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, 2019

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, 2019, 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 $101.0 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 6, 2020 was 33,582,234.

The registrant intends to file a definitive proxy statement pursuant to Regulation 14A in connection with its 2020 Annual Meeting of Shareholders within 120 days of the end of its fiscal year ended December 31, 2019. Portions of such definitive proxy statement are incorporated by reference into Part III of this Annual Report on Form 10-K.

Table of Contents

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 may include, but are not limited to, statements regarding therapeutic benefits and plans and objectives for regulatory approvals of AQST-108, Libervant ™ and our other product candidates; ability to obtain FDA approval and advance AQST-108, Libervant and our other product candidates to the market; statements about our growth and future financial and operating results and financial position, regulatory approval and pathways, clinical trial timing and plans, our and our competitors’ orphan drug approval and resulting drug exclusivity for our products or products 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 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 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); 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 time 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 coronavirus and potential impact on global businesses as well as on clinical trials, sourcing, regulatory approval and commercialization of our products and product candidates; risks related to the outsourcing of certain sales, 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 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 risks and 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 or 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"). 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. Our principal executive offices are located in Warren, New Jersey.

Overview

We are a pharmaceutical company focused on developing and commercializing differentiated products to address unmet medical needs. We have proprietary products focused on the treatment of diseases of the Central Nervous System, or CNS, including one commercial-product, one commercial-stage product and a late-stage pipeline product candidate. We believe that the characteristics of these patient populations and shortcomings of available treatment options create opportunities for the development and commercialization of meaningfully differentiated medicines. In December 2018, we commercially launched the first of our CNS products, Sympazan® (clobazam) Oral Film, for use as an adjunctive therapy for seizures associated with Lennox-Gastaut Syndrome, or LGS, in patients two years and older. In November 2019, we received FDA approval of our product, Exservan®, which has been licensed for European marketing and for which we are seeking a licensee in the U.S.

Our most advanced proprietary product is Libervant™ (diazepam) Buccal Film. Libervant is a buccally, or inside of the cheek, administered soluble film formulation of diazepam. Epilepsy patients have been underserved for some time with little choice beyond device-based products such as rectally administered gels and a recently approved diazepam nasal spray. Aquestive is developing Libervant as an alternative to the current standard of care rescue therapy for patients with refractory epilepsy, which is a rectal gel, that is invasive, inconvenient, and difficult to administer. As a result, a large portion of the patient population has not received adequate treatment or foregoes treatment altogether. It is anticipated that Libervant, if approved by the U.S. Food and Drug Administration (FDA), will enable a larger share of these patients to receive more appropriate treatment by providing consistent therapeutic dosing in a non-invasive and innovative treatment form for epileptic seizures. The Company filed an NDA for Libervant in November 2019. The filing was accepted by the FDA in February 2020 and we have received a PDUFA goal date of September 27, 2020. 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 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. We believe that our product candidate Libervant is "clinically superior" to the two currently FDA-approved products with the same moiety and for the same indication as Libervant, as qualifying as "a major contribution to patient care" within the meaning of the FDA regulation and guidance. However, such a demonstration to overcome such seven-year market exclusivity is difficult to establish with limited precedents and there can be no assurance that we will be successful in these efforts. 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 "Competition" section below in this Item 1. Business of this Form10-K.

We have developed a proprietary pipeline of complex molecule products addressing large market opportunities beyond CNS indications, including AQST-108, a sublingual film formulation of epinephrine for the treatment of anaphylaxis. In February of 2020, we had a constructive face-to-face pre-Investigational New Drug (IND) application meeting with the FDA for this drug candidate. A pre-IND meeting provides an opportunity for an open communication between a drug sponsor and the FDA to discuss the sponsor's IND development plan and to obtain the agency's guidance for clinical studies for the sponsor's new drug candidate. The FDA has confirmed that the clinical development for AQST-108 will be reviewed under the 505(b)(2) pathway as proposed by Aquestive and that no additional studies would be necessary prior to opening the proposed IND application. The FDA indicated that there appears to be an unmet medical need among patients who resist the standard of care use of intramuscular injection in the treatment of anaphylaxis and that AQST-108 may potentially address some of those unmet needs. Aquestive expects to move forward with opening an IND and initiating its pharmacokinetic (PK) clinical trials before the end of 2020.

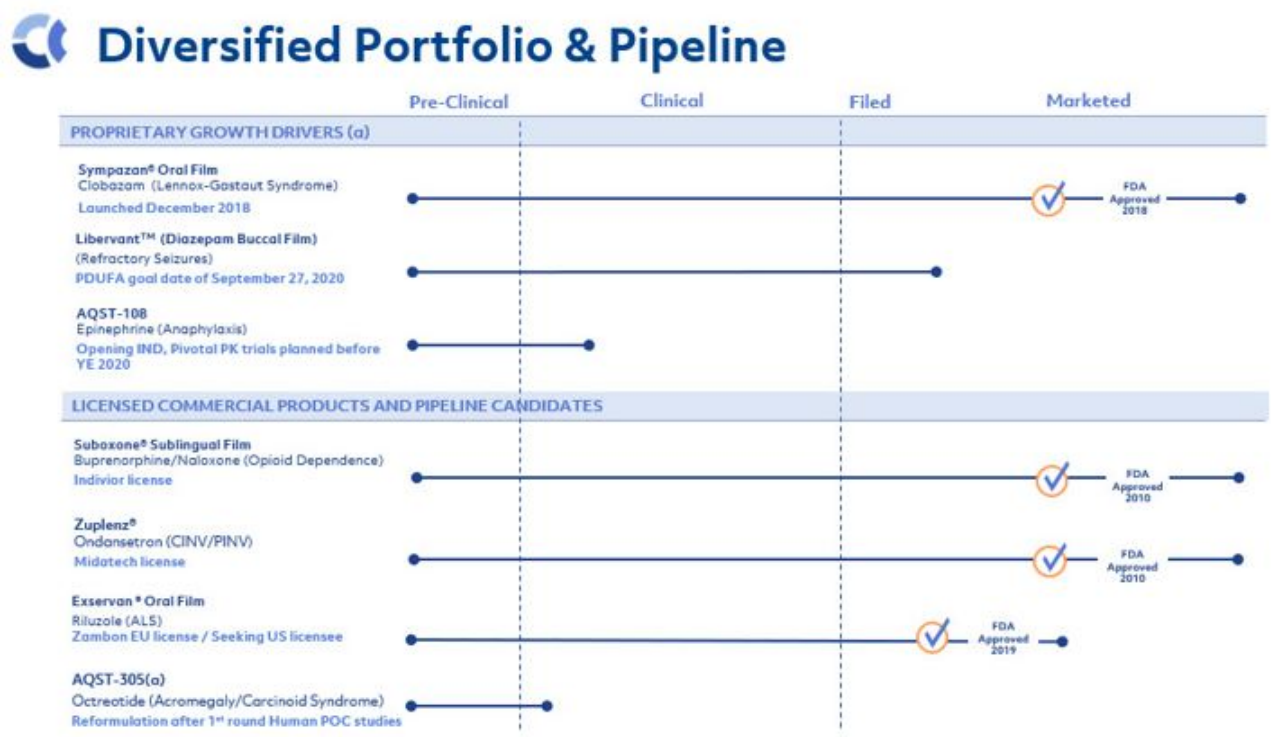
In addition to these products and product candidates, we have a portfolio of commercialized and development-stage drug products that we license to other companies. These products include Suboxone®, a sublingual film formulation of buprenorphine

and naloxone, for the treatment of opioid dependence, and Exservan (riluzole), an oral film product for the treatment of amyotrophic lateral sclerosis (ALS).

We manufacture all of our licensed and proprietary products at our FDA and Drug Enforcement Agency, or DEA, inspected facilities and anticipate that our current manufacturing capacity is sufficient for commercial quantities of our products and product candidates currently in development. We have produced over 2.2 billion doses of Suboxone since 2010. Our products are developed using our proprietary PharmFilm® technology and know-how. Our patent portfolio currently comprises at least 200 issued patents worldwide, of which at least 40 are U.S. patents, and more than 90 pending patent applications worldwide.

Our Product Portfolio and Pipeline

The following table outlines our pipeline of products and product candidates



(a) Aquestive holds rights for worldwide commercialization

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, a benzodiazepine used as an adjunctive therapy for seizures associated with LGS. We developed Sympazan as an alternative to the Onfi® brand and clobazam generic, which were previously only available in either tablet form or liquid suspensions. LGS patients often have difficulty swallowing pills and large volume suspensions leading 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. Following approval by the FDA, we launched Sympazan in December 2018.

- **Libervant** – a buccally, or inside of the cheek, administered soluble film formulation of diazepam. Aquestive is developing Libervant as an alternative to the current standard of care rescue therapy for patients with refractory epilepsy, which as a rectal gel, is invasive, inconvenient, and difficult to administer, as well as a recently approved nasal spray. Libervant was designated an orphan drug by the FDA and has been granted a PDUFA goal date of September 27, 2020. More details on this product approval are described in the “Competition” section of this Item I. Business of this Form 10-K.

Proprietary Complex Molecule Portfolio

We are utilizing our technology and know-how to target acceptable market opportunities by developing orally administered complex molecule therapies as alternatives to invasively administered standard of care injectable therapeutics. We currently have two active complex molecule programs in clinical development. The first is focused on the oral delivery of the hormone epinephrine. The second is focused on the delivery of a peptide known as octreotide. If it achieves regulatory approval, which we cannot assure, octreotide would be the first peptide delivered orally using our technology and may create other opportunities for peptides and biologics.

The active programs in our complex molecule portfolio are:

- **AQST-108** – a "first of its kind" oral sublingual film formulation delivering systemic epinephrine that is in development for the treatment of anaphylaxis using Aquestive's proprietary PharmFilm® technologies. 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 EpiPen®, a single-dose, pre-filled automatic injection device. As a result of its administration via subcutaneous or intra-muscular injection, many patients and their caregivers are reluctant to use currently available products, resulting in increased hospital visits and overall cost of care to treat anaphylactic events. The data from a completed Phase 1 dose escalation study demonstrated that AQST-108 achieved similar ranges of mean values of maximum concentration (Cmax) and time to reach maximum concentration (Tmax) to that reported for injectables EpiPen® and Auvi-Q®, provided a greater total exposure (AUC0-t; area under the curve) than that reported for EpiPen and Auvi-Q, had less interpatient variability when compared to degree of variation (CV%) data reported for EpiPen and Auvi-Q, 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 will improve patient compliance and lower the total cost of care. After a constructive pre-IND meeting with the FDA in early February 2020, the Company is in the process of preparing the IND for AQST-108, which is expected to be submitted to the FDA in the coming months. The Company expects to utilize the 505(b)(2) regulatory approval pathway for AQST-108 and expects to begin clinical trials later in 2020.

- **AQST-305** – a sublingual film formulation of octreotide, a small peptide that has a similar pharmacological profile to natural somatostatin, for the treatment of acromegaly, as well as severe diarrhea and flushing associated with carcinoid syndrome. Acromegaly is a hormone disorder that results from the overproduction of growth hormone in middle-aged adults. Octreotide is the standard of care for the treatment of acromegaly. The current market leader, Sandostatin®, is administered via deep subcutaneous or intramuscular injections once a month. This monthly treatment regimen can result in loss of efficacy 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 of the treatment cycle. ASQST-305 has shown promising preclinical results. We completed a human proof of concept study in Canada. As a result of the early stage proof of concept work, further optimization of this formulation is currently underway.

Licensed Products

Our portfolio also includes products and product candidates that we have licensed, or will seek to license, for commercialization. In the years ended December 31, 2019 and 2018, our licensed product portfolio generated over $1 billion in revenue for our licensees in each year, resulting in $49.7 million and $67.2 million in revenue to Aquestive, respectively. Our key licensed products and products that we intend to license include:

- **Suboxone** – a sublingual film formulation of buprenorphine and naloxone that is marketed in the United States and internationally for the treatment of opioid dependence. Suboxone Sublingual Film was launched by licensee, Indivior Inc., or Indivior, in 2010. Suboxone Sublingual Film is the most prescribed branded product in its category and is the first sublingual film product for the treatment of opioid dependence. We are the sole and exclusive supplier and manufacturer of Suboxone Sublingual Film and Indivior's authorized generic product of the drug.

On October 15, 2019, Indivior publicly announced that, in order to mitigate the impact from the recent passage of H.R. 438 – Continuing Appropriations Act, 2020, and Health Extenders Act of 2019, which came into effect on October 1, 2019, and which includes changes to the methodology for calculating average manufacturers price for branded dosage, Indivior has discontinued offering its authorized generic sublingual film product. As of early March 2020, Suboxone branded products retain approximately 43% of film market share. We do not expect any meaningful revenue in 2020 and in future years from sales of the authorized generic product of Suboxone, but we do expect the branded Suboxone products for U.S. and rest of world to continue to provide meaningful revenue in the future.

Since the launch of this product in 2010, we have produced over 2.2 billion doses of Suboxone. On February 20, 2019, Dr. Reddy's Labs and Alvogen, Inc. launched competing generic formulations of this product at risk, and on February 22, 2019 Mylan Pharmaceuticals, Inc. announced it launch of a similar generic formulation. We filed and continue to pursue patent infringement lawsuits against these companies. More details regarding these lawsuits are described in the "Legal Proceedings" section below in Item 3 of this Form 10-K.

- **Exservan (riluzole) Oral Film** – utilizing Aquestive's proprietary PharmFilm® technology, has been developed for the treatment of amyotrophic lateral sclerosis (ALS). Exservan may potentially fulfill a critical need for ALS patients, given it can be administered safely and easily, twice daily, without water. 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 in November 2019. During the 2019 fourth quarter, the Company granted a license to Zambon S.p.A ("Zambon") for the development and commercialization of Exservan in the European Union (EU) for the treatment of ALS. Zambon is a multinational pharmaceutical company with a focus on the central nervous system (CNS) therapeutics 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 will be 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. The Company seeks to license the commercialization rights for Exservan in the United States.

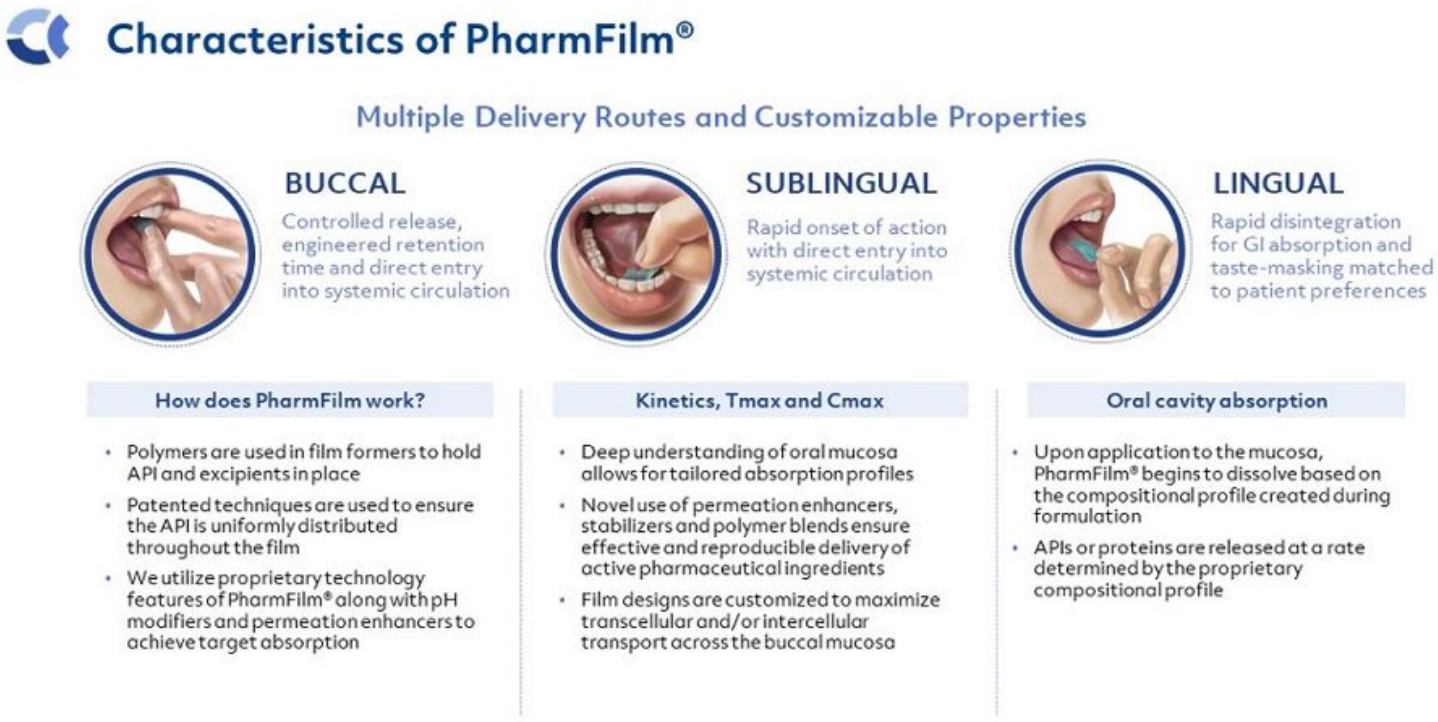
- **Zuplenz** – an oral soluble film formulation of ondansetron, a 5-HT antagonist approved for the treatment of nausea and vomiting associated with chemotherapy and post-operative recovery. Ondansetron is available as intravenous injections, intramuscular injections, orally dissolving tablets, oral solution tablets, and film. Generic and branded products are available, with the branded product marketed as Zofran® by GlaxoSmithKline. 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 are the sole and exclusive manufacturer of Zuplenz for Fortovia.

- **APL-130277** – a sublingual film formulation of apomorphine, which is a dopamine agonist in development to treat episodic off-periods in Parkinson's disease. APL-130277 is being developed by a licensee as a sublingual alternative to an injectable form of apomorphine. We licensed intellectual property for APL-130277 to Cynapsus Therapeutics, Inc., a company that was acquired by Sunovion Pharmaceuticals Inc., or Sunovion. Sunovion received a Complete Response Letter from the FDA on January 29, 2019 and announced that no additional clinical trials were necessary to submit a revised NDA. Sunovion announced in November 2019 that the NDA was re-submitted, and its PDUFA goal date was May 21, 2020. Assuming FDA approval for this product candidate, which we cannot assure, we intend to explore royalty monetization opportunities for the expected royalty and milestone revenue streams from this product which, if successful, could lead to additional non-dilutive capital for the Company.

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 200 issued patents worldwide, of which at least 40 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 where there are unmet patient needs or shortcomings in current standards of care. We believe there remains significant opportunity to develop additional products in the CNS market. Additionally, our know-how and proprietary position have broad application beyond CNS, and we plan to explore the applications of PharmFilm® in other disease areas.

Our Management Team

Our management team is a critical component to the development of our business model and the execution of our strategy. We are led by executives with an average of over 18 years of relevant senior leadership experience, including developing and commercializing branded and generic pharmaceuticals at large multinational pharmaceutical companies such as Johnson & Johnson, GlaxoSmithKline PLC, Novartis AG and AstraZeneca. Additionally, our team has significant experience in the commercialization of pharmaceutical products, translational science, drug evaluation, clinical development, significant FDA experience, regulatory affairs and business development. During 2019 we hired our Chief Medical Officer. Our management team is supervised and supported by a board of directors with expertise in finance, strategy, medicine and drug development.

Our Strategy

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

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

- ***Advance our late stage proprietary portfolio of CNS product candidates to solve critical healthcare problems and make a meaningful improvement in the lives of patients and caregivers.*** We have focused development efforts on three proprietary CNS products, two of which have been approved and one product candidate in development. These products and product candidates address treatment challenges associated with epilepsy and ALS. We have received FDA approval and subsequently began, in December 2018, distribution and sales of Sympazan. We received FDA approval of Exservan in November 2019. We completed the rolling submission for our NDA filing with the FDA for our drug candidate Libervant, with a PDUFA goal date of September 27, 2020. A competitor was approved for a diazepam nasal product in January 2020 and was granted orphan exclusivity. As described in more detail above under "Our Product Portfolio and Pipeline" and below under "Competition", we believe and intend to seek to demonstrate to the FDA that our product candidate Libervant is clinically superior to the two existing approved products utilizing the same active moiety in that it represents a major contribution to patient care when compared to device driven rectal and nasal applications, although there can be no assurances that we will be successful. See additional information concerning the Libervant FDA approval process in the "Competition" section of Item 1. Business of this Form-10K.

- ***Scale our commercial platform to maximize the value of our proprietary product candidates.*** In order to maximize the value of our proprietary product candidates, we are continuing our plan to self-commercialize our proprietary product candidates. We will continue to right size our capabilities in marketing, sales, payor and market access management and medical affairs in order to appropriately support the products we commercialize and the revenue opportunity they represent.

- ***Exploit our technology and know-how to develop oral versions of more complex injectable drugs and other drug delivery administrations to address unmet patient needs.*** Based on promising preclinical and early clinical results, we intend to continue to develop oral transmucosal versions of epinephrine, a product that is currently available in injectable form. We believe the success of these efforts may lead to additional opportunities in developing oral transmucosal versions of some proteins, peptides and other complex molecule drugs, which have historically been administered by means other than oral intake, such as injection or infusion or nasal spray.

- ***Continue to identify product opportunities within CNS and other markets to expand our proprietary product pipeline.*** We intend to identify additional product candidates that provide clinical differentiation and solve unmet needs. In the CNS space, we will leverage our relationships with key stakeholders including patients, caregivers, key opinion leaders and patient advocacy groups to identify new product opportunities. Additionally, we will continue to evaluate other therapeutic areas, indications and products where we believe that our expertise and know-how can create differentiation and value.

- ***Acquire and market products, or establish licensing relationships to develop and manufacture products, utilizing new chemical entities.*** We intend to continue to seek and to evaluate strategically expanding our product portfolio by considering the development of products that would incorporate new chemical entities to treat disorders with high unmet need.

- ***Continue to expand and solidify our intellectual property portfolio for our products, product candidates and manufacturing processes.*** We believe that our global intellectual property portfolio is a significant source of competitive advantage. We have built a two-tier patent estate consisting of composition-of-matter and method of manufacture patents and patent applications. We intend to seek to expand our intellectual property estate, where appropriate, as we advance our PharmFilm® and other technologies and as we develop new and existing product candidates.

Market Overview

CNS Market

CNS diseases affect the brain or spinal cord and cause neurological and psychiatric disorders. Driven by an increase in mental health awareness and an aging population, the global market for therapeutics indicated for CNS disorders was estimated by EvaluatePharma to be $82 billion in 2018, with anticipated growth to $115 billion by 2024.

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 is currently marketed as a product administered rectally, and a recently approved nasal spray product which is not yet available commercially. Historically, the rectal gel has been the only rescue medication available on 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 to reduce the burden associated with this rescue therapy. 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 and affects 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 $336 million with more than 603,000 prescriptions filled in 2019. Sympazan was developed to reduce the burden associated with drug administration and cost.

Amyotrophic Lateral Sclerosis

ALS is a progressive neurodegenerative disease affecting nerve cells responsible for controlling voluntary muscle movement. Patients suffering from ALS have progressive degeneration of motor neurons, which ultimately leads to death, primarily due to respiratory failure. Diagnosis of ALS typically occurs between the ages of 40 and 60, with more than 15,000 patients living with ALS in the U.S.

There are currently no treatments available that reverse the damage caused by ALS. However, there are two treatment molecules that have been shown to slow disease progression, riluzole, marketed as Rilutek or Tiglutik, and edaravone marketed as Radicava.

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

As a result of the degenerative muscle function associated with ALS, patients eventually lose the ability to swallow. Because riluzole may slow disease progression and delay the need for a tracheotomy, dysphagia represents a barrier to treatment for many of these patients. We developed Exservan to allow patients to remain on riluzole therapy for more extended periods of time, delaying the need for procedures like tracheotomies, prolonging the quality of life for those patients and lowering the overall cost of treatment. Exservan is approved for marketing in the U.S., and the Company is seeking a marketing licensee for this product in the U.S. Exservan has been licensed to Zambon for marketing in the EU.

Other Therapeutic Areas

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

Anaphylaxis

Anaphylaxis is a systemic allergic reaction caused by a wide range of allergen exposure, estimated to affect one in 50 people in the United States. Anaphylaxis typically occurs quickly once allergen exposure has occurred and, if untreated, can lead to death via airway restriction.

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, dominates the market. In addition, in the past, manufacturing issues that resulted in injector malfunctions had led to patient concern regarding the reliability of auto-injectors. EpiPen, which is marketed by Mylan Pharmaceuticals, Inc., represents over 70% of the current branded market on a prescription volume basis. Proper dosing and the ability to effectively administer epinephrine in a timely, reliable manner is critical for patients experiencing anaphylaxis 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, a “first of its kind” oral sublingual film formulation delivering systemic epinephrine that is in development for the treatment of anaphylaxis using Aquestive’s proprietary PharmFilm® technologies, to offer a more convenient and cost-effective oral form of epinephrine as an alternative to the current standard of care. We expect to open an IND with the U.S. FDA in mid-2020 to continue to pursue the development and approval of this product under the 505(b)(2) regulatory approval pathway.

Acromegaly

Acromegaly is a hormone disorder that results from the overproduction of growth hormone in middle-aged adults. The condition is typically caused by a benign tumor present in the pituitary gland that excretes excessive amounts of growth hormone and leads to exaggerated bone growth over time. Due to the gradual progression of the disorder, patients are often not diagnosed for years. The prevalence of acromegaly is estimated to be 77cases per million people, indicating approximately 25,000 diagnosed patients within the United States.

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

The market leading product for acromegaly is octreotide, which is marketed as Sandostatin LAR by Novartis, and is administered monthly via depot injections.

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

Proprietary CNS Product Candidate

Libervant™ (diazepam)Buccal Film

Libervant™ is a buccally, or inside of the check, administered soluble film formulation of diazepam. Epilepsy patients have been underserved for some time with little choice beyond device-based products such as rectally administered gels and a recently approved diazepam nasal spray. As an early administered buccal film product that quickly dissolves when applied to the buccal mucosa, Libervant has a rapid onset of action and provides a consistent therapeutic dosing. See “Our Product Portfolio and Pipeline” above and “Competition” below.

We are developing Libervant, which has been designated an orphan drug and received a PDUFA goal date of September 27, 2020, as an alternative to currently approved diazepam products in the form of a rectal gel and a recently approved nasal spray, the latter of which received orphan drug market exclusivity for this drug. It is anticipated that Libervant, if approved by the FDA, will enable a portion of the patient population who do not receive adequate treatment or forego treatment altogether to receive an alternative treatment by providing consistent therapeutic dosing in a non-invasive and innovative treatment form for epileptic seizures. As a first oral product available utilizing this active moiety for this indication, we believe, and we intend to seek to demonstrate to the FDA that, Libervant is clinically superior in that it represents a major contribution to patient care for this group of patients within the meaning of the FDA regulations and guidance. The FDA has recently indicated that, when evaluating clinical superiority for drugs demonstrating a “major contribution to patient care,” it may consider, where appropriate, such factors as convenience of treatment location, duration of drug administration, longer periods between doses, and potential for self-administration. 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 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. We believe that our product candidate Libervant is “clinically superior” to the two currently FDA-approved products with the same moiety and for the same indication as Libervant, as qualifying as “a major contribution to patient care” within the meaning of the FDA regulation and guidance. However, such a demonstration to overcome such seven-year market exclusivity is difficult to establish with limited precedents and there can be no assurance that we will be successful in these efforts. 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.

Proprietary Complex Molecule Candidates

AQST-108 (Epinephrine)

AQST-108 is a sublingual film formulation of epinephrine that we are developing for the treatment of anaphylaxis, a severe and potentially life-threatening allergic reaction.

Anaphylaxis is a severe systemic allergic reaction that can be triggered by certain foods, insect stings, certain medications and latex, among other allergens. Signs and symptoms of anaphylaxis typically occur within seconds or minutes of exposure and may include low blood pressure, skin rash or itching, constriction of the airway and difficulty breathing and nausea and vomiting. If not treated immediately, anaphylaxis can lead to death due to airway restriction or cardiac arrest. Anaphylaxis 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. Epinephrine injection is the current standard of treatment intended to reverse the potentially severe manifestation of anaphylaxis, which may include red rash, throat swelling, respiratory problems, gastrointestinal distress and loss of consciousness. Epinephrine, a non-selective adrenergic agonist, is administered via intramuscular injection. Because anaphylaxis can progress quickly, the ability to administer a reliable and accurate dose of epinephrine as quickly as possible following a reaction is critical for patient recovery and survival. Epinephrine is typically administered in a single-dose, pre-filled automatic injection device, or an auto-injector. People with known allergies and who are at risk for anaphylaxis are advised to carry an auto-injector with them at all times and self-administer at the first signs of an anaphylactic reaction. The EpiPen® and similar products can be inconvenient to transport and many patients and caregivers dislike injections as a delivery method. Additionally, injector malfunction issues and user administration errors may prevent successful and timely dosing which can result in danger to patients.

We are developing AQST-108, a “first of its kind” oral sublingual film formulation delivering systemic epinephrine that is in development for the treatment of anaphylaxis using Aquestive’s proprietary PharmFilm® technologies, as an alternative to the currently marketed intramuscular injections. We believe there is a market opportunity for a non-injectable, easier to administer product with a fast onset of action. A product with this profile would enable patients to conveniently and rapidly self-administer a reliable and accurate dose of epinephrine during an anaphylactic reaction, which we believe would result in greater patient compliance. Subject to our achieving regulatory approval of this product candidate, which we cannot assure, we believe AQST-108 has the potential to reduce the treatment burden currently associated with intramuscular injections and may lower costs to the healthcare system associated with anaphylaxis, such as hospitalizations, due to inaccurate or untimely dosing.

We have conducted proof-of-concept studies to demonstrate our ability to deliver epinephrine via a non-invasive sublingual film. The data from our completed Phase 1 dose escalation study demonstrated that AQST-108 achieved similar ranges of mean values of maximum concentration (Cmax) and time to reach maximum concentration (Tmax) to that reported for injectables EpiPen and Auvi-Q®, provided a greater total exposure (AUC0-t; area under the curve) than that reported for EpiPen and Auvi-Q, had less interpatient variability when compared to degree of variation (CV%) data reported for EpiPen and Auvi-Q, and was well tolerated, with no study participants discontinuing participation due to an adverse event. We believe that this proof of concept study in humans demonstrates our ability to deliver epinephrine via the oral cavity.

In February of 2020, we had a constructive face-to-face pre-Investigational New Drug (IND) application meeting with the FDA. A pre-IND meeting provides an opportunity for an open communication between a drug sponsor and the FDA to discuss the sponsor’s IND development plan and to obtain the agency’s guidance for clinical studies for the sponsor’s new drug candidate. The FDA has confirmed that the clinical development for AQST-108 will be reviewed under the 505(b)(2) regulatory approval pathway, as proposed by Aquestive, and that no additional studies would be necessary prior to opening the proposed IND application. The FDA indicated that there appears to be an unmet medical need among patients who resist the standard of care use of intramuscular injection in the treatment of anaphylaxis and that AQST-108 may potentially address some of those unmet needs. Aquestive expects to move forward with opening an IND and initiating its pharmacokinetic (PK) clinical trials before the end of 2020.

AQST-305 (Octreotide)

AQST-305 is a sublingual film formulation of octreotide, an 8 amino acid peptide that has a similar pharmacological profile to natural somatostatin, for the treatment of acromegaly. We completed human proof of concept studies in Canada in 2019 and, based on the results of these studies, we are completing additional reengineering of the formulation.

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

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

We have designed AQST-305 for twice daily administration, which we believe will reduce the burden of monthly depot intramuscular injections and address the potential loss of efficacy over the treatment life cycle with currently marketed products.

AQST-305 can be administered by the patient, rather than having to receive monthly injections in a physician's office. Additionally, because AQST-305 is administered twice-daily, we believe patients would receive a consistent dose of octreotide and will not need to be concerned with the potential loss of efficacy that may otherwise result when receiving only a monthly dosage administered via injection. Subject to our achieving FDA approval of this product candidate, which we cannot assure, we believe AQST-305 will reduce the burden for patients who are looking for a non-invasive, pain-free, easier to administer product.

Licensed Products and Product Candidates

Suboxone (Buprenorphine and Naloxone)

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

Suboxone Sublingual Film was launched in partnership with Indivior in 2010 to treat opioid dependence pursuant to a commercialization agreement. We have granted Indivior an exclusive worldwide license to this product. Since the launch of the product in 2010, over 2.2 billion doses have been delivered to patients. We are the sole and exclusive manufacturer of Suboxone Sublingual Film worldwide for Indivior. See “Material Agreements – Commercial Exploitation Agreement with Indivior” section in this Form 10-K. On February 20, 2019, Dr. Reddy’s Labs and Alvogen, Inc. launched competing generic formulations of this product and, on February 22, 2109, Mylan Pharmaceuticals, Inc. announced its launch of a similar generic formulation. In early 2019 Indivior, through Sandoz Inc., began to market and sell an authorized generic sublingual film product for Suboxone. On October 15, 2019, Indivior publicly announced the discontinuance of production of the authorized generic sublingual film product in order to mitigate the impact from the recent passage of H.R. 438 – Continuing Appropriations Act, 2020, and Health Extender Act of 2019, which came into effect on October 1, 2019 and which includes changes to the methodology for calculating average manufacture price branded drugs. In addition, although Indivior, through the branded Suboxone, has continued to retain significant market share, we have continued to anticipate the erosion of this sunsetting product over time.

Zuplenz (Ondansetron)

Zuplenz is an oral soluble film formulation of ondansetron, a 5-HT_3 antagonist approved for the treatment of nausea and vomiting associated with chemotherapy and post-operative recovery. Ondansetron is available as intravenous injections, intramuscular injections, orally dissolving tablets, oral solution, tablets, and film. Generic and branded products are available, with the branded product marketed as Zofran by GlaxoSmithKline. We licensed commercial rights for Zuplenz to Fortovia (formerly Midatech Pharma PLC) in the United States, Canada, and China. Fortovia launched Zuplenz in the United States in 2015. We are the sole and exclusive manufacturer of Zuplenz for Fortovia.

APL-130277 (Apomorphine)

APL-130277 is a sublingual film using apomorphine, a dopamine agonist indicated as an intermittent therapy to overcome episodic off periods in Parkinson’s disease. Parkinson’s disease affects approximately 650,000 people in the United States aged greater than 45 years old. APL-130277 is designed to address an unmet need in patients who suffer from dysphagia and/or patients who have discontinued or avoided use of the existing injectable product due to site irritation. We licensed intellectual property rights for PharmFilm® technology associated with APL-130277 to Cynapsus Therapeutics, Inc., which was acquired by Sunovion Pharmaceuticals, Inc. (Sunovion). Subject to receiving FDA approval, which we cannot assure, we will earn royalties and other milestone payments contingent upon worldwide sales of APL-130277. See “Material Agreements – License Agreement with Sunovion Pharmaceuticals, Inc.” in this Form 10-K. In January 2019, we learned that Sunovion received a Complete Response Letter (a CRL) from the FDA in response to its submission of an NDA for APL-130277. In a subsequent press release, Sunovion advised that additional information and analyses were required, but that no new clinical studies were required. In the 2019 fourth quarter, Sunovion announced that the FDA had given a PDUFA goal date of May 21, 2020 after a resubmission of the NDA for this product. Assuming FDA approval for this product candidate, we intend to explore royalty monetization opportunities for the expected royalty and milestone revenue streams from this product which, if successful, could lead to additional non-dilutive capital for the Company.

Manufacturing and Product Supply

We operate two redundant manufacturing and primary packaging facilities located in Portage, Indiana, where we currently manufacture proprietary CNS products, as well as our licensed products, Suboxone and Zuplenz, 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 1.1 billion doses in the last four years. As a company, our research and development laboratories are registered with the DEA for Schedule II-V drugs.

We are subject to various regulatory requirements, such as the regulations of the FDA, the DEA, and other foreign health authorities such as the Australian Government Department of Health's Therapeutics Goods Administration, or 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 experiences 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 intend to 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 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. We believe, and intend to seek to demonstrate to the FDA, that our product candidate Libervant is "clinically superior" to the two currently FDA-approved products with the same moiety and for the same indication as Libervant, as qualifying as "a major contribution to patient care" within the meaning of the FDA regulation and guidance. However, such a demonstration to overcome such seven-year market exclusivity is difficult to establish with limited precedents and there can be

no assurance that we will be successful in these efforts. 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., or the Indivior License Agreement. Indivior, Inc. is the successor in interest to Reckitt Benckiser Pharmaceuticals, Inc. Pursuant to the Indivior License Agreement, we have agreed to manufacture and supply Indivior's requirements of Suboxone for both United States and international markets 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 API for the manufacture of Suboxone directly from Indivior. The Indivior License Agreement specifies a minimum annual threshold quantity of Suboxone that we are obligated to fill and requires Indivior to provide us with a forecast of its requirements at various specified times throughout the year.

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

In addition to the purchase price for the Suboxone supplied, under the Indivior License Agreement, we are to be paid low single digit percentage royalty payments tied to net sales value, subject to annual maximum amounts and limited to the life of related United States or international patents. Indivior exercised its right to buy out its future royalty obligations based on sales in the United States in 2012. Indivior remains obligated to pay royalties for all sales outside the United States.

The Indivior License Agreement contains customary contractual termination provisions in the event of bankruptcy or corporate dissolution, the intellectual property surrounding Suboxone is found to be invalid, or either party commits a material breach of the Indivior License Agreement. Additionally, Indivior may terminate 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 has automatically renewed for successive one-year periods. One-year renewals are expected to continue in the absence of Indivior's written notice of its intent not to renew at least one year prior to the expiration of any prior renewal term.

Supplemental Agreement with Indivior

On September 24, 2017, we entered into an agreement with Indivior, or the Indivior Supplemental Agreement. Pursuant to the Indivior Supplemental Agreement, we conveyed to Indivior all of our existing and future rights in the settlement of various ongoing patent enforcement legal actions and disputes related to the Suboxone product. We also conveyed to Indivior the right to sublicense manufacturing and marketing capabilities to enable an Indivior licensed generic 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. Once paid, all payments made under the Indivior Supplemental Agreement are non-refundable. 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 this agreement are suspended until adjudication of related patent infringement litigation occurs. 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 such market occur.

Indivior is our largest customer and the combined revenue received from Indivior pursuant to the Indivior License Agreement and the Indivior Supplemental Agreement represented 86% of our total revenue for the year ended December 31, 2019 and 89% of the total revenue in 2018.

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 we granted Sunovion an exclusive, worldwide license (with the right to sub-license) to certain intellectual property, including existing and future patents and patent applications, covering all oral films containing APL-130277 (apomorphine) for the treatment of off episodes in Parkinson's disease patients, as well as two other fields. Our licensee, Sunovion, as sponsor of APL-130277, submitted an NDA to the FDA on March 29, 2018; on the PDUFA date in January 2019, Sunovion received a CRL. In the 2019 fourth quarter, Sunovion announced that it had received a PDUFA goal date of May 21, 2020 after the resubmission of its NDA.

In consideration of the rights granted to Sunovion under the Sunovion License Agreement, we received aggregate payments totaling $18.0 million to date. In addition to the upfront payment of $5.0 million we have also earned an aggregate of $13.0 million 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. We are also entitled to receive certain contingent one-time milestone payments related to product availability and regulatory approval in the United States and Europe, certain one-time milestone payments based on the achievement of specific annual net sales thresholds of APL-130277, and ongoing mid-single digit percentage royalty payments related to the net sales of APL-130277 (subject to reduction to low-single digit percentage royalty payments in certain circumstances), subject to certain minimum payments. The maximum aggregate milestone payments that may be paid to us pursuant to the Sunovion License Agreement is equal to $45.0 million. With the exception of the Initial Milestone Payments, there can be no guarantee that any such milestones will in fact be met or payable. This Sunovion License Agreement will continue until terminated by us or Sunovion in accordance with the termination provisions of the Sunovion License Agreement.

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

As more fully described in the Sunovion License Agreement, Sunovion generally may terminate the Sunovion License Agreement if (i) we fail to use commercially reasonable efforts to defend the Licensed Patents in response to a Patent Infringement Claim (as defined in the Sunovion License Agreement); (ii) we are in material breach of the Sunovion License Agreement, which breach is not remedied after receiving notice thereof; (iii) prior to commercialization of APL-130277, upon certain notice to us, if Sunovion has abandoned further development of APL-130277; or (iv) at any time after December 31, 2024, for any reason upon certain notice to us. Sunovion may also terminate the Sunovion License Agreement if it can establish that a Material Decline (as defined in the Agreement) has occurred in a jurisdiction as a result of us licensing to a third-party any Licensed Patents to develop or commercialize apomorphine either alone or in combination with another active agent, for any human use, solely with respect to such jurisdiction(s) that have suffered a Material Decline, upon certain notice to us. Aquestive may terminate the agreement for any reason at any time after January 1, 2020.

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

Agreement to Terminate CLA with KemPharm

In March 2012, the Company entered into an agreement with KemPharm, Inc., or KemPharm, to terminate a Collaboration and License Agreement entered into 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 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 $1.0 million from its 10% share of milestone payments paid to KemPharm under its licensing of KP-415 and KP-484. There can be no guarantee that such payments will be made in the future.

Intellectual Property

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

In addition, we intend to seek orphan drug exclusivity in jurisdictions in which it is available. A prerequisite to orphan drug exclusivity in the United States and in the European Union is orphan drug designation. An orphan drug designation may be granted where a drug is developed specifically to treat a rare or uncommon medical condition. If a product which has an orphan drug designation subsequently receives the first regulatory approval for the indication for which it has such designation, the product is entitled to orphan 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 seven years in the United States and 10 years in the European Union. Orphan drug exclusivity does not prevent competitors from developing or marketing different drugs for the indication protected by exclusivity, or the same drug for a different indication.

Patents

Our patent portfolio currently comprises at least 200 issued patents worldwide, of which at least 40 are U.S. patents, and more than 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 2037. The pending patent applications filed in 2017 will provide composition of matter and process of making protection for our PharmFilm® dosage formulations of diazepam, epinephrine and octreotide and, if issued as patents, will likely expire by 2037. 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 least19 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 2037, excluding any patent term adjustment or patent term extension.

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

We note that several of our issued patents are or have been involved in administrative proceedings, such as reexamination and inter partes review at the U.S. Patent and Trademark Office, or USPTO, and opposition at the European Patent Organization, or EPO.

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 business partners and other third parties that receive our confidential information. There can be no assurance, however, that these agreements will provide meaningful protection or adequate remedies for our trade secrets in the event of unauthorized use or disclosure of such information.

Trademarks

We also rely on trademarks to develop and maintain our competitive position. Our trademarks or registered trademarks are filed in the United States and other select geographical 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, or fast track status, is given to drugs that offer major advances in treatment or provide a treatment where no adequate therapy exists. The FDA endeavors to review applications subject to Standard Review within ten to twelve months, whereas the FDA's goal is to review Priority Review applications within six to eight months.

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

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

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

As a condition of NDA approval, the FDA may require a REMS, 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

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

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

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

In addition, any distribution of prescription drug products and pharmaceutical samples must comply with the U.S. Prescription Drug Marketing Act, or PDMA, a part of the FDCA. In addition, Title II of the Federal Drug Quality and Security Act of 2013, known as the Drug Supply Chain Security Act or the DSCSA, has imposed new "track and trace" requirements on the distribution of prescription drug products by manufacturers, distributors, and other entities in the drug supply chain. These requirements are being phased in over a ten-year period. The DSCSA ultimately will require product identifiers (*i.e.*, serialization) on prescription drug products in order to establish an electronic interoperable prescription product system to identify and trace certain prescription drugs distributed in the United States. The DSCSA replaced the prior drug "pedigree" requirements under the PDMA and preempts existing state drug pedigree laws and regulations. The DSCSA also establishes new requirements for the licensing of wholesale distributors and third-party logistic providers. These licensing requirements preempt states from imposing licensing requirements that are inconsistent with, less stringent than, directly related to, or otherwise encompassed by standards established by 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 changes the way healthcare is financed by both governmental and private insurers and significantly impacts the pharmaceutical industry. Changes that may affect our business include those governing enrollment in federal healthcare programs, reimbursement changes, benefits for patients within a coverage gap in the Medicare Part D prescription drug program, or commonly known as the donut hole, rules regarding prescription drug benefits under the health insurance exchanges, changes to the Medicaid Drug Rebate program, expansion of the Public Health Service’s 340B drug pricing discount program, or 340B program, fraud and abuse, and enforcement. These changes impact existing government healthcare programs and are resulting in the development of new programs, including Medicare payment for performance initiatives and improvements to the physician quality reporting system and feedback program.

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

Some of the provisions of the PPACA have yet to be implemented, and there continue to be judicial and Congressional challenges to certain aspects of the PPACA, some of which have been successful, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the PPACA. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the PPACA or otherwise circumvent some of the requirements for health insurance mandated by the PPACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the PPACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the PPACA have been signed into law. The Tax Cuts and Jobs Act of 2017 includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the PPACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain PPACA-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Further, the Bipartisan Budget Act of 2018, or the BBA, among other things, amends the PPACA, effective January 1, 2019, to increase from 50% to 70% the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the Medicare Part D donut hole. Congress will likely consider other legislation to replace elements of the PPACA.

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

In addition, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At the federal level, the Trump administration's budget proposal for fiscal years 2019 and 2020 contains 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 contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. The Department of Health and Human Services, or HHS, has already started the process of soliciting feedback on some of these measures and, at the same time, is immediately implementing others under its existing authority. While some proposed measures will require authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that 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 form other countries and bulk purchasing. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

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

Coverage and Reimbursement

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

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

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

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

Federal law requires that any manufacturer that participates in the Medicaid Drug Rebate program also participate in the 340B program in order for federal funds to be available for the manufacturer's drugs under Medicaid and Medicare Part B. The 340B program requires participating manufacturers to agree to charge statutorily defined covered entities no more than the 340B "ceiling price" for the manufacturer's covered outpatient drugs. These 340B covered entities include a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as hospitals that serve a disproportionate share of low-income patients. The 340B ceiling price is calculated using a statutory formula, which is based on the AMP and rebate amount for the covered outpatient drug as calculated under the Medicaid Drug Rebate program. Any changes to the definition of AMP and the Medicaid rebate amount under the PPACA or other legislation could affect our 340B ceiling price calculations and negatively impact our results of operations.

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

Coverage for covered outpatient drugs under Part D is not standardized. Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Although Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, they have some flexibility to establish those categories and classes and are not

required to cover all of the drugs in each category or class. Medicare Part D prescription drug plans may use formularies to limit the number of drugs that will be covered in any therapeutic class and/or impose differential cost sharing or other utilization management techniques.

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

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

The containment of healthcare costs has become a priority of federal, state and foreign governments, and the prices of drugs have been a focus in this effort. The United States government, state legislatures, and foreign governments have shown significant interest in implementing cost-containment programs to limit the growth of government-paid healthcare costs, including price controls, restrictions on reimbursement, and requirements for substitution of generic products for branded prescription drugs. For example, the PPACA expanded manufacturers' rebate liability under the Medicaid program from fee-for-service Medicaid utilization to include the utilization of Medicaid managed care organizations as well, increased the minimum Medicaid rebate due for most innovator drugs, and capped the total rebate amount for innovator drugs at 100% of AMP. The PPACA and subsequent legislation also changed the definition of AMP. In addition, the PPACA requires pharmaceutical manufacturers of branded prescription drugs (excluding orphan drugs) to pay a branded prescription drug fee to the federal government. Each such manufacturer pays a prorated share of the branded prescription drug fee of $42.8 billion in 2019, based on the dollar value of its branded prescription drug sales to certain federal programs identified in the law. The PPACA also expanded the Public Health Service's 340B program to include additional types of covered entities. Substantial new provisions affecting compliance have also been enacted, which may affect our business practices with healthcare practitioners, and a significant number of provisions are not yet, or have only recently become, effective. It appears likely that the PPACA will continue the pressure on pharmaceutical pricing, especially under the Medicare and Medicaid programs, and may also increase our regulatory burdens and operating costs.

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

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

As of December 31, 2019, we had 232 employees (including contract and temporary workers). All of these employees are located in the U.S. Of these employees, 34 are directly involved in research and development, 113 are involved in manufacturing operations, 45 are involved in commercialization and sales activities and the remainder are within General and Administration.

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

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

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 to 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. The trading price of our common stock may decline due to these risks. 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.

Risks Related to Our Financial Condition and Need for Additional Capital

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

We have a limited operating history. To date, we have focused primarily on developing a broad product portfolio and have obtained regulatory approval for four of our products:

- Suboxone, the first sublingual film product for the treatment of opiod dependence;
- Zuplenz, the first approved prescription oral soluable film for the prevention of chemotherapy-induced, radiotherapy-induced, and post-operative nausea and vomiting;
- Sympazan, an oral soluable film formulation of clobazam for the treatment of seizures associated with a form of epilepsy known as Lennox-Gastaut Syndrome, or LGS, which was commercially launched in December 2018, and
- Exservan, which has been developed for the treatment of ALS, was approved by the FDA in November 2019 and for which during the 2019 fourth quarter, we granted a license to Zambon S.p.A. for development and commercialization in the EU.

In December 2019, we completed the rolling submission of our NDA filing with the FDA for our product candidate Libervant. Our NDA filing for Libervant was accepted by the FDA on February 10, 2020 and received PDUFA goal date by the FDA of September 27, 2020. We will be required to demonstrate to the FDA that Libervant is “clinically superior” to the currently FDA-approved drugs as qualifying as a “major contribution to patient care” within the meaning of FDA regulations and guidance, which we cannot assure. See “Our Product Portfolio and Pipeline” and “Competition” in Item 1. Business above.

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 products and product candidates are still in their early stages and we may not generate substantial revenue from sales of our self-developed products and product candidates in the near term, if ever. As of December 31, 2019, we had an accumulated deficit of $130,474.

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 partnerships and collaborations and from our self-developed products. The extent of future net losses will depend, in part, on the rate of future expenditures and our ability to generate revenue. To date, only three of our products, Suboxone, Zuplenz, each being a licensed product, and Sympazan, our first self-developed, self-commercialized product, have been commercialized, and if our other product candidates are not successfully developed or commercialized, or if revenue is insufficient following marketing approval of such product candidates, we will not achieve profitability and our business may fail.

The development, regulatory approval process, and commercialization of drug candidates involves 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, but we expect to continue to incur substantial expenses, which we expect to increase as we expand our development and commercialization activities and product portfolio. Some of the expenses we expect to continue to incur include:

- conducting clinical trials of our product candidates;
- seeking regulatory approval for any of our product candidates that successfully complete clinical development;
- commercialization activities, including product sales, marketing, manufacturing and distribution, for our products, if approved;
- maintaining, expanding and protecting our intellectual property portfolio;
- acquiring or in-licensing new technologies or development-stage or approved products;
- adding clinical, scientific, operational, financial, 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.

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

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

Our operations have consumed and will continue to consume substantial amounts of cash. We had $49,326 in cash and cash equivalents as of December 31, 2019. We currently have no committed sources of future funding or capital.

We expect that our existing cash and cash equivalents combined with our anticipated revenue from our licensed product activities including expected milestone payments, other co-development payments and royalty payments, manufacturing and supply revenues at anticipated levels, sales of our proprietary product at anticipated levels, and assuming satisfaction of all conditions and requirements for further issuances and available purchasers thereof, potential additional proceeds from future issuances of up to $30,000 under our 12.5% Senior Secured Notes due 2025 (the "Senior Secured Notes"), the net proceeds from our equity issuance in December 2019, potential future monetization of certain royalty streams or other license rights for our licensed product Apomorphine (subject to all conditions and requirements under the Senior Secured Notes Indenture dated July 15, 2019) and, if needed and available to us, which cannot be assured, further access to the capital markets under our shelf-registration statement filed with the SEC and declared effective September 17, 2019, will be adequate to fund our expected cash requirements for the next 12 months. However, we have based this expectation on assumptions that could change or prove to be inaccurate and, additionally, we could utilize our available financial resources sooner than we expect.

We continue to be in the process of transitioning to a company newly commercializing its self-developed products, with our commercialization activities beginning with regulatory approval of our first proprietary product, Sympazan, in December 2018. For our commercialization efforts to be successful we must continue to train, deploy and further recruit, contract for and develop an effective sales and marketing organization and infrastructure. To become and remain profitable we must continue to develop, obtain timely regulatory approval of, and successful commercialize or out-licenses or monetize, those of our proprietary products and product candidates that we believe will have the most market potential and commercial success. In addition, our commercialization effects may take longer to achieve than planned. Our business or operations may also change and we may also encounter unanticipated or unbudgeted events or expenses that may require cash resources more rapidly than planned. We are unable to determine or forecast with certainty when or if we will achieve or sustain profitability.

Our cash resources on hand are not sufficient by themselves to fund our expected development, commercialization and other operations and activities, and we will continue to require external resources of funding and capital to develop and seek regulatory approval of our product candidates and for the commercialization of our approved products. The amount of additional funding and capital will depend on many factors, many of which may be beyond our control.

We expect to continue to spend substantial amounts to commercialize our epilepsy products, Sympazan (launched in December 2018) and, if approved by the FDA, Libervant, which we cannot assure, and our other proprietary product candidates. We expect our expenses to continue to significantly increase as we continue to devote substantial financial resources to our ongoing product development, research and development activities, pre-clinical activities, clinical trials, regulatory approval activities, and commercialization activities. We also expect to continue to incur significant losses and negative cash flows for the foreseeable future and we therefore are dependent upon external financing and funding to achieve our operating plan. Based on our operating budget and business plan, we will need to raise substantial additional financing by various means, including, among others, through public or private equity or debt financings, third-party funding, marketing and distribution arrangements, as well as other collaborations, strategic alliances and licensing arrangements, or any combination of these approaches. Our existing resources will not be adequate to permit us to complete clinical development of our product candidates or fund our operations and additional resources will be needed to complete such development and to support our continued operations. We will therefore continue to explore a variety of funding alternatives, including both dilutive and non-dilutive financing options and strategic partnerships.

Our expectation of the period of time through which our financial resources will be adequate to support our operations is based on assumptions that may prove to be inaccurate and, additionally, we could deplete our available cash resources sooner than we currently expect. In addition, our operating plan and budget could change as a result of many factors and we may encounter unforeseen or unplanned expenses, difficulties, delays or other unforeseen or unplanned factors, and we may need to seek additional funds sooner than planned, whether through public or private equity or debt financings, third-party funding, marketing and distribution arrangements, as well as other collaborations, strategic alliances and licensing arrangements, or any combination of these approaches, and we cannot assure we will be successful in any of these efforts.

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 in the time period planned our royalty streams or other license rights such as Apomorphine. We also are 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, and there is no assurance when or if any such payments may be due. Our operating revenues have fluctuated in the past and can be expected to fluctuate in the future. We also have substantial ongoing debt repayment and debt service obligations. 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 longer than planned to achieve anticipated sales levels of our proprietary products.

We have historically relied upon sales of Suboxone and Zuplenz, our two commercialized licensed products, milestone payments and other fees from co-development and research services, fees from licensed proprietary technologies and patent rights, and royalties based on specified product sales, together with private sales of equity or debt securities and proceeds from our debt facilities, to fund our operations. Due to the at-risk launch of Suboxone generics in the marketplace, as well as the cessation of manufacture and sale of the authorized generic of Suboxone, our revenue will continue to be adversely impacted. Delays in obtaining funding could adversely affect our ability to develop and commercially introduce products, if approved, and cause us to be unable to comply with our obligations. Even if we believe we have sufficient capital and cash resources for our current or expected operating plans, we may seek additional capital and cash resources if market conditions are favorable or if we have specific strategic considerations or we otherwise believe it to be advisable. Any additional capital raising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our current and future product candidates.

Unless and until we become profitable, we will continue to need to raise additional capital and/or other financing or funding in the future, any of which could be material. Our ability to secure additional equity financing could be significantly impacted by numerous factors including our operating performance and prospects, 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, restrictions under our 12.5% Senior Secured Notes Indenture, investor sentiment and general market conditions, and there can be no assurance that we will continue to be successful in raising equity 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.

Our ability to obtain additional debt financing is also subject, in addition to the limitations and restrictions under the Indenture for our Senior Secured Notes, to a number of additional factors, including market conditions, our operating performance and lender sentiment. To the extent we are able to obtain needed funding through additional debt financing, any such debt financing may be coupled with an equity component, such as warrants for our shares, which could also result in dilution to our stockholders. The incurrence of additional debt would also result in increased fixed payment obligations. If we were to default on any of our indebtedness, which currently is secured by substantially all of our assets, we could lose such assets including our intellectual property.

We also may seek to obtain additional funding in the near future through the monetization of royalty streams from our licensed product Apomorphine, subject to regulatory approval thereof, (and subject to the conditions and requirements under the Indenture for our Senior Secured Notes including our note repurchase obligations at the option of the holders), but we cannot be assured of any such royalty streams or monetization. We also may seek to obtain additional funding through third-party funding, marketing and distribution arrangements, as well as other collaborations, strategic alliances and licensing arrangements, or any combination of these approaches. In addition, payments made by potential collaborators or licensors generally will depend upon our achievement of negotiated development and regulatory milestones. Failure to achieve these milestones may harm our future liquidity and funding position.

The first reopener (for up to $10 million) under the Indenture for our Senior Secured Notes is, among other conditions, subject to the completion of the NDA filing for our product candidate Libervant and the consent, in their discretion, of the holders of a majority of the outstanding original principal amount of the Senior Secured Notes. We have an opportunity to seek additional funding under the Indenture for the Senior Secured Notes if the FDA approves the NDA for up to $30 million of our product candidate Libervant. We cannot assure any additional financing under the Indenture for the Senior Secured Notes.

We completed the rolling submission of our NDA filing for Libervant in November 2019, and the FDA accepted our NDA filing on February 10, 2020. Due to FDA approval of and FDA grant of orphan drug exclusivity for a competitive product in January 2020, we are required to demonstrate to the FDA, and the FDA would need to conclude, that Libervant is “clinically superior” to the two current FDA-approved products with the same active moiety and for the same indication as Libervant as qualifying as “a major contribution to patient care” within the meaning of the FDA regulations and guidance, which is difficult to establish with limited precedents and we cannot assure that we will be successful. Any delay in obtaining FDA approval to market Libervant in the U.S., or any failure to obtain such approval, would reduce, delay or possibly eliminate a significant revenue source and line of business which has been part of our strategy and business plan, which we would need to replace with other proprietary product candidates, which we cannot assure.

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 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, although we cannot be assured that any of these actions would be available 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.

We do not have any committed external source of funds other than potential milestone payments and royalties under certain of our collaboration agreements. Until such time, if ever, as we can generate sufficient revenue to fully fund our operations, we 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, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. Debt financings may be coupled with an equity component, such as warrants to purchase shares of our common stock, which could also result in dilution of existing stockholders' ownership. The incurrence of 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 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 authority 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 products launched;
- 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, pre-clinical 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, 2019, we had an aggregate principal amount of $70.0 million of outstanding indebtedness. In the future, we may need to borrow additional funds.

Because of our indebtedness:

- we may have difficulty satisfying our obligations with respect to our existing indebtedness including the repayment of such indebtedness;
- we may have difficulty obtaining financing in the future (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 other partnered 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 for our Senior Secured Notes) 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 our Senior Note Indenture and Senior Secured 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 our two approved licensed products, Suboxoe and Zuplenz, our first self-commercialized product, Sympazan, and, our product candidate Libervant subject to FDA approval of Libervant including our ability to demonstrate to the FDA, and have the FDA conclude, that Libervant is "clinically superior" to the currently FDA-approved products for the same active moiety for the same indication as Libervant, which we cannot assure, as well as our other licensing and collaboration development activities. 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 86% of our revenues for 2019 and approximately 89% of our revenues for 2018 and in the future will continue to account for a substantial part of our revenues. However, there can be no assurance that the claims against Indivior could not materially and adversely affect Indivior which, if this were to occur, could impact our supply and licensing relationship with Indivior and the volume and timing of its purchases from us and our revenues from Indivior, which could have a material adverse financial impact on our business, prospects, liquidity, financial condition and operating results. On July 11, 2019, Reckitt Benckiser Group plc, the predecessor in interest of Indivior, reached an agreement with the U.S. Department of Justice (DOJ) and the Federal Trade Commission (FTC) to resolve the FTC's investigation into the sales and marketing of Suboxone Film by its former pharmaceuticals business, now Indivior, a business that was wholly demerged from Reckitt Benckiser in 2014. Reckitt Benckiser will pay a total of up to $1.4 billion to fully resolve all federal investigations. As of this filing, Indivior has not publicly disclosed any settlement or other disposition of this matter with the DOJ.

Further, our license agreement with Indivior, 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 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, our licensing agreement with Indivior 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 may not terminate our 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 recently announced that it had notified Sandoz, Inc. of Indivior's intention to cease production of the Sandoz authorized generic product of Suboxone, which can be expected to have a material impact on our manufactured product sales and revenues.

Under a Commercial Exploitation Agreement dated August 2008, or the Indivior License Agreement, we agreed to manufacture and supply Indivior's requirements for Suboxone, a sublingual film formulation, both inside and outside the U.S., on an exclusive basis. The initial term of the Indivior License Agreement was seven years from the commencement date and thereafter automatically renews for successive one-year periods, unless either party provide the other with written notice of its intent not to renew at least one year prior to the expiration of the then renewal term.

In early 2019, certain third-party pharmaceutical companies launched at risk, generic film products for buprenorphine-naloxone. Also, in early 2019 Indivior, through Sandoz Inc., began to market and sell an authorized generic sublingual film product for Suboxone, which has been well received in the marketplace and which we also exclusively manufactured and supplied. On October 15, 2019, Indivior publicly announced that, in order to mitigate the impact from the recent passage of H.R. 438 – Continuing Appropriation Act, 2020, and Health Extenders Act of 2019, which came into effect on October 1, 2019 and which includes changes to the methodology for calculating average manufacturer price for branded drugs Indivior had given notice to Sandoz of Indivior's intention to cease production of the authorized generic sublingual film product.

Indivior has historically accounted for a substantial part of our total annual revenues and, for fiscal 2019, accounted for approximately 86% of our annual revenues. While we had a strong order book for Suboxone products and the authorized generic film for 2019, as a result of Indivior's above decision, our manufacturing and supply revenue for the Sandoz authorized generic product has ceased, which will materially negatively affect our manufacture and supply revenues and our results of operations. In addition, although the branded Suboxone has continued to retain significant market share, we have continued to plan 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. Such 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 such 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 our management's time and attention away from our other business operations, which could also significantly harm our business. For more information, please see Item 3. – Legal Proceedings – Antitrust Litigation" in this Annual Report on Form 10-K.

While we continue to plan to seek to monetize our drug product Apomorphine, there is no assurance that we will be able to monetize our drug product candidate Apomorphine in the amount or at the time we have planned, or at all, which, if this were to occur, would have a material adverse impact on our financial position and capital needs.

Although we anticipate monetizing the expected revenue steam from our Apomorphine product candidate, which is out-licensed to Sunovion Pharmaceuticals, or Sunovion. Sunovion has not at this point obtained regulatory approval of this drug candidate. We cannot be assured of when, or if, Apomorphine will receive regulatory approval or, if approved, whether we will be successful in monetizing any anticipated revenue stream derived from Apomorphine or whether such expected revenue stream will be at a level we have planned or anticipated.

We have out-licensed our product candidate Apomorphine to Sunovion, pursuant to which Sunovion has an exclusive worldwide license for Apomorphine. Sunovion also is responsible for seeking FDA and other regulatory approval of Apomorphine. In November 2019, Sunovion resubmitted its NDA to the FDA. While the Company has planned for Sunovion obtaining FDA approval for Apomorphine during 2020, we are not responsible for or involved in obtaining such regulatory approval, and there can be no assurance that the FDA or any non-U.S. regulatory authority will grant approval of Apomorphine or, if approved, will be for all of the indications which we have planned for. In addition, assuming FDA and other regulatory approval of Apomorphine, the anticipated or actual commercialization success and the anticipated market, patient, physician and third-party payer acceptance of Apomorphine, may not be the level we have anticipated or planned for. Any failure to obtain FDA and other regulatory approval of Apomorphine at the time and for indications we have planned for, or at all, or any failure to achieve the commercial success and acceptance of Apomorphine at the financial level we have anticipated or planned for, would have a material adverse effect on our funding sources and capital position needed for our operations.

In addition, under the Company's Indenture for the Senior Secured Notes, in the event we monetize our anticipated revenue stream from our license of our drug product, Apomorphine, we are required to offer the Noteholders the right to reduce the outstanding principal amount of the Senior Secured Notes in the amount of $40 million (if the first re-opener under the Indenture has not been funded) or up to $50 million (if the first re-opener under the Senior Secured Notes has been funded), plus 12.5% prepayment premium, accrued and unpaid interest thereon, to the extent elected by the Noteholders. While the pay down of outstanding principal amounts under the Senior Secured Notes upon any such monetization of Apomorphine would improve the Company's capital position by reason of having less debt outstanding and netting only the additional cash from the monetization transaction, any such pay down would reduce the amount from such monetization available to us for our other funding needs. In addition, if the gross amount available to us from any such monetization is less than we had anticipated or planned for, and the Senior Note holders elect to have the outstanding principal amount under the Senior Secured Notes paid down pursuant to the Indenture, the amount available for our other funding needs would be less than we would have anticipated and planned for, which would have a material adverse impact on our business, financial position and funding needs.

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

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

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 pre-clinical 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.

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 currently approved diazepam products in the form of rectal gel and a recently approved nasal spray. 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). The FDA's Center for Drug Evaluation and Research granted Valtoco orphan-drug exclusivity on January 10, 2020. A company that obtains FDA approval for a designated orphan drug receives orphan drug 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 limits a subsequently approved product from being marketed in the U.S. during the exclusivity period for the same active moiety for the same orphan drug indication, except in a case where the drug candidate sponsor is able to demonstrate, and the FDA concludes, that the later approved drug is "clinically superior" to the approved product, 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 a 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, and such demonstration to the satisfaction of the FDA is difficult to establish with limited precedents.

We intend to seek to demonstrate to the FDA that our product candidate Libervant is "clinically superior" to the two currently FDA-approved products as qualifying as a "major contribution to patient care" within the meaning of the FDA regulations and guidance. However, there can be no assurance that we will be successful in these efforts. Any failure to obtain FDA approval of or demonstrate "clinical superiority" for Libervant would have a material adverse effect on our business, prospects, financial condition and results of operations.

C***linical 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 pre-clinical trials, and we do not know whether future pre-clinical 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 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 pre-clinical studies or clinical trials, which may require us to conduct additional pre-clinical studies or clinical trials or to abandon projects that we had expected to be promising;
- reports from pre-clinical 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 of our clinical trials are suspended or terminated, our costs may substantially increase and the commercial prospects of our product candidates may be harmed and our ability to generate product revenue from sales of any of these product candidates will be delayed or not realized at all. Significant pre-clinical study or clinical trial delays also could shorten any periods during which we may have the exclusive rights to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates.

We have directly marketed just a single product, Sympazan, and that effort is in its very early stages after being only recently launched. 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 have relied on our third-party licensees to commercialize our two lincensed products, Suboxone and Zuplenz, 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, first 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 it is or may be available will be materially adversely affected.

Factors that may affect our ability to commercialize our existing product as well as our 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 partnerships with third parties to commercialize our product candidates outside of the United States. We may have difficulty establishing relationships with third parties on terms that are acceptable to us, or in all of the regions where we wish to commercialize our products, or at all. If we are unable to build our own distribution and marketing capabilities or to find suitable partners for the commercialization of our 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.

If we are unable to successfully establish strong capabilities in sales, marketing, and distribution for our approved products, we may not be successful in commercializing our products if and when they obtain regulatory approved.

We currently have resources dedicated toward the sales, marketing, and distribution of our self-developed products and product candidates. We have limited experience in this area, with Sympazan being our first self-developed product which we began commercializing in December 2018. To commercialize any of our products and product candidates that receive FDA and other regulatory authority marketing approval, we need to continue to build our marketing, sales, distribution, managerial and other non-technical capabilities and make arrangements with third parties to perform certain of these services, and we may not be successful in doing so.

We currently have outsourced to a third-party outsourcing firm and contract employees of our sales and marketing functions to sell, market and distribute Sympazan and other our product candidates which may receive FDA and other regulatory approval. If we are unable to enter into satisfactory collaborations with third parties for the commercialization of approved products on acceptable terms or at all, or if any such third parties do not devote sufficient resources to the commercialization of our product or otherwise fail in these commercialization efforts, we may not be able to successfully commercialize our approved products or any of our product candidates that receive regulatory approval. In entering into arrangements with third parties to perform sales, marketing services and distribution, our product revenues or the profitability of our product revenue could also be lower than if we were to directly market and sell any of our products ourselves. We also have less control over third parties than if we performed the services and functions ourselves. If we do not establish sales, marketing and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

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.

Even if any of our product candidates receives marketing approval, they may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

Even if the FDA or other regulatory authorities approve the marketing of any product candidates that we develop, physicians, patients, third-party payors or the medical community may not accept or use them. Efforts to educate the medical community and third-party payors on the benefits of our product candidates generally require significant resources and may not be successful. If any of our product candidates do not achieve an adequate level of acceptance, we may not generate significant product revenue or any profits from operations.

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.

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

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

In addition, clinical trials by their nature utilize a sample of the potential patient population. However, with a limited number of subjects and limited duration of exposure, certain unusual or unexpected side effects of our product candidates may only be uncovered when a significant larger number of patients are exposed to the product. If safety problems occur or are identified after one our products reached the market, the FDA or comparable foreign regulatory authorities may require that we amend the labeling of our products, recall our product, or even withdraw approval for our product. Significant adverse events deemed to be caused by our products or product candidates, either before or after receipt of marketing approval, could have a material adverse effect on the development of our drug candidates and our business as a whole.

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

We cannot predict whether our competitors or potential competitors, some of whom we collaborate with, may bring legal actions against us based on our research, development and commercialization activities, as well as any product candidates or products resulting from these activities, claiming, among other things, infringement of their intellectual property rights, breach of contract, 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 such market, which could adversely impact our potential revenue from such product candidates. Some of our competitors have substantially greater resources than we do and could be able to sustain the cost of litigation to a greater extent and for longer periods of time than we 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 certain drug; 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 that we are developing. 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 that we are developing or the use of competitive or alternative products as the standard of care to be followed by patients and healthcare providers could result in decreased use of our products or product candidates or negatively impact our ability to gain market acceptance and market share. For example, Suboxone, which treats opioid addiction, has as one of its active ingredients an opioid, buprenorphine. Revisions to regulations or guidelines suggesting the reduced use of opioid drugs such as buprenorphine could result in decreased use of Suboxone.

We face significant competition from other 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 as well. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these 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 approved products or product candidates that we are currently developing or that we may develop. In addition, our competitors may file citizen petitions with the FDA in an attempt to persuade the FDA that our 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, including marketed products and product candidates in development by third parties;
- 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 existing products and product candidates that may receive regulatory approval in the future; 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 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 our 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 at 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, and its implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization on entities subject to the rule, such as health plans, 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 their provisions are open to a variety of interpretations. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance and/or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements.

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

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability, or the ability of any future collaborators, to profitably sell any products for which we, or they, obtain marketing approval. Among 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, without limitation, our ability to commercialize and the prices we may obtain for any of our product candidates and that are approved for sale, are the following:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs, although this fee does not apply to sales of certain products approved exclusively for orphan indications;

- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;

- expansion of manufacturers' rebate liability under the Medicaid Drug Rebate Program by increasing the minimum rebate for both branded and generic drugs and revising the definition of "average manufacturer price," or AMP, for calculating and reporting Medicaid drug rebates on outpatient prescription drug prices and extending rebate liability to prescriptions for individuals enrolled in Medicare Advantage plans;

- addition of more entity types eligible for participation in the Public Health Service 340B drug pricing program, or the 340B program;

- established the Medicare Part D coverage gap discount program by requiring manufacturers to provide a 50% point-of-sale-discount off the negotiated price of applicable brand drugs to eligible beneficiaries during their coverage gap period as a condition for the manufacturers' outpatient drugs to be covered under Medicare Part D;

- the Bipartisan Budget Act of 2018, or BBA, 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

- established the Center for Medicare and Medicaid Innovation within CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

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

Further, legislative changes to or regulatory changes under the PPACA remain possible in the U.S. Congress and under the Trump administration. The nature and extent of any legislative or regulatory changes to the PPACA, including repeal and replacement initiatives, are uncertain at this time. It is possible that the PPACA repeal and replacement initiatives, if enacted into law, could ultimately result in fewer individuals having health insurance coverage or in individuals having insurance coverage with less generous benefits, 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, among other things, 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, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. At the federal level, the Trump administration’s budget proposal for fiscal year 2019 and 2020 contains 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 contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. The Department of Health and Human Services, or HHS, has started the process of soliciting feedback on some of these measures and, at the same, is immediately implementing others under its existing authority. While some proposed measures will require authorization through additional legislation to become effective, Congress and the Trump administration have indicated that they will 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 these and other healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved drug. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our drugs. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

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

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

On December 22, 2017, the TCJA was enacted. The TCJA is major tax legislation that, among other things, contains significant changes to corporate taxation, including reducing the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%; limiting the tax deduction for interest expense; limiting the deduction for net operating losses and eliminating net operating loss carrybacks, in each case, for losses arising in taxable years beginning after December 31, 2017 (though any such tax losses may be carried forward indefinitely); eliminating certain requirements of the PPACA, including the individual mandate; and modifying or repealing many business deductions and credits, including reducing the business tax credit for certain clinical testing expenses incurred in the testing of certain drugs for rare diseases or conditions generally referred to as "orphan drugs". The effect of the TCJA on us and our affiliates, whether adverse or favorable, is uncertain and may not become evident for some period of time. You are urged to consult your tax adviser regarding the implications of the TCJA on an investment in our common stock.

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

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

Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of 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.

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 our clinical trial sites and will force us to rely heavily on CROs to ensure the proper and timely conduct of our clinical trials and compliance with applicable regulations, including GCP. Failure to comply with applicable regulations in the conduct of the clinical trials for our product candidates may require us to repeat clinical trials, which would delay the regulatory approval process.

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

Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we 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 breaches or terminates their agreements with us, we would need to identify an alternative source for the thin film foil manufacture and supply of foil to us for the purposes of our development and commercialization of the applicable products. Identifying an appropriately qualified source of alternative thin film foil supply for any one or more of these product candidates could be time consuming, and we may not be able to do so without incurring material delays in the development and commercialization of our product candidates, 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 result in a significant loss of revenues and results and result 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 partners, and we expect to face competition in seeking appropriate partners. If we are unable to enter into any development and commercial collaborations and/or sales and marketing arrangements on acceptable terms, if at all, we may be unable to successfully develop and seek regulatory approval for our product 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 this 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 collaboration partner may not devote sufficient resources to the development or commercialization of our product candidates or may otherwise fail in development or commercialization efforts, which could adversely affect our ability to develop 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 partner may be insufficient to cover the cost of this development. Moreover, collaborations and sales and marketing arrangements are complex and time consuming to negotiate, document and implement, and they may require substantial resources to maintain.

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

- we may be required to undertake the expenditure of substantial operational, financial and management resources;
- we may be required to issue equity securities that would dilute our stockholders' percentage of ownership;
- we may be required to assume substantial actual or contingent liabilities;
- strategic collaborators could terminate the arrangement or allow it to expire, which would delay the development and 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 it 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, 2019 and 2018, Indivior represented 86% and 89% 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

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 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.

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 our 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 growth in our revenues. 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.

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.

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

Our headquarters are located in Warren, New Jersey and we have manufacturing facilities in Portage, Indiana. If we encounter any disruptions to our operations at these sites or one were to shut down for any reason, including by fire, natural disaster, such as a hurricane, tornado or severe storm, power outage, systems failure, labor dispute or other unforeseen disruption, then we may be prevented from effectively operating our business. Our coverage for natural disasters may be somewhat limited for floods or earthquakes and we may not carry sufficient business interruption insurance 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 financial condition and results of operations could be adversely affected by the recent coronavirus outbreak.

In late 2019, a novel strain of coronavirus, now known as COVID-19, which has proved to be highly contagious, emerged in Wuhan, China. Persons affected by the coronavirus have now been confirmed in other countries, including the United States. Our operations could be adversely affected to the extent that the coronavirus or other epidemics were to substantially impact the United States. Depending on the scope and severity of the coronavirus, our operations could potentially experience disruptions, such as temporary closure of our offices or manufacturing facilities, delays or suspensions in our clinical trials and/or suspension of services, which may materially and adversely affect our business, financial condition and results of operations. We do not currently source our raw materials from China and we intentionally keep safety stock of active pharmaceutical ingredients (API), drug product, critical raw materials and components. However, shelf life of these items affects reorder points and we may not be able to sustain long periods of disruption. Depending on the scope and severity of the outbreak, our suppliers of API and intermediate raw materials and components used in our drug products, could experience disruption in their businesses resulting in

a material and adverse impact on our supply chain continuity. Further, if our licensees' businesses are similarity affected, they might delay or reduce purchases of drug products from us, which could materially and adversely affect our business, financial condition and results of operations. The extent to which the coronavirus may impact us will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of the coronavirus and the actions to contain the coronavirus or treat its impact.

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.

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

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

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, certain policies of the Trump administration may impact our business and industry. Namely, the Trump administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuing of guidance, and reviewing and approving of marketing applications. While some of the prior Executive Orders have since been rescinded, if new executive actions impose constraints on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

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

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

We intend to seek FDA approval through the 505(b)(2) regulatory pathway for each of our product candidates described in this 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).

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

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

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

We do not know whether any future clinical trials we may conduct will demonstrate consistent or adequate efficacy and safety to obtain regulatory approval to market our product candidates. If any product candidate for which we are conducting

clinical trials is found to be unsafe or lack efficacy, we will not be able to obtain regulatory approval for it. If we are unable to bring any of our current or future product candidates to market, our business would be materially harmed and our ability to create long-term stockholder value will be limited.

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

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

- inability to raise or delays in raising funding necessary to initiate or continue a trial;
- delays in obtaining regulatory approval to commence a trial;
- delays in reaching agreement with the FDA on final trial design;
- imposition of a clinical hold for safety reasons or following an inspection of our clinical trial operations or trial sites by the FDA or other regulatory authorities;
- delays in reaching agreement on acceptable terms with prospective CROs and clinical trial sites, or failure by such CROs to carry out the clinical trial at each site in accordance with the terms of our agreements with them;
- delays in obtaining required institutional review board, or IRB, approval at each site;
- difficulties or delays in having patients complete participation in a trial or return for post-treatment follow-up;
- clinical sites electing to terminate their participation in one of our clinical trials, which would likely have a detrimental effect on subject enrollment and on our ability to successfully conduct or complete such clinical trial at alternative sites; or
- time required to add new clinical sites.

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

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

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

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

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

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

- regulatory authorities may withdraw their approval of the product or impose restrictions on its distribution;
- the FDA may require implementation of a Risk Evaluation and Mitigation Strategy, or REMS;
- regulatory authorities may require the addition of labeling statements, such as warnings or contraindications;
- we may be required to change the way the product is administered or conduct additional clinical studies;
- we could be sued and held liable for substantial damages for harm caused to patients; or
- 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.

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

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during a product candidate's clinical development and may vary among jurisdictions.

It is possible that none of our other existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval in the United States or other jurisdictions.

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

- the FDA or comparable foreign regulatory authorities may disagree that our changes to branded reference drugs meet the criteria for the 505(b)(2) regulatory pathway or foreign regulatory pathways;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective or comparable to its branded reference product for its proposed indication;
- the results of any clinical trials we conduct may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- a competitor's drug candidate may receive FDA or other regulatory approval and obtain orphan drug market exclusivity for the U.S. or foreign jurisdictions, and we may not be able to demonstrate to the FDA or other applicable regulatory authority that our drug candidate with the same active moiety for the same indication is "clinically superior" to the approved drug;

- we or third-party API or component manufacturers with which we may contract may be unable to maintain a compliance status acceptable to the FDA or comparable foreign regulatory authorities or the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes identified in our marketing application; and

- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may change significantly in a manner rendering our clinical data insufficient for approval.

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

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

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

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

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

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 Item 3. Legal Proceedings of this Annual Report on Form 10-K.

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 Item 3. Legal Proceedings of this Annual Report on Form 10-K, 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 Item 3. Legal Proceedings.

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 licensing partners initiated legal proceedings against a third-party to enforce a patent covering one of our products or product candidates, the defendant could counterclaim, 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 Item 3. Legal Proceedings.

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

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and/or applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our owned and licensed patents and/or applications and any patent rights we may own or license in the future. We rely on our outside counsel or our licensing partners to 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 and this circumstance could harm our business.

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

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

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

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 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.

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 increase 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 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

The trading market in our common stock has been extremely limited and substantially less liquid than the average trading market for a stock quoted on the NASDAQ Global Market.

Prior to our IPO there was no market for shares of our common stock. Since our initial listing on the NASDAQ Global Market on July 25, 2018, the trading market in our common stock has been limited and less liquid than the average trading market for many other companies quoted on the NASDAQ Global Market. The quotation of our common stock on the NASDAQ Global Market does not assure that a meaningful, consistent and liquid trading market currently exists. If an active trading market for our common stock does not sufficiently develop or continue, such an absence of an active trading market for our common stock could adversely affect our stockholders' ability to sell our common stock at then current market prices in short time periods. An inactive market may also impair our ability to raise capital to continue to fund operations by selling shares of our common stock and may impair our ability to acquire other companies or technologies by using our common stock as consideration. Additionally, market visibility for our common stock may be limited and such lack of visibility may have a depressive effect on the market price for our common stock.

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.

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, 2019, our executive officers and directors beneficially owned approximately 7.1% of our outstanding common stock. In addition, Bratton Capital Management L.P. beneficially owned, directly, approximately 34.3% of our outstanding common stock as of December 31, 2019, not including the shares beneficially owned individually by one of our directors, Douglas Bratton. 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.

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

We entered into employment agreements with Keith J. Kendall, our Chief Executive Officer, and A. Mark Schobel, our Chief Innovation and Technology Officer, pursuant to which they are each entitled to receive an additional tax indemnification payment, or a "gross-up" payment, if the payments and benefits under their respective employment agreements or any other benefits plans and programs trigger excise tax liability under Section 4999 of the Internal Revenue Code of 1986, as amended, or the Code, for "excess parachute payments." Under Sections 280G and 4999 of the Code, the excise tax is triggered by change in control-related payments that, 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.

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," 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 required new or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act, or the subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our consolidated financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock.

We have incurred significantly increased costs as a result of operating as a public company, and our management has been required to devote substantial time to new compliance initiatives.

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

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.

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

We have an equity incentive plan and we have granted and intend in the future to grant equity compensation awards to our employees and directors. We have registered all shares of common stock that we may issue under our stock-based compensation plans as a result, these shares, can be freely sold in the public market upon issuance, subject to the restrictions imposed under Rule 144 under the Securities Act (unless such shares have been registered by us for resale under a registration statement), which may cause our stockholders to experience additional dilution.

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 in the future experience ownership changes in the future as a result of subsequent shifts in our stock ownership, including an ownership change as a result of the combined effect of our initial public offering and future equity offerings. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards to offset United States federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us.

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

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

Provisions in our certificate of incorporation and bylaws, as well as provisions of Delaware law, could make it more difficult for a third-party to acquire us, or 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 bylaws designate the Court of Chancery of the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our bylaws provide that, subject to limited exceptions, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, any action asserting a claim against us arising pursuant to any provision of the Delaware General Corporation Law, our certificate of incorporation or our bylaws, any action to interpret, apply, enforce or determine the validity of our certificate of incorporation or our bylaws or any other action asserting a claim against us that is governed by the internal affairs doctrine. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of our certificate of incorporation described above. This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and employees. Alternatively, if a court were to find these provisions of our certificate of incorporation inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business and financial condition.

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 current good manufacturing practices, or cGMP, manufacturing operations. The lease contains an option to purchase the facility at any time during the lease term along with a right of first refusal to purchase the facility. In October 2017, we extended our Melton facility lease which will expire during March 2023 under the same terms and conditions as the prior lease. Our current monthly base rent for this facility is $19,800.

We also lease a 73,000-square-foot facility (Ameriplex) in Portage, Indiana, to house additional packaging, R&D and other operations. As amended, this lease has a term that extends through September 30, 2022 and contains a renewal option that could extend the lease through September 30, 2026. Our monthly base rent for this facility is currently $47,089.

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. Our monthly base rent for this facility is currently $36,268.

Item 3. Legal Proceedings

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

Beginning in August 2013, we were informed of ANDA filings in the United States by Watson Laboratories, Inc. (now Actavis Laboratories, Inc., or "Actavis"), Par Pharmaceutical, Inc.("Par"), Alvogen Pine Brook, Inc. ("Alvogen"), Teva Pharmaceuticals USA, Inc. ("Teva"), Sandoz Inc. ("Sandoz"), and Mylan Technologies Inc. ("Mylan"), for the approval by the FDA of generic versions of Suboxone Sublingual Film in the United States. We filed patent infringement lawsuits against all six generic companies in the U.S. District Court for the District of Delaware. After the commencement of the ANDA patent litigation against Teva, Dr. Reddy's Laboratories ("DRL") acquired the ANDA filings for Teva's buprenorphine and naloxone sublingual film that are at issue in these trials.

Of these, cases against three of the six generic companies have been resolved.

- *Mylan* and *Sandoz* settled without a trial. Sandoz withdrew all challenges and became the distributor of the authorized generic.
- All cases against *Par* were resolved pursuant to a May 2018 settlement agreement between us, Indivior, and Par and certain of its affiliates.
- *Actavis* was found to infringe the '514 patent and cannot enter the market until the expiration of the patent in 2024, and the Federal Circuit affirmed that ruling on July 12, 2019.
- *DRL* and *Alvogen* were found not to infringe under a different claim construction analysis, and the Federal Circuit affirmed that ruling on July 12, 2019. *Teva* has agreed to be bound by all DRL adjudications.

Subsequent to the above, all potential generic competitors without a settlement agreement were also sued for infringement of two additional new patents that contain new claims not adjudicated in the original case against DRL and Alvogen. On July 12, 2019, the Federal Circuit affirmed the decisions from the previously decided cases. The remaining case against Actavis was dismissed in light of the infringement ruling above, which prevents Actavis from entering the market until 2024. The case(s) against the remaining defendants regarding the additional asserted patents have not been finally resolved. A *Markman* hearing in the cases against Dr. Reddy's and Alvogen was held on October 17, 2019. On November 5, 2019, the Court issued its *Markman* opinion construing the disputed terms of the asserted patents. On January 9, 2020, the Court entered into a stipulated order of non-infringement of the '305 patient based on the Court's claim construction ruling, and we and Indivior preserved our rights to appeal the claim construction ruling. On November 19, 2019, the magistrate judge issued an order granting DRL and Alvogen's requests to file amended answers to add antitrust counterclaims against us and Indivior. We and Indivior appealed the magistrate judge's decision to the District Judge on December 4, 2019, DRL and Alvogen opposed the appeal. The parties are awaiting further action from the Court on the appeal. On January 17, 2020, we filed a motion to dismiss DRL's and Alvogen's antitrust counterclaims for failure to state a claim and briefing on that motion is ongoing. No trial date has been set in those cases, which are pending in the U.S. District Court for the District of New Jersey. We are not able to determine or predict the ultimate outcome of this proceeding.

On February 19, 2019, the Federal Circuit issued its mandate reversing the District of New Jersey's preliminary injunction 'against Dr. Reddy's. Following issuance of the mandate, the District of New Jersey vacated preliminary injunctions against both Dr. Reddy's and Alvogen. Dr. Reddy's, Alvogen, and Mylan all launched generic versions of Suboxone Sublingual Film, and the launches by Dr. Reddy's and Alvogen are "at risk" because the products are the subject of the ongoing patent infringement litigations.

On March 22, 2019, we and Indivior brought suit against Aveva Drug Delivery Systems, Inc., Apotex Corp., and Apotex Inc. for infringement of the '150, '514, '454, and '305 patents, seeking an injunction and potential monetary damages. Following a negotiated settlement between all parties, on December 3, 2019, the parties submitted a Notice of Settlement and a Joint Motion to Approve Consent Judgment. The Court entered an Order dismissing the suit on December 8, 2019.

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

- The first, a declaratory judgment action brought by BDSI against Indivior and Aquestive, seeks declarations of invalidity and non-infringement of U.S. Patents Nos. 7,897,080, or the '080 patent, 8,652,378, or the '378 patent, and 8,475,832, or the '832 patent. This case is stayed pending final resolution of the above-mentioned appeals on related patents.
- The second was filed by us and Indivior related to BDSI's infringing Bunavail product, and alleges infringement of our patent, U.S. Patent No. 8,765,167, or the '167 patent, and seeks an injunction and potential monetary damages. Shortly after the case was filed, BDSI filed four (4) IPR's challenging the asserted '167 patent. On March 24, 2016, the Patent Trial and Appeal Board, or the PTAB, issued a final written decision finding that all claims of the '167 patent were valid. The case was stayed in May 2016 pending the final determination of the appeals on those decisions. Following the PTAB's February 7, 2019 decisions on remand denying institution, we and Indivior submitted a notice to the Court on February 15, 2019 notifying the Court that the stay should be lifted as result of the PTAB's decisions. We are awaiting further action from the Court.

- On January 13, 2017, we also sued BDSI asserting infringement of the ’167 patent by BDSI’s Belbuca product and seeking an injunction and potential monetary damages. On August 7, 2019, the Court granted BDSI’s motion to dismiss the Complaint without prejudice and denied BDSI’s motion to stay as moot. On November 11, 2019, we filed a new Complaint against BDSI in the Eastern District of North Carolina. On November 27, 2019, BDSI filed a motion to stay the case pending BDSI’s appeal of the PTAB’s remand and we opposed the motion. The motion to stay remains pending. BDSI’s appeal of the PTAB’s remand decisions to the Federal Circuit was docketed on March 13, 2019, and on March 20, 2019, we moved to dismiss the appeal for lack of jurisdiction. On August 29, 2019, the Federal Circuit granted the motion to dismiss BDSI’s appeal. On September 30, 2019, BDSI filed a petition for rehearing *en banc*, which we opposed. The Federal Circuit denied BDSI’s petition on January 13, 2020. After the Federal Court denied BDSI’s petition on January 13, 2020, BDSI filed a motion to dismiss the complaint, and we opposed the motion on February 2, 2020. The parties are awaiting further action from the Court.

Antitrust Litigation

On September 22, 2016, forty-one states and the District of Columbia, or the States, brought suit against Indivior and us in the U.S. District Court for the Eastern District of Pennsylvania, alleging violations of federal and state antitrust statutes and state unfair trade and consumer protection laws relating to Indivior’s launch of Suboxone Sublingual Film in 2010 and seeking an injunction, civil penalties, and disgorgement. After filing, the case was consolidated for pre-trial purposes with the *In re Suboxone (Buprenorphine Hydrochloride and Naloxone) Antitrust Litigation*, MDL No. 2445, or the Suboxone MDL, a multidistrict litigation relating to putative class actions on behalf of various private plaintiffs against Indivior relating to its launch of Suboxone Sublingual Film. While we were not named as a defendant in the original Suboxone MDL cases, the action brought by the States alleges that we participated in an antitrust conspiracy with Indivior in connection with Indivior’s launch of Suboxone Sublingual Film and engaged in related conduct in violation of federal and state antitrust law. We moved to dismiss the States’ 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. The fact discovery period closed July 27, 2018, but the parties agreed to conduct certain fact depositions in August 2018. The expert discovery phase closed May 30, 2019, but additional reports and depositions were conducted through August 1, 2019. *Daubert* briefing is ongoing. The remainder of the case schedule, including summary judgment briefing, is stayed pending resolution of Indivior’s appeal of the district court’s class certification ruling in a co-pending multi-district litigation to which we are not a party. 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 Complaint

On December 5, 2019, Neurelis Inc. filed a Complaint against us in the Superior Court of California, County of San Diego, alleging Unfair Competition, Defamation, and Malicious Prosecution in connection with the Company’s activities related to the pursuit of FDA approval for our product candidate, Libervant™. 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 Friday, January 31, 2020, which Neurelis is expected to oppose. Neurelis filed a motion for leave to file a supplemental complaint on February 5, 2020, which we will oppose. A hearing on our anti-SLAPP motion and Neurelis’s motion for leave is scheduled for April 24, 2020. 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.

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 6, 2020, we had approximately 130 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

In August 2016, in connection with the Credit Agreement and Guaranty we entered into with Perceptive Credit Opportunities Fund, LP, or Perceptive, we issued 863,400 warrants to purchase shares of our common stock. On January 1, 2018, in connection with our conversion into a Delaware corporation, we exchanged such warrants for new identical warrants that were immediately exercisable upon issuance into shares of our common stock at an exercise price of $0.01 per share. Immediately prior to the pricing of the Company's IPO in July 2018, Perceptive received 863,400 shares of our common stock issuable pursuant to the automatic exercise of such warrants.

In April 2018, we 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 our employees, consultants and directors in connection with services provided by such parties to us.

On July 15, 2019, the Company completed the private placement of up to $100 million aggregate principal amount of it 12.5% Senior Secured Notes due 2025 (the "Senior Secured Notes") and issued warrants for 2 million shares of common stock (the "Warrants"), $0.001 par value per share, through its structuring agent, Morgan Stanley & Co., LLC, and entered into a Purchase Agreement and related Indenture governing the Senior Secured Notes, and also simultaneously entered into related agreements including a Collateral Agreement with U.S. Bank National Association as trustee and collateral agent, and Lien Subordination and Intercreditor Agreement for the benefit of Madryn Health Partners, other institutional noteholders, and U.S. Bank National Association. The Company subsequently registered for resale on Registration Statement on Form S-3 (Registration No. 333-233719) up to 2 million shares of Aquestive common stock, $0.001 par value per share, issuable on exercise of the Warrants.

The recipients of securities in each of these transactions acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof, and appropriate legends were affixed to the securities issued in these transactions. All of the foregoing securities were, at issuance deemed restricted securities for purposes of the Securities Act. The sales of the above securities were deemed to be exempt from registration under the Securities Act in reliance upon Section 4(a)(2) of the Securities Act (or Regulation D promulgated thereunder), or Rule 701 promulgated under Section 3(b) of the Securities Act.

See also Item 2 of Part II of the Company's Quarterly Report on Form 10-Q filed with the SEC on September 4, 2018 for information regarding securities issued under the Company's Performance Unit Plans.

Item 6. Selected Financial Data

The following table sets forth our selected financial data. We derived the statement of operations data for the years ended December 31, 2019, 2018, 2017 and 2016 and the balance sheet data as of December 31, 2019, 2018 2017, and 2016 from our audited financial statements. Our historical results are not necessarily indicative of results to be expected for any period in the future. The selected financial data presented below should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and the related notes thereto, included elsewhere in this Annual Report on Form 10-K. The selected financial data in this section are not intended to replace our financial statements and the related notes thereto.

Statement of Operations Data:

	Year Ended December 31,			
(In thousands, except per share data amounts)	**2019**	**2018**	**2017**	**2016**
Revenues	$ 52,609	$ 67,430	$ 66,918	$ 51,785
Costs and expenses:				
Manufacture and supply	20,361	20,988	19,820	16,378
Research and development	20,574	23,112	22,133	15,450
Selling, general and administrative	64,342	72,269	25,078	20,804
Total costs and expenses	105,277	116,369	67,031	52,632
Loss from operations	(52,668)	(48,939)	(113)	(847)
Other expenses:				
Interest expense	(9,318)	(7,711)	(7,707)	(6,143)
Interest income	636	552	—	—
Loss on extinguishment of debt	(4,896)	—	—	(757)
Loss on impairment of investment	—	—	—	(1,006)
Change in fair value of warrant	—	(5,278)	(1,123)	(750)
Other expense	—	—	—	(99)
Net loss before income taxes	(66,246)	(61,376)	(8,943)	(9,602)
Income taxes	—	—	—	—
Net loss	(66,246)	(61,376)	(8,943)	(9,602)
Dividends on redeemable preferred interests	—	—	(2,480)	(2,342)
Net loss attributable to common shares/ members' interests	(66,246)	(61,376)	(11,423)	(11,944)
Comprehensive net loss	$ (66,246)	$ (61,376)	$ (11,423)	$ (11,944)
Net loss per share – basic and diluted	$ (2.61)	$ (2.96)		
Weighted-average number of common shares outstanding - basic and diluted	25,356,098	20,725,526		

Balance Sheet Data:

	December 31,			
Selected Balance Sheet Data:	**2019**	**2018**	**2017**	**2016**
Cash and cash equivalents	$ 49,326	$ 60,599	$ 17,379	$ 9,209
Working capital (current assets minus current liabilities)	49,759	41,249	12,813	12,526
Total assets	78,479	86,851	43,116	39,389
Loans Payable, net	60,338	47,203	45,507	38,650
Total liabilities	84,601	76,771	69,611	56,965
Accumulated deficit	(130,474)	(61,376)	(120,093)	(108,670)
Total stockholders' equity/members' deficit	(6,122)	10,080	(68,596)	(57,197

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 solve patients' therapeutic problems and to meet patients' unmet medical needs. We have three commercial products, including one proprietary product and two out-licensed products, another FDA-approved product that has been out-licensed for commercialization in European markets following applicable regulatory approvals, as well as a late-stage proprietary product pipeline focused on the treatment of central nervous system, or CNS, diseases. We believe that the characteristics of the patient populations our products address and the shortcomings of available treatments create opportunities for the development and commercialization of meaningfully differentiated medicines.

We generated revenue of $52,609 and $67,430 in 2019 and 2018, respectively, largely from commercial products licensed to our licensees in the form of manufacturing and supply revenue. Total revenues also included licensing, royalty and co-development and research fees. Our license revenue is subject to the normally uneven timing of co-development and licensing milestone payments, and to the variable product sales volumes achieved by our licensees, for which we receive royalties as well as manufacturing revenues. Suboxone, which was launched in 2010, was our first licensed pharmaceutical product to be commercialized, and we have other licensing relationships that contribute to our revenue and future revenue opportunities. Sympazan, which was launched in December 2018, is the first proprietary pharmaceutical product commercialized directly by the Company.

In 2013, we made a strategic decision to develop our own pipeline of proprietary pharmaceutical products and to pursue commercialization of these products. Revenues from these development efforts began being realized in late 2018 with Sympazan, an oral soluble film formulation of clobazam used as an adjunctive therapy for seizures associated with a rare, intractable form of epilepsy know as Lennox-Gastaut Syndrome, LGS. Following approval by the FDA we launched Sympazan in December 2018. Substantial investments have been made since 2013 in the development of our proprietary pipeline. We expect to continue these investments in the commercialization of Sympazan in 2020, and to invest in the pre-launch commercialization phase of the additional product candidates in our pipeline, assuming FDA approval. These development and commercialization expenses have utilized and, in the future will utilize, funds generated from licensing, manufacturing and proprietary related revenues and from our capital raising and debt financing. As of December 31, 2019, we had $49,326 in cash and cash equivalents. As a result of our investments in product development and recent investments in pre-launch commercialization initiatives, our historical operating expenses, and the settlement of obligations related to our Performance Unit Plan and our initial public offering completed in July 2018 and our recent offering of common stock in December 2019 coupled with our prior capitalization, we had net stockholders' deficit of $6,122 as of December 31, 2019. For the years ended December 31, 2019 and 2018, we incurred net losses of $66,246 and $61,376, respectively.

Exservan, utilizing Aquestive's proprietary PharmFilm technology, has been developed for the treatment of amyotrophic lateral sclerosis (ALS). Exservan is expected to fulfill a critical need for ALS patients, since it can be orally administered safely and easily, twice daily without water. We believe that Exservan, can bring meaningful assistance to patients who are diagnosed with ALS and face difficulties swallowing or administering other forms of medication. Exservan was approved by the FDA on November 22, 2019. During the 2019 fourth quarter, we announced the granting of a license to Zambon S.p.A. for the development and commercialization of Exservan Oral Film in the EU for 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 for Exservan in the EU, and we will be entitled to be paid, subject to the terms of the license agreement, development milestone payments and low double-digit royalties payable on net sales of the product in the EU. Zambon will exclusively be responsible for obtaining the regulatory approval and marketing of Exservan in the EU, and Aquestive will exclusively be responsible for the manufacture of the product. We are seeking an appropriate licensee for the commercialization rights for Exservan in the United States.

Our most advanced proprietary product candidate, which we intend to self-commercialize, subject to FDA approval with market access, is Libervant:

Libervant is a buccally, or inside of the cheek, administered soluble film formulation of diazepam. Epilepsy patients have been underserved for some time with little choice beyond device-based products such as rectally administered gels and a recently approved nasal spray. Aquestive is developing Libervant as an alternative to the current standard of care rescue therapy for patients with refractory epilepsy, which is a rectal gel that is invasive, inconvenient, and difficult to administer. As a result, a large portion of the patient population has not received adequate treatment or foregoes treatment altogether. It is anticipated that Libervant will enable a larger share of these patients to receive more appropriate treatment by providing consistent therapeutic dosing in a non-invasive and innovative treatment form for epileptic seizures. The Company filed an NDA for Libervant in November 2019. The filing was accepted by the FDA in February 2020 and we have received a PDUFA goal date of September 27, 2020. A competitive product with orphan drug exclusivity was approved in January 2020. We believe that Libervant will, if approved by the FDA, represent a "major contribution to patient care" within the meaning of FDA regulation and guidance, as compared to available treatment options, and further expand patient choice as the first orally administered dosage form available to manage seizure clusters in epilepsy patients. There can be no assurance that we will be successful in these efforts. More details on this product approval are described in detail in the "Our Product Portfolio and Pipeline" and "Competition" sections in Item 1. Business of this Form-10K.

We have also developed a proprietary pipeline of complex molecule-based products addressing market opportunities beyond CNS indications, which include:

- AQST-108, a "first of its kind" oral sublingual film formulation delivering systemic epinephrine that is in development for the treatment of anaphylaxis using Aquestive's proprietary PharmFilm® technologies. 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 EpiPen®, a single-dose, pre-filled automatic injection device. As a result of its administration via subcutaneous or intra-muscular injection, many patients and their caregivers are reluctant to use currently available products, resulting in increased hospital visits and overall cost of care to treat anaphylactic events. The data from the previously completed Phase 1 dose escalation study demonstrated that AQST-108 achieved similar ranges of mean values of maximum concentration (Cmax) and time to reach maximum concentration (Tmax) to that reported for injectables EpiPen and Auvi-Q®, provided a greater total exposure (AUC0-t; area under the curve) than that reported for EpiPen and Auvi-Q, had less interpatient variability when compared to degree of variation (CV%) data reported for EpiPen and Auvi-Q, 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 will improve patient compliance and lower the total cost of care. After a constructive pre-IND meeting with the FDA in early February, the Company is in the process of preparing the IND for AQST-108 expected to be submitted to the FDA in the coming months. The Company expects to utilize the 505(b)(2) regulatory approval pathway for AQST-108 and expects to begin clinical trials later in 2020.

- AQST-305 – a sublingual film formulation of octreotide, a small peptide that has a similar pharmacological profile to natural somatostatin, for the treatment of acromegaly, as well as severe diarrhea and flushing associated with carcinoid syndrome. Acromegaly is a hormone disorder that results from the overproduction of growth hormone in middle-aged adults. Octreotide is the standard of care for the treatment of acromegaly. The current market leader, Sandostatin, is administered via deep subcutaneous or intramuscular injections once a month. This monthly treatment regimen can result in loss of efficacy 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 of the treatment cycle. ASQST-305 has shown promising preclinical results. We began a human proof of concept study in Canada during the third quarter of 2018. As a result of the early stage proof of concept study, further optimization of this formulation is currently underway.

In addition to these product candidates, we have a portfolio of commercialized and development-stage licensed products. 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 manufacturing agreement with Indivior to deliver both the branded Suboxone, globally through Indivior, and the authorized generic sublingual film formulation of buprenorphine and naloxone, which was distributed through Sandoz Inc. ("Sandoz") for United States market. As of February 2020, the branded Suboxone accounted for approximately 43% of the oral film products prescribed in the U.S. for recovery from opioid addiction. See "Financial Operations Overview" below concerning Indivior's announced intention to cease production of the authorized generic film product.

In early 2019, certain third-party pharmaceutical companies launched, at risk, generic film products for buprenorphine-naloxone. Also, in early 2019, Indivior, through Sandoz, began to market and sell an authorized generic sublingual film product for Suboxone, which we also exclusively manufactured and supplied. On October 15, 2019, Indivior publicly announced that, in order to mitigate the impact from the recent passage of H.R. 438 – Continuing Appropriations Act, 2020, and Health Extenders Act of 2019, which came into effect on October 1, 2019, and which includes changes to the methodology for calculating average manufacturer price for branded drugs, Indivior had given notice to Sandoz of Indivior's intention to cease production of the authorized generic sublingual film product. As of early March 2020, Suboxone branded products retain approximately 43% of film market share. Indivior accounted for 86% and 89% of our total annual revenues for fiscal 2019 and 2018, respectively. Our total revenue mix will shift to a higher proportionate share of proprietary product sales in future years as we continue to grow Sympazan revenues and pursue the launch of other products, assuming FDA approval. While volume is expected to decrease in 2020 for Suboxone branded only, our manufacturing price for Suboxone has been increased starting in the first quarter of 2020 which is expected to positively impact gross margin contribution from manufacturing and supply revenue.

We manufacture all of our licensed and proprietary products at our FDA- and DEA-inspected facilities and anticipate that our current manufacturing capacity is sufficient for commercial quantities of our products and product candidates currently in development. Not all collaborative or licensed products of the Company that may be commercially launched in the future will necessarily be manufactured by the Company. We have produced over 2 billion doses of Suboxone since 2006. Our products are developed using our proprietary PharmFilm® technology and know-how. Our patent portfolio currently comprises at least 200 issued patents worldwide, of which at least 40 are U.S. patents, and more than 90 pending patent applications worldwide.

On July 27, 2018, we closed our initial public offering ("IPO") and on August 15, 2018, the underwriter's overallotment option was exercised. A total of 4,925,727 shares of common stock were issued. On July 25, 2018, the Company began trading on the Nasdaq Global Market under ticker symbol "AQST". Total net proceeds to Aquestive after underwriters' discounts and other costs and expenses of the IPO were $63,482.

On July 15, 2019, we completed a private placement of $70,000 of 12.5% Senior Secured Notes due June 2025 ("Notes" or "Senior Secured Notes") and warrants for the purchase of up to 2 million common shares, against which 428,571 common shares were issued in December 2019 upon exercise. The new financing provided net proceeds of $66,054 after expenses. The net proceeds of the financing were used to repay all outstanding obligations under the Company's prior credit facility of $52,944. We used the remaining net cash proceeds of $13,110 for the continued commercialization and advancement of our proprietary products and pipeline candidates, and other general corporate purposes. Our Notes are discussed in Note 12, 12.5% Senior Secured Notes, to our Consolidated Financial Statements and in Liquidity and Capital Resources.

On September 11, 2019, we filed with the SEC a Registration Statement on Form S-3, which was declared effective on September 17, 2019 (File No. 333-233716) (the "S-3 Registration Statement"). Under the S-3 Registration Statement we may sell up to $150 million of our securities including, without limitation, common stock, preferred stock, warrants, and debt securities. On September 11, 2019, we 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 $25.0 million. No shares have been sold pursuant to this "at-the-market" offering as of the date of this report. The agreement does not have an expiration date but can be canceled by us at any time for convenience with 10 days written notice. On December 12, 2019, we sold 8,050,000 common shares for gross proceeds of $40,250 in an underwritten public offering under the S-3 Registration Statement, that netted $37,295 after the underwriting discount and offering costs. We have also reserved under the S-3 Registration Statement up to an additional 4,228,082 shares of our common stock for sale by our stockholders and for the exercise of warrants held by the holders of our 12.5% Senior Secured Notes. Under our S-3 Registration Statement we are subject to, among other requirements applicable to our continuing eligibility to offer and sell securities pursuant to that short-form registration statement, the "baby shelf" registration requirements, which generally provide that a registrant which does not satisfy a minimum public float requirement (determined by the market value of publicly-traded shares held by nonaffiliates of the registrant) of at least $75 million at the time it files its Form S-3 registration statement, may not offer and sell in a primary offering more than one-third of its public float in any twelve month period (the "one-third limit"). However, if a registrant who did not satisfy the minimum public float requirement at the time of filing of its Form S-3 registration statement, subsequently increases its public float in excess of $75 million (determined as of any date within 60 days prior to the filing of its Form 10-K), the one-third limit will not apply for the twelve month period until the public float determination is once again made in connection with its next subsequently filed Form 10-K, assuming for this purpose compliance with all other Form S-3 primary offering and other requirements. As of a date within 60 days prior to our filing of this Annual Report on Form 10-K, our public float held by nonaffiliates was in excess of $75 million and therefore the one-third limit does not apply, assuming that we otherwise satisfy all other Form S-3 offering requirements and subject to the re-determination of this public float test in connection with the filing of our next Annual Report on Form 10-K. We cannot assure that we will at all times satisfy the minimum public float requirement or other requirements for eligibility for primary offerings under the Form S-3 registration requirements.

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 2020 and future periods over time as we:

- focus on the approval of Libervant for marketing in the U.S. and, subsequently its commercialization,
- continue to clinically develop AQST-108 along the 505(b)(2) pathway with PK clinical trials to begin in 2020; and
- continue to grow Sympazan sales as a precursor and complement to the eventual launch of Libervant, if approved.

We will continue to manage the timing and level of expenses in light of the declining revenues related to Suboxone, offset in part by the revenue contribution from Sympazan and while focusing on the development and commercialization of Libervant and AQST-108, if approved.

Our business has been financed through a combination of revenue from licensed product and proprietary product activities, proceeds from our IPO, equity investments and other equity issuances, and proceeds from our debt instruments and facilities. Significant additional funding is expected to be required in order to execute our business strategy and operations.

Until we become profitable, if ever, we expect to need to raise significant additional capital through equity or debt issuances, or both, in the future 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 have options to seek to obtain additional financing in the future through the issuance of our common stock, through other public or private equity or debt financings, through potential non-dilutive capital raising events that may result from royalty streams that may be realizable from our licensed products, and through collaborations or licensing arrangements with other companies or 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 for the Senior Secured Notes) 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 licensors generally will depend upon our achievement of negotiated development and regulatory milestones. Failure to achieve these milestones may harm our future capital position. See “Funding Requirements” below for a discussion of Aquestive’s cash needs.

Financial Operations Overview

Revenues

Our revenues to date have been earned from our product development pipeline, marketed product activities and self-developed medicines. These activities generate revenues in four primary categories: manufacturing 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 filled orders once quality assurance validates the quality of the manufactured product. In 2019 under ASC 606, we record revenues once the manufactured product passes quality control. Our licensees are responsible for all other aspects of commercialization of these products and the Company has no role in or ability to participate in commercialization including marketing, pricing, sales and regulatory strategy. In 2018 under ASC 605, we recorded revenues when product is shipped and title passed to the customers.

We expect future manufacture and supply revenue from licensed products to be based on volume demand for such licensed products and manufacturing and supply rights under new collaborations for product development and additional licensing of our intellectual property.

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

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

Proprietary Product Sales

As we commercialize our proprietary CNS product candidates for which we receive regulatory approval to market such product, beginning with Sympazan, we may directly sell such product to consumers in the United States, resulting in an additional source of revenue which we refer to as proprietary product sales. We commercialized our first proprietary CNS product, Sympazan, in December 2018. We currently sell Sympazan through wholesalers for distribution through retail pharmacies. Additionally, we may choose to select a licensee to commercialize our product candidates in certain markets inside and outside of the United States. To date, the only revenue generated from our self-developed and self-commercialized pharmaceutical products is from the sale of Sympazan in the United States.

Revenues from sales of products are recorded net of prompt payment discounts, wholesaler service fees, returns allowances, rebates and co-pay card 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 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.

Prompt Pay Discounts

The prompt pay reserve is based upon discounts offered to wholesalers as an incentive to meet certain payment terms. We accrue discounts to wholesalers based on contractual terms of agreements. We account for these discounts at the time of sale as a reduction to gross product sales and a reduction to accounts receivable.

Wholesaler Service Fees

Our customers include major national and regional wholesalers with whom we have contracted a fee for service based on a percentage of gross product sales. This fee for service is recorded as a reduction to gross product sales and an increase to accrued expenses at the time of sale and is recorded based on the contracted percentage.

Returns Allowances

We allow customers to return product that is damaged or received in error. In addition, we allow Sympazan to be returned beginning six months prior to, and twelve months following, product expiration. We estimate our sales returns reserve based on industry averages until such time that we have accumulated enough data to apply a historical trend analysis. The returns reserve is recorded at the time of sale as a reduction to gross product sales and accounts receivable.

Rebates

Rebates include third party managed care, Medicaid and Medicare Part D rebates and other government rebates. Rebates are accrued based upon an estimate of claims to be paid for product sold into trade by the Company. The provisions for government rebates were based on contractual terms and government regulations. We monitor legislative changes to determine what impact such legislation might have on our Company. We account for these deductions as a reduction of gross product sales and an increase in accrued expenses.

Co-Pay Support Programs

Co-pay support costs represent the costs to help offset a customer's co-pay or cover a predetermined amount of prescription costs based on business rules. We account for these deductions as a reduction of gross product sales and an increase in accrued expenses.

Costs and Expenses

Our costs and expenses are primarily the result of the following activities: generation of manufacture and supply revenues; development of and the regulatory approval process for our pipeline of proprietary product candidates and selling, general and administrative expenses, including pre-launch and post launch commercialization efforts related to our CNS product candidates, intellectual property procurement, protection, prosecution and litigation expenses, corporate management functions, 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 comprised primarily of costs and expenses related to manufacturing our proprietary dissolving film products for our marketed licensed pharmaceutical products and for our newly approved proprietary products including raw materials, direct labor and fixed overhead 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. Fixed and semi-fixed overhead principally consists of indirect payroll, facilities rent, utilities and depreciation for leasehold improvements and production machinery and equipment.

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 will continue to seek to rationalize and reduce costs to reflect the declining production volumes of Suboxone. We reduced the cost of manufacturing and supply in late 2019 in order to recognize the declining volume of Suboxone that begin in 2019 and will continue declining in 2020. 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 and we expand our efforts to 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 legal, 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.

Costs related to the commercialization of our CNS products began in the second half of 2017 and significantly increased in 2018 leading up to the launch of Sympazan in December 2018. Significant investments in commercialization were made in 2019. We will continue to invest in the commercialization of Sympazan in 2020 but those costs will be rationalized to the expected near-term opportunity Sympazan represents. In the late part of the year we would expect additional expenses to occur in order to launch Libervant should it be approved.

Sympazan is the precursor and compliment to the launch of Libervant if it is approved and granted access to market. 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 as a product, its value as way to introduce prescribers to the epilepsy market to Aquestive and Pharmfilm technology and the investment we are making in this form of commercialization and marketing spend supporting it. The current commercial organization would launch Libervant, subject to its approval, without expecting to immediately add costs, although marketing and selling expenses will increase if Libervant is approved and ready to be marketed. Until any Libervant launch is clear, we do not plan to increase the costs of our commercial organization and will continue to improve the efficiency of the Sympazan commercial investments.

As part of the commercial launch of Sympazan, we entered into contractual arrangements with a third-party logistics provider (3PL) and wholesalers for distribution of our products. We also entered into arrangements for our contracted sales force, market access and medical affairs teams. With this increased activity related to the commercial launch of Sympazan, our sales and marketing expenses increased in 2019. Our general and administrative costs increased as a result of becoming a public company, including costs related to additional personnel and accounting, audit, legal, regulatory and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, director and officer insurance costs, and investor and public relations costs. 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 revenues, the marketing and sales costs related to Sympazan and other external factors affecting our business as we continue to focus on the core drivers of value to our stockholders:

- Seeking to obtain the approval and subsequent launch of Libervant, subject to approval for marketing in the U.S.;
- The continued, accelerated development of AQST-108 along the 505(b)(2) pathway with PK clinical trials to begin in 2020; and
- Growing the revenue contributions from Sympazan as a first step to position Aquestive in the epilepsy community.

Interest Expense

Interest expense consists of interest costs related to our debt facility, as well as amortization of loan costs and debt discount. Our interest cost, which under our Perceptive credit facility was subject to changes in one-month LIBOR, represented a monthly cash payment obligation. Our 12.5% Senior Secured Notes due 2025 issued on July 15, 2019 are discussed in Note 11, 12.5% Senior Secured Notes, to our Consolidated Financial Statements and in Liquidity and Capital Resources. Interest expense has increased based on additional borrowings under such new Notes. Under the new facility, interest is fixed at 12.5%.

Interest Income

Interest income consists of earnings derived from an interest-bearing account. There is no minimum amount to be maintained in the account nor any fixed length of period for which interest is earned.

Change in Fair Value of Perceptive Warrant

Changes in the fair value of Perceptive warrants resulted from non-cash periodic revaluations of the warrants issued to Perceptive Credit Opportunities Fund in connection with the Perceptive debt facility. Effective with the automatic exercise of the warrants by Perceptive prior to our IPO in July 2018, these warrants are no longer outstanding and no future related charges to earnings will be incurred.

Results of Operations

Comparison of Years Ended December 31, 2019 and 2018

Management's discussion and analysis of our results of operations for the year ended December 31, 2018 compared to the year ended December 31, 2017 may be found in the Management's Discussion and Analysis of Financial Condition and Results of Operations sections of our Form 10-K, filed with the SEC on March 14, 2019.

We recorded revenue of $52,609 and $67,430 in 2019 and 2018, respectively, generating net losses of $66,246 and $61,376 for each of those years, respectively.

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

Revenues

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

			Change	
	2019	2018	$	%
(In thousands, except %)				
Manufacture and supply revenue	$ 38,739	$ 37,319	$ 1,420	4%
License and royalty revenue	6,959	24,699	(17,740)	(72%)
Co-development and research fees	4,042	5,184	(1,142)	(22%)
Proprietary product sales, net	2,869	228	2,641	NM
Revenues	$ 52,609	$ 67,430	$ (14,821)	(22%)

Revenues decreased 22% or $14,821 in 2019 to $52,609 compared to $67,430 in 2018. The change is primarily attributable to differences in license and royalty revenue and co-development and research fees that by their respective nature are variable as to timing and magnitude, offset in part by increases in manufacture and supply revenue and proprietary product sales revenue from Sympazan, launched in December 2018. Additionally, under the Indivior Supplemental Agreement license fees which are variable are currently suspended following the "at risk" launches of several generic buprenorphine-naloxone products into the Suboxone market. These may be recoverable in the future under certain conditions.

Manufacture and supply revenue increased approximately 4% or $1,420 in 2019 to $38,739 as compared to $37,319 in 2018 due to increased pricing associated with our Suboxone product which began in late 2018 and continued in 2019, offset in part by total lower volumes of Suboxone and the Suboxone authorized generic. As discussed above, Indivior announced in the fourth quarter 2019 its intention to cease the sale and marketing of the authorized generic, which will impact our manufacturing and supply revenue beginning in 2020. The branded Suboxone products have continued to experience market share erosion as generic competition continues to take more market share. We continue to plan for the further erosion of this sunsetting product over time.

License and royalty revenue decreased 72% or $17,740 in 2019 to $6,959 compared to $24,699 in 2018. This decrease was primarily related to license fees on our licensed products Suboxone and APL-130277(Apomorphine). License fees totaled $5,806 in the 2019 period compared to $23,500 of license fees recognized during the 2018 period. Suboxone related license fees were $15,250 lower in 2019 as compared to those of 2018 while Apomorphine related license fees were $4,000 less in 2019 when compared to 2018. Suboxone related license fees were lower compared to 2018 as a result of two factors: the uneven timing and magnitude of the various payments owed to the Company by Indivior and the fact that certain license fees due from Indivior have been suspended pending the outcome of litigation related to infringement claims against generic products launched "at risk". Included in license and royalty revenue was $1,000 from our 10% share of milestone payments paid to KemPharm during September 2019 under its licensing of KP-415 and KP-484. There can be no assurance that any such payments will likely be made in the future. Milestones from other licensed products such as Sunovion's APL-130277 product are expected to be earned after 2019 based on Sunovion's announcement of a May 21, 2020 PDUFA goal date and an expected launch commercially later in 2020, subject to Apomorphine being approved by the FDA. Royalty revenues earned on Suboxone and Zuplenz increased modestly year-over-year on similar product sales volumes flowing through our licensees' sales and distribution channels. 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.

Co-development and research fees decreased 22% or $1,142 in 2019 to $4,042 compared to $5,184 in 2018. The decrease was driven by the timing of the achievement of research and development performance obligations on licensed products, and related milestones, both of which are normally expected to fluctuate significantly one reporting period to the next.

Proprietary product sales, net increased $2,641 due to the launch of our first proprietary self-developed medicine, Sympazan, in December 2018. We can give no assurance as to the level of anticipated sales of Sympazan due to its recent commercial launch.

Expenses:

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

			Change	
	2019	2018	$	%
(In thousands, except %)				
Manufacturing and supply	$ 20,361	$ 20,988	$ (627)	(3%)
Research and development	20,574	23,112	(2,538)	(11%)
Selling, general and administrative	64,342	72,269	(7,927)	(11%)
Interest expense	9,318	7,711	1,607	21%
Interest income	(636)	(552)	(84)	15%
Loss on extinguishment of debt	4,896	-	4,896	NM
Other	-	5,278	(5,278)	NM

Manufacturing and supply costs and expenses decreased 3% or $627 to $20,361 in 2019 compared to $20,988 in 2018. This decrease was driven by $2,873 in lower volumes of Suboxone branded and authorized generic products in 2019 compared to 2018 as well as the non-cash reversal of an accrual for manufacturing related costs that no longer represented an obligation of the Company. Further there was a $194 decrease in share-based compensation expenses during 2019 as compared to 2018. These decreases were offset, in part by $4,093 of higher standard production costs and unfavorable mix of produced product period over period.

Research and development expenses decreased 11% or $2,538 to $20,574 in 2019 as compared to $23,112 in 2018. This decrease was due to $2,186 of compensation costs allocable to research and development expenses and associated with the issuance of non-voting common shares and related withholding taxes, which the Company elected to pay on behalf of the former performance unit holders in 2018, approximately $700 in lower personnel costs period over period and decreased project spend driven by the timing of clinical trial activities on our proprietary products in development. These decreases were offset in part by $323 of increased share-based compensation period over period.

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

	Year Ended December 31,	
(In thousands)	**2019**	**2018**
Clinical Trials	$ 8,742	$ 8,526
Labor - R&D staff	5,177	5,809
Regulatory Submission Costs & Support	342	-
All Other R&D	6,313	8,777
Total	$ 20,574	$ 23,112

Selling, general and administrative expenses decreased 11% or $7,927 to $64,342 in 2019 as compared to $72,269 in 2018 primarily due to $24,767 of compensation cost allocable to selling, general and administrative expenses and associated with the issuance of the non-voting common shares and related withholding taxes, which the Company elected to pay on behalf of the former performance unit holders in 2018. This decrease was offset in part by $5,687 of higher investments in our commercialization activities for Sympazan. These costs included those for internal and contracted personnel, external consultants and other resources that enabled us to establish key commercial functions such as sales and marketing, market access and medical affairs. In addition, in 2019, we incurred increases of $3,944 in share-based compensation expense; $1,472 in legal fees in connection with the ongoing state antitrust litigation and other patent related matters, and $1,508 in insurance premiums, as the largest components of the change in selling, general and administrative expenses.

Interest expense increased 21% or $1,607 to $9,318 in 2019 compared to $7,711 in 2018. This was the result of higher debt balances starting in the third quarter 2019, which resulted in higher cash interest costs, and this increase was further impacted by higher amortization of debt discount and loan acquisition costs associated with the issuance of our Senior Secured Notes due 2025. Prior to July 15, 2019, our interest expense was subject to fluctuations based on one-month LIBOR and was approximately 12% to12.5% during that earlier part of 2019. Our new Senior Secured Notes due 2025 issued on July 15, 2019 carry a 12.5% fixed interest rate per annum, with an increased principal amount outstanding thereunder.

Interest income increased 15% or $84 in 2019 as compared to 2018, as a result of investing the net cash proceeds from our equity offering which occurred in December 2019 and the refinancing of our debt facility in July 2019 in an interest-bearing account.

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.

Other expenses decreased by $5,278 in 2019 compared to 2018, principally due to the expense incurred associated with the fair value of Perceptive warrants. For periods prior to our IPO, which was closed on July 27, 2018, we remeasured the fair value of outstanding warrants each quarter in accordance with the AICPA Practice Aid, Valuation of Privately-Held Company Equity Securities issued as compensation. Market pricing of $15.00, the initial price at which the Company's common stock was offered, was used in determining fair value at the time of exercise of those warrants. For information concerning the warrants issued in connection with our 12.5% Senior Secured Notes due 2025 issued on July 18, 2019, see Note 12, 12.5% Senior Secured Notes, to our Consolidated Financial Statements.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception in January 2004, we have incurred significant losses and, as of December 31, 2019, we have net stockholders' deficit of $6,122. We have funded our operations primarily with equity and debt financings and milestone and royalty payments from our collaboration licensees and manufacturing and supply revenues. In the period from our 2018 IPO through December 31, 2019, we received net proceeds from debt and equity issuances of approximately $167,295 as follows:

- $63,946 from our IPO including the over-allotment option;
- $66,054 from debt facilities further described below; and
- $37,295 net proceeds from our equity offering of common stock in December 2019.

We generate revenue from licensed products and proprietary product sales, net and related activities, but the costs to generate these revenues and the costs and expenses of our proprietary CNS and complex molecule development programs, related commercialization efforts, PUP costs and interest and warrant valuation expenses have resulted in the $130,274 deficit we have accumulated since our inception.

We had $49,326 in cash and cash equivalents as of December 31, 2019. We have no committed sources of capital.

Public Equity Offerings

On July 27, 2018, we closed the IPO of 4,500,000 shares of common stock at an offering price of $15.00 per share. We received net proceeds of approximately $57,543, after deducting underwriting discounts, commissions, and offering related transaction costs of approximately $9,957. On August 15, 2018, the underwriters exercised their over-allotment option and the Company issued 425,727 additional shares at $15.00 per share. The Company received additional net proceeds of approximately $5,939, after deducting underwriter discounts of approximately $447. The Company's IPO produced total gross proceeds of approximately $73,886 and we received net proceeds of approximately $63,482, after deducting underwriter discounts and costs and expenses of the offering.

On December 17, 2019, we completed an underwritten equity offering of 8,050,000 shares of common stock pursuant to our S-3 Registration Statement, including exercise of the underwriter's over-allotment option, resulting in gross proceeds of approximately $40,250 before underwriting discounts and other costs and expenses of the offering. Total net proceeds to Aquestive after deducting the underwriting discount and offering expenses were $37,295.

12.5% Senior Secured Notes

On July 15, 2019, we issued $70,000 aggregate principal amount of our 12.5% Senior Secured Notes due 2025 and Warrants under the Indenture for such Senior Secured Notes ("Indenture"). In addition, the Indenture provides opportunity to issue up to $30,000 of additional Notes under certain conditions for a total possible issuance amount of $100,000.

The net proceeds from the Senior Secured Notes were $66,054, after deducting expenses of the transaction. We used a portion of the net proceeds to repay an aggregate amount of $52,092 of existing indebtedness, comprised of the outstanding principal amount, all accrued and unpaid interest and applicable prepayment and end-of-term fees, owed to Perceptive under the Credit Agreement and Guaranty (described below). We used the remaining net cash proceeds of approximately $13,110 for the continued commercialization and advancement of our proprietary products and pipeline candidates, and other general corporate purposes.

The additional Senior Secured Notes can be issued if we satisfy certain conditions and achieve certain milestones related to the filing and approval of our epilepsy product candidate Libervant and there are available purchasers for the additional Senior Secured Notes. Specifically, on or prior to March 31, 2021, we have the option to issue an additional $10,000 aggregate principal amount of the Senior Secured Notes if we filed a new drug application for our candidate Libervant with the FDA, provided we have obtained the written consent of the holders of a majority in aggregate principal amount of outstanding Senior Secured Notes, in its discretion, which cannot be assured (first reopener), and, on or prior to March 31, 2021, up to an additional $30,000 (less the amount of any first additional Senior Secured Notes issued by us) if the Company obtains approval from the FDA to market Libervant in the U.S. There can be no assurance that such additional financing will be consummated.

Interest on the Senior Secured Notes accrues at a rate of 12.5% per annum and is payable quarterly in arrears on March 30th, June 30th, September 30th and December 30th of each year commencing on September 30, 2019. On each payment date commencing on September 30, 2021, we will also pay an installment of principal of the Senior Secured Notes pursuant to a fixed amortization schedule. The stated maturity date of the Senior Secured Notes is June 30, 2025.

Collateral for the loan consists of a priority lien on substantially all assets, including intellectual property, of the Company.

Under the Indenture, we have the right to monetize our royalty and milestone interests in our licensed product, Apomorphine APL-130277, which would not be expected prior to FDA approval of the product. Upon any such monetization we may offer to purchase each holder's Senior Secured Notes on a pro rata basis at a repurchase price in cash equal to 112.5% of the principal amount of such Notes, plus accrued interest and unpaid interest, if any, thereon to the repurchase date. The maximum amount that can be offered for repurchase is $40,000, or $50,000 if the first reopener has been issued and funded. The amount of Senior Secured Notes repurchased will be at the discretion of the holders of the Senior Secured Notes. See Note 11, 12.5% Senior Secured Notes, to our Consolidated Financial Statements. To the extent that the Noteholders do not elect repayment of the debt in connection with any such monetization, the amount not elected up to $40 million (or $50 million if the first reopener has been funded) is required to be held in a collateral account until Libervant is approved by the FDA to be marketed in the U.S.

The Indenture permits us, upon the continuing satisfaction of certain conditions, including that we (on a consolidated basis) have at least $75,000 of net revenues for the most recently completed twelve calendar month period, to enter into an asset-based borrowing facility ("ABL Facility") not to exceed $10,000. The ABL Facility may be collateralized by assets constituting only inventory, accounts receivable and the proceeds thereof of the Company.

Affirmative and negative covenants and restrictions specified in the Indenture are considered typical for loans of this nature, including, but not limited to, requirements relating to preservation of corporate existence, publicly traded status, intellectual property and business interests; limitations or prohibitions of dividend payments or other distributions, repurchases of

shares, asset transfers or dispositions, creation or occurrence of additional liens and security interests, and entering into licensing or monetization arrangements other than as permitted under the Indenture.

The Indenture also restricts the incurrence of additional indebtedness except only such indebtedness as is expressly permitted under the terms of the Indenture (which includes the ABL Facility) on the terms and conditions set forth in the Indenture and such indebtedness as may be permitted under limitations set forth in the Indenture. The Indenture also restricts the issuance of any "Disqualified Stock" including, generally, mandatorily redeemable securities or securities redeemable at the option of the holder or securities convertible or exchangeable at the option of the holder for indebtedness of the Company or for other Disqualified Stock.

Events of default under the Indenture include various commonly specified conditions including, but not limited to, bankruptcy, insolvency, material adverse changes, failure to meet Indenture payment or other obligations, compliance with regulatory requirements and preservation of the corporate existence and business operations of the Company. As of December 31, 2019, the Company was in compliance with covenants under the Indenture.

In connection with this financing, we issued to the holders of the Senior Secured Notes unregistered Warrants to purchase up to an aggregate of 2,000,000 shares of common stock at a price of $4.25 per Warrant. Warrants for 428,571 of common shares were exercised in December 2019 generating proceeds of $1,820. The Company registered the Warrants and associated shares as part of our S-3 Registration described above.

Credit Agreement and Guaranty

On August 16, 2016, we entered into a Credit Agreement and Guarantee with Perceptive Credit Opportunities Fund, which we amended on May 21, 2018, or, as so amended, the Loan Agreement. At closing, we borrowed $45,000 under the Loan Agreement and were permitted to borrow up to an additional $5,000 within one year of the closing date based on achievement of a defined milestone. In March 2017, we met our performance obligations under the terms of the Loan Agreement and received the remaining $5,000 available to us under the Loan Agreement. Proceeds under the Loan Agreement were used to repay an existing debt obligation of $37,500, with the balance available for general corporate purposes. The loan from Perceptive was originally scheduled to mature on August 16, 2020.

Upon the consummation of our IPO, the maturity date was extended to December 16, 2020. The loan bore interest, payable monthly, at one-month LIBOR, plus 9.75%, subject to a minimum rate of 11.75%. The loan was interest-only through April 2019, as amended.

Additionally, pursuant to the Loan Agreement, commencing on May 31, 2019, seven monthly principal payments were due in the amount of $550. Thereafter, monthly principal payments in the amount of $750 were due through the maturity date (as extended), at which time the full amount of the remaining outstanding loan balance was due. Our tangible and intangible assets were subject to first priority liens. Other significant terms included financial covenants, change of control triggers and limitations on additional indebtedness, asset sales, acquisitions and dividend payments. The Loan Agreement contained certain financial covenants, which included (1) a minimum liquidity requirement pursuant to which we were required to maintain a monthly cash balance of $4,000 at all times and (2) a minimum revenue requirement pursuant to which on a quarterly basis (calculation date) we were required to maintain minimum revenues for the twelve consecutive trailing months ended prior to the calculation date. Further, under the Loan Agreement, as amended, we were permitted, subject to Perceptive' s consent, to monetize the royalty and fees derived from sales of certain Apomorphine products and, in connection with such monetization, Perceptive had agreed to release liens related to these royalties and fees. Further, the Loan Agreement originally contained a requirement that we make a mandatory prepayment in the amount of 25% of the net cash proceeds to us upon consummation of our IPO; however, as amended, in connection with the consummation of our IPO, such requirement did not apply.

Upon the closing of our IPO, Perceptive received 863,400 shares of common stock issuable pursuant to the automatic exercise of warrants from APL's ownership interest for a total exercise price of $116.

In July 2019, in connection with our issuance of our Senior Secured Notes (see above), we repaid all outstanding amounts due under the Loan Agreement.

Cash Flows

The following table provides information regarding our cash flows for the years ended December 31, 2019 and 2018:

(In thousands)	**2019**	**2018**
Net cash used for operating activities	$ (60,210)	$ (12,991)
Net cash used for investing activities	(663)	(1,824)
Net cash provided by financing activities	49,600	58,035
Net (decrease) increase in cash and cash equivalents	$ (11,273)	$ 43,220

Net Cash Used for Operating Activities

Net cash used for operating activities for the year ended December 31, 2019 was $60,210. The use of cash can be understood as represented by three major factors: (1) our net loss of $66,246 partially offset by (2) non-cash operating expenses totaling $17,160 and by (3) 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 operating activities for the year ended December 31, 2018 was $12,991. The use of cash can be understood as represented by three major factors: (1) our net loss of $61,376 partially offset by (2) non-cash operating expenses totaling $40,387 and by (3) cash provided by changes in operating assets and liabilities of $7,998. The non-cash operating expenses of $40,387 primarily resulted from $29,940 of share-based compensation which included $27,298 related to the termination of the Company's Performance Unit Plans in the second quarter of 2018 and $2,642 of share-based compensation expense recorded in the second, third and fourth quarters of 2018. Other significant components included non-cash charges of $5,278 related to an increase in the fair value of the Perceptive warrants through the date of exercise and $5,169 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 $663 for the year ended December 31, 2019 compared to $1,824 for the year ended December 31, 2018. 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 $49,600 for the year ended December 31, 2019 compared to cash provided by financing activities of $58,035 for the year ended December 31, 2018. The net cash provided in 2019 is the result of the proceeds from the issuance of our 12.5% Senior Secured Notes of $13,110, after repayment of the existing Perceptive Loan Agreement; net proceeds derived from our equity offering in December 2019 of $37,295; and various other proceeds from the exercise of warrants by noteholders of our 12.5% Senior Secured Notes and purchases under the Company's employee stock purchase plan. Additionally, in 2019 we used $2,827 for withholding taxes associated with tax reimbursement payments from the share-based compensation recorded during 2018. Net cash provided by financing activities was $58,035 for the year ended December 31, 2018, which was primarily a result of $63,946 of net proceeds received from our IPO of common stock, offset in part $6,027 related to the payment of withholding taxes associated with the share-based compensation recorded during 2018.

Funding Requirements

We expect that our existing cash and cash equivalents combined with our anticipated revenue from our licensed product activities, including expected milestone payments, other co-development payments and royalty payments, manufacturing and supply revenues at anticipated levels, sales of our proprietary product at anticipated levels, cash on hand, and, subject to satisfaction of all conditions to and requirements for further issuances of our 12.5% Senior Notes, and assuming available purchasers thereof, potential additional proceeds from future issuances of up to $30,000 of additional Senior Secured Notes, the net proceeds from our equity offering of common stock in December 2019, potential future monetization of certain royalty streams or other license rights for Apomorphine (subject to all conditions and requirements under the Senior Secured Notes Indenture) and if needed and available to it, further access to the capital markets under our shelf-registration statement filed with the SEC and declared effective September 17, 2019, will be adequate to fund our expected cash requirements for the next 12 months. We have based this expectation on assumptions that could change, or prove to be inaccurate, and, additionally, we could utilize our available financial resources sooner than we currently expect.

The key assumptions underlying this expectation include:

- continued revenue from our proprietary and licensed products at planned levels;
- our ability to monetize royalty streams or other license or proprietary rights for our product candidate Apomorphine at anticipated levels, which cannot be assured (and which is subject to conditions and requirements under the Indenture for our 12.5% Senior Secured Notes including note repurchase obligations at 112.5% of principal amount of such repurchased notes and accrued and unpaid interest thereon, at the option of the holders (see "12.5% Senior Secured Notes" above)) and which monetization would not be expected prior to FDA approval of this drug candidate.

- access to the capital markets if and at the time needed for any necessary future funding;
- continuing review of our cost structure and cost and expense reductions consistent with our anticipated revenues and funding;
- our ability to issue and assuming available purchasers of, additional Senior Secured Notes in an aggregate amount up to $30,000 principal amount under the Indenture for our 12.5% Senior Secured Notes due 2025, based on satisfying certain conditions related to our Libervant product candidate which we cannot assure (see "12.5% Senior Secured Notes" above);
- continued funding of appropriate commercialization costs for Sympazan, our first proprietary product launched in December 2018, and continued funding of our development and, subject to FDA approval to market Libervant in the U.S., commercialization of our product candidate Libervant and our other proprietary product candidates;
- the infrastructure and administrative costs to support being a public company;
- continued compliance with all covenants under our 12.5% Senior Secured Notes; and
- absence of significant unforeseen cash requirements.

We continue to be in the process of transitioning to a company newly commercializing its self-developed products, with our commercialization activities first beginning in December 2018 with regulatory approval of our first proprietary product Sympazan. For our commercialization efforts to be successful we must continue to train, deploy and further develop an effective sales and marketing organization and infrastructure. To become and remain profitable we must continue to develop, obtain timely regulatory approval of, and successfully commercialize or otherwise out-license or monetize, those of our proprietary products and product candidates that we believe will have the most market potential and commercial success. We may encounter difficulties and delays in the regulatory approval process for our drug candidates, including Libervant and our commercialization efforts may take longer to achieve than planned. Our business or operations may change and we may also encounter unanticipated or unbudgeted events or expenses that may require cash resources more rapidly than planned. We are unable to determine or forecast with certainty when or if we will achieve or sustain profitability.

We will continue to manage business costs to appropriately reflect the declining state of Suboxone revenues, the marketing and sales costs related to Sympazan and other external factors affecting our business as we continue to focus on the core drivers of value for our stockholders. We will continue to invest and devote financial resources to our ongoing product development activities in support of Libervant and AQST-108, research and development activities, pre-clinical activities, clinical trials, regulatory approval activities, and commercialization activities. We will continue to seek to rationalize our costs as Suboxone revenue declines. Additionally, we will seek to conservatively manage our pre-launch spending as to both timing and level relating to Libervant, including seeking to rationalize the costs associated with marketing and selling Sympazan. In this regard, absent spending on launch activities for Libervant we expect to spend less on commercialization in 2020 compared to 2019. Even as such, we expect to continue to incur losses and negative cash flows and we therefore we expect to be dependent upon external financing and funding to achieve our operating plan.

Our cash resources on hand may not be sufficient by themselves to fund our expected development, commercialization and other operations and activities, and we will expect to continue to require external sources of funding and capital to develop and seek regulatory approval of our product candidates and for the commercialization of our approved products. The amount and timing of our future funding requirements, both short-term and long-term, will depend on many factors, including:

- Our ability to achieve successful commercialization of our proprietary product Sympazan and the cost and timing of our future commercialization activities;
- Continued revenues at planned levels from our manufacture and sale of branded Suboxone to Indivior and continued market acceptance of such branded product, without any sales of the authorized generic version of Suboxone;
- Sunovion Pharmaceuticals, Inc. achieving in the time period we have anticipated regulatory approval of Apomorphine, which we out-licensed to Sunovion and which, subject to regulatory approval of this drug candidate, which we cannot assure, is expected to provide the opportunity for a significant non-dilutive capital source for us;
- Achieving regulatory approval in the time period we have anticipated of our product candidate Libervant which has been part of our business plan and strategy. We completed the filing of our NDA for Libervant with the FDA in the fourth quarter 2019, and the FDA has granted a PDUFA goal date of September 27, 2020. See our "Product Portfolio and Pipeline" and "Competition" sections above contained in Item 1. Business for further discussion of the FDA approval process and market access:

- Continuing 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;
- Patient and doctor acceptance of and our ability to obtain adequate reimbursement for our products which we commercialize;
- The effect of competing products, including generic products, on our commercialized and licensed products, including Suboxone; and
- All other costs of executing our business plan and absence of unforeseen cash requirements.

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 in the time period planned our royalty streams or other license rights such as Apomorphine. We also are 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, and there is no assurance when or if any such payments may be due. 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. 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.

Management will continue to monitor the Company's cash requirements and liquidity, including expected revenue from manufacture and supply sales and proprietary sales, expected license and milestone revenues, any available proceeds from any monetization of royalty streams or other license rights, any future potential issuances of additional Notes under the Indenture for our Senior Secured Notes, reductions in cash spend, net proceeds of future equity financing, if needed and available to it, which cannot be assured, or other future access to the capital markets under our shelf registration statement filed with the SEC and effective September 17, 2019 or other potential available sources of liquidity and, if management believes operating results and the above funding sources are not sufficient or available for existing or projected cash requirements, management will seek to take further steps intended to improve the Company's financial position and liquidity, such as by modifying our operating plan, adjusting the timing and scope of our development activities, seeking to further reduce costs and adjusting cash spend, and evaluating and pursuing other potential opportunities or alternatives to obtain additional liquidity.

On July 15, 2019 we issued $70,000 aggregate principal amount of our 12.5% Senior Secured Notes due 2025 and related Warrants, resulting in approximately $66,082 in net proceeds, after transaction expenses. In connection with the issuance of the Senior Secured Notes, we repaid approximately $52,092 representing all amounts outstanding or due under our Perceptive debt facility. The Indenture governing the Senior Secured Notes provides opportunity to potentially issue in the future up to an aggregate of $30,000 of additional Senior Secured Notes based on our satisfaction of certain conditions and requirements under the Indenture, which we cannot assure, and having available purchasers of such additional Senior Secured Notes. The Indenture also permits us, upon the continuing satisfaction of certain conditions, including that we (on a consolidated basis) have at least $75,000 of net revenues for the most recently completed twelve calendar month period, to enter into an asset-based borrowing facility not to exceed $10,000 (the "ABL Facility"). The ABL Facility may be collateralized by assets constituting only inventory, accounts receivable and the proceeds of the Company. See "12.5% Senior Secured Notes" above.

On September 11, 2019, we filed with the SEC a Registration Statement on Form S-3, which was declared effective on September 17, 2019 (File No. 333-233716) (the S-3 Registration Statement"). Under the S-3 Registration Statement we may sell up to $150 million of our securities, including without limitation, common stock, preferred stock, warrants, and debt securities. On September 11, 2019, we 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 $25.0 million. No shares have been sold pursuant to this agreement as of the date of this report. The equity distributions agreement does not have an expiration date but can be canceled by us at any time for convenience with 10 days written notice. In December 2019, we sold $40,250 in common stock in an underwritten public offering under the S-3 Registration Statement, further described below. We have also reserved under the S-3 Registration Statement up to an additional 4,228,082 shares of our common stock for sale by our stockholders and pursuant to the exercise of warrants held by our stockholders.

In December 2019, the Company completed an underwritten offering of 8,050,000 shares of common stock, pursuant to its S-3 Registration Statement, including exercise of the underwriters' over-allotment option, resulting in net proceeds to the Company of approximately $37,295, after deducting the underwriting discount and offering expenses paid by the Company.

Unless and until we become profitable, we will continue to need to raise additional capital and/or other financing or funding, any of which could be material, to further advance the development of our other product candidates, most importantly Libervant and AQST-108, which are subject to regulatory approval, and commercialization of our product candidates and to meet our other cash requirements, including debt service. We do not currently have any committed external sources of financing. 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, restrictions under our Senior Secured Note Indenture, and general market conditions, and there can be no assurance that we will continue to be successful in raising equity 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. We may also seek to obtain additional funding in the future through the monetization of royalty streams from our product Apomorphine, subject to regulatory approval thereof, which product candidate is licensed to Sunovion Pharmaceuticals, Inc. (and subject to the conditions and requirements under the Indenture for our 12.5% Senior Secured Notes due 2025 including our note repurchase obligations at the option of the holders), but we cannot assure of any such royalty streams or monetization.

Our ability to obtain any additional indebtedness or other debt financing is limited by the terms of the Indenture for our Senior Secured Notes and the Indenture also restricts or prohibits certain types of equity financing (see “12.5% Senior Secured Notes” above). To the extent we are able to obtain needed funding through additional debt financing, any such debt financing me be coupled with an equity component, such as warrants for our shares, which could also result in dilution to our stockholders. The incurrence of additional debt would also result in increased fixed payment obligations.

We may also seek to obtain additional funding through third-party funding, marketing and distribution arrangements, as well as other collaborations, strategic alliances and licensing arrangements, or any combination of these approaches. We may not be able to raise additional capital or 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, prospects and financial condition and on our ability to execute and achieve 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 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. To the extent that we raise additional funds through collaborative, strategic alliances or licensing arrangements with third parties, it may be necessary to relinquish (subject to required consent under our Indenture for the disposition or transfer of assets other than Apomorphine) valuable rights to our intellectual property or future revenue or grant licenses on terms that are not favorable to us or that we may not otherwise consider relinquishing or granting, including rights to future product candidates. In addition, payments made by potential collaborators or licensors generally will depend upon our achievement of negotiated development and regulatory milestones. Failure to achieve these milestones may harm our future liquidity and funding position.

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, delay, significantly scale back, or even discontinue some or all of our 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.

Our costs associated with operating as a new public company have increased, and we expect to incur additional costs to support the obligation of a public company to various regulatory agencies, to investors and in order to comply with certain legislation and regulations. These expenditures include the costs of additional employees with specific skills and experiences such as SEC reporting, higher insurance expense, and internal controls as well as additional costs to outside service providers such as audit, tax, and legal fees.

Contractual Obligations and Commitments

Our contractual obligations relate to our debt agreement and operating leases for our facilities. The following table sets forth a summary of our contractual obligations as of December 31, 2019:

Contractual Obligations (In thousands)	Total	Less than one year	One to three years	Four to five years	After five years
12.5% Senior Secured Notes debt principal and interest	$ 106,611	$ 8,896	$ 30,854	$ 52,204	$ 14,657
Operating lease obligations	4,094	1,274	2,820	—	—
Total contractual obligations	$ 110,705	$ 10,170	$ 33,674	$ 52,204	$ 14,657

Operating Lease Obligations

We have entered into various lease agreements for production and research facilities and offices. Most leases contain renewal options. Certain leases contain purchase options and require us to pay for taxes, maintenance and operating expenses. All of our leases are currently classified as operating leases. See Item 2 Properties for a further description.

Off-Balance Sheet Arrangements

We did not have any material off balance sheet arrangements as of December 31, 2019, except for operating leases, nor do we have any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities.

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

Our Company's revenues to date have been earned from licensed commercialized products, research and development services provided to customers, licensing of patent-protected intellectual property and commercialization of a proprietary product. These activities generate revenues in four primary categories: manufacturing and supply revenue, co-development and research fees, license and royalty revenue, and proprietary product sales, net. In the future, as other proprietary products may become commercially marketed, the relative weight of these two revenue types is expected to shift in favor of our self-developed CNS and other pipeline product candidates.

In May 2014, the FASB issued ASU 2014-09, *Revenue for Contracts with Customers*, and subsequently issued a number of amendments to this update. The new standard, as amended, or ASC 606, provides a single comprehensive model to be used in accounting for revenue arising from contracts with customers and supersedes previous revenue recognition guidance. The standard's core principle is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services.

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 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 good that is distinct. When identifying our performance obligations, we consider all goods or services promised in the contract regardless of whether explicity stated in the contract or implied by customary business practice. Our performance obligations consist of mainly of transferring of goods and services identified in the contracts, purchase orders or invoices.

The Company's performance obligation with respect to its proprietary product sales is satisfied at a point in time which transfers control upon delivery of the product to its customers. The Company considers control to have transferred upon delivery because the customer has legal title to the asset, physical possession of the asset has been transferred, the customer has significant risks and rewards of ownership of the asset and the Company has present right to payment at that time. At the time of sale, estimates for several revenue deductions are recorded. When estimating the impact of these revenue deductions from gross sales for a reporting period, knowledge of historical trends and judgmental estimates are required for each deduction. For sales of Sympazan, returns allowances and prompt pay discounts are estimated based on historical return rates if available, as well as on contractual terms, and these estimates are recorded as a reduction of receivables. Estimates affecting accrued liabilities include those related to wholesaler service fees, co-pay card redemption costs and Medicare, Medicaid and other rebates and are similarly based on historical results and contract terms.

Total reductions of proprietary product sales in 2019 were $1,377, of which $203 affected Accounts receivable and $1,174 affected Accrued expenses as of December 31, 2019. Total reductions of proprietary product sales in 2018 were $591, of which $104 affected Accounts receivable and $481 affected Accrued expenses as of December 31, 2018.

With respect to manufacturing and supply revenue stream, a quantity is ordered and manufactured according to the customer's specifications and represents a single performance obligation. The products manufactured are exclusively for specific customers and have no alternative use. Under the customer arrangements, the Company is entitled to receive payments for progress made to date once the acceptance requirements surrounding quality control are satisfied. Thus, revenues related to this product stream are recognized at a point in time when the manufactured product passes quality control testing.

Royalty revenues are estimated based on the provisions of contracts with customers and recognized in the same period that the royalty-based products are sold to the Company's strategic licensees, as all royalties are directly attributable to the Company's manufacturing activities, and are therefore recognizable at the same time the manufacturing revenue is recognizable. In addition to usage-based royalties, licensing contracts may contain provisions for one-time payments related to certain license fees and milestone achievements. Revenue recognition of these license fees and milestone payments depend on the nature of the specific contract, typically license and milestone payments are recognized at a point in time in the period they are achieved. However, there are limited instances where, upon review of the contract, it determined that the license is non-distinct and limited in nature and does not provide benefit to the customer without purchasing the product, the upfront licensing fees are recognized over time (typically length of the contract).

Co-development and research fee revenue is recorded over time based upon the progress of services provided in order to complete the specific performance obligation identified in the related contract.

Revenues from the sale of products and services and the subsequent related payments are evidenced by a contract with the customer, which includes all relevant terms of sale. For manufacturing and supply and proprietary product sales, invoices are generally issued upon the transfer of control and co-development and research revenue is typically invoiced based on the contractual payment schedule, or upon completion of the service. Invoices are typically payable 30 to 60 days after the invoice date, however some payment terms may reach 105 days depending on the customer. The Company performs a review of each specific customer's credit worthiness and ability to pay prior to acceptance as a customer. Further, the Company performs periodic reviews of its customers' creditworthiness, prospectively.

Contract Assets

In limited situations, certain customer contractual payment terms require billing to occur in arrears; accordingly, some portions, or all, of the Company's performance obligations are completed before we are contractually entitled to bill the customer. In these situations, billing occurs subsequent to revenue recognition, which results in a contract asset. These contract assets are reflected as a component of Trade and other receivables, net on the Consolidated Balance Sheet.

Contract Liabilities

In other limited situations, certain customer contractual payment terms allow advanced billings; accordingly, customer cash payments may be received before satisfaction of some or all contractual performance obligations. In these situations, billing occurs in advance of revenue recognition, which results in contractual obligations. These contract liabilities are reflected as Deferred revenue in the Consolidated Balance Sheet. As remaining performance obligations are satisfied, a portion of the deferred revenue balance is recognized in the Company's result of operations.

Warrants and Warrant Liability

12.5% Senior Secured Notes

The Warrants issued in conjunction with the Senior Secured Notes expire on June 30, 2025 and entitle the holders thereof to purchase two million shares of the Company's common stock at $4.25 and include specified registration rights. Management estimated the fair value of these Warrants to be approximately $6,800, assisted by an independent third-party appraiser. The fair value of these 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 these Warrants was presented in additional-paid in capital in the accompanying Consolidated Balance Sheets.

Perceptive Loan

We classified the Perceptive Warrants as a liability on our balance sheets up to the effective date of our IPO, July 24, 2018, as they were free-standing financial instruments with the potential to require us to transfer assets upon exercise. The Perceptive Warrants were initially recorded at fair value on date of grant and were subsequently remeasured to fair value at each balance sheet date. We utilized a third-party professional appraisal firm to assist in determining fair value of the Perceptive Warrant due to the absence of available Level 1 and 2 inputs prior to the IPO date. The fair value for period prior to the IPO date was based on unobservable Level 3 inputs. Changes in fair value of the Perceptive Warrants were reported in Other expense in the statement of operations and comprehensive loss through the effective date of our IPO, July 24, 2018.

The terms of the Perceptive Warrants conveyed the right to purchase 863,400 shares of our common stock, and this right was automatically exercised at the time of the IPO through issuance of common shares at a total price of $116. As a result, the warrant liability was classified to additional paid in capital during the third quarter of 2018. A Level 1 market pricing of $15.00, the initial price at which the Company's common stock was offered, was used in determining fair value of the warrants as of the effective exercise date.

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

We account for uncertain tax positions in accordance with the provision of ASC 740. When uncertain tax positions exist, we recognize the tax benefit of tax provisions to the extent that the benefit of tax positions will more likely than not be realized. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position, as well as consideration of the available facts and circumstances. To date, we have not had any significant uncertain tax positions.

Share-Based Payments

Share-Based Compensation Equity Awards

We provide certain employees, non-employee directors and consultants with performance incentives under our share-based compensation plans. Under these plans, we may grant restricted stock units and stock options in order to align long-term financial interest of selected participants with those of our 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. Compensation cost relating to share-based payments transactions is recognized in the Consolidated Statements of Operations and Comprehensive Income (Loss) for the year ended December 31, 2019, at their fair values at their grant dates. All share-based payments to employees, including grants of employee stock options are recognized in the statement of operations as compensation expense over the vesting period of the awards. We determine the fair value of option awards using the Black-Scholes-Merton option pricing model that incorporates certain assumptions, such as the risk-free interest rate, expected volatility, expected dividend yield and expected life of the options. Restricted stock units are valued based upon the value of the Company's underlying common stock. See Note 15 to the Consolidated Financial Statements contained in Item 8. Financial Statements and Supplementary Data for additional discussion.

Non-Voting Common Share Issuance

Prior to the Company's conversion from an LLC to a C corporation, share-based compensation had been issued pursuant to two Performance Unit Plans, both of which were within the scope of FASB ASC Subtopic 718-30, *Compensation – Stock Compensation – Awards Classified as Liabilities.* The fair value of this compensation was measurable by the increase in fair value at the time of settlement over the fair value determined at the grant date. Because the Company was privately owned during this time and had no public market for its LLC membership interests, significant judgements and estimates were necessarily inherent in the determination of fair values at various grant dates. Accordingly, the Company's Board of Directors relied on various inputs to assist in their assessment of fair value, including relevant third-party investments, use of an enterprise value approach or use of an independent third-party valuation. Pursuant to the Performance Unit Plans, vested grants were not exercisable prior to either a change in control of the Company or completion of an IPO. These performance conditions rendered the grants contingent and, accordingly, expense recognition was deferred until either of the conditions were satisfied. On April 16, 2018, these Performance Unit Plans were formally terminated through actions of both the Board of Directors and the required approvals of certain plan participants. As a result, vesting of unvested performance units was accelerated and the Company issued non-voting common shares to compensate the performance unit holders. Immediately prior to the consummation of the IPO, all of the Company's outstanding shares of non-voting common stock that had been issued in April 2018 were automatically converted to 4,922,353 shares of the voting common stock of Aquestive.

In accordance with ASC 718, *Compensation — Stock Compensation*, the Company recorded a total charge to earnings representing the cost of this compensation totaling $27,298, consisting of $19,123 which relates to the estimated fair market value at the issuance date of the 4,922,353 non-voting common shares and $8,175 related to withholding taxes which the Company committed to pay on behalf of the performance unit holders. This compensation expense was estimated using an independent third-party valuation prepared in accordance with the American Institute of Certified Public Accountants Practice Aide, Valuation of Privately-Held Company Equity Securities Issued as Compensation. This valuation assumed a discount for lack of marketability of 34%, taking into consideration the illiquid nature of the security as well as other qualitative characteristics that would make it less marketable than the more senior securities. Volatility was assumed at 90%, based on that of comparable public companies. The weighted average cost of capital of 27.5% was also based on that of comparable public companies as well as market interest rate data. If we had made different assumptions in determinations of fair value at either the grant dates or at the time of issuance of the non-voting common shares issued in settlement of those grants, our equity-based compensation expense, net loss and net loss per share of common stock could have been significantly different.

Recent Accounting Pronouncements

Refer to Note 3 "Summary of Significant Accounting Policies" in the accompanying Notes to our Consolidated Financial Statements for a discussion of recent accounting pronouncements.

JOBS Act

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

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

We are also a "smaller reporting company," meaning that 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," and have either: (i) a public float of less than $250 million or (ii) annual revenues of less than $100 million during the most recently completed fiscal year and (A) no public float or (B) a public float of less than $700 million. As a "smaller reporting company," we are subject to reduced disclosure obligations in our SEC filings compared to other issuers, including with respect to 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.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

Prior to July 15, 2019, our exposure to market risk due to changes in interest rates related primarily to the increase or decrease in the amount of interest expense from fluctuations in one-month LIBOR associated with our debt facility. For each 1% increase in one-month LIBOR in excess of the floor of 2%, our annual interest expense would increase by approximately $500,000. However, our Senior Secured Notes due 2025 issued on July 15, 2019 carry a 12.5% fixed interest rate per annum, thereby eliminating market risk due to changes in interest rates. Our cash and cash equivalents are maintained in FDIC protected accounts with no exposure to material changes in interest rates. At December 31, 2019, our interest rate on deposited cash was 1.55%. We do not purchase, sell or hold derivatives or other market risk sensitive instruments to hedge interest rate risk or for trading purposes.

Our accounts receivables are concentrated predominantly with Indivior. With the recent launch of Sympazan, our concentration with three large regional wholesalers of pharmaceutical products is not significant presently but may become so in future periods should Sympazan sales increase and should other pipeline products become approved by the FDA and become distributed through these three regional, or other, wholesalers. In the event of non-performance or non-payment by either Indivior or the wholesalers, there may be a material adverse impact on our financial condition, results of operations or net cash flow.

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, 2019, 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, 2019, 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, 2019. 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, 2019.

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

The information required by this item is incorporated by reference to the information set forth in the sections titled "Proposal 1 – Election of Directors," "Executive Officers," "Information Regarding the Board and Corporate Governance" and "Delinquent Section 16(a) Reporting" in our 2020 Proxy Statement, expected to be filed with the SEC within 120 days following the end of our fiscal year.

Item 11. Executive Compensation

The information required in this item in incorporated by reference to the information set forth in the section titled "Executive Officer and Director Compensation" in our 2020 Proxy Statement, expected to be filed with the SEC within 120 days following the end of our fiscal year.

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

The information required by this item is incorporated by reference to the information set forth in the section titled "Security Ownership of Certain Beneficial Owners and Management" and "Equity Compensation Plan Information" in our 2020 Proxy Statement, expected to be filed with the SEC within 120 days following the end of our fiscal year.

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

The information required by this item is incorporated by reference to the information set forth in the section titled "Transactions with Related Persons" and "Information regarding the Board and Corporate Governance – Board Independence" in our 2020 Proxy Statement, expected to be filed with the SEC within 120 days following the end of our fiscal year.

Item 14. Principal Accountant Fees and Services

The information required by this item is incorporated by reference to the information set forth in the section titled "Independent Registered Public Accounting Firm Fees" contained in Proposal 2 in our 2020 Proxy Statement, expected to be filed with the SEC within 120 days following the end of our fiscal year.

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	Form of Warrant (filed as Exhibit 4.2 to the Current Report on Form 8-K filed on July 16, 2019 and incorporated by reference herein).
4.4	Description of Debt Securities Issued under Indenture under Indenture dated as of July 15, 2019 (filed as Item 1.01) to the Current Report on Form 8-K filed on July 16, 2019 and incorporated by reference therein).
4.5	Description of Warrant issued under the Indenture dated as of July 15, 2019 (filed as Item 1.01 to the Current Report on Form 8-K filed on July 16, 2019 and incorporated by reference herein).
4.6	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).
4.7	Description of Securities Registered under Section 12 of the Exchange Act (filed herewith).
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 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	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).
10.4+	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).
10.5+	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).
10.6+	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).
10.7+	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).

10.8†	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).
10.9†	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).
10.10†	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).
10.11†	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).
10.12	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).
10.13+	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).
10.14+	Aquestive Therapeutics, Inc. Employee Stock Purchase Plan as Amended (filed herewith).
10.15+	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).
10.16+	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).
10.17+	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).
10.18+	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).
10.19	Equity Distribution Agreement dated as of September 11, 2019 between the Company and Piper Jaffray & Co. (filed as Exhibit 1.2 to Registration Statement on Form S-3 (File No. 333-233716) and incorporated by reference herein).
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 11, 2020

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 11, 2020
/s/John T. Maxwell John T. Maxwell	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 11, 2020
/s/ Douglas K. Bratton Douglas K. Bratton	Member of the Board of Directors	March 11, 2020
/s/ Gregory B. Brown Gregory B. Brown, M.D.	Member of the Board of Directors	March 11, 2020
/s/ John Cochran John Cochran	Member of the Board of Directors	March 11, 2020
/s/ Santo J. Costa Santo J. Costa	Chairman of the Board of Directors	March 11, 2020
/s/ Nancy S. Lurker Nancy S. Lurker	Member of the Board of Directors	March 11, 2020
/s/ James S. Scibetta James S. Scibetta	Member of the Board of Directors	March 11, 2020

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, 2018 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, 2019, 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, 2018 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, 2019, 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 revenue from contracts with customers as of January 1, 2019 due to the adoption of Accounting Standards Codification 606, *Revenue from Contracts with Customers*.

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 11, 2020

AQUESTIVE THERAPEUTICS, INC.

Consolidated Balance Sheets
(In thousands, except per share/unit amounts)

	December 31, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 49,326	$ 60,599
Trade and other receivables, net	13,130	6,481
Inventories	2,859	5,441
Prepaid expenses and other current assets	2,999	1,680
Total current assets	68,314	74,201
Property and equipment, net	9,726	12,207
Intangible assets, net and other assets	439	443
Total assets	$ 78,479	$ 86,851
Liabilities and stockholders' (deficit)/equity		
Current liabilities:		
Accounts payable	$ 12,274	$ 20,436
Accrued expenses	5,475	7,195
Deferred revenue	806	721
Loans payable, current	—	4,600
Total current liabilities	18,555	32,952
Loans payable, net	60,338	42,603
Deferred revenue, net of current portion	4,348	—
Asset retirement obligations	1,360	1,216
Total liabilities	84,601	76,771
Commitments and contingencies (note 18)		
Stockholders' (deficit)/equity:		
Common stock, $.001 par value. Authorized 250,000,000 shares; 33,562,885 and 24,957,309 shares issued and outstanding at December 31, 2019 and 2018, respectively	34	25
Additional paid-in capital	124,318	71,431
Accumulated deficit	(130,474)	(61,376)
Total stockholders' (deficit)/equity	(6,122)	10,080
Total liabilities and stockholders' (deficit)/equity	$ 78,479	$ 86,851

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,	
	2019	**2018**
Revenues	$ 52,609	$ 67,430
Costs and expenses:		
Manufacture and supply	20,361	20,988
Research and development	20,574	23,112
Selling, general and administrative	64,342	72,269
Total costs and expenses	105,277	116,369
Loss from operations	(52,668)	(48,934)
Other income (expenses):		
Interest expense	(9,318)	(7,711)
Interest income	636	552
Loss on the extinguishment of debt	(4,896)	—
Change in fair value of warrant	—	(5,278)
Net loss before income taxes	(66,246)	(61,376)
Income taxes	—	—
Net loss	$ (66,246)	$ (61,376)
Comprehensive loss	$ (66,246)	$ (61,376)
Net loss per share – basic and diluted	$ (2.61)	$ (2.96)
Weighted-average number of common shares outstanding - basic and diluted	25,356,098	20,725,526

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 January 1, 2018*	5,000	$ —	$ (26,495)	$ —	$ (26,495)
Effect of Stock Split	15,072,647	15	(15)	—	—
Common Stock issued to performance unit plan participants	4,922,353	5	19,118	—	19,123
Reclassification of warrant liability to equity	—	—	12,952	—	12,952
Cash received for warrant exercise	—	—	116	—	116
Common Stock issued upon initial public offering	4,925,727	5	68,709	—	68,714
Issuance costs of initial public offering	—	—	(5,232)	—	(5,232)
Share-based compensation	31,582	—	2,278	—	2,278
Net loss	—	—	—	(61,376)	(61,376)
Balance at December 31, 2018	24,957,309	$ 25	$ 71,431	$ (61,376)	$ 10,080
Adoption of ASU 2014-09, ASU 2018-07	—	—	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
Share-based compensation	70,627	—	6,723		6,723
Net loss	—	—	—	(66,246)	(66,246)
Balance at December 31, 2019	33,562,885	$ 34	$ 124,318	$ (130,474)	$ (6,122)

* Represents balances as of December 31, 2017 as adjusted for the reorganization from LLC to C corporation business structure effective as of the close of business on that date.

See accompanying notes to the consolidated financial statements

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

	Year Ended December 31,	
	2019	2018
Cash flows from operating activities:		
Net loss	$ (66,246)	$ (61,376)
Adjustments to reconcile net loss to net cash (used for) operating activities:		
Depreciation and amortization	2,905	3,236
Change in fair value of warrant	—	5,278
Share-based compensation	7,071	29,940
Amortization of debt issuance costs and discounts	1,929	1,696
Loss on the extinguishment of debt	4,896	—
All other non-cash expenses	359	237
Changes in operating assets and liabilities:		
Trade receivables and other receivables, net	(6,815)	(409)
Inventories	2,582	(1,427)
Prepaid expenses and other current assets	(1,366)	(1,140)
Accounts payable	(7,872)	11,319
Accrued expenses	746	281
Deferred revenue	1,601	(626)
Net cash used for operating activities	(60,210)	(12,991)
Cash flows from investing activities:		
Capital expenditures	(663)	(1,824)
Net cash (used for) investing activities	(663)	(1,824)
Cash flows from financing activities:		
Proceeds from issuance of common stock and warrant exercises	39,317	68,830
Proceeds from issuance of debt	70,000	—
Debt repayment	(50,000)	—
Payments for financing costs	(3,946)	(4,768)
Premium paid to retire debt	(2,944)	—
Payments for taxes on share-based compensation	(2,827)	(6,027)
Net cash provided by financing activities	49,600	58,035
Net (decrease)/increase in cash and cash equivalents	(11,273)	43,220
Cash and cash equivalents:		
Beginning of period	60,599	17,379
End of period	$ 49,326	$ 60,599
Supplemental disclosures of cash flow information:		
Cash payments for interest	$ 7,340	$ 6,049
Net increase in capital expenditures included in accounts payable and accrued expenses:	104	104
Net (decrease) increase in offering costs included in accounts payable and accrued expenses	—	(588)
Accrued withholding tax for share based compensation	—	2,515
Deferred financing costs charged to additional paid in capital	540	5,232
Warrants issued in connection with long-term debt	6,800	—
Noncash component of warrants exercised	—	12,952

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. Corporate Organization and Company Overview

(A) 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 critical healthcare challenges, having been formed effective on January 1, 2018 via the conversion of MonoSol Rx, LLC to a Delaware corporation, and a simultaneous name change. The Company has a commercial proprietary product and a late-stage proprietary product pipeline focused on the treatment of diseases of the central nervous system, or CNS, and is developing orally administered complex molecules as alternatives to more invasive therapies. Aquestive is pursuing its business objectives through commercialization of its own products and through in-licensing and out-licensing arrangements. 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.

Aquestive 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, 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.

(B) Corporate Conversion, Reorganization, Stock Splits and Equity Offerings

Corporate Conversion and Reorganization

Until December 31, 2017, the Company conducted its business through MonoSol Rx, LLC, a Delaware limited liability company, or MonoSol, which was originally formed in Delaware in January 2004. On January 1, 2018, MonoSol converted from a Delaware LLC into a Delaware corporation pursuant to a statutory conversion and changed its name to Aquestive Therapeutics, Inc. In connection with this conversion, the holders of membership units of MonoSol contributed their interests in MonoSol to Aquestive Partners, LLC, or APL, in exchange for proportionate interests in APL. As a result of the exchange, APL was issued 5,000 shares of voting common stock in the Company and became the parent and sole stockholder of the Company.

Stock Splits

In April 2018, the Board approved an amendment to the Certificate of Incorporation of the Company to:

(i) increase the authorized number of capital stock from 25,000 to 350,000,000 shares, followed by a reduction of the authorized total to 250,000,000 in July 2018,

(ii) authorize Non-Voting Common Stock, and

(iii) affect a split of the Company's common stock, par value $0.001 per share, such that each share be subdivided and reclassified into 37,212 shares of Voting Common Stock, par value $0.001 per share. Subsequently and in consideration of pricing considerations in connection with the Company's planned initial public stock offering (the IPO), a reverse split was implemented, converting 12.34 outstanding shares into a single share of common stock of the same par value.

The net effect of these stock splits has been presented in these financial statements as if they occurred on January 1, 2018.

Initial Public Offering of Common Stock

On July 27, 2018, the Company closed the initial public offering ("IPO") of 4,500,000 shares of common stock at an offering price of $15.00 per share. The Company received net proceeds of approximately $57,543 after deducting underwriting discounts, commissions, and offering related transaction costs of approximately $9,957. The underwriters' over-allotment option was exercised in August 2018 and the Company issued 425,727 additional common shares at $15.00 per share in exchange for additional net proceeds of approximately $5,939, after deducting underwriter discounts of approximately $447. The sale of these common shares provided total net proceeds of $63,482. Immediately prior to the consummation of the IPO, all of the Company's outstanding shares of non-voting common stock was automatically converted to 4,922,353 shares of voting common stock to settle all obligations to performance unit plan participants.

Follow-On Public Offering of Common Stock

On December 17, 2019, Aquestive 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

(A) 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.

(B) 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, 2019 and 2018, cash and cash equivalents consisted of cash in bank accounts and money market funds.

(C) Concentration of Credit Risk

Cash and cash equivalents are maintained at one federally insured financial institution. The Company has not experienced any losses in such accounts and management believes that the Company is not exposed to any credit risk due to the financial position of the banking institution. Indivior is our largest customer, and these details on this relationship are outlined in Note 5. Indivior does not represent a material credit risk.

(D) 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 90 days, depending on the customer and type of invoice.

The Company evaluates the collectability of accounts receivable based on a combination of factors. Neither receivables nor revenues are recorded unless collection is reasonably assured. 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 $124 and $58 as of December 31, 2019 and 2018, respectively.

(E) 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, in accordance with ASU 2015-11, *Inventory (Topic 330): Simplifying the Measurement of Inventory*. 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.

(F) 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.

(G) 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.

(H) 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.

(I) Revenue from Contracts with Customers

The Company’s revenues include (i) sales of manufactured products pursuant to contracts with commercialization partners, (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. Revenues recorded during the year ended December 31, 2018 were reflected based on the prior standards specified in ASC 605, *Revenue Recognition*, which provided that revenue is recognized when (1) persuasive evidence of an arrangement exists, (2) delivery has occurred or services have been rendered, (3) the price is fixed or determinable and (4) collectability is reasonably assured.

Manufacture and Supply Revenue – Beginning on January 1, 2019 with the adoption of ASC 606, the Company records revenues from products manufactured under contract with commercialization partners when manufacturing processes are complete and internal quality standards have been met. Shipment of these products typically occurs within days of completion of the Company's quality assessments. Prior to that date, revenue was recorded under standards established by ASC 605, generally resulting in revenue recognition upon shipment and transfer of title for manufactured products.

Proprietary Product sales - Revenues from proprietary product sales are recorded 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 card redemption costs, Medicare, Medicaid and other rebates, and these estimates are reflected as a component of accrued liabilities.

License and Royalty Revenue – Effective upon adoption of ASC 606, 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 under ASC 606 is estimated and recognized when sales under supply agreements with commercial partners are recorded, absent any contractual constraints or collectability uncertainties. Royalties based on sales of Suboxone and Zuplenz in 2019 are recorded in this manner. Royalties recorded in 2018 under ASC 605 were based on reported sales data and collectability assessments.

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.

The Company also operates under a certain collaborative arrangement under which the parties share revenues and expenses related to development, manufacturing and commercialization of a product. This contractual arrangement falls within the scope of FASB ASC Subtopic 808-10, *Collaborative Arrangements*, and revenues and expenses are recorded based on the guidance in FASB ASC Subtopic 605-45, *Revenue Recognition – Principal Agent Considerations*. Revenue earned and expenses incurred under this agreement as of December 31, 2019 and 2018 was not material.

(J) Research and Development

Costs incurred in connection with research and development activities are expensed as incurred. Research and development expenses include (i) employee-related expenses, including salaries, benefits, travel and share-based compensation expense, (ii) external research and development expenses incurred under arrangements with third parties, such as contract research and contract manufacturing organizations, investigational sites and consultants, (iii) the cost of acquiring, developing and manufacturing clinical study materials, and (iv) costs associated with preclinical and clinical activities and regulatory operations. Non-refundable advance payments for goods and services that will be used in future research and development activities are expensed when the activity is performed or when the goods have been received, rather than when payment is made, in accordance with ASC 730, *Research and Development.*

(K) 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.

(L) 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. During 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-Merton 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.

(M) 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.

(N) 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, 2019 and 2018, the Company's comprehensive included only its net loss.

(O) 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. As of December 31, 2019, the Company has no level 3 assets or liabilities.

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 refinancing during 2019. 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 12 for further information on these warrants.

(P) 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.

(R) Deferred Offering Costs

Deferred Offering costs, consisting primarily of direct incremental legal, accounting and other fees relating to the Company's ATM ("At-the-Market" Facility), were capitalized as incurred. As of December 31, 2019, deferred offering costs of $149 were included as a component of Prepaid expenses and other current assets.

(S) 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 May 2014, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, 2014-09, *Revenue from Contracts with Customers*, and subsequently issued a number of amendments to this update. The new standard, as amended in Accounting Standards Codification, or ASC, 606, provides a single comprehensive model to be used in accounting for revenue arising from contracts with customers and supersedes previously applicable revenue recognition guidance provided by ASC 605. The new standard's stated core principle is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. In addition, the standard requires disclosure of the nature, amount, timing and uncertainty of revenue and cash flows arising from contracts with customers. See also Note 3/(I) above.

The Company adopted this standard on January 1, 2019 using the modified retrospective method and recorded a cumulative effect adjustment of $2,832 to its accumulated deficit upon adoption. This adjustment related to the deferral of $3,100 of previously recognized license revenue net of the acceleration of $268 of co-development fees and royalties. Under the modified retrospective method of adoption, the comparative information in the consolidated financial statements has not been revised and continues to be reported under ASC 605. The Company is generally recognizing existing manufacture and supply revenue, co-development milestones and fees and royalty revenue earlier than it would have under the previous standard.

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 June 2018, the FASB issued ASU 2018-07, *Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*, which aligns accounting for share-based payments issued to nonemployees to that of employees under the existing guidance of Topic 718, with certain exceptions. This update supersedes previous guidance for equity-based payments to nonemployees under *Subtopic 505-50, Equity—Equity-Based Payments to Non-Employees.* The Company adopted this standard on January 1, 2019 using the modified retrospective method and charged a cumulative effect adjustment of $20 to its accumulated deficit upon adoption.

Recent Accounting Pronouncements Not Adopted as of December 31, 2019:

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)* which establishes a comprehensive new lease accounting model. The new standard: (i) clarifies the definition of a lease; (ii) requires a dual approach to lease classification similar to current lease classifications; and (iii) causes lessees to recognize leases on the balance sheet as a lease liability with a corresponding right-of-use (ROU) asset for leases with a lease-term of more than twelve months. The new standard is effective for the Company for fiscal years and interim periods beginning after December 15, 2019 and requires modified retrospective application. The standard is effective for the Company beginning January 1, 2020. Accordingly, the Company will reflect its ROU assets, lease liabilities and any cumulative-effect adjustment to retained earnings in its consolidated financial statements beginning on January 1, 2020. Upon adoption, the lease liability will be equal to the present value of future lease payments and a right-of-use asset will be based on the lease liability, subject to adjustment for items such as initial direct costs. For income statement purposes, the new standard retains a dual model similar to ASC 840, requiring leases to be classified as either operating or financing. Operating leases will continue to result in straight-line expense while financing leases will result in a front-loaded expense pattern (similar to current accounting guidance by lessees for operating and capital leases, respectively, under ASC 840).

There are a number of practical expedients available to the Company at transition. The transitional practical expedients provide that the Company may elect to not re-assess: (i) whether its contracts contain a lease under the new definition, (ii) the classification of those leases and (iii) the accounting for any initial direct costs previously incurred. The Company may also elect to not recognize a ROU asset and lease liability for those leases with a remaining lease term of 12 months or less. The Company will apply these practical expedients upon adoption.

Upon adoption, ROU assets and lease liabilities will be recognized on the Company's consolidated balance sheets. The lease liability recognized upon adoption is based upon the present value of the sum of the remaining minimum lease payments (as previously identified under ASC 840) and any amounts probable of being owed under a residual value guarantee (if applicable), to be determined using an appropriate discount rate, based on the Company's ability to borrow on a collateralized basis over a similar remaining term and in a similar economic environment. The ROU asset to be recorded is based on the lease liability and adjusted for any prepaid or accrued lease payments, the remaining balance of any lease incentives, initial indirect costs and impairments (if applicable).

The recognition of lease liabilities and corresponding ROU assets is expected to have a material impact on the Company's consolidated balance sheet. The Company estimates that it will record approximately $4,000 of lease liabilities and ROU assets, respectively, as of January 1, 2020, the difference representing previously recorded lease-related assets and liabilities. The Company does not believe the adoption of this standard will have a material impact on its consolidated statements of operations, stockholders' equity or cash flows. Refer to Note 18, *Commitments and Contingencies*, for further information on the Company's existing leases.

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments – Credit Losses (Topic 326)*, amending existing guidance on the accounting for credit losses on financial instruments within its scope. The guidance introduces an expected loss model for estimating credit losses, replacing the incurred loss model. The new guidance also changes the impairment model for available-for-sale debt securities, requiring the use of an allowance to record estimated credit losses (and subsequent recoveries). The new guidance is effective for the Company beginning after December 15, 2020. The Company is currently evaluating the impact of adoption on its consolidated financial statements.

In August 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments*, providing guidance on the classification of certain cash receipts and payments in the statement of cash flows intended to reduce diversity in practice, including cash flows related to debt prepayment or extinguishment costs and contingent consideration that may be paid following a business combination. The guidance is effective for the Company for fiscal years beginning after December 31, 2019. Early adoption is permitted. The Company does not expect a material effect of the standard on its Consolidated Statement of Cash Flows.

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 to the users of financial statements. There were certain required disclosures that have been removed or modified. In addition, the update added the following disclosures: (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 standard will become effective for the Company for its periods beginning after December 15, 2019; early adoption is permitted. The Company does not expect a material effect of the standard on its consolidated financial statements.

In August 2018, the FASB issued ASU 2018-15, *Intangibles—Goodwill and Other Internal-Use Software (Subtopic 350-40: Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That is a Service Contract*, which aligns the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software. The update provides guidance distinguishing between capitalizable service contract implementation costs and contract costs required to be expense. In addition, the update requires that the term of the hosting arrangement is to include the non-cancelable period of the arrangement plus periods covered by (i) an option to extend the arrangement if the customer is reasonably certain to exercise that option; (ii) an option to terminate the arrangement if the customer is reasonably certain not to exercise the termination option and (iii) an option to extend (or not to terminate) the arrangement in which exercise of the option is in the control of the vendor. This standard will become effective for the Company beginning January 1, 2021. The amendments may be applied either retrospectively or prospectively to all implementation costs incurred after the date of adoption. The Company is currently evaluating the impact of ASU 2018-15 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.

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 2019 and beyond include expenses related to continuing development and clinical evaluation of its products, 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. As of December 31, 2019, we had working capital of $49,759.

In July 2019, the Company retired its outstanding $50,000 debt through a new indenture in a face amount of $70,000, obtaining additional net funding of $13,110 after payment of related costs and expenses. In December 2019, a portion of the warrants issued to the holders of this new debt were exercised, providing additional funding of $1,821. Also, in December 2019, the Company closed a public offering of 8,050,000 common shares that provided cash of $37,295 after settlement of underwriter discounts, legal and other professional fees and filing costs.

The Company expects that its anticipated revenues from licensed and proprietary products, cash on hand and the funds received from the debt refinancing and equity offering, potential monetization of its out-licensed apomorphine product candidate, subject to regulatory approval which cannot be assured, and access to the capital markets under its shelf registration statement, will be adequate to meet its expected operating, investing, and financing needs for the next twelve months. To the extent additional funds are necessary to meet liquidity needs as the Company continues to execute its business strategy, the Company anticipates that additional funding requirements will be obtained through monetization of certain royalty streams or through additional debt or equity financings, and continuing expense reduction initiatives, or a combination of these potential sources of funds, although the Company can provide no assurance that these sources of funding will be available on reasonable terms, if at all. We have based this expectation on assumptions that could change or prove to be inaccurate and, additionally, we could utilize our available financial resources sooner than we expect.

Note 5. Revenues and Trade Receivables, Net

The Company's revenue was comprised of the following:

	Year Ended December 31,	
	2019	2018
Manufacture and supply revenue	$ 38,739	$ 37,319
License and royalty revenue	6,959	24,699
Co-development and research fees	4,042	5,184
Proprietary product sales, net	2,869	228
Revenues	$ 52,609	$ 67,430

Disaggregation of Revenue

The following table provides disaggregated net revenue by geographic area:

	Year Ended December 31,	
	2019	2018
United States	$ 48,293	$ 64,565
Ex-United States	4,316	2,865
Revenues	$ 52,609	$ 67,430

Ex-United States revenues are derived primarily from products manufactured for the Australian and Malaysian markets and in 2019 includes services provided to a Brazilian customer.

Accounts receivable, net consist of the following:

	December 31,	
	2019	2018
Accounts receivable	$ 9,094	$ 6,610
Contract and other receivables	4,363	33
Less: allowance for bad debt	(124)	(58)
Less: sales-related allowances	(203)	(104)
Trade and other receivables, net	$ 13,130	$ 6,481

Other receivables totaled $4,363 and $33 as of December 31, 2019 and 2018, 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 allowances are estimated in relation to revenues recognized for sales of Sympazan beginning with the launch of this product in December 2018.

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

	December 31,	
	2019	2018
Allowance for doubtful accounts at beginning of year	$ 58	$ 55
Additions charged to bad debt expense	66	53
Write-downs charged against the allowance	(—)	(50)
Recoveries of amounts previously reserved	—	—
Allowance for doubtful accounts at end of year	$ 124	$ 58

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

	December 31,	
	2019	2018
Balance at December 31, 2018	$ 104	$ —
Provision related to sales in 2019	244	104
Credits and payments	(145)	—
Balance at December 31, 2019	$ 203	$ 104

Concentration of Major Customers

Customers are considered major customers when sales exceed 10% of total net sales for the period or outstanding receivable balances exceed 10% of total receivables. For the years ended December 31, 2019, and 2018, Indivior, Inc. (“Indivior”) represented approximately 86% and 89% of the total revenues for each period, respectively. As of December 31, 2019, and 2018, the Company’s outstanding receivable balance from Indivior represented approximately 80% and 78% of gross receivables for each period, respectively.

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. (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, for markets 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 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. Indivior exercised its right to buy out its future royalty obligations in the United States under this agreement in 2012. Indivior remains obligated to pay royalties for all sales outside the United States.

The Indivior License Agreement contains customary contractual termination provisions, including a filing for bankruptcy or corporate dissolution, an invalidation of the intellectual property surrounding Suboxone, or 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 Indivior provides the Company with written notice of its intent not to renew at least one year prior to the expiration of the initial or renewal term.

Supplemental Agreement with Indivior

On September 24, 2017, the Company entered into an agreement with Indivior, 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 allow 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 date of launch of the competing generics 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.

In April 2016, the Company entered into a license agreement with Cynapsus Therapeutics Inc. (which was later succeeded to in interest by Sunovion), referred to as the Sunovion License Agreement, pursuant to which the Company granted Sunovion an exclusive, worldwide license (with the right to sub-license) to certain intellectual property, including existing and future patents and patent applications, covering all oral films containing APL-130277 (apomorphine) for the treatment of off episodes in Parkinson's disease patients, as well as two other fields. The Company's licensee, Sunovion, as sponsor of APL-130277, submitted an NDA to the FDA on March 29, 2018; on the PDUFA date in January 2019, Sunovion received a CRL. In the 2019 fourth quarter, Sunovion announced that it had received a PDUFA date of May 21, 2020 after the submission of its NDA.

In consideration of the rights granted to Sunovion under the Sunovion License Agreement, the Company received aggregate payments totaling $18,000 to date. In addition to the upfront payment of $5,000, the Company has also earned an aggregate of $13,000 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. The Company is also entitled to receive certain contingent one-time milestone payments related to product availability and regulatory approval in the United States and Europe, certain one-time milestone payments based on the achievement of specific annual net sales thresholds of APL-130277, and ongoing mid-single digit percentage royalty payments related to the net sales of APL-130277 (subject to reduction to low-single digit percentage royalty payments in certain circumstances), subject to certain minimum payments. The maximum aggregate milestone payments that may be paid to the Company pursuant to the Sunovion License Agreement is equal to $45,000. With the exception of the Initial Milestone Payments, there can be no guarantee that any such milestones will in fact be met or payable.

This Sunovion License Agreement will continue until terminated by the Company or Sunovion in accordance with the termination provisions of the Sunovion License Agreement. Absent early termination, the Sunovion License Agreement continues (on a country-by-country basis) until the expiration of all applicable licensed patents. Upon termination, all rights to intellectual property granted to Sunovion to develop and commercialize products will revert to the Company and Sunovion must continue to pay royalties to the Company on each sale of their remaining inventory of products commercialized by Sunovion which include apomorphine as their API.

Agreement to Terminate CLA with KemPharm

In March 2012, the Company entered into an agreement with KemPharm, Inc. ("KemPharm"), to terminate a Collaboration and License Agreement entered into in April 2011. Under this 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 $1.0 million from its 10% share of milestone payments paid to KemPharm, under its licensing of KP-415 and KP-484. There can be no guarantee that such payments will be made in the future.

Note 7. Inventory

Inventory consists of the following:

	December 31,	
	2019	2018
Raw material	$ 1,244	$ 1,283
Packaging material	1,096	2,975
Finished goods	519	1,183
Total inventory	$ 2,859	$ 5,441

Note 8. Property and Equipment, Net

		December 31,	
	Useful Lives	2019	2018
Machinery	3-15 yrs	$ 21,088	$ 20,681
Furniture and fixtures	3-15 yrs	1,150	1,150
Leasehold improvements	(a)	21,333	21,333
Computer, network equipment and software	3-7 yrs	2,787	2,579
Construction in progress		1,412	1,655
		47,770	47,398
Less: accumulated depreciation and amortization		(38,044)	(35,191)
Total property and equipment, net		$ 9,726	$ 12,207

(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 $2,854 and $3,186 for the years ended December 31, 2019 and 2018, respectively.

Note 9. Intangible Assets, Net and Other Assets

The following table provides the components of identifiable intangible assets, all of which are finite lived:

	December 31,	
	2019	2018
Purchase technology-based intangible	$ 2,358	$ 2,358
Purchased patent	509	509
	2,867	2,867
Less: accumulated amortization	(2,714)	(2,663)
Intangible assets, net	153	204
Other Assets, Primarily Security Deposits	286	239
Total Intangible Assets, Net and Other Assets	$ 439	$ 443

Amortization expense was $51 and $50 for each of the years ended December 31, 2019 and 2018, respectively. During the remaining life of the purchased patent, estimated annual amortization expense is $50 for each of the years from 2020 to 2022.

Note 10. Accrued Expenses

Accrued expenses consisted of the following:

	December 31,	
	2019	2018
Accrued compensation	$ 3,758	$ 3,604
Accrued employment tax expenses for share-based compensation	—	2,515
Real estate and personal property taxes	300	388
Accrued distribution expenses	1,174	481
Other	243	207
Total accrued expenses	$ 5,475	$ 7,195

Note 11. 12.5% Senior Secured Notes and Loans Payable

12.5% Senior Secured Notes

On July 15, 2019, the Company completed the private placement of up to $100 million aggregate principal of its 12.5% Senior Secured Notes due 2025 (the "Notes") and issued warrants for two million shares of common stock (the "Warrants"), $.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 and U.S. Bank National Association in dual roles providing terms governing an asset-based loan facility.

Upon closing, the Company issued $70,000 of the principal of the 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. In addition to the Initial Notes, the Indenture may provide access to further loans of up to $30,000 that may become available in two tranches of Additional Notes tied to the NDA filing for and FDA approval of Libervant, an important part of our drug candidate pipeline. Provided that no events of default exist, the Company may elect, in its discretion and subject to approval of the holder of a majority of the outstanding principal amount of the Notes, to offer to the Lenders participation in a $10,000 additional offering of 12.5% senior secured notes (the "First Additional Offering") under terms similar to the Initial Notes, on or before March 31, 2021, upon the filing of the Libervant NDA with the FDA. A second identical funding opportunity would allow the Company to obtain, on or before March 31, 2021, an additional $20,000 if the first option has been elected and funded, or, if not elected or funded, an additional $30,000 may be offered for issuance following FDA approval of Libervant for marketing in the U.S. There can be no assurance that any such additional financing will be consummated.

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, related early repayment fees and legal and other fees incurred in obtaining this loan and executing this Indenture.

The 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. 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:

2020	$ -
2021	3,500
2022	10,500
2023	17,500
2024 and thereafter	38,500
Total	$ 70,000

The Company may elect, at its option, to prepay the Notes at any time at premiums that range from 101.56% of outstanding principal if prepayment occurs on or after the 5th anniversary of the issue date of the Notes to 112.5% 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 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 Notes at 101% of the remaining principal plus accrued interest at the election of the lenders.

Collateral for the loan 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. In the event that asset-based loans of up to $10,000 ("ABL Facility") may be obtained, subject receivables and inventory assets will provide a second priority lien to senior secured note holders. The Company's license of its IP to a third-party drug development enterprise (specifically, Sunovion Pharmaceutical's APL-130277 product) is one of the various assets serving as collateral for this loan. The loan indenture permits the Company to monetize this asset while specifying that a portion of the proceeds, up to $40,000 if the First Additional Offering has not been elected or funded, or, $50,000 if it has been elected and funded, must be applied to prepay the Initial Notes, at 112.5% of the principal amount of the Notes being repurchased, plus accrued and unpaid interest, if any, thereon to the date of repurchase, to the extent elected by the Note holders, assuming that such monetization, up to such $40,000 or $50,000 level, as applicable, equals or exceeds those levels and if such monetization does not equal or exceed such level, such prepayment would be pro-rated among the Note holders. To the extent that Lenders do not elect repayment of the debt at the date of monetization, the amount not elected up to $40,000 (or $50,000 if an additional tranche is issued) will be held in a collateral account until approval of Libervant by the FDA, at which time this cash collateral is to be released to the Company. Proceeds in excess of $40,000 (or $50,000 if an additional tranche is issued) can be used immediately for general corporate purposes.

The Company capitalizes legal and other third-party costs incurred in connection with obtaining debt as deferred debt issuance costs and applies the unamortized portion as a reduction of the outstanding face amount of the related loan in accordance with ASU 2015-03, *Interest – Imputation of Interest: Simplifying the Presentation of Debt Issuance Costs*. Similarly, the Company amortizes debt discounts, such as those represented by warrants issued to its lenders, and offsets those as a direct reduction of its outstanding debt. Amortization expense arising from deferred debt issuance costs and debt discounts related to the 12.5% Notes and the Perceptive loan for the years ended December 31, 2019 and 2018 were $1,929 and $1,696, respectively. Unamortized deferred debt issuance costs and deferred debt discounts totaled $9,662 and $2,797 as of December 31, 2019 and 2018, respectively.

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 Notes 3 and 12).In May 2018, the Company and Perceptive agreed to make certain amendments to the loan agreement then in effect that provided for:

1. the postponement of the initial loan principal payment to May 2019,
2. a delay of the loan maturity date to December 16, 2020, and
3. with Perceptive's consent, an agreement to permit monetization of the royalties and fees that may be derived from sales of certain apomorphine products and a concurrent agreement for the release of the liens related to these royalties and fees.

As of December 31, 2018, the Company was in compliance with all financial covenants. In July 2019, this loan was paid in full in connection with the completion of the sale of the 12.5% 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 12. Warrants

Warrants Issued to 12.5% Senior Secured Noteholders

The Warrants that were issued in conjunction with the 12.5% Senior Secured Notes expire on June 30, 2025 and entitle the Lenders to purchase two million shares of the Company's common stock at $4.25 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 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.

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.

Warrants Issued to Perceptive Credit Opportunities Fund, LP

A seven-year warrant issued to Perceptive in connection with the Company's August 2016 debt refinancing included certain put rights that could have required a net-cash settlement and was therefore classified as a liability, rather than as equity. Accordingly, fair value of this warrant was re-valued at each succeeding balance sheet date through the date of its exercise in July 2018 at the time of the Company's IPO. As a result, $5,278 was charged against 2018 earnings to reflect the increase in value of this warrant during that period in 2018. Also, as a result of the exercise of the warrant, Perceptive received 863,400 shares of common stock in exchange for proceeds from the July 2018 exercise of $116, concurrent with which the remaining warrant liability of $12,952 was reclassified to additional paid in capital during the third quarter of 2018. A Level 1 market price of $15.00, the initial price at which the Company's common stock was publicly offered, was used in determining fair value as of the warrants' conversion date.

Note 13. Asset Retirement Obligation

The Company's asset retirement obligation, or ARO, consists of estimated future spending related to removing certain leasehold improvements at its Portage, Indiana, laboratory, the Ameriplex production facility and the Warren, New Jersey, laboratory and returning all facilities to their original condition. Below is a schedule of activity in the Company's liability for AROs for the years ended December 31, 2019 and 2018:

Balance at December 31, 2017	$ 1,081
Additions	5
Accretion	130
Balance at December 31, 2018	1,216
Additions	—
Accretion	144
Balance at December 31, 2019	$ 1,360

Depreciation expense related to the ARO assets included in overall depreciation expense for the periods ended December 31, 2019 and 2018 were $24 and $27, respectively.

Note 14. 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 years ended December 31, 2019 and 2018, 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, 2019	Year Ended December 31, 2018
Numerator:		
Net loss	$ (66,246)	$ (61,376)
Denominator:		
Weighted-average number of common shares – basic and diluted	25,356,098	20,725,526
Loss per common share – basic and diluted	$ (2.61)	$ (2.96)

As of December 31, 2019 and 2018, respectively, the Company's potentially dilutive instruments included 2,231,092 and 1,033,492 options to purchase common shares and 73,839 and 205,175 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, 2019 were potentially dilutive warrants for the purchase of 1,571,429 common shares.

Note 15. Share-Based Compensation

The Company's share-based incentive plan costs reflected in the Consolidated Statements of Operations and Comprehensive Loss for the year ended December 31, 2019 included costs related to restricted stock unit awards (RSUs) and stock option grants and, for the year ended December 31, 2018, also included costs related to non-voting common shares as well. As further detailed below, non-voting common shares were issued in April 2018 to compensate participants in the Company's previously maintained Performance Unit Plans at the time that those incentive plans were terminated. RSUs and options were granted pursuant to the Aquestive Therapeutics, Inc. 2018 Equity Incentive Plan, which was first adopted by the Board of Directors on June 15, 2018. The Company's Board of Directors also adopted the Aquestive Therapeutics, Inc. Employee Stock Purchase Plan in June 2018 and the Company began rollout of the plan in late 2018. Initial employee purchases under terms of this plan were made in 2019.

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

Expense classification:	Year Ended December31, 2019	Year Ended December 31, 2018
Manufacturing and supply	$ 231	$ 414
Research and development	720	2,583
Selling, general and administrative	6,120	26,943
Total share-based compensation expenses	$ 7,071	$ 29,940
Share-based compensation from:		
Non-voting common shares (A)	$ —	$ 27,298
Restricted Stock Units (B)	1,863	1,085
Stock Options (B)	5,173	1,557
Employee Stock Purchase Plan (C)	35	—
Total share-based compensation expenses	$ 7,071	$ 29,940

(A) Non-Voting Common Share Issuance

The Company had two Performance Unit Plans, both of which fell within the scope of FASB ASC Subtopic 718-30, *Compensation – Stock Compensation – Awards Classified as Liabilities.* Pursuant to the Plans, vested grants were not exercisable prior to either a change in control of the Company or completion of an IPO. These performance conditions rendered the grants contingent and deferred expense recognition until either of the conditions were satisfied. Neither of these conditions were satisfied as of December 31, 2017, and accordingly, no compensation expense was recorded during that year.

On April 16, 2018, the Company terminated the Performance Unit Plans. The termination was executed in accordance with the provisions of the Plans' termination, which required both Board of Directors and the certain plan participant approval. As a result, the Company accelerated the vesting of any unvested performance units and issued non-voting common shares to compensate the performance unit holders. Immediately prior to the consummation of the IPO, all of the Company's outstanding shares of non-voting common stock were automatically converted to 4,922,353 shares of voting common stock.

In accordance with ASC 718, *Compensation — Stock Compensation,* the Company recorded a total charge to earnings of $27,298 comprised of $19,123 which relates to the fair market value of the non-voting shares at the date the shares were granted and $8,175 related to withholding taxes which the Company elected to pay on behalf of the performance unit holders to reflect the compensation cost associated with the issuance of to 4,922,353 non-voting common shares. The compensation expense was estimated using an independent third-party valuation prepared in accordance with the American Institute of Certified Public Accountants Practice Aide, Valuation of Privately Held Company Equity Securities Issued as Compensation.

The assumptions for the determination of the fair value of these non-voting shares are provided in the following table:

Valuation assumptions:	
Discount for lack of marketability	34%
Volatility	90%
Weighted average cost of capital	27.5%

The discount for lack of marketability reflected the illiquid nature of the security as well as other qualitative characteristics that would make it less marketable than the more senior securities. Volatility was based on that of comparable public companies. The weighted average cost of capital was also based on that of comparable public companies as well as market interest rate data.

(B) Share-Based Compensation Equity Awards

The Company provides certain employees, non-employee directors and consultants with performance incentives under the Aquestive Therapeutics, Inc. 2018 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 pursuant to terms of the Plan are subject to graded vesting over a service period, which is typically two or 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, 2019, there were approximately 1.6 million shares available for grant under the Plans.

Restricted stock unit awards (RSUs)

The following table summarizes the Company's awards of restricted stock units for the years ended December 31, 2018 and 2019:

	Number of Units	Weighted Average Grant Date Fair Value Per Share
	(In thousands)	
Unvested at Plan adoption	—	$ —
Granted	265	14.83
Vested	(60)	15.03
Unvested, December 31, 2018	205	$ 14.77
Granted	—	—
Forfeited	(6)	
Vested	(125)	14.94
Unvested, December 31, 2019	74	$ 14.64

The Company recognized charges to 2019 and 2018 earnings totaling $1,863 and $1,085 related to RSUs, respectively. The total grant date fair market value of shares vested in 2019 and 2018 was $1,869 and $896, respectively.

As of December 31, 2019, there was approximately $867 of unrecognized compensation costs related to restricted stock units awarded of which approximately $800 is expected to be recognized during 2020 and the balance to be recognized in 2021.The RSUs granted to senior management vest in equal quarterly installments over two years; the RSUs granted to key employees are subject to a three-year graduated vesting schedule. These RSUs are not subject to performance-based criteria other than continued employment. There were no RSU grants prior to the year ended December 31, 2018.

Stock option awards

The following table summarizes the Company's stock option activity for the period from January 1, 2018 through December 31, 2019:

(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 January 1, 2018	—			$ —
Granted	1,033	$ 14.72	9.55	
Exercised, Forfeited, Expired	—			
Outstanding at December 31, 2018	1,033	$ 14.72	9.55	$ —
Granted	1,258	6.66	9.29	
Forfeited	(60)	$ 5.78	9.40	
Exercised, Expired	—			$ —
Outstanding at December 31, 2019	2,231	$ 10.42	8.94	$ 689
Vested or expected to vest at December 31, 2019	2,077	$ 10.41	8.94	$ 644
Exercisable at December 31, 2019	404	$ 14.83	8.56	$ —

The weighted average grant date fair value of stock options granted during 2019 and 2018 was $4.95 and $10.83, respectively. The fair values of stock options granted were estimated using the Black-Scholes-Merton pricing model based on the following assumptions:

	Years Ended December 31,	
	2019	2018
Expected dividend yield	0%	0%
Expected volatility	85% - 106%	85% - 90%
Expected term (years)	5.5 – 6.1	5.8 - 6.1
Risk-free interest rate	1.5% – 2.6%	2.8 - 2.9%
Forfeiture rate	5%	5%
Exercise prices	$ 3.36 - $8.05	$ 6.54 - $18.67

Aquestive anticipates reinvesting earnings for the foreseeable future in product development and other avenues of share-value growth and accordingly anticipates no dividend payouts. Volatility was determined based on that of comparable public companies, given the lack of any definitive history regarding its own publicly-traded common stock. The expected term of the award was calculated using the simplified method. A weighted average was utilized taking into account the two vesting periods to determine the expected term in years. 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 life of the options.

As of December 31, 2019, $9,361 of total unrecognized compensation expenses related to non-vested stock options is expected to be recognized over a weighted average period of 1.9 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 9.0 years. Options granted to senior management and Board members vest in equal quarterly or monthly increments over three years; options granted to key employees are subject to a three-year graduated 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 2019, employees purchased 56,378 shares through this plan.

Note 16. Employee Benefit Plans

The Company sponsors a defined-contribution 401(k) plan covering all full-time employees and makes matching employer contributions as defined by the terms of that plan. The Company may also make discretionary contributions. Total contributions made to the plan by the Company for the years ended December 31, 2019 and 2018 were $819 and $837, respectively.

Note 17. Income Taxes

From the period January 1, 2017 through October 31, 2017, the Company was a limited liability company ("LLC") that passed through income and losses to its members for U.S. federal and state income tax purposes. From November 1, 2017 through December 31, 2017, the LLC elected to be taxed as a C corporation. On January 1, 2018, the LLC was converted into a Delaware corporation and treated as a C corporation for tax purposes.

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, 2019 and 2018 are as follows:

	December 31,	
	2019	2018
Deferred tax assets:		
Accounts receivable	$ 126	$ 16
Inventory	69	120
Accrued expenses	835	15
NOL carryforwards	23,687	10,899
Interest limitation imposed by the TJCA	5,748	2,124
Stock Compensation	2,505	1,224
Other	783	260
Property and equipment	1,741	1,380
Orphan Drug and R&D Tax Credits	4,621	3,917
	40,115	19,955
Deferred tax liabilities:		
Intangible assets	(58)	(39)
Prepaid expenses	-	(407)
	(58)	(446)
Valuation Allowance	(40,057)	(19,509)
Net deferred tax asset/(liability)	$ —	$ —

At December 31, 2019 and 2018, the Company had federal net operating loss carryforwards of $85,905 and $41,385, respectively, a significant portion of which carryforward for an indefinite period. At December 31, 2019 and 2018, the Company also had state net operating loss carryforwards of $80,266 and $39,217, 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 163j create new limitations on deductible interest expense. The Company’s interest expense deduction under 163j will be limited for tax purposes based on a calculation of 30% of its EBITDA on a tax basis. 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 $40,057, and $19,509 have been established at December 31, 2019 and 2018, 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, 2019 and 2018. The Company did not have any unrecognized tax benefits and has not accrued any interest or penalties for the years ended December 31, 2019 and 2018. 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 years ended December 31, 2019 and 2018, respectively, as follows:

	Year Ended December 31,	
	2019	2018
Income taxes at statutory rate	21.00%	21.00%
Increase (decrease) resulting from:		
State income tax	6.76	7.04
Permanent differences	(0.04)	(7.09)
Research & development credit	2.32	4.40
Return to provision	0.98	1.48
Effect of state rate change	-	0.41
Valuation allowance	(31.02)	(27.24)
Effect of the deferred rate change	—	—
Effective tax rate	0.00%	0.00%

The TCJA was signed into law on December 22, 2017. In December 2017, the SEC staff issued Staff Accounting Bulletin No. 118 (“SAB 118”) to address the application of U.S. GAAP to situations in which an entity does not have the necessary information available, prepared or analyzed in reasonable detail to complete the accounting for certain income tax effects of the TCJA. That guidance specifies that, for income tax effects of the TCJA that can be reasonably estimated but for which the accounting and measurement analysis is not yet complete, entities should report provisional amounts in the reporting period that includes the enactment date and those provisional amounts can be adjusted for a measurement period not to exceed one year from the enactment date.

We did not identify items for which the income tax effects of the 2017 TCJA have not been completed and could not be reasonably estimated as of December 31, 2017, and as such, our financial results reflect the income tax effects of the TCJA for which the accounting under ASC Topic 740 is complete.

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% sur tax for taxpayers with allocated net income over $1 million for 2020 and 2021. 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 18. Commitments and Contingencies

(A) Operating Leases

The Company has entered into various lease agreements for production and research facilities and offices. Most leases contain renewal options. Certain leases contain purchase options and require the Company to pay for taxes, maintenance and operating expenses. All of the Company's leases are classified as operating leases.

Production and Research Facilities, Portage, Indiana

The Company leases a 73,000-square-foot facility (Ameriplex) in Portage, Indiana, to house additional packaging, R&D and other operations. As amended, this lease has a term that extends through September 30, 2022 and contains a renewal option that could extend the lease through September 30, 2026.

The Company also leases its current 8,400-square-foot production facility (Melton) in Portage, Indiana, which houses certain research and development offices and current good manufacturing practices, or cGMP, manufacturing operations. The lease contains an option to purchase the facility at any time during the lease term along with a right of first refusal to purchase the facility. In October 2012, the Company entered into an additional five-year extension of the lease of this facility, through March 31, 2018, under the same terms and conditions. In October 2017, the Company extended its lease located in Portage, Indiana, which will expire during March 2023 under the same terms and conditions as its former lease.

Office and Laboratory Facilities, Warren, New Jersey

The Company leases its headquarters and principal laboratory facility in Warren, New Jersey. Pursuant to various amendments in February 2011, June 2012 and May 2013, the Company has secured additional space to provide for the growth of its laboratory facilities and corporate and administrative requirements. The lease included five two-year renewal options, one of which was exercised in July 2016 to extend this lease through August 31, 2018. During September 2017, the Company entered into a lease for additional space through August 31, 2018. In 2018. The Company entered into an Amended and Restated Lease Agreement which added additional office space and extended the lease through February 29, 2020. In July 2019, the Company entered into the First Amendment to Lease which extended the term to August 31, 2023.

Rent expense for all leased manufacturing facilities and sales, laboratory and office space were $1,613 and $1,393 for the years ended December 31, 2019 and 2018, respectively.

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	0
Total	$ 4,094

(B) 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

Beginning in August 2013, Aquestive was informed of ANDA filings in the United States by Watson Laboratories, Inc. (now Actavis Laboratories, Inc., or "Actavis"), Par Pharmaceutical, Inc.("Par"), Alvogen Pine Brook, Inc. ("Alvogen"), Teva Pharmaceuticals USA, Inc. ("Teva"), Sandoz Inc. ("Sandoz"), and Mylan Technologies Inc. ("Mylan"), for the approval by the FDA of generic versions of Suboxone Sublingual Film in the United States. Patent infringement lawsuits were filed against all six generic companies in the U.S. District Court for the District of Delaware. After the commencement of the ANDA patent litigation against Teva, Dr. Reddy's Laboratories ("DRL") acquired the ANDA filings for Teva's buprenorphine and naloxone sublingual film that are at issue in these trials.

Of these, cases against three of the six generic companies have been resolved.

- *Mylan* and *Sandoz* settled without a trial. Sandoz withdrew all challenges and became the distributor of the authorized generic.
- All cases against *Par* were resolved pursuant to a May 2018 settlement agreement between us, Indivior, and Par and certain of its affiliates.
- *Actavis* was found to infringe the '514 patent and cannot enter the market until the expiration of the patent in 2024, and the Federal Circuit affirmed that ruling on July 12, 2019.
- *DRL* and *Alvogen* were found not to infringe under a different claim construction analysis, and the Federal Circuit affirmed that ruling on July 12, 2019. *Teva* has agreed to be bound by all DRL adjudications.

Subsequent to the above, all potential generic competitors without a settlement agreement were also sued for infringement of two additional new patents that contain new claims not adjudicated in the original case against DRL and Alvogen. On July 12, 2019, the Federal Circuit affirmed the decisions from the previously decided cases. The remaining case against Actavis was dismissed in light of the infringement ruling above, which prevents Actavis from entering the market until 2024. The case(s) against the remaining defendants regarding the additional asserted patents have not been finally resolved. A *Markman* hearing in the cases against Dr. Reddy's and Alvogen was held on October 17, 2019. On November 5, 2019, the Court issued its *Markman* opinion construing the disputed terms of the asserted patents. On January 9, 2020, the Court entered into a stipulated order of non-infringement of the '305 patent based on the Court's claim construction ruling, and Aquestive and Indivior reserved our rights to appeal the claim construction ruling. On November 19, 2019, the magistrate judge issued an order granting DRL and Alvogen's requests to file amended answers to add antitrust counterclaims. Aquestive and Indivior appealed the magistrate judge's decision to the District Judge on December 4, 2019, DRL and Alvogen opposed the appeal. The parties are awaiting further action from the Court on the appeal. On January 17, 2020, a motion was filed to dismiss DRL's and Alvogen's antitrust counterclaims for failure to state a claim and briefing on that motion is ongoing. No trial date has been set in those cases, which are pending in the U.S. District Court for the District of New Jersey. We are not able to determine or predict the ultimate outcome of this proceeding.

On February 19, 2019, the Federal Circuit issued its mandate reversing the District of New Jersey's preliminary injunction against Dr. Reddy's. Following issuance of the mandate, the District of New Jersey vacated preliminary injunctions against both Dr. Reddy's and Alvogen. Dr. Reddy's, Alvogen, and Mylan all launched generic versions of Suboxone Sublingual Film, and the launches by Dr. Reddy's and Alvogen are "at risk" because the products are the subject of the ongoing patent infringement litigations.

On March 22, 2019, the Company and Indivior brought suit against Aveva Drug Delivery Systems, Inc., Apotex Corp., and Apotex Inc. for infringement of the '150, '514, '454, and '305 patents, seeking an injunction and potential monetary damages. Following a negotiated settlement between all parties, on December 3, 2019, the parties submitted a Notice of Settlement and a Joint Motion to Approve Consent Judgment. The Court entered an Order dismissing the suit on December 8, 2019.

Aquestive is also seeking to enforce its patent rights in multiple cases against BioDelivery Sciences International, Inc. ("BDSI"). Two cases are currently pending but stayed in the U.S. District Court for the Eastern District of North Carolina:

- The first, a declaratory judgment action brought by BDSI against Indivior and Aquestive, seeks declarations of invalidity and non-infringement of U.S. Patents Nos. 7,897,080, or the '080 patent, 8,652,378, or the '378 patent, and 8,475,832, or the '832 patent. This case is stayed pending final resolution of the above-mentioned appeals on related patents.

- The second was filed by the Company and Indivior alleges infringement of Aquestive's U.S. Patent No. 8,765,167, or the '167 patent, by BDSI's Bunavail product and seeks an injunction and potential monetary damages. BDSI subsequently filed four (4) IPR's challenging the asserted '167 patent and on March 24, 2016, the Patent Trial and Appeal Board, or the PTAB, issued a final written decision finding that all claims of the '167 patent were valid. The case was stayed in May 2016 pending the final determination of the appeals on those decisions. Following the PTAB's February 7, 2019 decisions on remand denying institution, we and Indivior submitted a notice to the Court on February 15, 2019 notifying the Court that the stay should be lifted as result of the PTAB's decisions. We are awaiting further action from the Court.

- In January 2017, the Company initiated a suit against BDSI asserting infringement of the '167 patent by BDSI's Belbuca product and seeking an injunction and potential monetary damages. Subsequently, the Court granted BDSI's motion to dismiss the Complaint without prejudice. In November 2019, a new Complaint was filed against BDSI in the Eastern District of North Carolina, and BDSI filed a motion to stay the case pending its appeal of the PTAB's remand. The motion to stay remains pending. In March 2019, the Company moved to dismiss the appeal for lack of jurisdiction, and, in August, the Federal Circuit granted this motion to dismiss BDSI's appeal. In September 2019, BDSI filed a petition for rehearing *en banc*, which was denied by the Federal Circuit on January 13, 2020. Subsequently, BDSI filed a motion to dismiss the complaint, which was opposed by the Company on February 2, 2020. The parties are awaiting further action from the Court.

Antitrust Litigation

On September 22, 2016, forty-one states and the District of Columbia, or the States, brought suit against Indivior and the Company 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. The case was later consolidated with a multidistrict putative class action, the *In re Suboxone (Buprenorphine Hydrochloride and Naloxone) Antitrust Litigation*, MDL No. 2445, or the Suboxone MDL. The action brought by the States alleges that the Company participated in an antitrust conspiracy with Indivior and also engaged in related conduct in violation of federal and state antitrust law. The Company's motion to dismiss was denied by the Court and in response we filed an answer denying the States' claims in November 2017. The fact discovery period and the expert discovery phase closed on or before May 30, 2019, but additional reports and depositions were conducted through August 1, 2019. The remainder of the case schedule is stayed pending resolution of Indivior's appeal of a certain District Court class certification ruling. 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 Complaint

On December 5, 2019, Neurelis Inc. filed a Complaint in the Superior Court of California, County of San Diego, alleging Unfair Competition, Defamation, and Malicious Prosecution in connection with the Company's activities related to its pursuit of FDA approval for Libervant™. Neurelis also filed a First Amended Complaint on December 9, 2019, alleging the same three causes of action. Various answers and motions have been filed by the parties since that time, and a hearing is scheduled for April 24, 2020. We are not able to determine or predict the ultimate outcome of this proceeding or provide a reasonable estimate, or range of estimate, of the possible outcome or loss, if any, in this matter.

Note 19. Quarterly Financial Data (unaudited)

The following tables contain selected quarterly financial information from 2019 and 2018 (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, 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)

	Three Months Ended			
	March 31, 2018	June 30, 2018	September 30, 2018	December 31, 2018
Revenues	$ 23,411	$ 13,928	$ 13,267	$ 16,824
Manufacture and supply	5,636	4,973	5,592	4,787
Total costs and expenses	18,106	46,614	22,471	29,173
Net income (loss)	4,099	(36,493)	(15,038)	(13,944)
Basic and diluted net income (loss) per common share	$ 0.27	$ (1.90)	$ (0.64)	$ (0.56)

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

Exhibit 4.7

DESCRIPTION OF SECURITIES

References to "we" or "our" herein are, unless the context otherwise indicates, only to Aquestive Therapeutics, Inc.

Description of Capital Stock

The following is a summary of information concerning our capital stock. The summaries and descriptions below do not purport to be complete statements of the relevant provisions of our restated certificate of incorporation and our amended and restated bylaws, and are entirely qualified by these documents. We refer to our restated certificate of incorporation as our certificate of incorporation, and we refer to our amended and restated bylaws as our bylaws.

Authorized Capital Stock

Our authorized capital stock consists of 250,000,000 shares of common stock, par value $0.001 per share, and 10,000,000 shares of preferred stock, par value $0.001 per share.

Common Stock

Outstanding Shares

The holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of the stockholders. The holders of our common stock do not have any cumulative voting rights. Holders of our common stock are entitled to receive ratably any dividends declared by the board of directors out of funds legally available for that purpose, subject to any preferential dividend rights of any outstanding preferred stock.

Voting Rights

Each holder of common stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders. The affirmative vote of holders of at least 66 2/3% of the voting power of all of the then-outstanding shares of capital stock, voting as a single class, will be required to amend certain provisions of our certificate of incorporation, including provisions relating to amending our bylaws, the classified board, the size of our board, removal of directors, director liability, vacancies on our board, special meetings, stockholder notices, actions by written consent and exclusive jurisdiction, provided, however, that this restriction shall not apply to, and such 66 2/3% vote shall not be required for, any such amendment, change or repeal approved by the affirmative vote of at least a majority of the then current duly elected board of directors, in which case such action shall require only the vote of stockholders as required under Delaware law.

Dividends

Subject to preferences that may apply to any outstanding preferred stock, holders of our common stock are entitled to receive ratably any dividends that our board of directors may declare out of funds legally available for that purpose on a non-cumulative basis.

Liquidation

In the event of our liquidation, dissolution or winding up, holders of our common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities, subject to the satisfaction of any liquidation preference granted to the holders of any outstanding shares of preferred stock.

Rights and Preferences

Holders of our common stock have no preemptive, conversion or subscription rights, and there are no redemption or sinking fund provisions applicable to our common stock. The rights, preferences and privileges of the holders of our common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of our preferred stock that we may designate and issue in the future.

Preferred Stock

Our board of directors has the authority, without further action by the stockholders, to issue up to 10,000,000 shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each such series, to fix the rights, preferences and privileges of the shares of each wholly unissued series and any qualifications, limitations or restrictions thereon and to increase or decrease the number of shares of any such series, but not below the number of shares of such series then outstanding.

Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of the common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring or preventing a change in our control that may otherwise benefit holders of our common stock and may adversely affect the market price of the common stock and the voting and other rights of the holders of common stock.

Classified Board

Our certificate of incorporation provides that our board of directors is divided into three classes of directors, with the classes as nearly equal in number as possible. As a result, approximately one-third of our board of directors will be elected each year. The classification of directors has the effect of making it more difficult for stockholders to change the composition of our board. Our certificate of incorporation also provides that, subject to any rights of holders of preferred stock to elect additional directors under specified circumstances, the number of directors will be fixed exclusively pursuant to a resolution adopted by our board of directors.

Action by Written Consent; Special Meetings of Stockholders

Our certificate of incorporation provides that stockholder action can be taken only at an annual or special meeting of stockholders and cannot be taken by written consent in lieu of a meeting. Our certificate of incorporation and bylaws also provide that, except as otherwise required by law, special meetings of the stockholders can be called only by or at the direction of the board of directors pursuant to a resolution adopted by a majority of the total number of directors. Stockholders are not permitted to call a special meeting or to require the board of directors to call a special meeting.

Removal of Directors

Our certificate of incorporation provides that our directors may be removed only for cause by the affirmative vote of at least 66 2/3% of the votes that all our stockholders would be entitled to cast in an annual election of directors, voting together as a single class, at a meeting of the stockholders called for that purpose.

Advance Notice Procedures

Our bylaws establish an advance notice procedure for stockholder proposals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to the board of directors. Stockholders at an annual meeting are only able to consider proposals or nominations specified in the notice of meeting or brought before the meeting by or at the direction of the board of directors or by a stockholder who was a stockholder of record on the record date for the meeting, who is entitled to vote at the meeting and who has given our secretary timely written notice, in proper form, of the stockholder’s intention to bring that business before the meeting.

Super Majority Approval Requirements

The Delaware General Corporation Law generally provides that the affirmative vote of a majority of the shares entitled to vote on any matter is required to amend a corporation's certificate of incorporation or bylaws, unless either a corporation's certificate of incorporation or bylaws requires a greater percentage. A majority vote of our board of directors or the affirmative vote of holders of at least 66 2/3% of the total votes of the outstanding shares of our capital stock entitled to vote with respect thereto, voting together as a single class, is required to amend, alter, change or repeal the bylaws. In addition, the affirmative vote of the holders of at least 66 2/3% of the total votes of the outstanding shares of our capital stock entitled to vote with respect thereto, voting together as a single class, is required to amend, alter, change or repeal, or to adopt any provisions inconsistent with, any of the provisions in our certificate of incorporation relating to amendments to our certificate of incorporation and bylaws and as described under "Action by Written Consent; Special Meetings of Stockholders", "Classified Board" and "Removal of Directors" above.

Authorized but Unissued Shares

Our authorized but unissued shares of common stock and preferred stock will be available for future issuance without stockholder approval. These additional shares may be utilized for a variety of corporate purposes, including future public offerings to raise additional capital and corporate acquisitions.

Exclusive Forum

Our certificate of incorporation provides that, subject to limited exceptions, the state or federal courts located in the State of Delaware will be the sole and exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, (iii) any action asserting a claim against us arising pursuant to any provision of the Delaware General Corporation Law, our certificate of incorporation or our bylaws, or (iv) any other action asserting a claim against us that is governed by the internal affairs doctrine. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of our certificate of incorporation described above.

Section 203 of the Delaware General Corporation Law

We are subject to the provisions of Section 203 of the Delaware General Corporation Law, or Section 203. In general, Section 203 prohibits a publicly-held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a three-year period following the time that this stockholder becomes an interested stockholder, unless the business combination is approved in a prescribed manner. A "business combination" includes, among other things, a merger, asset or stock sale or other transaction resulting in a financial benefit to the interested stockholder. An "interested stockholder" is a person who, together with affiliates and associates, owns, or did own within three years prior to the determination of interested stockholder status, 15% or more of the corporation's voting stock.

Under Section 203, a business combination between a corporation and an interested stockholder is prohibited unless it satisfies one of the following conditions: before the stockholder became interested, the board of directors approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder; upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 75% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding, shares owned by persons who are directors and also officers, and employee stock plans, in some instances; or at or after the time the stockholder became interested, the business combination was approved by the board of directors of the corporation and authorized at an annual or special meeting of the stockholders by the affirmative vote of at least two-thirds of the outstanding voting stock which is not owned by the interested stockholder.

A Delaware corporation may "opt out" of these provisions with an express provision in its original certificate of incorporation or an express provision in its certificate of incorporation or bylaws resulting from a stockholders' amendment approved by at least a majority of the outstanding voting shares. We have not opted out of these provisions. As a result, mergers or other takeover or change in control attempts of us may be discouraged or prevented.

EXHIBIT 10.14

AQUESTIVE THERAPEUTICS, INC.

EMPLOYEE STOCK PURCHASE PLAN

Adopted by the Board of Directors effective as of January 1, 2019
Approved by the Stockholders June 13, 2019

Amended by the Board of Directors on December 5, 2019 effective for the first offering Period Commencing on or after January 2, 2020

AQUESTIVE THERAPEUTICS, INC.
EMPLOYEE STOCK PURCHASE PLAN

SECTION 1. PURPOSE OF THE PLAN.

The Aquestive Therapeutics, Inc. Employee Stock Purchase Plan (the "**Plan**") is intended to provide Eligible Employees (as defined below) the opportunity to increase their proprietary interest in Aquestive Therapeutics, Inc. (the "**Company**") by conveniently purchasing shares of the Company's common stock, par value $0.001 per share (the "**Stock**"). The Plan is composed of two components: a 423 Component and a Non-423 Component. The 423 Component is intended to qualify under Section 423 of the Internal Revenue Code of 1986, as amended (the "**Code**"). Accordingly, the provisions of the 423 Component will be construed in a manner consistent with the requirements of Section 423 of the Code. The Plan also authorizes participation in the Plan under the Non-423 Component under terms that do not meet the requirements of Section 423 of the Code. The Company shall be permitted to grant rights to purchase Stock under separate offerings not having identical terms (provided that such terms are not inconsistent with the terms of the Plan and, with respect to an offering under the 423 Component, the requirements of Section 423 of the Code), and offerings may run concurrently (in whole or in part) with each other. Each offering under the Non-423 Component shall be separate and distinct from (and shall not be included in or be part of) any offering under the 423 Component, and each offering to a Participating Company shall be treated as an offering that is separate from any other offering made to another Participating Company, in each case, even if such offerings are running concurrently (in whole or in part) and/or have common terms and conditions.

SECTION 2. DEFINITIONS.

(a) "**423 Component**" means the portion of the Plan under which any right to purchase Stock shall be granted in a manner that is intended to satisfy the requirements of Section 423 of the Code.

(b) "**Affiliate**" means any branch or representative office or other disregarded entity of the Company or a Subsidiary, as determined by the Committee, whether now or hereafter existing.

(c) "**Board**" means the Board of Directors of the Company, as constituted from time to time.

(d) "**Change in Control**" shall have the meaning set forth in the Company's most recently adopted equity incentive plan, as in effect from time to time (and shall include a "Change of Control" as defined in any such plan); provided, that until the Aquestive Therapeutics, Inc. 2018 Equity Incentive Plan is replaced with a successor plan that includes a definition of Change in Control or Change of Control, Change in Control shall mean an event described in Sections 2.S(a) through 2.S(d) of the Aquestive Therapeutics, Inc. 2018 Equity Incentive Plan.

(e) **"Committee"** means the duly constituted committee appointed by the Board to administer the Plan, as described in Section 3. If no such committee is appointed, the Compensation Committee of the Board shall be the Committee.

(f) **"Compensation"** means all of an Eligible Employee's base salary or wages. "Compensation" shall exclude (i) commissions, bonuses and special incentive payments, (ii) equity compensation and income attributable to equity-based awards (including, without limitation, amounts realized from the exercise of any stock option and any dividends paid with respect to equity awards), (iii) all non-cash items, (iv) pre-tax contributions made by the Participant under Sections 401(k) or 125 of the Code or under any similar arrangements available under laws outside the United States and (v) allowances and other miscellaneous payments, including, without limitation, moving or relocation allowances, cost-of-living equalization payments, car allowances, tuition reimbursements, imputed income attributable to cars or life insurance, severance pay, fringe benefits, and benefits received under employee benefit plans. The Committee shall determine whether a particular item not listed in this Section 2(f) is included in Compensation.

(g) **"Effective Date"** means the date as of which the Plan is adopted by the Board, subject to approval of the Plan by the stockholders of the Company.

(h) **"Eligible Employee"** means any individual who (i) is an Employee of a Participating Company, (ii) does not own 5% or more of the total combined voting power or value of all classes of stock of the Company or any Parent or Subsidiary, including, for purposes of this provision, through application of the rules of Section 424(d) of the Code and (iii) is not a "highly compensated employee" (within the meaning of Section 414(q) of the Code) that is subject to Section 16 of the Securities Exchange Act of 1934, as amended. The foregoing notwithstanding, an individual who is a citizen or resident of a jurisdiction other than the United States (even if he or she is also a citizen of the United States or a resident alien) shall not be considered an Eligible Employee if, as determined in the sole discretion of the Committee, (i) his or her participation in the Plan is prohibited by the laws or regulations of any country which has jurisdiction over him or her or (ii) compliance with the laws and regulations of the foreign country that has jurisdiction over him or her would cause the Plan or an offering under the 423 Component to violate Section 423 of the Code.

(i) "**Employee**" means an individual who is a common-law employee of a Participating Company and, if such employee is employed in the United States, whose earnings are reported on a Form W-2. For the avoidance of doubt, the term "Employee" shall not include any consultant, independent contractor or non-employee director of a Participating Company.

G) **"Fair Market Value"** means, on any given date (i) if the Stock is listed on any established U.S. stock exchange or a U.S. national market system, the closing sales price for such Stock (or, if no closing sales price was reported on that date, as applicable, on the last preceding trading date such closing sales price was reported) as quoted on such exchange or system on the day of determination, as reported in *The Wall Street Journal* or such other source as the Committee deems reliable; (ii) if (i) does not apply, then if the Stock is regularly quoted by a recognized U.S. securities dealer but selling prices are not reported, the mean between the high bid and low asked prices for the Stock on the day of determination (or, if no bids and asks were reported on that date, as applicable, on the last preceding trading date such bids and asks were reported); or (iii) if (i) and (ii) do not apply, such value as the Committee in its discretion may in good faith determine in accordance with Section 423 of the Code.

(k) **"Non-423 Component"** means the portion of the Plan under which the right to purchase Stock may be granted in a manner that is not intended to satisfy the requirements of Section 423 of the Code.

(1) **"Offering Period"** means a period with respect to which the right to purchase Stock may be granted under the Plan, as determined pursuant to Section 4(a).

(m) **"Parent"** has the meaning given to such term under U.S. Treasury Regulation Section 1.424-l(f). As used in this Plan, "Parent" shall mean a Parent of the Company.

(n) **"Participant"** means an Eligible Employee who elects to participate in the Plan, as provided in Section 4(b).

(o) **"Participating423 Company"** means any of the following that is designated by the Committee as participating in the 423 Component: (i) the Company, (ii) any present or future Parent or (iii) any present or future Subsidiary.

(p) **"Participating Company"** means each Participating 423 Company and Participating Non-423 Company.

(q) **"Participating Non-423 Company"** means any of the following that is designated by the Committee as participating in the Non-423 Component: (i) the Company, (ii) any present or future Parent, (iii) any present or future Subsidiary or (iv) any present or future Affiliate. Unless determined otherwise by the Committee, only entities incorporated or formed outside of the United States shall be Participating Non-423 Companies.

(r) **"Plan Account"** means the account established for each Participant pursuant to Section 8(a).

(s) **"Purchase Price"** means the price at which Participants may purchase Stock under the Plan, as determined pursuant to Section 8(b).

(t) **"Subsidiary"** means a subsidiary corporation of the Company as that term is defined in Section 424(f) of the Code.

(u) **"Trading Day"** means any day on which the U.S. stock exchange upon which the Stock is listed is open for trading or, if the Stock is not listed on an established U.S. stock exchange or U.S. national market system, a business day, as determined by the Committee in good faith.

SECTION 3. ADMINISTRATION OF THE PLAN.

(a) **General.** The Plan shall be administered by the Committee. To the extent permitted by applicable law, the Committee may delegate some or all of its authority with respect to the Plan to any executive officer of the Company or any other person or persons designated by the Committee, in each case, acting individually or as a committee.

(b) **Committee Authorities.** The Committee shall have the exclusive power and authority to administer the Plan, including without limitation the right and power to interpret the provisions of the Plan and make all determinations deemed necessary or advisable for the administration of the Plan (including, without limitation, a determination as to whether a Change in Control has occurred, whether to designate the Company, a Parent or Subsidiary as a Participating 423 Company or as a Participating Non-423 Company and whether to establish separate offerings). All such actions, interpretations and determinations which are done or made by the Committee shall be final, conclusive and binding on the Company, the Participating Companies, the Participants and all other parties and shall not subject the Committee (or its members) to any liability.

SECTION 4. ENROLLMENT AND PARTICIPATION.

(a) **Offering Periods.** Two Offering Periods shall commence in each calendar year, which shall be the periods commencing on January 1 and ending on June 30 and commencing on July 1 and ending on December 31; provided, however, that the first Offering Period may commence on a different date as determined by the Committee, but shall end on June 30 of the year commenced if commenced prior to June 30 or on December 31 of the year commenced if commenced after June 30.

(b) **Enrollment.** Any individual who, on the day preceding the first day of an Offering Period, qualifies as an Eligible Employee may elect to become a Participant in the Plan for such Offering Period by executing the enrollment form prescribed for this purpose by the Committee. The enrollment form shall be filed with the Company or its designee according to procedures established by the Committee.

(c) **Duration of Participation.** Once enrolled in the Plan, a Participant shall continue to participate in the Plan (according to the elections made on the Participant's most recently-filed enrollment form) until he or she ceases to be an Eligible Employee, withdraws from the Plan under Section 6(a) or reaches the end of the Offering Period in which his or her contributions were discontinued under Section S(c) or Section 9(b). A Participant who discontinued his or her contributions under Section S(c) or withdrew from the Plan under Section 6(a) may again become a Participant, if he or she then is an Eligible Employee, by following the procedure described in Section 4(b). A Participant whose employee contributions were discontinued automatically under Section 9(b) shall automatically resume participation at the beginning of the next Offering Period in which such Participant's participation would not be limited by Section 9(b), if he or she then is an Eligible Employee.

SECTIONS. EMPLOYEE CONTRIBUTIONS.

(a) **Frequency of Employee Contributions.** A Participant may make contributions to the Plan for purchasing shares of Stock by means of payroll deductions (unless payroll deductions are not permitted under applicable laws or regulations or unless the Company determines that another means of making employee contributions is necessary or appropriate for legal or administrative reasons).

(b) **Amount of Employee Contributions.** An Eligible Employee shall designate on the enrollment form the portion of his or her Compensation that he or she elects to contribute to the Plan with respect to the applicable Offering Period. Such portion shall be a whole percentage of the Eligible Employee's Compensation, on an after-tax basis, but not less than 1% nor more than 25% of the Eligible Employee's Compensation with respect to the applicable Offering Period. A Participant may not change the rate of his or her contributions during an Offering Period unless the Participant seeks (i) to discontinue contributions under Subsection (c) or (ii) to withdraw from the Plan under Section 6(a), and, in either such case, the Company will cease contributions on behalf of the Participant as soon as reasonably practicable (which shall not be until the payroll period following receipt of the applicable form or later).

(c) **Discontinuing Employee Contributions.** A Participant may discontinue contributions by filing a new enrollment form. Any contributions made from payroll shall cease as soon as reasonably practicable (which shall not be until the payroll period following receipt or later). A Participant who has discontinued employee contributions may not resume such contributions until the next Offering Period. If a Participant discontinues contributions , previously made contributions shall remain in the Participant's Plan Account (and will be used to purchase shares) unless and until the Participant withdraws from the Plan in accordance with the provisions of Section 6.

SECTION 6. WITHDRAWAL FROM THE PLAN.

(a) **Withdrawal.** A Participant may elect to withdraw from the Plan by filing the prescribed form with the Company or its designee at any time before the last day of an Offering Period. As soon as reasonably practicable thereafter, contributions shall cease and all employee contributions made by the Participant for the current Offering Period shall be refunded to the Participant in cash, without interest. No partial withdrawals shall be permitted.

(b) **Re-enrollment After Withdrawal.** A former Participant who has withdrawn from the Plan shall not be a Participant until he or she re-enrolls in the Plan under Section 4(b). Re-enrollment shall be effective only at the commencement of an Offering Period.

SECTION 7. CHANGE IN EMPLOYMENT STATUS.

(a) **Termination of Employment.** Termination of employment with a Participating Company, or otherwise ceasing to be an Eligible Employee, for any reason, including death, shall be treated as an automatic withdrawal from the Plan under Section 6(a), unless, with respect to an offering under the Non-423 Component, otherwise required by applicable laws or regulations. A transfer from one Participating Company to another shall not be treated as a termination of employment.

(b) **Leave of Absence.** For purposes of the Plan, employment shall not be deemed to terminate when the Participant goes on a military leave, a sick leave or another *bona fide* leave of absence, if the leave was approved by a Participating Company in writing or if such leave of absence is protected under applicable laws or regulations. Employment shall be deemed to terminate in any event when the approved leave ends, unless the Participant immediately returns to work.

(c) **Death.** In the event of the Participant's death, any amounts then held in the Participant's Plan Account and any shares of Stock then held in the Participant's name by the Company or the broker designated by the Company shall be paid or transferred to the Participant's estate or as otherwise required by applicable laws of descent and distribution, or as may be otherwise provided pursuant to Section 8(e).

SECTIONS. PLAN ACCOUNTS AND PURCHASE OF SHARES.

(a) **Plan Accounts.** The Company shall maintain a Plan Account on its books in the name of each Participant. Whenever an amount is contributed to the Plan, such amount shall be credited to the Participant's Plan Account. Amounts credited to Plan Accounts shall not be trust funds and may be commingled with the general assets of the Company or any Parent or Subsidiary and applied to general corporate purposes, unless otherwise required by applicable law or regulation. Unless required by applicable law or regulation, no interest will be paid or credited with respect to any amounts held in a Participant's Plan Account.

(b) **Purchase Price.** The Purchase Price for each share of Stock purchased at the close of an Offering Period shall be the lesser of:

(i) 85% of the Fair Market Value of such share on the last Trading Day of such Offering Period; or

(ii) 85% of the Fair Market Value of such share on the first Trading Day of such Offering Period.

The Committee may round the Purchase Price up (but not down) to a whole cent, and in no event shall the Purchase Price be less than the par value of the shares of Stock being purchased.

(c) **Number of Shares Purchased.** As of the last day of each Offering Period, each Participant shall be deemed to have elected to purchase the number of shares of Stock calculated in accordance with this Subsection (c), unless the Participant has withdrawn from the Plan under Section 6(a) or Section 7. The amount then in the Participant's Plan Account shall be divided by the Purchase Price, and the number of shares that results shall be purchased with the funds in the Participant's Plan Account. The foregoing notwithstanding, no Participant shall purchase more than 500 shares of Stock (subject to adjustment pursuant to Section 14(b)) with respect to any Offering Period (or, if the Board determines that a different number of Offering Periods shall commence in each calendar year in accordance with Section 4(a), a proportionate number of shares of Stock (subject to adjustment pursuant to Section 14(b)) with respect to any Offering Period) nor more than the amounts of Stock set forth in Sections 9(b) and 14(a). Unless otherwise determined by the Committee, any fractional share, as calculated under this Subsection (c), shall be rounded down to the next lower whole share, with the Purchase Price for such fractional share to be carried over to the next Offering Period as provided in Section 8(g). To the extent permitted by law, the Committee may adjust the individual share limit set forth in this Section 8(c) from time to time without shareholder approval, provided that any such change shall not apply until the Offering Period commencing after such change is made.

(d) **Available Shares Insufficient.** In the event that the aggregate number of shares of Stock that all Participants elect to purchase during an Offering Period exceeds the maximum number of shares of Stock remaining available for issuance under Section 14(a), then the number of shares of Stock each Participant shall purchase shall be determined by multiplying the number of shares of Stock available for issuance by a fraction, the numerator of which is the number of shares of Stock that such Participant has elected to purchase and the denominator of which is the number of shares of Stock that all Participants have elected to purchase.

(e) **Issuance of Shares.** Shares of Stock shall be issued either in book entry form or in certificates. Certificates, if any, representing the shares of Stock purchased by a Participant under the Plan shall be issued to the Participant, or book entry in the Participant's name shall be made, as soon as reasonably practicable after the close of the applicable Offering Period, except that the Committee may determine that such certificates shall be held for each Participant's benefit by a broker designated by the Committee. Shares may be registered in the name of the Participant or jointly in the name of the Participant and his or her spouse as joint tenants with right of survivorship or as community property or in such other manner of taking title as may be permitted under applicable law or regulation; provided, however, that unless otherwise required by applicable law or specified by the Participant in writing, shares of Stock purchased under the Plan will be registered in the name of the Participant.

(f) **Transfer of Shares.** If certificates representing shares of Stock are not otherwise issued to the Participant in connection with the purchase of such shares at the end of an Offering Period, a Participant may elect to transfer any number of shares of Stock previously purchased under the Plan by providing notification and transfer instructions to Company or the broker designated by the Company, in accordance with procedures established under the Plan. As soon as administratively practicable following receipt of a Participant's election to transfer shares of Stock, the Company or the designated broker shall cause a transfer of the shares or a certificate representing the number of shares to be transferred to be delivered to the Participant or a broker designated by the Participant.

(g) **Unused Cash Balances.** Any amount remaining in the Participant' s Plan Account that represents the Purchase Price for shares that could not be purchased by reason of Subsection (c) above, Section 9(b) or Section 14(a) or otherwise shall be carried forward and applied toward the purchase of whole shares for the next following Offering Period, subject to earlier withdrawal by the Participant in accordance with Section 6 or termination of employment or cessation as an Eligible Employee in accordance with Section 7.

SECTION 9. LIMITATIONS ON STOCK OWNERSHIP.

(a) **Five Percent Limit.** Any other provision of the Plan notwithstanding, no Participant shall be granted a right to purchase Stock under the Plan if such Participant, immediately after his or her election to purchase such Stock, would own stock possessing 5% or more of the total combined voting power or value of all classes of stock of the Company or any Parent or Subsidiary. For purposes of this Subsection (a), the following rules shall apply:

(i) the attribution rules of Section 424(d) of the Code shall be applied in determining ownership of Stock;

(ii) each Participant shall be deemed to own any stock that he or she has a right or option to purchase under this Plan or any other plan or arrangement; and

(iii) each Participant shall be deemed to have the right to purchase under this Plan with respect to each Offering Period 500 shares of Stock (as adjusted pursuant to Section 8(c)), subject to adjustment pursuant to Section 14(b).

(b) **Dollar Limit.** Any other provision of the Plan notwithstanding, consistent with Treasury Regulation Section l.423-2(i), no Participant shall purchase Stock under this Plan and all other employee stock purchase plans of the Company or any Parent or Subsidiary at a rate that exceeds $25,000 in fair market value of the Stock (determined at the time the option is granted) for each calendar year in which any option granted to the Participant is outstanding at anytime.

For purposes of this Subsection (b), the Fair Market Value of Stock shall be determined as of the beginning of the Offering Period in which such Stock is purchased. Employee stock purchase plans not described in Section 423 of the Code shall be disregarded. If a Participant is precluded by this Subsection (b) from purchasing additional Stock under the Plan, then his or her employee contributions shall automatically be discontinued, and shall resume (in accordance with the Participant ' s most recently-filed enrollment form) at the beginning of the earliest Offering Period in which this Section 9(b) would not prohibit such participation, provided that he or she then is an Eligible Employee.

SECTION 10. RIGHTS NOT TRANSFERABLE.

The rights of any Participant under the Plan, or the interest in any Stock or moneys to which any Participant may be entitled under the Plan, shall not be transferable by voluntary or involuntary assignment or by operation of law, or in any manner other than by beneficiary designation or the laws of descent and distribution. If a Participant attempts to transfer, assign or otherwise encumber his or her rights or interest under the Plan, other than as permitted by this Section 10, such act shall be treated as an election by the Participant to withdraw from the Plan under Section 6(a).

SECTION 11. NO RIGHTS AS AN EMPLOYEE.

Nothing in the Plan or in any right granted under the Plan shall confer upon the Participant any right to continue in the employ of a Participating Company for any period of specific duration or interfere with or otherwise restrict in any way the rights of the Participating Companies or of the Participant, which rights are hereby expressly reserved by each, to terminate his or her employment at any time and for any reason, with or without cause, to the fullest extent permitted by applicable laws or regulations.

SECTION 12. NO RIGHTS AS A STOCKHOLDER.

A Participant shall have no rights as a stockholder with respect to any shares of Stock that he or she may have a right to purchase under the Plan until such shares have been purchased on the last day of the applicable Offering Period.

SECTION 13. SECURITIES LAW REQUIREMENTS.

Shares of Stock shall not be issued under the Plan unless the issuance and delivery of such shares comply with (or are exempt from) all applicable requirements of law, including, without limitation, the U.S. Securities Act of 1933, as amended, the rules and regulations promulgated thereunder, all state securities laws and regulations, any applicable non-U.S. securities laws and regulations, and the regulations of any stock exchange or other securities market on which the Company's securities are then traded.

SECTION 14. STOCK OFFERED UNDER THE PLAN.

(a) **Authorized Shares.** The aggregate number of shares of Stock available for purchase under the Plan as of the Effective Date shall be 250,000, and on January 1st of each year during which the Plan is in effect, the number of shares available for purchase under the Plan shall be increased by the lesser of (x) 1.0% of the number of shares of Stock outstanding as of the immediately preceding December 31 (calculated on a fully diluted basis), (y) 50,000 shares of Stock and (z) such lesser number of shares of Stock as the Board may determine, in each case, as subject to adjustment as provided in this Section 14. Shares of Stock issued under the Plan may be shares already outstanding or newly issued or treasury shares.

(b) **Changes in Capitalization.** In the event of a reorganization, recapitalization, stock split, spin-off, split-off, split-up, stock or extraordinary cash dividend or other distribution, combination of shares, merger, amalgamation, consolidation or any other change in the corporate structure of the Company, or a sale by the Company of all or part of its assets, the Committee shall make such adjustments to the aggregate number of shares of Stock offered under the Plan, the maximum annual increase number in clause (y) of Section 14(a), the share limitation described in Section 8(c) (and the corresponding number of shares specified in clause (iii) of Section 9(a)) and/or the price of shares that any Participant has elected to purchase under the Plan as may be necessary to prevent the dilution or enlargement of Participants' rights. The Plan shall in no event be construed to restrict in any way the Company's right to undertake a dissolution, liquidation, merger, amalgamation, consolidation or other reorganization or corporate transaction of any kind or type.

(c) **Change in Control.** Any other prov1s10n of the Plan notwithstanding, immediately prior to the effective time of a Change in Control, the Plan shall terminate and shares shall be purchased pursuant to Section 8 as if the Offering Period during which such Change in Control occurs was scheduled to end on the day immediately preceding such Change in Control, unless the Plan is expressly assumed by the surviving corporation, the buyer or an affiliate of the foregoing. In addition, in anticipation of a Change in Control, the Committee may take any action under the Plan as it deems necessary or appropriate, including, without limitation, terminating the Plan and preventing Participants from continuing or increasing their contributions to the Plan.

SECTION 15. WITHHOLDING

To the extent any payments or distributions under the Plan are determined by any Participating Company to be subject to U.S. Federal, state or local taxes, or the taxes of a jurisdiction other than the United States, the Participating Company is authorized (but not obligated) to withhold any required taxes. The Participating Company may satisfy any withholding obligation by (i) withholding shares of Stock purchased under the Plan; (ii) withholding from the proceeds from the sale of shares of Stock purchased under the Plan, either through a voluntary sale or through a mandatory sale arranged by the Company; (iii) deducting cash from a Participant's Plan Account; (iv) deducting cash from a Participant's other cash compensation payable to him or her by any Participating Company or (v) any other method deemed appropriate by the Participating Company, in each case, as approved by the Committee. A Participant's election to participate in the Plan authorizes any Participating Company to take any of the actions described in the preceding sentence.

SECTION 16. GOVERNING LAW

To the extent that U.S. Federal laws do not otherwise control, the validity and construction of the Plan shall be construed and enforced in accordance with the laws of the State of Delaware, without giving effect to the choice of law principles thereof.

SECTION 17. NON-423 COMPONENT AND SUB-PLANS

The Board and/or the Committee may adopt procedures and sub-plans to this Plan that are necessary or appropriate to permit or facilitate participation in the Plan by Eligible Employees who are employed or located in a jurisdiction other than the United States or to generally operate the Plan in jurisdictions outside the United States (provided that such would not result in (i) the Plan failing to be eligible to qualify under Section 423 of the Code or (ii) any offering under the 423 Component not complying with Section 423 of the Code). Without limiting the generality of, but consistent with, the foregoing, the Board and/or the Committee are expressly authorized to adopt rules, procedures, and sub-plans, which, for purposes of the Non-423 Component, may be beyond the scope of Section 423 of the Code, regarding, without limitation, eligibility to participate in the Plan, excluding Employees in certain countries under the Non-423 Component (even if employed by a Participating Company), handling and making of employee contributions under the Plan, satisfying payroll taxes, determining beneficiaries, withholding procedures and issuances of Stock, any of which may vary from time to time and between jurisdictions, as determined by the Board and/or the Committee.

SECTION 18. TAX QUALIFICATION.

The 423 Component is intended to be exempt from the application of Section 409A of the Code under Section l.409A-l(b)(5)(ii) of the U.S. Treasury Regulations. Purchases of stock by Participants who are U.S. taxpayers participating in the Non-423 Component are intended to be exempt from the application of Section 409A of the Code under the short-term deferral exception and any ambiguities will be construed and interpreted in accordance with such intent. Subject to the provisions of this Section 18, Participants who are U.S. taxpayers participating in the Non-423 Component shall be subject to such terms and conditions as shall permit his or her participation in the Plan to satisfy the requirements of the short-term deferral exception to Section 409A of the Code, including the requirement that the shares subject to the right to purchase Stock under the Plan be delivered within the short-term deferral period. The foregoing notwithstanding, neither the Company nor any Parent or Subsidiary shall have any liability to a Participant or any other person if the right to purchase Stock under the Plan that is intended to be exempt from or compliant with Section 409A of the Code is not so exempt or compliant or for any action taken by the Committee, the Board, the Company or any Parent or Subsidiary in relation thereto. Although the Company may endeavor to (i) qualify the 423 Component or Non- 423 Component for special tax treatment under the laws and regulations of the United States or of a jurisdiction other than the United States or (ii) avoid adverse tax treatment (e.g., under Section 409A of the Code), the Company makes no representation to that effect and expressly disavows any covenant to maintain special or to avoid unfavorable tax treatment, any other provision of the Plan notwithstanding, including this Section 18. The Company and each Parent and Subsidiary shall be unconstrained in their corporate activities without regard to any potentially negative tax impact on any one or more Participants.

SECTION 19. SEVERABILITY.

If any particular provision of the Plan is found to be invalid or otherwise unenforceable, such provision shall not affect the other provisions of the Plan, and the Plan shall be construed in all respects as if such invalid provision were omitted.

SECTION 20. AMENDMENT AND TERMINATION.

The Board shall have the right to amend, suspend or terminate the Plan, and to shorten an Offering Period (and refund Participant contributions in the event of any such shortening, suspension or termination) at any time and without notice. Except as provided in Section 14, any increase in the aggregate number of shares of Stock to be issued under the Plan shall be subject to approval by a vote of the stockholders of the Company. In addition, any other amendment of the Plan shall be subject to approval by a vote of the stockholders of the Company to the extent required by applicable law, rule or regulation, including, without limitation, Section 423 of the Code.

[End of Document]

Exhibit 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 statement (No. 333-226399) on Form S-8 and (No. 333-233716) on Form S-3 of Aquestive Therapeutics, Inc. and subsidiaries (the Company) of our report dated March 11, 2020, with respect to the consolidated balance sheets of the Company as of December 31, 2018 and 2019, the related consolidated statements of operations and comprehensive loss, stockholders' deficit, and cash flows for each of the years in the two-year period ended December 31, 2019, and the related notes (collectively, the consolidated financial statements), which report appears in the December 31, 2019 annual report on Form 10-K of the Company.

Our report refers to a change in the method of accounting for revenue from contracts with customers as of January 1, 2019 due to the adoption of Accounting Standards Codification, *Revenue from Contracts with Customers*.

/s/ KPMG LLP

New York, New York
March 11, 2020

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 11, 2020

/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, John T. Maxwell, 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 11, 2020

/s/ JOHN T. MAXWELL
John T. Maxwell
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, 2019, 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 11, 2020

/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, John T. Maxwell, 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, 2019, 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 11, 2020

/s/ JOHN T. MAXWELL
John T. Maxwell
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.