purchaser, that, in each case, challenges or seeks to prevent or delay the consummation of any of the transactions contemplated by any of the Transaction Documents to which the Purchaser is party.

Section 4.6 Access to Information. The Purchaser acknowledges that it has (a) reviewed the Counterparty License Agreement and such other documents and information relating to the Licensed Patents and the Products and (b) had the opportunity to ask such questions of, and to receive answers from, representatives of the Seller concerning the Counterparty License Agreement, the Licensed Patents and the Products, in each case, as it deemed necessary to make an informed decision to purchase, acquire and accept the Purchased Assets in accordance with the terms of this Purchase and Sale Agreement. The Purchaser has such knowledge, sophistication and experience in financial and business matters that it is capable of evaluating the risks and merits of purchasing, acquiring and accepting the Purchased Assets in accordance with the terms of this Purchase and Sale Agreement.

Section 4.7 Funds Available. The Purchaser has sufficient funds on hand or binding and enforceable commitments to provide it with sufficient funds to satisfy its obligations, in each case to pay the Purchase Price, and the Purchaser has no reason to believe, and has not been provided with oral or written notice that any of its investors are not required or do not intend, for any reason, to satisfy their obligations under such commitments. The Purchaser acknowledges and agrees that its obligations under this Purchase and Sale Agreement are not contingent on obtaining financing.

ARTICLE V
COVENANTS

The parties hereto covenant and agree as follows:

Section 5.1 Books and Records; Notices.

(a) Promptly (but in no event more than five Business Days) after receipt by the Seller of notice of any action, suit, claim, demand, dispute, investigation, arbitration or other proceeding (commenced or threatened) relating to the transactions contemplated by any Transaction Document, the Purchased Assets or the Counterparty License Agreement or any default or termination by any Person under the Counterparty License Agreement, the Seller shall, except to the extent prohibited by Applicable Law, (i) inform the Purchaser in writing of the receipt of such notice and the substance thereof and (ii) if such notice is in writing, furnish the Purchaser with a copy of such notice and any related materials with respect thereto.

(b) The Seller shall keep and maintain, or cause to be kept and maintained, at all times full and accurate books and records adequate to reflect accurately all financial information it has received, and all amounts paid or received under the Counterparty License Agreement, with respect to the Royalties.

(c) Promptly (but in no event more than five Business Days) following receipt by the Seller of any material written notice, certificate, offer, proposal, correspondence, report or other communication relating to the Royalties or the Purchased Assets or, to the extent relating to or involving the Purchased Assets, the Counterparty License Agreement, the Licensed Patents or the Products, including, but not limited to, any Quarterly Royalty Reports under the Counterparty License Agreement, the Seller shall (i) inform the Purchaser in writing of such receipt and (ii) furnish the Purchaser with a copy of such notice, certificate, offer, proposal, correspondence, report or other communication, but in all cases excluding customary correspondence with a Patent Office relating to any pending patent applications.

(d) The Seller shall provide the Purchaser with written notice as promptly as practicable (and in any event within five Business Days) after becoming aware of any of the following: (i) the occurrence of a Voluntary Seller Bankruptcy or an Involuntary Seller Bankruptcy; (ii) any material breach or default by the Seller of or under any covenant, agreement or other provision of the Counterparty License Agreement or any Transaction Document to which it is party; (iii) any representation or warranty made by the Seller in the Counterparty License Agreement, any of the Transaction Documents or in any certificate delivered to the Purchaser pursuant to this Purchase and Sale Agreement shall prove to be untrue, inaccurate or incomplete in any material respect on the date as of which made; or (iv) any change, effect, event, occurrence, state of facts, development or condition that would be a Material Adverse Change.

(e) The Seller shall notify the Purchaser in writing not less than 30 days prior to any change in, or amendment or alteration of, the Seller's (i) legal name, (ii) form or type of organizational structure or (iii) jurisdiction of organization.

(f) Subject to applicable confidentiality restrictions and Applicable Laws relating to securities matters, the Seller shall make available such other information as the Purchaser may, from time to time, reasonably request with respect to (i) the Purchased Assets or (ii) the condition or operations, financial or otherwise, of the Seller that is reasonably likely to impact or affect the performance of the Seller's obligations hereunder or the Seller's compliance with the terms, provisions and conditions of this Purchase and Sale Agreement.

Section 5.2 Confidentiality; Public Announcement.

(a) Except as otherwise required by Applicable Law, by the rules and regulations of any securities exchange or trading system or by the FDA or any other Governmental Authority with similar regulatory authority and except as otherwise set forth in this Section 5.2, all Confidential Information furnished by the Seller to the Purchaser, as well as the terms, conditions and provisions of this Purchase and Sale Agreement and any other Transaction Document (collectively, the "Covered Information"), shall be kept confidential by the parties hereto and shall be used by the parties only in connection with this Purchase and Sale Agreement and any other Transaction Document and the transactions contemplated hereby and thereby. Notwithstanding the foregoing, each of the parties hereto may disclose such information to (i) its actual and potential partners, directors, employees, managers, officers, agents, investors (including any holder of debt securities of such party and such holder's advisors, agents and representatives), co-investors, insurers and insurance brokers, underwriters, financing parties, equity holders, brokers, advisors, lawyers, lenders, bankers, trustees and representatives and (ii) third parties in order to comply with any Applicable Law, and (solely with respect to the Purchaser) only after compliance with Section 5.2(b); provided, that such Persons listed in clause (i) above shall be informed of the confidential nature of such information and shall be obligated to keep such information confidential pursuant to obligations of confidentiality no less onerous than those set out herein.

(b) In the event that (i) either party is required by Applicable Law or by the rules and regulations of any securities exchange or trading system to disclose any of the terms, conditions and provisions of this Purchase and Sale Agreement and any other Transaction Document or (ii) the Purchaser is required by Applicable Law or by the rules and regulations of any securities exchange or trading system to disclose any other Covered Information, such party will notify the non-disclosing party promptly (unless such notice is prohibited by Applicable Law) so that the non-disclosing party may seek, at its own expense, a protective order or other appropriate remedy or, in the sole discretion of the non-disclosing party, waive compliance with the terms of this Section 5.2. In addition, the Seller will consult with the Purchasers in connection with the Seller's seeking confidential treatment from the Securities and Exchange Commission of the relevant provisions of this Purchase and Sale Agreement to the extent possible under the rules of the Securities and Exchange Commission, and will provide the Purchaser with a reasonable opportunity to comment on such confidential treatment request; provided, however, that the final decision as to disclosure of the terms of this Purchase and Sale Agreement with the Securities and Exchange Commission shall be in the sole discretion of the Seller. In the event that no such protective order or other remedy is obtained, or the non-disclosing party does do not waive in writing compliance with the terms of this Section 5.2, the disclosing party will (i) furnish only that portion of the Covered Information that it is advised by counsel (which may be internal counsel) is legally required and will exercise commercially reasonable efforts to obtain reliable assurance that confidential treatment will be accorded the Covered Information and (ii) provide the Seller with written notice of such disclosure promptly, but in any case, no later than three (3) days following such disclosure (unless such notice is prohibited by Applicable Law).

(c) The Seller and the Purchaser acknowledge that each party hereto may, after execution of this Purchase and Sale Agreement, make a public announcement of the transactions contemplated by the Transaction Documents. The Seller and the Purchaser agree that, after the execution of this Purchase and Sale Agreement, public announcements may be issued in the form of one or more press releases, and in disclosures contained in documents to be filed with or furnished to the Securities and Exchange Commission, in each case subject to the Purchaser or the Seller having a reasonable prior opportunity to review such public announcement, and either party hereto may thereafter disclose any information contained in such press release or Securities and Exchange Commission documents at any time without the consent of the other party hereto. Notwithstanding the foregoing, the Seller shall have sole discretion in determining the contents of disclosure materials with respect to the transactions contemplated by the Transaction Documents that the Seller files or furnishes to the Securities and Exchange Commission.

Section 5.3 Reasonable Best Efforts; Further Assurances.

(a) Subject to the terms and conditions of this Purchase and Sale Agreement, each party hereto will use its reasonable best efforts to take, or cause to be taken, all actions and to do, or cause to be done, all things necessary under Applicable Laws to consummate the transactions contemplated by the Transaction Documents to which the Seller or the Purchaser, as applicable, is party, including to (i) perfect the sale, assignment, transfer, conveyance and granting of the Purchased Assets to the Purchaser pursuant to this Purchase and Sale Agreement, (ii) execute and deliver such other documents, certificates, instruments, agreements and other writings and to take such other actions as may be necessary or desirable, or reasonably requested by the other party hereto, in order to consummate or implement expeditiously the transactions contemplated by any Transaction Document to which the Seller or the Purchaser, as applicable, is party, (iii) perfect, protect, more fully evidence, vest and maintain in the Purchaser good, valid and marketable rights and interests in and to the Purchased Assets free and clear of all Liens (other than those permitted by the Transaction Documents), (iv) create, evidence and perfect the Purchaser’s back-up security interest granted pursuant to Section 2.1(d) and (v) enable the Purchaser to exercise or enforce any of the Purchaser’s rights under any Transaction Document to which the Seller or the Purchaser, as applicable, is party, including following the Closing Date.

(b) The Seller and the Purchaser shall cooperate and provide assistance as reasonably requested by the other party hereto, at the expense of such other party hereto (except as otherwise set forth herein), in connection with any litigation, arbitration, investigation or other proceeding (whether threatened, existing, initiated or contemplated prior to, on or after the date hereof) to which the other party hereto, any of its Affiliates or controlling persons or any of their respective officers, directors, equityholders, controlling persons, managers, agents or employees is or may become a party or is or may become otherwise directly or indirectly affected or as to which any such Persons have a direct or indirect interest, in each case relating to any Transaction Document, the Purchased Assets or the transactions described herein or therein but in all cases excluding any litigation brought by the Seller (for itself or on behalf of any Seller Indemnified Party) against the Purchaser or brought by the Purchaser (for itself or on behalf of any Purchaser Indemnified Party) against the Seller.

(c) The Seller and the Purchaser shall each comply with all Applicable Laws with respect to the Transaction Documents to which it is party, the Counterparty License Agreement (in the case of the Seller), the Purchased Assets and all ancillary agreements related thereto, the violation of which would be a Material Adverse Change.

(d) The Seller shall not enter into any contract, agreement or other legally binding arrangement (whether written or oral), or grant any right to any other Person, in any case that would reasonably be expected to conflict with the Transaction Documents or serve or operate to limit or circumscribe any of the Purchaser's rights under the Transaction Documents (or the Purchaser's ability to exercise any such rights).

(e) The Seller shall use good faith efforts to get the Counterparty Instruction countersigned by the Counterparty prior to the Closing. However, if such countersignature is not obtained prior to the Closing, the Seller shall use good faith efforts for ninety (90) days following the Closing to get the Counterparty Instruction countersigned by the Counterparty as soon as practicable following the Closing. For the avoidance of doubt, in the absence of bad faith, the Seller's failure to obtain the Counterparty's countersignature to the Counterparty Instruction shall not constitute a breach of this covenant.

Section 5.4 Payments on Account of the Purchased Assets.

(a) If Counterparty, any Sublicensee or any other Person makes any future payment in respect of the Purchased Assets to the Seller (or any of its Subsidiaries) directly on account of the Purchased Assets, then (i) the portion of such payment that represents Royalties shall be held by the Seller (or such Subsidiary) in trust for the benefit of the Purchaser in a segregated account, (ii) the Seller (or such Subsidiary) shall have no right, title or interest whatsoever in such portion of such payment and shall not create or suffer to exist any Lien thereon and (iii) the Seller (or such Subsidiary) promptly, and in any event no later than five (5) Business Days following the receipt and identification by the Seller (or such Subsidiary) of such portion of such payment, shall remit such portion of such payment, without interest, to the Purchaser Account pursuant to Section 5.4(b).

(b) The Seller shall make all payments required to be made by it to the Purchaser pursuant to this Purchase and Sale Agreement by wire transfer of immediately available funds to the account listed on Exhibit 5.4(b) (or to such other account as the Purchaser shall notify the Seller in writing from time to time) (the "Purchaser Account").

(c) If Counterparty, any Sublicensee or any other Person makes any payment to the Purchaser of Royalties relating to periods prior to the Royalties Commencement Date, then (i) such payment shall be held by the Purchaser in trust for the benefit of the Seller in a segregated account, (ii) the Purchaser shall have no right, title or interest whatsoever in such payment and shall not create or suffer to exist any Lien thereon and (iii) the Purchaser promptly, and in any event no later than five (5) Business Days following the receipt and identification by the Purchaser of such payment, shall remit such payment, without interest, to the Seller Account pursuant to Section 5.4(d).

(d) The Purchaser shall make all payments required to be made by it to the Seller pursuant to this Purchase and Sale Agreement by wire transfer of immediately available funds to the account listed on Exhibit 5.4(d) (or to such other account as the Seller shall notify the Purchaser in writing from time to time) (the "Seller Account").

(e) If the Counterparty (or any Sublicensee) reduces the amount of any Royalties paid to the Purchaser as a result of any Set-off against such Royalties in respect of any amount owing from the Seller to such party, then, in the event that the Seller is unable to resolve such party's claim with respect to such amount owing within ninety (90) days following payment of Royalties affected by such Set-off such that the Purchaser receives the amount previously Set-off against such Royalties, the Seller shall promptly, and in any event no later than five (5) Business Days, following the expiration of such period, pay to the Purchaser a sum equal to such Set-off amount; provided, however, that this Section 5.4(e) shall not apply to any reduction of Royalties by the Counterparty (or any Sublicensee) in connection with any dispute under the Counterparty License Agreement over amounts payable in respect of royalties, milestone payments or any other payments arising out of, related to or resulting from the sale by Counterparty or any of its Affiliates, successors, Sublicensees, subcontractors or agents of any and all Products in the Territory.

Section 5.5 Counterparty License Agreement.

(a) The Seller (i) shall perform and comply in all material respects with its duties and obligations under the Counterparty License Agreement, (ii) except as set forth under this Purchase and Sale Agreement, shall not forgive, release or compromise any amount owed to or becoming owing to it under the Counterparty License Agreement, (iii) shall not, without the consent of the Purchaser (such consent not to be unreasonably withheld, delayed or conditioned) assign, amend, modify, supplement, restate, waive, cancel or terminate (or consent to any cancellation or termination of), in whole or in part, any rights constituting or involving, affecting or relating to the Purchased Assets or the right to receive the Royalties under the Counterparty License Agreement, (iv) shall not breach in any material respects any of the provisions of the Counterparty License Agreement relevant to the Purchased Assets, (v) except pursuant to Section 5.6, shall not enter into any new agreement or legally binding arrangement in respect of the Purchased Assets, the Royalties or the Products (in respect of the Territory in the Field), (vi) shall not, without the consent of the Purchaser (such consent not to be unreasonably withheld, delayed or conditioned), waive any obligation of, or grant any consent to, Counterparty under the Counterparty License Agreement in respect of the Purchased Assets or, to the extent relevant to the Purchased Assets, under or in respect of the Products (in respect of the Territory in the Field), (vii) shall not alter or change the payment instructions contained in the Counterparty Instruction without the prior written consent of the Purchaser, and (viii) except pursuant to Section 5.6, shall not agree to do any of the foregoing. Notwithstanding anything to contrary contained anywhere in this Purchase and Sale Agreement, in no event shall it be considered unreasonable for Purchaser to withhold its consent in the event the requested consent would reasonably be expected to have a material adverse effect on the Purchaser's rights to receive, or the amount of, the Royalties under the Counterparty License Agreement.

(b) The Seller shall not, without the consent of the Purchaser (such consent not to be unreasonably withheld, delayed or conditioned) and except as set forth in Section 5.5(a), withhold any consent, exercise or waive any right or option, fail to exercise any right or option or exercise or fail to exercise any action in respect of, affecting or relating to the Purchased Assets, the Products (in respect of the Territory in the Field) or the Counterparty License Agreement in any manner that would, in each case, (i) be a Material Adverse Change or (ii) conflict with or cause a default under, or breach or termination of, this Purchase and Sale Agreement or any other Transaction Document.

(c) Promptly after (i) receiving notice from Counterparty or any other Person (A) terminating the Counterparty License Agreement (in whole or in part), (B) alleging a material breach of or material default under the Counterparty License Agreement by the Seller or (C) asserting the existence of any facts, circumstances or events that, alone or together with other facts, circumstances or events, could reasonably be expected (with or without the giving of notice or passage of time, or both) to give rise to a material breach of or default under the Counterparty License Agreement by the Seller or the right to terminate the Counterparty License Agreement (in whole or in part) by Counterparty or any other Person or (ii) the Seller otherwise has knowledge of any fact, circumstance or event that, alone or together with other facts, circumstances or events, would (with or without the giving of notice or passage of time, or both) give rise to a material breach of or default under the Counterparty License Agreement by the Seller or give the right to terminate the Counterparty License Agreement (in whole or in part) by Counterparty or any other Person, in each case, the Seller shall (A) promptly (and in any event within five Business Days) give a written notice to the Purchaser describing in reasonable detail the relevant breach, default or termination event, including a copy of any written notice received from Counterparty or the other relevant Person, and, in the case of any breach or default or alleged breach or default by the Seller, describing in reasonable detail any corrective action the Seller proposes to take, and (B) in the case of any material breach or default or alleged breach or default by the Seller, use its reasonable best efforts to promptly cure such breach or default (if it is curable by the Seller) and shall give written notice to the Purchaser upon curing such breach or default; provided, however, that, if the Seller fails to promptly cure any such breach or default, the Purchaser shall, to the extent permitted by the Counterparty License Agreement, be entitled to take any and all actions the Purchaser considers reasonably necessary to promptly cure such breach or default, and the Seller shall cooperate with the Purchaser for such purpose and reimburse the Purchaser promptly (but in no event later than ten Business Days) following demand for all reasonable costs and expenses incurred in connection therewith.

(d) Promptly after the Seller obtains knowledge of a material breach of or default under, or an alleged material breach of or default under, the Counterparty License Agreement by Counterparty or any other Person (each, a "Defaulting Party") or of the existence of any facts, circumstances or events that, alone or together with other facts, circumstances or events, would (with or without the giving of notice or passage of time, or both) give rise to a material breach of or material default under the Counterparty License Agreement by a Defaulting Party or the right to terminate the Counterparty License Agreement (in whole or in part) by the Seller, in each case, the Seller shall (i) promptly (but in any event within five Business Days) give a written notice to the Purchaser describing in reasonable detail the relevant breach, default or termination event and (ii) proceed in consultation with the Purchaser and take such permissible actions (including commencing legal action against the Defaulting Party and the selection of legal counsel reasonably satisfactory to the Purchaser) to enforce compliance by the Defaulting Party with the relevant provisions of the Counterparty License Agreement and to exercise any or all of the Purchaser's or the Seller's rights and remedies, whether under the Counterparty License Agreement or by operation of law, with respect thereto. The Purchaser shall have the right to participate in, with counsel appointed by it, any meeting, discussion, action, suit or other proceeding relating to any such material breach, material default or termination event or alleged material breach, material default or termination event, including any counterclaim, settlement discussions or meetings. All reasonable costs and expenses (including attorneys' fees and expenses) incurred by Seller or Purchaser (other than fees for Purchaser's separate counsel in the event Seller is already using counsel approved by Purchaser) in connection with the enforcement of the Counterparty License Agreement shall, to the extent not reimbursed by the Counterparty pursuant to the Counterparty License Agreement, be borne by Seller; provided, however, that in no event shall the Seller be obligated to bear the reasonable costs and expenses incurred by the Purchaser pursuant to this Section 5.5(d) in an amount greater than [*****].

(e) The Seller shall, subject to the provisions of the Counterparty License Agreement and any rights of Counterparty thereunder, take any and all actions, and prepare, deliver and file any and all documents and instruments, that are reasonably necessary to preserve and maintain the Licensed Patents in the jurisdictions set forth in Exhibit C or such other jurisdictions agreed to in writing between the Seller and Counterparty in accordance with the Counterparty License Agreement, including payment of maintenance fees or annuities relating thereto, at the sole expense of the Seller (or Counterparty, as applicable in accordance with the Counterparty License Agreement. Except in accordance with the Counterparty License Agreement, and with the consent of the Purchaser (such consent not to be unreasonably withheld, delayed or conditioned), the Seller shall not disclaim or abandon, or fail to take any action necessary or desirable to prevent the disclaimer or abandonment of, any Licensed Patents.

(f) The Seller shall diligently enforce its rights under Section 8.2 and Section 8.3 of the Counterparty License Agreement with respect to any alleged or threatened infringement of any of the Licensed Patents by any other Person in the Field (an "Infringement"), and against any claims of invalidity or unenforceability (each, an "Invalidity Claim"), in any jurisdiction in the Territory. In the event that the Seller becomes aware, or receives written notice, of any actual or suspected Infringement of any Licensed Patents in the Field or of any Invalidity Claim, then promptly (and in any event within five Business Days) following the Seller becoming aware or receiving such notice of such Infringement or Invalidity Claim, the Seller shall inform the Purchaser of such Infringement or Invalidity Claim (and shall provide the Purchaser with a copy of such written notice, if applicable). The Seller and the Purchaser shall consult with each other (and the Counterparty) with a view to determining the appropriate course of action to take with respect to such Infringement or Invalidity Claim. To the extent the Seller has the right pursuant to Section 8.2 or Section 8.3 of the Counterparty License Agreement to institute suit or other legal proceedings to enforce the Licensed Patents against a third party in respect of any Infringement or to defend the Licensed Patents against any Invalidity Claim, then promptly (and in any event within five Business Days) following the Seller becoming aware of such right of the Seller, the Seller shall provide notice of such right to the Purchaser. The Seller may, and if requested in writing by the Purchaser (at the Purchaser's expense) within five Business Days after receipt by the Purchaser of notice of such right pursuant to the foregoing sentence, shall, proceed, in consultation with the Purchaser and the Counterparty or allow the Counterparty to proceed in accordance with Section 8.2 or Section 8.3, as applicable, (i) in the case of Infringement, use commercially reasonable efforts to institute such a suit or other legal proceeding and enforce the Licensed Patents, and to exercise such rights and remedies, relating to such Infringement as shall be available to the Seller (or Counterparty, as applicable) under Applicable Law, or (ii) in the case of an Invalidity Claim, to use commercially reasonable efforts to defend the Licensed Patents against such Invalidity Claim, but, in each case of clauses (i) and (ii), subject to the terms and conditions of the Counterparty License Agreement. In connection with any such enforcement or defense of the Licensed Patents by Seller, the Seller shall employ counsel reasonably acceptable to the Purchaser. The Purchaser shall have the right, at its sole expense, to direct the Seller's exercise and enforcement of its rights (on its own behalf and on behalf of the Seller) under the Counterparty License Agreement in connection with any Infringement or Invalidity Claim to the fullest extent permitted under the terms of the Counterparty License Agreement; provided, that the Seller's exercise and enforcement of such rights shall not result in a breach of this Purchase and Sale Agreement or the Counterparty License Agreement or a Material Adverse Change. Without limiting the foregoing, if the Seller shall have a consent right pursuant to Section 8.3 of the Counterparty License Agreement with respect to any allegation that the activities of the Seller or the Counterparty infringe a third party's patent rights with respect to the Products, the Seller shall not grant such consent without first obtaining the prior written consent of the Purchaser (such consent not to be unreasonably withheld, delayed or conditioned). All out-of-pocket costs and expenses (including attorneys' fees and expenses) incurred by Seller or Purchaser in connection with the prosecution, maintenance, defense or enforcement of the Licensed Patents and the enforcement of Section 8.2 and Section 8.3 of the Counterparty License Agreement shall, to the extent not reimbursed by the Counterparty pursuant to the Counterparty License Agreement, be borne by the party incurring such out-of-pocket costs and expenses; provided, however, that any such out-of-pocket costs and expenses incurred in connection with the prosecution, maintenance, defense or enforcement of the Licensed Patents and the enforcement of Section 8.2 and Section 8.3 of the Counterparty License Agreement at the direction of the Purchaser shall, to the extent not reimbursed by the Counterparty pursuant to the Counterparty License Agreement, be borne by the Seller; provided, however, that in no event shall the Seller be obligated to bear the reasonable costs and expenses incurred by the Purchaser pursuant to this Section 5.5(f) in an amount greater than [*****]. Any reimbursement of costs by the Counterparty shall be paid to the party (Seller or Purchaser) who incurred such costs. Any settlement amounts or other amounts recovered by Seller/Purchaser in respect of lost Royalties (and not as recovery for expenses or other damages) shall be considered Royalties hereunder, shall be credited to the period for which such Royalties would have been earned for purposes of calculating the Contingent Payments and shall belong to the Purchaser.

(g) Except in connection with an assignment by the Seller to any other Person with which the Seller may merge or consolidate or to which the Seller may sell all or substantially all of its assets or all of its assets related to the Products in accordance with the provisions of Section 8.3, and except in connection with the Seller's commercial lending arrangements, the Seller shall not dispose of or encumber the Licensed Patents (in whole or in part).

(h) The Seller shall make available its relevant records and shall make reasonable efforts to make available relevant personnel to the Purchaser in connection with any prosecution of litigation by the Seller or the Purchaser against any party to the Counterparty License Agreement to enforce any of the Purchaser's rights under the Counterparty License Agreement, and provide reasonable assistance and authority to file and bring the litigation, including, if required to bring the litigation, being joined as a party plaintiff.

Section 5.6 Termination of the Counterparty License Agreement; Mergers, Consolidations and Asset Sales Involving Counterparty.

(a) Without limiting the provisions of Section 5.5, if Counterparty or the Seller terminates or provides written notice of termination of the Counterparty License Agreement (in whole or in part, including termination of the Counterparty License Agreement in respect of one or more jurisdictions in the Territory), or the Counterparty License Agreement otherwise terminates (in whole or in part), then, to the extent permitted by the survival provisions of the Counterparty License Agreement, [the Seller shall provide reasonable assistance to and reasonably cooperate with the Purchaser, at the Purchaser's sole discretion, cost and expense (including the Purchaser's payment of the Seller's reasonable attorneys' fees, if any, in connection therewith), in such efforts as the Purchaser shall undertake in connection with the negotiation of a license of the Intellectual Property, which shall include terms no less favorable to the Seller than those contained in the Counterparty License Agreement with respect to obligations and costs imposed on the Seller, disclaimers of the Seller's liability, intellectual property ownership and control, commercialization diligence and indemnification of the Seller, and which, so long as the Counterparty License Agreement has not been terminated in full, shall not conflict or materially interfere with the Seller's rights, obligations or performance under the Counterparty License Agreement. Should the Purchaser identify any such arrangement for a license of the Intellectual Property that is reasonably acceptable to the Seller, the Seller agrees to duly execute and deliver a new license agreement effecting such arrangement that satisfies the foregoing requirements promptly upon the written request of the Purchaser (any such license, an "Additional License Agreement" and the licensee under any such Additional License Agreement, the "Additional Licensee"). In the event the Seller enters into an Additional License Agreement, for no additional consideration from the Purchaser, the covenants of the Seller in this Article V with respect to the Counterparty License Agreement and the Counterparty shall apply to such Additional License Agreement and the related Additional Licensee, respectively, *mutatis mutandis*, and the Purchaser shall have the same rights with respect to the Additional License Agreement as those acquired under the Counterparty Agreement pursuant to this Purchase and Sale Agreement, except as otherwise expressly provided for herein. The Seller shall not take any action in connection with its negotiation of and entry into any Additional License Agreement with the intent of interfering with the Purchaser's receipt of the full value of the Purchased Assets and shall not, without the Purchaser's consent, enter into any Additional License Agreement if the economic terms of such Additional License Agreement are, in the aggregate, less favorable to the Purchaser than those of the Counterparty License Agreement. In connection with the Seller's entry into any Additional License Agreement, the Purchaser shall be entitled to receive, for no additional consideration from the Purchaser, (i) all royalties paid, owed, accrued or otherwise required to be paid to the Seller pursuant to the Additional License Agreement (net of any deduction or withholding from or Set-offs against such amounts made by the Additional Licensee in accordance with Section 5.4(e) hereof and the terms thereof) arising out of, related to or resulting from the sale by Additional Licensee or any of its Affiliates, successors, sublicensees, subcontractors or agents of any and all Products in the applicable territory up to an amount equal to the royalties that would be payable in respect of such sales at the royalty rate then applicable under the Counterparty License Agreement and (ii) all milestone payments paid, owed, accrued or otherwise required to be paid to the Seller by the Additional Licensee or any of its Affiliates or successors pursuant to the Additional License Agreement (net of any deduction or withholding from or Set-offs against such amounts made by the Additional Licensee in accordance with Section 5.4(e) hereof and the terms thereof); provided, however, that the aggregate amount payable to the Purchaser under this clause (ii) with respect to all Additional License Agreements shall [*****] (the amounts described in clauses (i) and (ii) above, subject to the limitations set forth therein, the "Substitute Amounts"). All payments of Substitute Amounts by any Additional Licensee pursuant to any related Additional License Agreement shall be made directly to the Purchaser; any amounts payable under any Additional License Agreement in excess of the Substitute Amounts shall remain the property of the Seller. At any time that there are still Contingent Payments that Seller may be entitled to earn, all such out-of-pocket fees and expenses of entering into and negotiating any such Additional License Agreement shall [*****]. Further, for the avoidance of doubt, such fees and expenses shall not include any development costs or any fees or expenses related to negotiation of other agreements (e.g., manufacturing or development agreements), which fees and expenses shall be borne by the Seller.

(b) If there occurs a merger or consolidation of the Seller, on the one hand, and Counterparty or any of its Affiliates, on the other hand, a sale of all or substantially all of the Seller's assets to Counterparty or a sale or assignment of the Counterparty License Agreement or the Licensed Patents by the Seller to Counterparty, and in any such event the Counterparty License Agreement is terminated in connection therewith, the Seller (or its successor) shall pay to the Purchaser royalties on Net Sales of the applicable Products for the term of the Counterparty License Agreement on the same basis as if the Counterparty License Agreement had continued and the Purchaser's rights with respect to the Purchased Assets and the covenants of the Seller under this Purchase and Sale Agreement shall continue to apply on the same basis as if the Counterparty License Agreement were in place between the Seller and Counterparty.

Section 5.7 Audits. The Seller shall, upon the reasonable written request of the Purchaser, cause an inspection or audit of Counterparty's books and records to be conducted pursuant to, and in accordance with, Section 3.10 of the Counterparty License Agreement; provided, however, that the Seller shall retain the exclusive right to inspect and audit Counterparty's books and records at any time and from time to time at its sole discretion for periods solely with respect to payments that are paid or payable to the Seller pursuant to the Counterparty License Agreement with respect to Net Sales and Royalties attributable to the period prior to the Royalties Commencement Date; provided, however, that if the period covered by such audit shall cover payments paid or payable to Seller and Purchaser, the parties shall cooperate with respect to the public accounting firm and the conduct of the audit. For the purposes of exercising the Purchaser's rights pursuant to this Section 5.7, subject to the Counterparty's rights under Section 3.10 of the Counterparty License Agreement, the Seller shall select such public accounting firm as the Purchaser shall reasonably recommend for such purpose. The Seller and the Purchaser agree that all of the expenses of any inspection or audit carried out pursuant to the Counterparty License Agreement, including such fees and expenses of such public accounting firm as are to be borne by the Seller pursuant to Section 3.10 of the Counterparty License Agreement together with each party's reasonable out-of-pocket costs incurred in connection with such examination or audit, shall instead by borne [*****]. The Seller will furnish to the Purchaser any inspection or audit report prepared in connection with such inspection or audit. The Purchaser shall have the right to require the Seller, in writing, subject to the cost sharing provision above, to exercise the Seller's rights under Section 3.11 of the Counterparty License Agreement to cause Counterparty to cure any underpayment of Royalties due from Counterparty in accordance with Section 3.11 of the Counterparty License Agreement.

Section 5.8 Tax Matters.

(a) Notwithstanding the accounting treatment thereof, for United States federal, state and local tax purposes, the Seller and the Purchaser shall treat the transactions contemplated by the Transaction Documents as a sale for United States federal, state and local tax purposes.

(b) The parties hereto agree not to take any position that is inconsistent with the provisions of this Section 5.8 on any tax return or in any audit or other administrative or judicial proceeding. If there is an inquiry by any Governmental Authority of the Seller or the Purchaser related to this Section 5.8, the parties hereto shall cooperate with each other in responding to such inquiry in a reasonable manner consistent with this Section 5.8.

Section 5.9 Existence. During the term of this Purchase and Sale Agreement and the term of the Counterparty License Agreement, the Seller shall (a) preserve and maintain its existence (provided, however, that nothing in this Section 5.9 shall prohibit the Seller from entering into any merger, consolidation or amalgamation with, or selling or otherwise transferring all or substantially all of its assets to, any other Person if the Seller is the continuing or surviving entity or if the surviving or continuing or acquiring entity assumes (either expressly or by operation of law) all of the obligations of the Seller), (b) preserve and maintain its rights, franchises and privileges unless failure to do any of the foregoing would not be a Material Adverse Change, and (c) qualify and remain qualified in good standing in each jurisdiction where the failure to preserve and maintain such qualifications would be a Material Adverse Change, including appointing and employing such agents or attorneys in each jurisdiction where it shall be necessary to take action under this Purchase and Sale Agreement.

ARTICLE VI
THE CLOSING

Section 6.1 Closing. The closing of the transactions contemplated hereby (the "Closing") shall take place on the date, which shall be no later than fourteen (14) Business Days following the date hereof, on which the conditions described in Section 6.2 have been satisfied (the "Closing Date") at the offices of Dechert LLP located at Three Bryant Park, New York, New York 10036, or such other place as the parties hereto mutually agree.

Section 6.2 Closing Deliverables of the Seller. At the Closing, the Seller shall deliver or cause to be delivered to the Purchaser the following:

(a) the Bill of Sale executed by the Seller;

(b) the Counterparty Instruction executed by the Seller;

(c) evidence reasonably satisfactory to the Purchaser of the release of any identified Liens on the Purchased Assets;

(d) a certificate of an executive officer of the Seller (the statements made in which shall be true and correct on and as of the Closing Date): (i) attaching copies, certified by such officer as true and complete, of (x) the organizational documents of the Seller and (y) resolutions of the governing body of the Seller authorizing and approving the execution, delivery and performance by the Seller of the Transaction Documents and the transactions contemplated herein and therein; (ii) setting forth the incumbency of the officer or officers of the Seller who have executed and delivered the Transaction Documents, including therein a signature specimen of each such officer or officers; and (iii) attaching a copy, certified by such officer as true and complete, of a good standing certificate of the appropriate Governmental Authority of the Seller's jurisdiction of organization, stating that the Seller is in good standing under the Applicable Laws of such jurisdiction; and

(e) such other certificates, documents and financing statements as the Purchaser may reasonably request, including a financing statement reasonably satisfactory to the Purchaser to create, evidence and perfect the sale, assignment, transfer, conveyance and grant of the Purchased Assets pursuant to Section 2.1 and the back-up security interest granted pursuant to Section 2.1(d).

Section 6.3 Closing Deliverables of the Purchaser. At the Closing, the Purchaser shall deliver or cause to be delivered to the Seller the following:

(a) the Bill of Sale executed by the Purchaser;

(b) the [*****]; and

(c) payment of the portion of the Purchase Price due at the Closing in accordance with Section 2.2(a).

Section 6.4 Seller's Conditions to Closing. The obligation of the Seller to consummate the transactions contemplated hereby is subject to the satisfaction (or waiver by the Seller in writing) on or before the Closing of the following conditions:

(a) The representations and warranties of Purchaser herein and in any other Transaction Documents shall be true and correct in all respects as of the date hereof and as of the date of the Closing as though made on Closing, except for any breaches of such representations or warranties that would not reasonably be expected to result in a Material Adverse Change; and

(b) The Purchaser shall have performed or complied with each obligation and covenant required by this Agreement and the Transaction Documents to be performed or complied with by the Purchaser on or before the Closing, including the delivery of all of the items in Section 6.3 above, except for any non-performance or non-compliance that would not reasonably be expected to result in a Material Adverse Change.

Section 6.5 Purchaser's Conditions to Closing. The obligation of the Purchaser to consummate the transactions contemplated hereby is subject to the satisfaction (or waiver by the Purchaser in writing) on or before the Closing of the following conditions:

(a) The representations and warranties of the Seller herein and in any other Transaction Documents shall be true and correct in all respects as of the date hereof and as of the date of the Closing as though made on Closing, except for any breaches of such representations or warranties that would not reasonably be expected to result in a Material Adverse Change;

(b) The Seller shall have performed or complied with each obligation and covenant required by this Agreement and the Transaction Documents to be performed or complied with by the Seller on or before the Closing, including the delivery of all of the items in Section 6.2 above, except for any non-performance or non-compliance that would not reasonably be expected to result in a Material Adverse Change; and

(c) There shall not have occurred any event since the date of this Agreement and no circumstances shall exist that constitute or would reasonably be expected to result in a Material Adverse Change.

Section 6.6 Termination. Notwithstanding anything to the contrary herein, this Agreement may be terminated and the transactions described herein abandoned at any time before the Closing:

(a) By the mutual written consent of the Seller and the Purchaser; and

(b) by the Seller if (A) the representations and warranties of the Purchaser herein and in any other Transaction Documents shall fail to be true and correct in all respects or the Purchaser shall have failed in any respect to perform or comply with any of its obligations or covenants required by this Agreement and the Transaction Documents to be performed or complied with by the Purchaser on or before the Closing and such failure would result in the failure to satisfy any of the conditions set forth in Section 6.4, which failure has not either been waived by the Seller or cured within ten (10) days after written notice thereof has been received by the Purchaser, provided, that the Seller is not then in breach of this Agreement as would prevent the conditions to Closing set forth in Section 6.5 from being satisfied or (B) any of the conditions set forth in Section 6.4 has become incapable of being satisfied on or before November 23, 2020 (the "Outside Date") and have not been waived by the Seller;

(c) by the Purchaser if (A) the representations and warranties of the Seller herein and in any other Transaction Documents shall fail to be true and correct in all respects or the Seller shall have failed, in any respect, to perform or comply with any of its obligations or covenants required by this Agreement and the Transaction Documents to be performed or complied with by the Seller on or before the Closing and such failure would result in the failure to satisfy any of the conditions set forth in Section 6.5, which failure has not either been waived by the Purchaser or cured within ten (10) days after written notice thereof has been received by the Seller, provided, that the Purchaser is not then in breach of this Agreement as would prevent the conditions to Closing set forth in Section 6.4 from being satisfied or (B) any of the conditions set forth in Section 6.5 has become incapable of being satisfied on or before the Outside Date and have not been waived in writing by the Purchaser; or

(d) by the Seller or the Purchaser, if the Closing does not occur on or before the Outside Date.

Section 6.7 Effect of Termination. If this Agreement is terminated and the transactions contemplated hereby are abandoned as described in Section 6.6, except as otherwise set forth herein, neither party hereto shall have any claim against the other except if the circumstances giving rise to such termination were caused by the other party's willful failure to comply with a material covenant set forth herein, in which event termination shall not limit or deny any legal or equitable right or remedy of said party.

ARTICLE VII
INDEMNIFICATION

Section 7.1 Indemnification by the Seller. The Seller agrees to indemnify and hold each of the Purchaser and its Affiliates and any and all of their respective partners, directors, managers, members, officers, employees, agents and controlling persons (each, a "Purchaser Indemnified Party") harmless from and against, and to pay to each Purchaser Indemnified Party the amount of, any and all Losses awarded against or incurred or suffered by such Purchaser Indemnified Party, involving a third party claim, demand, action or proceeding, arising out of (i) any breach of any representation, warranty or certification made by the Seller in any of the Transaction Documents to which the Seller is party or certificates given by the Seller to the Purchaser in writing pursuant to this Purchase and Sale Agreement or any other Transaction Document, (ii) any breach of or default under any covenant or agreement by the Seller to the Purchaser pursuant to any Transaction Document to which the Seller is party, (iii) any fees, expenses, costs, liabilities or other amounts incurred or owed by the Seller to any brokers, financial advisors or comparable other Persons retained or employed by it in connection with the transactions contemplated by this Purchase and Sale Agreement, (iv) any Retained Liabilities; provided, however, that the foregoing shall exclude any indemnification to any Purchaser Indemnified Party (A) that has the effect of imposing on the Seller any recourse liability for Royalties because of the insolvency or other creditworthiness problems of Counterparty or the insufficiency of the Royalties, whether as a result of the amount of cash flow arising from sales or licensing of the Products or otherwise, unless resulting from the failure of the Seller to perform its obligations under this Purchase and Sale Agreement, (B) that results from the bad faith, gross negligence or willful misconduct of such Purchaser Indemnified Party, (C) to the extent resulting solely from the failure of any Person (including the Purchaser) other than the Seller or its Affiliates to perform any of its obligations under any of the Transaction Documents or (D) to the extent resulting from acts or omissions of the Seller based upon the written instructions from any Purchaser Indemnified Party. Any amounts due to any Purchaser Indemnified Party hereunder shall be payable by the Seller to such Purchaser Indemnified Party upon demand.

Section 7.2 Indemnification by the Purchaser. The Purchaser agrees to indemnify and hold each of the Seller and its Affiliates and any and all of their respective partners, directors, managers, members, officers, employees, agents and controlling Persons (each, a "Seller Indemnified Party") harmless from and against, and will pay to each Seller Indemnified Party the amount of, any and all Losses (including attorneys' fees) awarded against or incurred or suffered by such Seller Indemnified Party, involving a third party claim, demand, action or proceeding, arising out of (i) any breach of any representation, warranty or certification made by the Purchaser in any of the Transaction Documents or certificates given by the Purchaser in writing pursuant hereto or thereto, (ii) any breach of or default under any covenant or agreement by the Purchaser pursuant to any Transaction Document to which the Purchaser is party and (iii) any fees, expenses, costs, liabilities or other amounts incurred or owed by the Purchaser to any brokers, financial advisors or comparable other Persons retained or employed by it in connection with the transactions contemplated by this Purchase and Sale Agreement; provided, however, that the foregoing shall exclude any indemnification to any Seller Indemnified Party (A) that results from the bad faith, gross negligence or willful misconduct of such Seller Indemnified Party, (B) to the extent resulting from the performance by any other Person (including the Seller) or the failure of any other Person (including the Seller) to perform any of its obligations under any of the Transaction Documents or (C) to the extent resulting from acts or omissions of the Purchaser based upon the written instructions from any Seller Indemnified Party. Any amounts due to any Seller Indemnified Party hereunder shall be payable by the Purchaser to such Seller Indemnified Party upon demand.

Section 7.3 Procedures. If any claim, demand, action or proceeding (including any investigation by any Governmental Authority) shall be brought or alleged against an indemnified party in respect of which indemnity is to be sought against an indemnifying party pursuant to Section 7.1 or Section 7.2, the indemnified party shall, promptly after receipt of notice of the commencement of any such claim, demand, action or proceeding, notify the indemnifying party in writing of the commencement of such claim, demand, action or proceeding, enclosing a copy of all papers served, if any; provided, that the omission to so notify such indemnifying party will not relieve the indemnifying party from any liability that it may have to any indemnified party under Section 7.1 or Section 7.2 unless, and only to the extent that, the indemnifying party is actually prejudiced by such omission. In the event that any such action is brought against an indemnified party and it notifies the indemnifying party of the commencement thereof in accordance with this Section 7.3, the indemnifying party will be entitled, at the indemnifying party's sole cost and expense, to participate therein and, to the extent that it may wish, to assume the defense thereof, with counsel reasonably satisfactory to such indemnified party, and, after notice from the indemnifying party to such indemnified party of its election so to assume the defense thereof, the indemnifying party will not be liable to such indemnified party under this Article VII for any legal or other expenses subsequently incurred by such indemnified party in connection with the defense thereof other than reasonable costs of investigation. In any such proceeding, an indemnified party shall have the right to retain its own counsel, but the reasonable fees and expenses of such counsel shall be at the expense of such indemnified party unless (a) the indemnifying party and the indemnified party shall have mutually agreed to the retention of such counsel, (b) the indemnifying party has assumed the defense of such proceeding and has failed within a reasonable time to retain counsel reasonably satisfactory to such indemnified party or (c) the named parties to any such proceeding (including any impleaded parties) include both the indemnifying party and the indemnified party and representation of both parties by the same counsel would be inappropriate due to actual or potential conflicts of interests between them based on the reasonable advice of counsel to the indemnifying party. It is agreed that the indemnifying party shall not, in connection with any proceeding or related proceedings in the same jurisdiction, be liable for the reasonable fees and expenses of more than one separate law firm (in addition to local counsel where necessary) for all such indemnified parties. The indemnifying party shall not be liable for any settlement of any proceeding effected without its written consent, but, if settled with such consent or if there be a final judgment for the plaintiff, the indemnifying party agrees to indemnify the indemnified party from and against any Loss by reason of such settlement or judgment. No indemnifying party shall, without the prior written consent of the indemnified party, effect any settlement, compromise or discharge of any claim or pending or threatened proceeding in respect of which any indemnified party is or could have been a party and indemnity could have been sought hereunder by such indemnified party, unless such settlement, compromise or discharge, as the case may be, (i) includes an unconditional written release of such indemnified party, in form and substance reasonably satisfactory to the indemnified party, from all liability on claims that are the subject matter of such claim or proceeding, (ii) does not include any statement as to an admission of fault, culpability or failure to act by or on behalf of any indemnified party and (iii) does not impose any continuing material obligation or restrictions on any indemnified party.

Section 7.4 Exclusive Remedy. The indemnification afforded by this Article VII shall be the sole and exclusive remedy for any and all Losses awarded against or incurred or suffered by a party hereto in connection with the transactions contemplated by the Transaction Documents, including with respect to any breach of any representation, warranty or certification made by a party hereto in any of the Transaction Documents or certificates given by a party hereto in writing pursuant hereto or thereto or any breach of or default under any covenant or agreement by a party hereto pursuant to any Transaction Document. Notwithstanding anything in this Purchase and Sale Agreement to the contrary, in the event of any breach or failure in performance of any covenant or agreement contained in any Transaction Document, the non-breaching party shall be entitled to specific performance, injunctive or other equitable relief pursuant to Section 8.1.

Section 7.5 Survival. The representations and warranties contained in this Purchase and Sale Agreement shall survive the Closing solely for purposes of Section 7.1 and Section 7.2 and shall terminate on the date that is the fourth anniversary of the Closing Date. No party hereto shall have any liability or obligation of any nature with respect to any representation or warranty after the termination thereof, unless another party hereto shall have delivered a notice to such party, pursuant to Section 7.3, claiming such a liability or obligation under Section 7.1 or Section 7.2, as applicable, prior to such fourth anniversary.

Section 7.6 Adjustment to Purchase Price. All indemnification payments paid pursuant to this Article VII or [*****], shall be treated as adjustments to the Purchase Price for tax purposes, except as otherwise required by Law.

ARTICLE VIII
MISCELLANEOUS

Section 8.1 Specific Performance. Each of the parties hereto acknowledges that the other party hereto will have no adequate remedy at law if it fails to perform any of its obligations under any of the Transaction Documents. In such event, each of the parties hereto agrees that the other party hereto shall have the right, in addition to any other rights it may have (whether at law or in equity), to specific performance of this Purchase and Sale Agreement.

Section 8.2 Notices. All notices, consents, waivers and other communications hereunder shall be in writing and shall be effective (a) upon receipt when sent through the mails, registered or certified mail, return receipt requested, postage prepaid, with such receipt to be effective the date of delivery indicated on the return receipt, (b) upon receipt when sent by an overnight courier, (c) on the date personally delivered to an authorized officer of the party to which sent or (d) on the date transmitted by facsimile or other electronic transmission with a confirmation of receipt, in all cases, with a copy emailed to the recipient at the applicable address, addressed to the recipient at the address specified on Exhibit 8.2.

Each party hereto may, by notice given in accordance herewith to the other party hereto, designate any further or different address to which subsequent notices, consents, waivers and other communications shall be sent.

Section 8.3 Successors and Assigns. The provisions of this Purchase and Sale Agreement shall be binding upon and inure to the benefit of the parties hereto and their respective successors and permitted assigns. The Seller shall not be entitled to assign any of its obligations and rights under this Purchase and Sale Agreement without the prior written consent of the Purchaser. The Purchaser shall be entitled to assign any of its obligations and rights hereunder without the consent of the Seller; provided, however, that the Purchaser shall provide the Seller with ten Business Days' prior written notice of such assignment, including the legal name of the proposed assignee, and will not be permitted to proceed with any such assignment if the Seller shall have notified the Purchaser in writing within ten Business Days of its receipt of such notice that, in the Seller's reasonable determination, the proposed assignee, or an Affiliate thereof, is a Competitor of the Seller. Notwithstanding the foregoing, either party hereto may, without the consent of the other party hereto, assign any of its obligations or rights under this Purchase and Sale Agreement to any other Person with which it may merge, consolidate or amalgamate or to which it may sell or otherwise transfer all or substantially all of its assets (or, solely in the case of the Seller, all of its assets related to the Products), provided that if the assigning party is not the continuing or surviving entity in connection with any of the foregoing transactions, the assignee under such assignment shall be required to assume (either expressly or by operation of law) all of the obligations of the assigning party hereunder. The Seller shall be under no obligation to reaffirm any representations, warranties or covenants made in this Purchase and Sale Agreement or any of the other Transaction Documents or take any other action in connection with any such assignment by the Purchaser.

Section 8.4 Independent Nature of Relationship. The relationship between the Seller and the Purchaser is solely that of seller and purchaser, and neither the Seller nor the Purchaser has any fiduciary or other special relationship with the other party hereto or any of its Affiliates. Nothing contained herein or in any other Transaction Document shall be deemed to constitute the Seller and the Purchaser as a partnership, an association, a joint venture or any other kind of entity or legal form.

Section 8.5 Entire Agreement. This Purchase and Sale Agreement, together with the Exhibits hereto (which are incorporated herein by reference) and the other Transaction Documents, constitute the entire agreement between the parties hereto with respect to the subject matter hereof and supersede all prior agreements, understandings and negotiations, both written and oral, between the parties hereto with respect to the subject matter of this Purchase and Sale Agreement. No representation, inducement, promise, understanding, condition or warranty not set forth herein (or in the Exhibits hereto or the other Transaction Documents) has been made or relied upon by either party hereto. Neither this Purchase and Sale Agreement nor any provision hereof is intended to confer upon any Person other than the parties hereto and the other Persons referenced in Article VII any rights or remedies hereunder.

Section 8.6 Governing Law.

(a) THIS PURCHASE AND SALE AGREEMENT SHALL BE GOVERNED BY AND CONSTRUED IN ACCORDANCE WITH THE INTERNAL SUBSTANTIVE AND PROCEDURAL LAWS OF THE STATE OF NEW YORK WITHOUT REFERENCE TO THE RULES THEREOF RELATING TO CONFLICTS OF LAW OTHER THAN SECTION 5-1401 OF THE GENERAL OBLIGATIONS LAW OF THE STATE OF NEW YORK, AND THE OBLIGATIONS, RIGHTS AND REMEDIES OF THE PARTIES HEREUNDER SHALL BE DETERMINED IN ACCORDANCE WITH SUCH LAWS.

(b) Each of the parties hereto hereby irrevocably and unconditionally submits, for itself and its property, to the non-exclusive jurisdiction of the Supreme Court of the State of New York sitting in New York County and of the United States District Court of the Southern District of New York, and any appellate court from any thereof, in any action or proceeding arising out of or relating to this Purchase and Sale Agreement, or for recognition or enforcement of any judgment, and each of the parties hereto hereby irrevocably and unconditionally agrees that all claims in respect of any such action or proceeding may be heard and determined in such New York State court or, to the extent permitted by Applicable Law, in such federal court. Each of the parties hereto agrees that a final judgment in any such action or proceeding shall be conclusive and may be enforced in other jurisdictions by suit on the judgment or in any other manner provided by Applicable Law.

(c) Each of the parties hereto hereby irrevocably and unconditionally waives, to the fullest extent it may legally and effectively do so, any objection that it may now or hereafter have to the laying of venue of any suit, action or proceeding arising out of or relating to this Purchase and Sale Agreement in any court referred to in Section 8.6(b). Each of the parties hereto hereby irrevocably waives, to the fullest extent permitted by Applicable Law, the defense of an inconvenient forum to the maintenance of such action or proceeding in any such court.

(d) Each of the parties hereto irrevocably consents to service of process in the manner provided for notices in Section 8.2. Nothing in this Purchase and Sale Agreement will affect the right of any party hereto to serve process in any other manner permitted by Applicable Law. Each of the parties hereto waives personal service of any summons, complaint or other process, which may be made by any other means permitted by New York law.

Section 8.7 Waiver of Jury Trial. EACH PARTY HERETO HEREBY WAIVES, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY RIGHT IT MAY HAVE TO A TRIAL BY JURY IN ANY LEGAL PROCEEDING DIRECTLY OR INDIRECTLY ARISING OUT OF OR RELATING TO THIS PURCHASE AND SALE AGREEMENT, OR THE TRANSACTIONS CONTEMPLATED HEREBY (WHETHER BASED ON CONTRACT, TORT OR ANY OTHER THEORY). EACH PARTY HERETO (A) CERTIFIES THAT NO REPRESENTATIVE, AGENT OR ATTORNEY OF THE OTHER PARTY HERETO HAS REPRESENTED, EXPRESSLY OR OTHERWISE, THAT THE OTHER PARTY HERETO WOULD NOT, IN THE EVENT OF LITIGATION, SEEK TO ENFORCE THE FOREGOING WAIVER AND (B) ACKNOWLEDGES THAT IT AND THE OTHER PARTY HERETO HAVE BEEN INDUCED TO ENTER INTO THIS PURCHASE AND SALE AGREEMENT BY, AMONG OTHER THINGS, THE MUTUAL WAIVERS AND CERTIFICATIONS IN THIS SECTION 8.7.

Section 8.8 Severability. If one or more provisions of this Purchase and Sale Agreement are held to be invalid, illegal or unenforceable by a court of competent jurisdiction, such invalidity, illegality or unenforceability shall not affect any other provision of this Purchase and Sale Agreement, which shall remain in full force and effect, and the parties hereto shall replace such invalid, illegal or unenforceable provision with a new provision permitted by Applicable Law and having an economic effect as close as possible to the invalid, illegal or unenforceable provision. Any provision of this Purchase and Sale Agreement held invalid, illegal or unenforceable only in part or degree by a court of competent jurisdiction shall remain in full force and effect to the extent not held invalid, illegal or unenforceable.

Section 8.9 Counterparts. This Purchase and Sale Agreement may be signed in any number of counterparts, each of which shall be an original, with the same effect as if the signatures thereto and hereto were upon the same instrument. This Purchase and Sale Agreement shall become effective when each party hereto shall have received a counterpart hereof signed by the other party hereto. Any counterpart may be executed by facsimile or other electronic transmission, and such facsimile or other electronic transmission shall be deemed an original.

Section 8.10 Amendments; No Waivers. Neither this Purchase and Sale Agreement nor any term or provision hereof may be amended, supplemented, restated, waived, changed or modified except with the written consent of the parties hereto. No failure or delay by either party hereto in exercising any right, power or privilege hereunder shall operate as a waiver thereof nor shall any single or partial exercise thereof preclude any other or further exercise thereof or the exercise of any other right, power or privilege. No notice to or demand on either party hereto in any case shall entitle it to any notice or demand in similar or other circumstances. No waiver or approval hereunder shall, except as may otherwise be stated in such waiver or approval, be applicable to subsequent transactions. No waiver or approval hereunder shall require any similar or dissimilar waiver or approval thereafter to be granted hereunder. Except as expressly provided herein, the rights and remedies herein provided shall be cumulative and not exclusive of any rights or remedies provided by Applicable Law.

Section 8.11 Cumulative Remedies. Except as set for the in this Purchase and Sale Agreement, the remedies herein provided are cumulative and not exclusive of any remedies provided by Applicable Law.

Section 8.12 Table of Contents and Headings. The Table of Contents and headings of the Articles and Sections of this Purchase and Sale Agreement have been inserted for convenience of reference only, are not to be considered a part hereof and shall in no way modify or restrict any of the terms or provisions hereof.

Section 8.13 Waiver of Immunity. To the extent that the Seller may in any jurisdiction claim for itself or its assets immunity (to the extent such immunity may now or hereafter exist, whether on the grounds of sovereign immunity or otherwise) from suit, execution, attachment (whether in aid of execution, before judgment or otherwise) or other legal process (whether through service or notice or otherwise), and to the extent that in any such jurisdiction there may be attributed to itself or its assets such immunity (whether or not claimed), the Seller irrevocably agrees with respect to any matter arising under this Purchase and Sale Agreement for the benefit of the Purchaser not to claim, and irrevocably waives, such immunity to the full extent permitted by the laws of such jurisdiction.

{SIGNATURE PAGE FOLLOWS}

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

AQUESTIVE THERAPEUTICS, INC.

By: _____
Name: Keith J. Kendall
Title: President and Chief Executive Officer

MAM PANGOLIN ROYALTY, LLC

By: _____
Name:
Title:

{Signature Page to Purchase and Sale Agreement}

EXHIBIT A

FORM OF BILL OF SALE

This BILL OF SALE ("Bill of Sale") is dated as of November [_], 2020 (the "Closing Date") by Aquestive Therapeutics, Inc., a Delaware corporation (the "Seller"), in favor of MAM Pangolin Royalty, LLC, a Delaware limited liability company (the "Purchaser").

RECITALS

WHEREAS, the Seller and the Purchaser are parties to that certain Purchase and Sale Agreement, dated as of the Closing Date (the "Purchase and Sale Agreement"), pursuant to which, among other things, the Seller agrees to sell, assign, transfer, convey and grant to the Purchaser, and the Purchaser agrees to purchase, acquire and accept from the Seller, all of the Seller's right, title and interest in, to and under the Purchased Assets, for the consideration described in the Purchase and Sale Agreement; and

WHEREAS, the parties hereto now desire to carry out the purposes of the Purchase and Sale Agreement by the execution and delivery of this instrument evidencing the Purchaser's purchase, acquisition and acceptance of the Purchased Assets;

NOW, THEREFORE, in consideration of the premises and the mutual agreements set forth in the Purchase and Sale Agreement and of other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, the parties hereto agree as follows:

1. The Seller, by this Bill of Sale, does hereby sell, assign, transfer, convey and grant to the Purchaser, and the Purchaser does hereby purchase, acquire and accept, the Purchased Assets, free and clear of any and all Liens, other than those Liens created in favor of the Purchaser by the Transaction Documents.

2. The parties hereto acknowledge that, except as expressly provided in the Purchase and Sale Agreement, the Purchaser is not assuming any liability or obligation of the Seller or any of the Seller's Affiliates of whatever nature, whether presently in existence or arising or asserted hereafter (including any liability or obligation of the Seller under the Counterparty License Agreement or any Additional License Agreement).

3. This Bill of Sale (i) is made pursuant to, and is subject to the terms of, the Purchase and Sale Agreement and (ii) shall be binding upon and inure to the benefit of the Seller, the Purchaser and their respective successors and permitted assigns, for the uses and purposes set forth and referred to above, effective immediately upon its delivery to the Purchaser. This Bill of Sale is subject in all respects to the terms and conditions of the Purchase and Sale Agreement, and all of the representations, warranties, covenants and agreements of Seller and Purchaser contained therein, all of which shall survive the execution and delivery of this Bill of Sale in accordance with the terms of the Purchase and Sale Agreement. Nothing contained in this Bill of Sale shall be deemed to supersede, enlarge or modify any of the obligations, agreements, covenants, representations or warranties of Seller and Purchaser contained in the Purchase and Sale Agreement. Notwithstanding anything to the contrary contained in this Bill of Sale, in the event of any conflict between the terms of this Bill of Sale and the terms of the Purchase and Sale Agreement, the terms of the Purchase and Sale Agreement shall control.

4. THIS BILL OF SALE SHALL BE GOVERNED BY AND CONSTRUED IN ACCORDANCE WITH THE INTERNAL SUBSTANTIVE AND PROCEDURAL LAWS OF THE STATE OF NEW YORK WITHOUT REFERENCE TO THE RULES THEREOF RELATING TO CONFLICTS OF LAW OTHER THAN SECTION 5-1401 OF THE GENERAL OBLIGATIONS LAW OF THE STATE OF NEW YORK, AND THE OBLIGATIONS, RIGHTS AND REMEDIES OF THE PARTIES HEREUNDER SHALL BE DETERMINED IN ACCORDANCE WITH SUCH LAWS.

5. This Bill of Sale may be executed in any number of counterparts, each of which so executed shall be deemed to be an original, but all of such counterparts shall together constitute but one and the same instrument.

6. The following terms as used herein shall have the following respective meanings:

"Affiliate" means, with respect to any Person, any other Person that, directly or indirectly, controls, is controlled by or is under common control with such Person. For purposes of this definition, "control" of a Person means the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of such Person, whether through the ownership of Voting Securities, by contract or otherwise, and the terms "controlled" and "controlling" have meanings correlative to the foregoing.

"Capital Securities" means, with respect to any Person, all shares, interests, participations or other equivalents (however designated, whether voting or non-voting) of such Person's capital, whether now outstanding or issued after the date hereof, including common shares, ordinary shares, preferred shares, membership interests or share capital in a limited liability company or other Person, limited or general partnership interests in a partnership, beneficial interests in trusts or any other equivalent of such ownership interest or any options, warrants and other rights to acquire such shares or interests, including rights to allocations and distributions, dividends, redemption payments and liquidation payments.

"Counterparty License Agreement" means that certain License Agreement, dated as of April 1, 2016, by and between the Seller (formerly MonoSol Rx, LLC) and Sunovion Pharmaceuticals Inc., a Delaware corporation (formerly Cynapsus Therapeutics Inc.), as amended by the First Amendment and the Second Amendment, as further amended in accordance with the provisions of this Purchase and Sale Agreement.

"FDA" means the U.S. Food and Drug Administration and any successor agency thereto.

"First Amendment" means that certain First Amendment to License Agreement, dated as of March 16, 2020, by and between the Seller and the Counterparty.

"Governmental Authority" means the government of the United States or any other nation or any political subdivision thereof, whether state or local, and any agency, authority (including supranational authority), commission, instrumentality, regulatory body, court, central bank or other Person exercising executive, legislative, judicial, taxing, regulatory or administrative powers or functions of or pertaining to government, including each Patent Office, the FDA and any other governmental authority in any jurisdiction.

"Patent Office" means the applicable patent office, including the United States Patent and Trademark Office and any comparable foreign patent office, for any Licensed Patents.

"Person" means any natural person, firm, corporation, limited liability company, partnership, joint venture, association, joint-stock company, trust, unincorporated organization, Governmental Authority or any other legal entity, including public bodies, whether acting in an individual, fiduciary or other capacity. "Product" has the meaning set forth in Section 1.1.46 of the Counterparty License Agreement.

"Purchased Assets" means, collectively, the Seller's (a) right, title and interest in, to and under the Counterparty License Agreement and any Additional License Agreement to receive all of the Royalties, (b) right to receive the Quarterly Royalty Reports produced by Counterparty pursuant to the Counterparty License Agreement and any comparable reports or information produced by any Additional License pursuant to any applicable Additional License Agreement, and (c) right to transfer, assign or pledge the foregoing, in whole or in part, and the payments, proceeds and income of and the rights to enforce each of the foregoing in accordance with the terms hereof.

"Quarterly Royalty Reports" has the meaning set forth in Section 1.1.48 of the Counterparty License Agreement.

"Royalties" means, without duplication, (a) all royalties and other amounts or fees paid, owed, accrued or otherwise required to be paid to the Seller pursuant to the Counterparty License Agreement (net of any deduction or withholding from or Set-offs against such amounts made by the Counterparty in accordance with the terms thereof) arising out of, related to or resulting from the sale by Counterparty or any of its Affiliates, successors, Sublicensees, subcontractors or agents of any and all Products in the Territory and, in each case, attributable to the period commencing on October 1, 2020, including all amounts due or to be paid to the Seller or any of its Affiliates under Section 3.3 or Section 3.4 of the Counterparty License Agreement (whether based upon Net Sales of the Products in the Territory or otherwise), (b) all milestone payments paid, owed, accrued or otherwise required to be paid to the Seller by the Counterparty or any of its Affiliates or successors pursuant to the Counterparty License Agreement (net of any deduction or withholding from or Set-offs against such amounts made by the Counterparty in accordance with the terms thereof) and, in each case, attributable to the achievement during the period from and after the date hereof of any regulatory or sales milestones set forth in Sections 3.1.2 and 3.1.3 of the Counterparty License Agreement (but excluding, for the avoidance of doubt, the $4,000,000 milestone payment payable pursuant to section 3.1.2 of the Counterparty License Agreement upon the first day of Product availability at a pharmacy in the United States, which shall remain the property of the Seller), (c) all amounts due or to be paid to the Seller pursuant to Sections 3.5, 3.6 or 3.11 of the Counterparty License Agreement in respect or in lieu of amounts described in clauses (a) and (b) above, (d) all Substitute Amounts paid or payable to the Seller or any of its Affiliates by one or more Additional Licensees under any Additional License Agreement, and (e) all proceeds (as defined under the UCC) of any of the foregoing.

"Second Amendment" means that certain Second Amendment to License Agreement, dated as of October 23, 2020, by and between the Seller and the Counterparty.

"Set-off" means any set-off, off-set, rescission, counterclaim, reduction, deduction or defense, subject to the limitations set forth in the Purchase and Sale Agreement.

"Sublicensee" means any sublicensee of Counterparty under the Counterparty License Agreement.

"Substitute Amounts" means all amounts payable to the Purchaser, subject to the limitations set forth in Section 5.6(a) of the Purchase and Sale Agreement, in respect of royalties and milestone payments paid, owed, accrued or otherwise required to be paid to the Seller pursuant to any Additional License Agreement.

"Territory" has the meaning set forth in Section 1.1.56 of the Counterparty License Agreement.

"Voting Securities" means, with respect to any Person, Capital Securities of any class or kind ordinarily having the power to vote for the election of directors, managers or other voting members of the governing body of such Person.

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

AQUESTIVE THERAPEUTICS, INC.

By: _____
Name:
Title:

MAM PANGOLIN ROYALTY, LLC

By: _____
Name:
Title:

EXHIBIT B

FORM OF COUNTERPARTY INSTRUCTION

[*****]

EXHIBIT C

INTELLECTUAL PROPERTY MATTERS

[*****]

EXHIBIT D

FORM OF COUNTERPARTY CONFIRMATION

[*****]

EXHIBIT 5.4(b)

PURCHASER ACCOUNT

Bank Name: [*****]
ABA Number: [*****]
Account Number: [*****]
Account Name: [*****]
Attention: [*****]

EXHIBIT 5.4(d)

SELLER ACCOUNT

Bank Name: [*****]
Account Number: [*****]
Account Name: [*****]
ABA Number: [*****]
ABA Number: [*****]
SWIFT Code: [*****]

EXHIBIT 8.2

NOTICE ADDRESSES

If to the Seller, to:

Aquestive Therapeutics, Inc.
[*****]
Attention: [*****]
Telephone: [*****]
Email: [*****]

with a copy (which shall not constitute notice) to:

Aquestive Therapeutics, Inc.
[*****]
Attention: [*****]
Telephone: [*****]
Email: [*****]

with a copy (which shall not constitute notice) to:

Dechert LLP
[*****]
Attention: [*****]
Telephone: [*****]
Facsimile: [******]
Email: [*****]

If to the Purchaser, to:

MAM PANGOLIN ROYALTY, LLC
c/o Marathon Asset Management, L.P.
[*****]
Attention: [*****]
Telephone: [*****]
Facsimile: [*****]
Email: [*****]

with a copy (which shall not constitute notice) to:

Holland & Knight LLP
[*****]
Attention: [*****]
Telephone: [*****]
Facsimile: [******]
Email: [*****]

SCHEDULE I

[*****]

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

The Board of Directors
Aquestive Therapeutics, Inc.:

We consent to the incorporation by reference in the registration statements (No. 333-226399 and No. 333-251984) on Form S-8 and (No. 333-233716 and No. 333-251979) on Form S-3 of Aquestive Therapeutics, Inc. and subsidiaries (the Company) of our report dated March 9, 2021, with respect to the consolidated balance sheets of the Company as of December 31, 2020 and 2019, the related consolidated statements of operations and comprehensive loss, changes in stockholders' deficit, and cash flows for each of the years in the three-year period ended December 31, 2020, and the related notes (collectively, the consolidated financial statements), which report appears in the December 31, 2020 annual report on Form 10-K of the Company.

Our report refers to a change in the method of accounting for leases as of January 1, 2020 due to the adoption of Accounting Standards Codification 842, *Leases.*

/s/ KPMG
New York, New York

March 9, 2021

Exhibit 31.1

Certification of Principal Executive Officer of Aquestive Therapeutics, Inc.
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Keith J. Kendall, certify that:

1. I have reviewed this Annual Report on Form 10-K of Aquestive Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 9, 2021

/s/ KEITH J. KENDALL
Keith J. Kendall
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

Certification of Principal
Financial Officer of Aquestive Therapeutics, Inc.
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, A. Ernest Toth, Jr., certify that:

1. I have reviewed this Annual Report on Form 10-K of Aquestive Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 9, 2021

/s/ A. ERNEST TOTH, JR.

A. Ernest Toth, Jr.
Interim Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

Certification of Principal Executive Officer
Pursuant to 18 U.S.C. Section 1350, as Adopted
Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), I, Keith J. Kendall, Chief Executive Officer of Aquestive Therapeutics, Inc., (the "Company"), hereby certify that, to the best of my knowledge:

1. The Company's Annual Report on Form 10-K for the year ended December 31, 2020, to which this Certification is attached as Exhibit 32.1 (the "Annual Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

2. The information contained in the Annual Report fairly presents, in all material respects, the financial condition of the Company at the end of the period covered by the Annual Report and the results of operations of the Company for the period covered by the Annual Report.

Dated: March 9, 2021

/s/ KEITH J. KENDALL
Keith J. Kendall
Chief Executive Officer
(Principal Executive Officer)

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Aquestive Therapeutics, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.

Exhibit 32.2

Certification of Principal Financial Officer
Pursuant to 18 U.S.C. Section 1350, as Adopted
Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), I, A. Ernest Toth, Jr., Interim Chief Financial Officer of Aquestive Therapeutics, Inc., (the "Company"), hereby certify that, to the best of my knowledge:

1. The Company's Annual Report on Form 10-K for the year ended December 31, 2020, to which this Certification is attached as Exhibit 32.1 (the "Annual Report"), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

2. The information contained in the Annual Report fairly presents, in all material respects, the financial condition of the Company at the end of the period covered by the Annual Report and the results of operations of the Company for the period covered by the Annual Report.

Dated: March 9, 2021

/s/ A. ERNEST TOTH, JR
A. Ernest Toth, Jr.
Interim Chief Financial Officer
(Principal Financial Officer)

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Aquestive Therapeutics, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.