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

FORM 10-K

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

For the Fiscal Year Ended December 31, 2018

Or

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

For the Transition Period from_____ to _____.

Commission File Number 001-38114

AVENUE THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**47-4113275**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

2 Gansevoort Street, 9th Floor, New York NY 10014
(Address of principal executive offices and zip code)

(781) 652-4500
(Registrant's telephone number, including area code)

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

(Title of Class)	**(Name of exchange on which registered)**
Common Stock, par value $0.0001 per share	**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 every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

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

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

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

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

The aggregate market value of the voting stock held by non-affiliates of the registrant the last business day of the registrant's most recently completed second fiscal quarter: $22,950,453 based upon the closing sale price of our common stock of $3.58 on that date. Common stock held by each officer and director and by each person known to own in excess of 5% of outstanding shares of our common stock has been excluded in that such persons may be deemed to be affiliates. The determination of affiliate status in not necessarily a conclusive determination for other purposes.

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of the latest practicable date.

Class of Common Stock	Outstanding Shares as of February 08, 2019
Common Stock, $0.0001 par value	16,502,310

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement for its 2019 Annual Meeting of Stockholders are incorporated by reference in Part III of this Annual Report on Form 10-K.

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SPECIAL CAUTIONARY NOTICE REGARDING FORWARD-LOOKING STATEMENTS

Certain matters discussed in this report may constitute forward-looking statements for purposes of the Securities Act of 1933, as amended (the "Securities Act") and the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from the future results, performance or achievements expressed or implied by such forward-looking statements. The words "anticipate," "believe," "estimate," "may," "expect" and similar expressions are generally intended to identify forward-looking statements. Our actual results may differ materially from the results anticipated in these forward-looking statements due to a variety of factors, including, without limitation, those discussed under the captions "Risk Factors," and elsewhere in this report. All written or oral forward-looking statements attributable to us are expressly qualified in their entirety by these cautionary statements. Such forward-looking statements include, but are not limited to, statements about our:

- expectations for increases or decreases in expenses;
- expectations for the clinical and pre-clinical development, manufacturing, regulatory approval, and commercialization of our pharmaceutical product candidates or any other products we may acquire or in-license;
- our use of clinical research centers and other contractors;
- expectations for incurring capital expenditures to expand our research and development and manufacturing capabilities;
- expectations for generating revenue or becoming profitable on a sustained basis;
- expectations or ability to enter into marketing and other partnership agreements;
- expectations or ability to enter into product acquisition and in-licensing transactions;
- expectations or ability to build our own commercial infrastructure to manufacture, market and sell our product candidates;
- acceptance of our products by doctors, patients or payors;
- our ability to compete against other companies and research institutions;
- our ability to secure adequate protection for our intellectual property;
- our ability to attract and retain key personnel;
- availability of reimbursement for our products;
- estimates of the sufficiency of our existing cash and cash equivalents and investments to finance our operating requirements, including expectations regarding the value and liquidity of our investments;
- the volatility of our stock price;
- expected losses; and
- expectations for future capital requirements.

The forward-looking statements contained in this report reflect our views and assumptions as of the effective date of this report. Except as required by law, we assume no responsibility for updating any forward-looking statements.

We qualify all of our forward-looking statements by these cautionary statements.

PART I

Item 1. Business

OVERVIEW

We are a specialty pharmaceutical company that seeks to acquire, license, develop and commercialize products principally for use in the acute/intensive care hospital setting. Our current product candidate is intravenous (IV) Tramadol, for the treatment of moderate to moderately severe post-operative pain. In 2016, we completed a pharmacokinetic (PK) study for IV Tramadol in healthy volunteers as well as an end of phase 2 (EOP2) meeting with the U.S. Food and Drug Administration (FDA). In the third quarter of 2017, we initiated a Phase 3 development program of IV Tramadol for the management of post-operative pain. Under the terms of certain agreements described herein, we have an exclusive license to develop and commercialize IV Tramadol in the United States. To date, we have not received approval for the sale of our product candidate in any market and, therefore, have not generated any sales revenue from our product candidates.

On June 26, 2017, we completed an initial public offering (IPO) of our common stock, resulting in net proceeds of approximately $34.2 million after deducting underwriting discounts, and other offering costs.

We have used the proceeds from our IPO to initiate our first Phase 3 trial of IV Tramadol in patients with moderate-to-severe pain following bunionectomy, which had its first patient dosed in September 2017. In May 2018, we announced the study met its primary endpoint and all key secondary endpoints.

Further, in December 2018, we initiated the second Phase 3 trial in patients with moderate-to-severe pain following abdominoplasty upon successful completion of the bunionectomy study. Based on the enrollment pace of similar studies, we anticipate that we will have topline data from this second Phase 3 trial as early as mid-2019.

In December 2017, we initiated an open-label safety study, which will run concurrently with the two Phase 3 trials.

If these studies meet their primary endpoints, we plan to submit a new drug application, or an NDA, for IV Tramadol to treat moderate to moderately severe postoperative pain pursuant to Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, or FDCA, by the end of 2019.

On November 12, 2018, we entered into a Stock Purchase and Merger Agreement (SPMA) with InvaGen Pharmaceuticals Inc. (InvaGen), Madison Pharmaceuticals Inc. (Merger Sub), and Fortress Biotech, Inc. (Fortress), pursuant to which InvaGen agreed to purchase, for $35 million, common shares representing 33.3% of the fully diluted capitalization of the Company (the Stock Purchase Transaction) and subsequently acquire the remaining issued and outstanding capital stock of the Company for $180 million, subject to certain reductions, in a reverse subsidiary merger transaction (the Merger Transaction). Pursuant to the terms and subject to the conditions set forth in the SPMA, InvaGen will, at second closing, hold 100% of the issued and outstanding equity interests of the Company. Consummation of the Merger Transaction is conditioned, among other things, upon FDA approval of IV Tramadol, its labeling and scheduling and the absence of any Risk Evaluation and Mitigation Strategy (REMS) restrictions in effect with respect to IV Tramadol, as well as the expiration of any waiting period applicable to the acquisition under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended.

The aggregate consideration to be paid by InvaGen under the SPMA is $215 million in cash, subject to certain potential reductions, which InvaGen intends to have sufficient immediately available funds to pay. In addition, we are subject to certain lock-up restrictions and agreed not to (subject to customary exceptions), during the period commencing at the signing of the SPMA until the Merger Transaction, issue, buy, sell, or otherwise subject to a security interest, pledge, hypothecation, mortgage or lien, any securities of the Company.

The SPMA was approved by a majority of our stockholders, including a majority of our non-affiliated stockholders, at our special shareholder meeting on February 6, 2019. On February 8, 2019, the Company and InvaGen consummated the Stock Purchase Transaction whereby InvaGen acquired 5,833,333 shares of our common stock at $6.00 per share for total gross consideration of $35.0 million, representing a 33.3% stake in our capital stock on a fully diluted basis.

We may seek to obtain additional capital through the sale of debt or equity financings or other arrangements to fund our operations and research and development activity; however, there can be no assurance that we will be able to raise needed capital under acceptable terms, if at all. The sale of additional equity may dilute existing stockholders and newly issued securities may contain senior rights and preferences compared to currently outstanding shares of common stock. Issued debt securities may contain covenants and limit our ability to pay dividends or make other distributions to stockholders. If we are unable to obtain such additional financing, future operations would need to be scaled back or discontinued.

We are a majority controlled subsidiary of Fortress.

CORPORATE INFORMATION

Avenue Therapeutics, Inc. was incorporated in Delaware on February 9, 2015. Our executive offices are located at 2 Gansevoort Street, 9th Floor, New York, NY 10014. Our telephone number is (781) 652-4500, and our email address is info@avenuetx.com.

We maintain a website with the address www.avenuetx.com. We make available free of charge through our Internet website our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K, and any amendments to these reports, as soon as reasonably practicable after we electronically file such material with, or furnish such material to, the SEC. We are not including the information on our website as a part of, nor incorporating it by reference into, this report. Additionally, the SEC maintains a website that contains annual, quarterly, and current reports, proxy statements, and other information that issuers (including us) file electronically with the SEC. The SEC's website address is http://www.sec.gov.

OUR STRATEGY

Our primary objective is to establish IV Tramadol as an invaluable part of a treating physician's repertoire of available pharmaceutical options for the management of postoperative pain. The key elements of our strategy include:

- *Complete our Phase 3 program for IV Tramadol.* We completed our first Phase 3 program in the second quarter of 2018 and expect to report topline data from the second of our two pivotal trials as early as mid-2019, respectively. We also initiated an open-label safety study in December 2017, which is expected to complete by mid-2019.

- *Obtain FDA approval of IV Tramadol for the management of moderate to moderately severe postoperative pain.* If our Phase 3 trials meet their primary endpoints, we plan to submit our NDA for IV Tramadol by the end of 2019. We intend to seek FDA approval of IV Tramadol pursuant to Section 505(b)(2) of the FDCA.

- *Maintain, expand and protect our intellectual property portfolio.* We intend to expand and protect our intellectual property in the area of IV administration of tramadol in order to maintain a defensible and valuable intellectual property portfolio.

The U.S. Postoperative Pain Market

We are currently focused on developing our proprietary product candidate, IV Tramadol, for the management of moderate to moderately severe postoperative pain. Even though the postoperative pain market is entrenched with low cost, generic pain relievers, we believe that there still remains a significant unmet medical need for safer and better-tolerated painkillers, which are also referred to as analgesics.

According to Decision Resources' Acute Pain Report of October 2014, or the 2014 Pain Report, sales of analgesics delivered via parenteral routes (IV, subcutaneous, and intramuscular injections) for the management of acute pain totaled approximately $965 million in the United States in 2013. According to the 2014 Pain Report, there were over ten million select common inpatient procedures performed, all of which likely required postoperative pain management, in the United States in 2013. According to IMS Health, injectable analgesics sold approximately $1 billion in the United States in 2017.

The major goal in the management of postoperative pain is minimizing the dose of medications to lessen side effects while still providing adequate pain relief for analgesia. This is best accomplished with multimodal and preemptive analgesia. An effective pain relief program should be individualized for the particular patient, operation, and circumstances. In clinical practice, as there is no standard set of guidelines to manage postoperative pain, hospitals and even hospital units have their own practice guidelines that are often based on physicians' prescribing practices. These local guidelines are rooted in physician experience as it relates to anticipated severity of pain due to a particular surgical procedure, and are often modified with consideration to things like staffing limitations, availability of specific drugs and/or formulations, access to patient controlled analgesia, or PCA, systems, and formulary restrictions. Thus, treatment regimens vary widely from hospital to hospital, physician to physician and patient to patient.

Understanding the range of available interventions and considering the type of surgery is essential to safe and effective pain management. The general consensus among pain management practitioners is that use of more than one modality (i.e., molecules with different mechanisms or with different routes of administration) is optimal for successful postoperative pain management. The most commonly prescribed agents in the immediate postoperative pain market are typically acetaminophen, or APAP, NSAIDS, and opioid analgesics. APAP and NSAIDs are not sufficiently effective as the sole agent for pain management after major surgery in most patients. However, when used in conjunction with opioids, APAP and NSAIDs offer substantial benefits as the quality of analgesia is often improved or enhanced due to their differentiated mechanism of action. Nevertheless, the substantial side effects associated with these agents represent an important concern for patients and physicians to address. NSAIDS in particular have their own serious side effects, including increased post-surgery bleeding, peptic ulcer disease and renal impairment, and is associated with hepatic side effects.

Traditional opioids offer safe and effective postoperative pain control and can be used in combination with other agents and techniques. However, the side effects of opioids, such as morphine, include sedation, dizziness, nausea, vomiting, constipation, physical dependence, tolerance, and respiratory depression. Physical dependence and addiction are clinical concerns that may prevent proper prescribing and, in turn, inadequate pain management. Less common side effects include delayed gastric emptying, hyperalgesia, immunologic and hormonal dysfunction, muscle rigidity, and myoclonus.

Therefore, there is still unmet medical need in the post-surgical setting. We believe that IV Tramadol, if approved, can fill this unmet need. If approved for its intended indication, we believe that IV Tramadol will be an opioid effective in treating moderate to moderately severe pain without some of the side effects often seen with traditional opioids.

The table below summarizes the available intravenous analgesic options in postoperative pain management currently available in the United States.

Available Classes	Pain Levels	Common Limitations & Contraindications
IV narcotics	Moderate to severe	Strong sedation Respiratory depression Constipation Risk of dependence
IV NSAIDS	Mild to moderately severe	Post-op bleeding risk GI side effects Renal impairment
IV acetaminophen	Mild to moderate	Hepatic impairment

Our Product Candidate

Tramadol, a synthetic dual-acting opioid, is a centrally acting analgesic with weak opioid agonist properties. It also works via the inhibition of serotonin and noradrenaline re-uptake and blocking nociceptive impulses at the spinal level. These opioid and non-opioid modes of action are synergistic, essentially providing "multimodal therapy" with the use of a single drug. Tramadol is also commonly combined with APAP or NSAIDS in clinical practice. Tramadol has a well-established efficacy and safety profile and has been used throughout the world for more than 30 years. In the United States, tramadol is approved and marketed as an oral agent for moderate to moderately severe pain in adults. Tramadol was first approved in the United States in 1995, under the trade name Ultram® immediate release tablet (Ortho-McNeil-Janssen). Ultracet®, a combination product containing tramadol and acetaminophen, is also marketed in the United States (Ortho-McNeil-Janssen). According to Symphony Health Solutions, over 40 million scripts for tramadol and tramadol-containing drugs have been prescribed annually in the United States since 2012.

Tramadol use is associated with fewer side effects compared with the use of other opioids for pain management. Tramadol causes less respiratory depression, has minimal effect on the body's hemodynamic function, and does not impair immune function. Tramadol also causes minimal gastrointestinal adverse effects, including reduced constipation compared to other opioids. The most common side effects are nausea and dizziness. Importantly, tramadol has low potential for abuse and addiction and is currently classified by the DEA as a Schedule IV controlled substance. For comparison, other opioids which have a high potential for abuse, including meperidine, morphine, hydromorphone and oxycodone, are all classified as Schedule II controlled substances.

Oral tramadol was generally well tolerated in clinical trials evaluating its analgesic safety and efficacy. It has demonstrated utility in patients with a risk of poor cardiopulmonary function, after surgery of the thorax or upper abdomen and when non-opioid analgesics are contraindicated.

The efficacy of oral and parenteral tramadol in relieving moderate to moderately severe postoperative pain associated with surgery was demonstrated in several comparative human clinical trials.

The clinical trials summarized below show that the overall analgesic efficacy of parenteral tramadol was similar to that of morphine and meperidine and comparable or superior to that of pentazocine:

- In a clinical trial published in *Drugs under Experimental and Clinical Research* (*http://www.ncbi.nlm.nih.gov/pubmed/9604144*) , 70 patients were treated with parenteral morphine or tramadol following abdominal surgery. Both drugs gave rapid and constant pain relief. The study investigators concluded that tramadol given by intramuscular injection has postoperative analgesic activity similar to morphine, and was better tolerated.

- In a clinical trial published in *Methods and Findings in Experimental and Clinical Pharmacology* (*http://www.ncbi.nlm.nih.gov/pubmed/8738073*), 48 patients after total hip or knee replacement were randomly distributed into three groups and received tramadol, meperidine or saline in a double-blind manner. The conclusion of the study was that meperidine and tramadol produced comparable analgesia, but meperidine induced sedation and respiratory depression while tramadol did not.

- In a clinical trial published in *International Journal of Pharmacological Research* (*http://www.ncbi.nlm.nih.gov/pubmed/9675626*), a total of 50 adults were given tramadol or pentazocine by intramuscular injection for three days post-surgery. The first dose of tramadol was significantly more effective than pentazocine after the first hour. Study investigators concluded that final judgements on efficacy and acceptability were in favor of tramadol while both produced good analgesia.

Advantages of IV Tramadol

Parenteral tramadol is approved and used for the management of moderate to moderately severe postoperative pain throughout much of the world. Parenteral formulations include IV, intramuscular, or IM, and subcutaneous, or SC, formulations. Based on our review of IMS Health data from 2014 to 2016, we believe that parenteral tramadol accounts for approximately 10% of the total IV analgesics used in Europe. There is no parenteral formulation currently approved in the United States.

We believe that the introduction of an IV formulation of tramadol in the United States will address many of the shortcomings of opioids, APAP and NSAIDs currently used in the postoperative setting.

We plan to administer IV Tramadol over approximately 15 minutes in our Phase 3 trials. We believe that our method of administration of IV Tramadol may provide significant benefits such as reduced side effects, compared to previously approved methods of administration of IV Tramadol in Europe, which is typically accomplished via a slow push over 2 to 3 minutes. In addition, we believe our IV Tramadol dosing regimen produces a similar Cmax (maximal blood level) and AUC (overall systemic exposure) to those of oral tramadol at steady state, which ensures an easy transition from IV to oral therapy in the post-surgical setting.

Based on the trials done in Europe and on the data generated with oral tramadol, we believe that IV Tramadol, if approved, will be an attractive option for physicians who treat postoperative pain, due to the following attributes:

- As an established analgesic, tramadol has documented efficacy and safety for moderate to moderately severe pain and physicians are already familiar with the drug.
- As a Schedule IV controlled substance, tramadol has less potential for addiction and abuse than other narcotics widely prescribed in the post-surgical setting. In the current environment where the opioid epidemic is a recognized problem in the United States and there are increasing restrictions on Schedule II opioids, a Schedule IV opioid such as tramadol may become a more attractive option.
- Tramadol's differentiated safety profile could make it an attractive alternative to currently available stand-of-care opioids. In particular, IV Tramadol could be a suitable choice for patients at risk for respiratory depression, elderly patients with cardiopulmonary compromise, patients with sleep apnea or contraindication to NSAIDS or those with a history of drug dependence or cannot tolerate traditional opioids.
- Importantly, there is a step-down therapy available for IV Tramadol. Patients are transitioned to oral therapy when they are discharged from the hospital or when they can tolerate oral medicine. Our IV Tramadol dosing regimen provides a similar PK profile to that of oral tramadol at steady state to ensure a smooth step-down process.

We believe that IV Tramadol, if approved, will be a useful and effective tool in the management of acute postoperative pain. Its potential advantages compared to current standard-of-care agents, along with the known efficacy, safety and tolerability profile for oral tramadol support the use of IV Tramadol in this setting. We believe that the risks associated with the use of IV Tramadol will be benign compared to other opioids, and consistent with that of the currently marketed oral tramadol products. Consequently, with the industry trend toward multimodal therapy and away from Schedule II narcotics, we believe that, if approved, IV Tramadol's unique profile could position it to become an invaluable part of a treating physician's repertoire of available pharmaceutical options in the management of postoperative pain.

Clinical Development History

Revogenex completed multiple nonclinical PK and toxicology studies in dogs, a Phase 1 dose proportionality study and a thorough QT/QTc (TQT) study of IV Tramadol in healthy volunteers, or the TQT Study. The dose proportionality study was designed to compare maximum exposure and cumulative exposures of IV Tramadol to that of oral tramadol, and to assess the dose proportionality of IV Tramadol in healthy adult volunteers. The TQT Study was done to evaluate whether IV Tramadol has the potential to affect the "corrected QT interval", or QTc, in healthy volunteers. The QTc represents electrical depolarization and repolarization of the heart ventricles. A lengthened QTc is a marker for the potential of ventricular arrhythmias. The results of these studies are consistent with tramadol's known toxicology profile, pharmacokinetics and pharmacology.

PK Study for IV Tramadol

In general, Phase 2 clinical trials include initial proof-of-concept efficacy studies, dose-finding studies, and initial safety assessments in the target (i.e., to-be-treated) population. We did not conduct Phase 2 clinical trials for IV Tramadol because tramadol is a known analgesic, and oral tramadol is labeled for "moderate to moderately severe pain" in the United States. Instead, we completed pharmacokinetic (PK) simulations and conducted a pharmacokinetic and safety study in healthy volunteers, in order to select a Phase 3 dose and dosing regimen designed to achieve exposure to tramadol similar to that provided by oral tramadol. In 2016, we completed a PK study for IV Tramadol in healthy volunteers. A PK study generally involves dosing an experimental medicine in healthy volunteers and taking a series of blood measurements from the study participants to understand how the body handles the drug. A PK study provides information on important parameters such as systemic exposure, maximal and minimal levels of drug concentration in the blood and their time courses. The PK study we conducted was used to select a dose and dosing regimen of IV Tramadol that achieves similar exposure to that provided by oral tramadol at steady state.

The PK study was designed as a three-way cross over study in 18 healthy volunteers. Each subject in the study served as his/her own control and received oral tramadol as well as two different doses of IV Tramadol. Based on the results of the PK study, we have decided to use a 50 mg dose in our pivotal Phase 3 program.

Our Clinical Development Strategy for IV Tramadol

At our EOP2 meeting with FDA, we discussed Phase 3 program requirements for IV Tramadol and confirmed the key elements of the Phase 3 program design. We plan to conduct two pivotal Phase 3 trials to evaluate the safety and efficacy of IV Tramadol, and one additional safety study. All three trials will enroll patients who require IV analgesia following surgery. We anticipate that approximately 1,000 patients will be enrolled in the Phase 3 program. We believe that the design of our Phase 3 program is consistent with the design of Phase 3 programs for other analgesics being developed by Trevena, Inc., Cara Therapeutics, Inc., and Recro Pharma, Inc.

Postoperative pain following bunionectomy (orthopedic surgery model). The first Phase 3 trial was conducted in patients undergoing bunionectomy surgery, which is considered an orthopedic surgical model. Approximately 405 patients were randomized 1:1:1 to one of two doses of IV Tramadol, or placebo, for 48 hours. The primary efficacy endpoint was Sum of Pain Intensity Difference over 48 hours (SPID 48), which is a measure of the overall effectiveness of the drug in reducing pain intensity during the 48-hour period. This trial commenced in the third quarter of 2017. In May 2018, we announced the trial met its primary endpoint and all key secondary endpoints.

Postoperative pain following abdominoplasty (soft tissue model). The second Phase 3 safety and efficacy trial will be conducted in patients undergoing abdominoplasty surgery, which is considered a soft-tissue surgical model. Approximately 360 patients will be randomized 3:3:2 to IV Tramadol, placebo or a standard-of-care comparator arm. The primary efficacy endpoint is Sum of Pain Intensity Difference over 24 hours (SPID 24). We initiated this trial in December 2018. Based on the enrollment pace of similar trials, we anticipate that we may have topline data to be reported as early as mid-2019.

Open-label safety study. We initiated the safety study in December 2017 and will run this study concurrently with the two Phase 3 trials. Approximately 250 patients will be enrolled in the safety study, which has an open label, single arm design. We anticipate that we will complete this study as early as mid-2019.

If these trials are successful, we plan to submit an NDA for the FDA's review and approval for IV Tramadol to treat moderate to moderately severe postoperative pain pursuant to Section 505(b)(2) of the FDCA by the end of 2019.

License Agreement with Revogenex Ireland Ltd.

Effective as of February 17, 2015, Fortress obtained a worldwide (with the exception of Canada, Central America and South America with respect to 50 mg and 100 mg IV Tramadol HCl injections) exclusive license to make, market and sell IV Tramadol pursuant to an agreement with Revogenex, a privately held company in Dublin, Ireland, or the License Agreement. Under the terms of the License Agreement, Fortress paid Revogenex an up-front licensing fee of $2.0 million upon execution and an additional $1.0 million on June 17, 2015; two additional milestones totaling $4.0 million are due upon the completion of certain development goals. Additional high single-digit to low double-digit royalty payments on net sales of licensed products are due. Royalties will be paid on a product-by-product and country-by-country basis until the expiration in each country of the valid patent claim. In return, Fortress obtained the exclusive worldwide rights to U.S. Patent No. 8,895,622 "Intravenous Administration of Tramadol" issued on November 25, 2014, or the '622 Patent, U.S. Patent No. 9,561,195 issued on February 7, 2017, or the '195 Patent, and U.S. Patent No. 9,566,253 issued on February 14, 2017, or the '253 Patent (with the exception of Canada, Central America and South America with respect to 50 mg and 100 mg IV Tramadol HCl injections). Additionally, Fortress acquired the rights to an open U.S. Investigational New Drug Application pertaining to IV Tramadol, as well as all supporting documentation and relevant correspondence with the FDA. Further, under the License Agreement, Fortress assumed the rights and obligations of Revogenex under its current manufacturing agreement with Zaklady Farmaceutyczne Polpharma (Polpharma), or the Manufacturing Agreement. Fortress transferred all its rights and obligations under the License Agreement and the Manufacturing Agreement to us pursuant to an Asset Transfer Agreement, dated as of May 13, 2015.

The License Agreement will terminate on a product-by-product and country-by-country basis upon the expiration of the last licensed patent right, unless the agreement is earlier terminated. In addition to standard early termination provisions, the License Agreement may also be terminated early by: (i) Revogenex if the NDA has not been filed by February 17, 2021 or February 17, 2022 in the event a Phase 3 Trial does not meet its endpoint, and we have failed to use commercially reasonable efforts to carry out all of the product development, (ii) Revogenex if the FDA does not issue an approval or otherwise issues a "not approvable" notice for the NDA within 27 months after the NDA has been filed with the FDA, although this termination right will be tolled if we are using commercial reasonable efforts in our negotiations with the FDA for approval and if we receive a "not approvable" notice, we will have a 15 month period to correct any issues and re-submit the NDA for approval, (iii) us if we reasonably determine prior to NDA approval that the development of IV Tramadol is not economically viable, or (iv) either Revogenex or us (provided we are using or have used commercially reasonable efforts to commercialize IV Tramadol) if, after the third anniversary date of the commercial launch, we fail to achieve annual net sales with respect to IV Tramadol of at least $20 million in any given calendar year, with certain exceptions.

Competition

The pharmaceutical industry is characterized by rapidly advancing technologies, intense competition and a strong emphasis of proprietary products. We face competition and potential competition from a number of sources, including pharmaceutical and biotechnology companies, generic drug companies, drug delivery companies and academic and research institutions. In addition, companies that are active in different but related fields represent substantial competition for us. Many of our competitors have significantly greater capital resources, larger research and development staffs and facilities and greater experience in drug development, regulation, manufacturing and marketing than we do. These organizations also compete with us to recruit qualified personnel, attract partners for joint ventures or other collaborations, and license technologies that are competitive with ours. To compete successfully in this industry, we must identify novel and unique drugs or methods of treatment and then complete the development of those drugs as treatments before our competitors do so.

We believe that IV Tramadol, if approved, will compete with a number of opioid and non-opioid drugs that are currently available for the management of acute pain or in development. The most commonly used opioids in the postoperative and acute pain settings are morphine, hydromorphone and fentanyl. The non-opioid drugs used in this setting include Ofirmev (IV acetaminophen) and IV formulations of NSAIDs such as Dyloject (diclofenac), Toradol (ketorolac), and Caldolor (ibuprofen). In addition, we also expect to compete with agents such as Exparel, a liposome injection of bupivacaine indicated for administration into the surgical site to produce postsurgical analgesia.

In addition to approved products, there are a number of product candidates in development for the management of acute pain. The late-stage pain development pipeline is replete with reformulations and fixed-dose combination products of already available therapies. Among specific drug classes, opioid analgesics and NSAIDs represent the greatest number of agents in development. Most investigational opioids that have reached the later stages of clinical development are new formulations of already marketed opioids. Likewise, investigational NSAIDs — mostly lower dose injectable reformulations of already approved compounds — are another significant area of late-stage drug development in the postoperative pain space. There are also several agents with novel mechanisms in clinical development, such as CR845 (Cara Therapeutics, Inc.) and TRV130 (Trevena, Inc.).

Intellectual Property and Patents

General

Our goal is to obtain, maintain and enforce patent protection for our proprietary technologies, including methods of treatment, to preserve our trade secrets, and to operate without infringing on the proprietary rights of other parties, both in the United States and in other countries. Our policy is to actively seek to obtain, where appropriate, the broadest intellectual property protection possible for our product candidates, proprietary information and proprietary technology through a combination of contractual arrangements and patents in the United States.

Patents and other proprietary rights are crucial to the development of our business. We will be able to protect our proprietary technologies from unauthorized use by third parties only to the extent that our proprietary rights are covered by valid and enforceable patents, supported by regulatory exclusivity or are effectively maintained as trade secrets. We have several patents and patent applications related to our proprietary technology, but we cannot guarantee the scope of protection of the issued patents, or that such patents will survive a validity or enforceability challenge, or that any of the pending patent applications will issue as patents.

Generally, patent applications in the United States are maintained in secrecy for a period of 18 months or more. The patent positions of biotechnology and pharmaceutical companies are highly uncertain and involve complex legal and factual questions. Therefore, we cannot predict the breadth of claims allowed in biotechnology and pharmaceutical patents, or their enforceability. To date, there has been no consistent policy regarding the breadth of claims allowed in biotechnology patents. Third parties or competitors may challenge or circumvent our patents or patent applications, if issued. If our competitors prepare and file patent applications in the United States that claim technology also claimed by us, we may have to participate in interference proceedings declared by the USPTO to determine priority of invention, which could result in substantial cost, even if the eventual outcome is favorable to us. Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that before we commercialize any of our products, any related patent may expire or remain in existence for only a short period following commercialization, thus reducing any advantage of the patent. However, the life of a patent covering a product that has been subject to regulatory approval may have the ability be extended through the patent restoration program, although any such extension could still be minimal.

If a patent is issued to a third party containing one or more preclusive or conflicting claims, and those claims are ultimately determined to be valid and enforceable, we may be required to obtain a license under such patent or to develop or obtain alternative technology, neither of which may be possible. In the event of litigation involving a third-party claim, an adverse outcome in the litigation could subject us to significant liabilities to such third party, require us to seek a license for the disputed rights from such third party, and/or require us to cease use of the technology. Moreover, our breach of an existing license or failure to obtain a license to technology required to commercialize our products may seriously harm our business. We also may need to commence litigation to enforce any patents issued to us or to determine the scope and validity of third party proprietary rights. Litigation would involve substantial costs.

IV Tramadol

Pursuant to the License Agreement described below, we have exclusive, worldwide commercialization rights to U.S. patent No. 8,895,622 ("the '622 Patent"). The '622 Patent is directed to and claims methods of: treating pain by administering a therapeutically effective dose of tramadol intravenously over a time period from 10 minutes to about 45 minutes (i.e., the rate of IV Tramadol administration); administration over that time period for treating pain in humans by intravenously administering tramadol in solution at a range of concentrations; a method for treating acute pain in humans by administering IV Tramadol over 10 to 30 minutes; a method of treating acute postoperative pain by administering tramadol to a human patient intra-operatively at wound closure, or from first demand of analgesia postoperatively intravenously over a time period from 10 to 30 minutes; administering further doses of IV Tramadol at two to six hour time intervals for at least 48 hours post-surgery and administering an intravenous opioid analgesic which is not tramadol to the patient to further treat the patient's pain. Further claims of the '622 patent are directed to the 50 mg tramadol dose. These methods of treatment may provide significant benefits (e.g., reduced side effects) over previously approved methods of administration of IV Tramadol, in which the dose was typically accomplished over a two to three minute period. Additional claims of the '622 Patent focus on the intravenous administration of tramadol over 15 (±2) minutes, which represents the preferred method of administration that we will be pursuing in obtaining approval of our product through the FDA. The '622 Patent further describes and claims pharmacokinetic properties of our proprietary method of treatment (e.g., Tmax, Cmax and AUC), which are different from the previously achieved pharmacokinetics of prior IV Tramadol formulations, such as Tramal® solution for injection (available outside the U.S.). This patent is scheduled to expire on April 12, 2032 (absent possible patent term extensions).

In view of additional prior art discovered after the issuance of the '622 Patent, we have focused efforts on obtaining further patent coverage for the technology. Pursuant to the License Agreement, we have exclusive, worldwide commercialization rights to all continuation patent filings of the '622 Patent. As a first step, we have prosecuted further claims in two continuation patent applications of the '622 patent in which all prior art which we uncovered in extensive searches was brought to the attention of the USPTO. The goal was to obtain further patent claims which patentably differentiate over such prior art. To date, our efforts have resulted in the issuance of U.S. Patent No. 9,561,195 (hereinafter referred to as "the '195 Patent" which was issued from U.S. Application Serial No. 14/550,279 on February 7, 2017),U.S. Patent 9,566,253 (hereinafter referred to as "the '253 Patent" which was issued from U.S. Application Serial No. 14/713,775 on February 14, 2017), U.S. Patent No. 9,962,343 (hereinafter referred to as "the '343 Patent" which was issued from U.S. Application Serial No. 14/550,279 on May 8, 2018), all of which are entitled "Intravenous Administration of Tramadol" and both of which contain the same disclosure (specification) as that of the '622 Patent. The '195, '253, and '343 patents are scheduled to expire on the same day as the expiration of the '622 patent (April 12, 2032; absent possible patent term extensions).

The '253 patent includes claims directed to a method of treating moderate to severe acute pain in a human patient by a dose of about 50 mg of IV Tramadol over a time period from 10 minutes to 20 minutes, and administering further doses of tramadol at two to six hour time intervals (each dose being administered intravenously over the same time period). The '343 patent includes claims directed to similar subject matter. There is also a continuation patent application pending with the USPTO.

The '195 patent includes claims directed to a method of treating moderate to severe acute pain by administering to a human patient a dose of about 50 mg of IV Tramadol over 10 to 20 minutes, and administering further doses of IV Tramadol at two to six hour time intervals to treat pain in said patient, (each dose administered over 10 to 20 minutes), such that the Cmax does not exceed the Cmax of 100 mg oral tramadol. The term Cmax refers to the maximum plasma concentration of tramadol achieved during a dosing interval. The claims of the '195 patent therefore further focus on a goal of the technology — that the blood plasma levels of tramadol resulting from our 50 mg intravenous dose to a patient would not be significantly greater than the blood plasma level of the blood plasma levels of tramadol that are already routinely experienced by patients in the United States who are administered an oral dose of 100 mg tramadol. Tramadol hydrochloride is approved in the United States for oral administration in an amount from 50 to 100 mg administered every four to six hours, not to exceed 400 mg/day.

The '253, '195 and '343 patents include further claims to the treatment method, including also administering one or more doses of an IV opioid analgesic that is not tramadol as rescue medicine to the patient to treat breakthrough pain. The claims are further directed to the use of the treatment method for postoperative pain, and claims are also directed to the treatment method resulting in a reduction in a side-effect associated with tramadol therapy selected from nausea, vomiting, or both.

We believe that the administration of a 50 mg IV Tramadol dose over the prolonged time interval is efficacious and also may advantageously lead to a lower incidence of side effects and increased drug tolerability. Additionally, we believe that the claims of both the '253 and '195 patents' patentably differentiate over all prior art that we are aware of and which was made of record with the USPTO.

The License Agreement grants us the rights to a further patent as U.S. Patent No. 9,693,949 ("the '949 Patent") to an IV Tramadol dosing regimen which was issued by the USPTO in 2017. This new patent describes and claims a dosing regimen in which our IV Tramadol product is dosed to a human patient(s) for treating acute pain in a manner such that the plasma levels obtained (including but not limited to Cmax and AUC) are very similar to treatment with a 100 mg oral dose of tramadol hydrochloride to a human patient(s) every six hours at steady state. This is accomplished by intravenously administering a first dose of tramadol 50 mg to a human patient; then intravenously administering a second dose of tramadol 50 mg about 2 hours after the first dose; intravenously administering a third dose of tramadol 50 mg about 2 hours after the second dose; and thereafter intravenously administering doses of tramadol 50 mg at dosage intervals of about 4 hours. It is believed that this dosing regimen may provide advantages over the commercially available oral doing regimen, and further allows the patient to be stepped down from the IV Tramadol dosing regimen to an oral dosing regimen with less concern about deleterious effects which might occur from a switch from IV to oral analgesic medicine (e.g., as would be the case where the switch to an oral version of the drug provides a much different Cmax and AUC than the IV dose provides at steady state). This new dosing regimen is the result of considerable experimentation by us, and a prior art search has not revealed any similar dosing regimen being used or published with respect to IV Tramadol infusions. The patent term of the '949 Patent may extend to at least May 24, 2036 (absent possible patent term extensions). A continuation of the '949 patent has issued as U.S. Patent 9,968,551 on May 18, 2018 claiming the same dosing regimen except that it includes claims that specify that the mean Cmax after the third administered dose of tramadol is similar to the mean Cmax at steady-state for a dosing regimen of 100 mg tramadol HCl administered orally every 6 hours, and/or specifies pharmacokinetic parameters for Cmax and/or AUC at steady-state. U.S. Patent No. 9,980,900 (a continuation-in-part of the '949 patent) issued on May 29, 2018 and is directed to the same doing regimen, except that it includes claims that specify the pharmacokinetic parameters after the third administered dose of tramadol. Further continuation patent applications are pending for (i) the 50 mg dosing regimen to human patients experiencing acute pain or acute post-operative pain; (ii) the 50 mg dosing regimen directed to administering a first dose of tramadol 50 mg to a human patient and thereafter intravenously administering additional doses of tramadol to the human patient(s) in an amount of about 50 mg tramadol at dosage intervals of about 4 hours, except that a second dose is intravenously administered as a loading dose at a shortened interval as compared to the dosage interval of about 4 hours, and (iii) administering the 50 mg dosing regimen as described with an NSAID as well.

The License Agreement also grants us the rights to two additional continuation applications to the '949 patent that are currently pending with the USPTO. These patent applications are directed to (i) administering a first dose of tramadol 60 mg to a human patient and thereafter intravenously administering additional doses of tramadol to the human patient(s) in an amount of about 60 mg tramadol at dosage intervals of about 6 hours, except that a second dose is intravenously administered as a loading dose at a shortened interval as compared to the dosage interval of about 6 hours, and (ii) administering the 60 mg dosing regimen as described with an NSAID as well.

The License Agreement also grants us the rights to U.S. Patent No. 10,022,321 ("the '321 Patent") to an IV Tramadol dosing regimen which was issued by the USPTO in 2018. This new patent describes and claims a dosing regimen in which our IV Tramadol product is dosed to a human patient(s) for treating acute pain by intravenously administering a first dose of tramadol 25 mg to a human patient; then intravenously administering a second dose of tramadol 25 mg about 2 hours after the first dose; intravenously administering a third dose of tramadol 25 mg about 2 hours after the second dose; and thereafter intravenously administering doses of tramadol 25 mg at dosage intervals of about 4 hours. A continuation application to the '321 patent is also pending with the USPTO.

The License Agreement further grants us the rights to a new patent application pending with the USPTO directed to the intravenous administration of tramadol co-administered with acetaminophen, and another new patent application pending with the USPTO directed to the intravenous administration of tramadol co-administered with ketorolac.

In sum, we believe that our patent filings will prevent third parties from marketing a generic version of our product without infringing claims of the patent(s) we are seeking. Further, we have conducted clearance searches of U.S. issued and foreign patents, and have not identified any bars to the commercialization of our tramadol technology.

In addition to the above patents, we have further patent continuation applications pending with the USPTO, as well as another patient application directed to an intravenous tramadol dosing regimen.

Other Intellectual Property Rights

We depend upon trademarks, trade secrets, and continuing technological advances to develop and maintain our competitive position. We also depend upon the skills, knowledge and experience of our scientific and technical personnel, as well as that of our advisors, consultants and other contractors. This knowledge and experience we call "know-how." To help protect our proprietary know-how which is not patentable, and for inventions for which patents may be difficult to enforce, we rely on trade secret protection and confidentiality agreements to protect our interests. To this end, we require all employees, scientific advisors, consultants, collaborators and other contractors, upon commencement of a relationship with us, to enter into confidentiality agreements, which prohibit the disclosure of confidential information and, in the case of parties other than our research and development collaborators, require disclosure and assignment to us of the ideas, developments, discoveries and inventions important to our business. These agreements are designed to protect our proprietary information and to grant us ownership of technologies that are developed in connection with their relationship with us. These agreements may not, however, provide protection for our trade secrets in the event of unauthorized disclosure of such information.

Supply and Manufacturing

The chemical name for tramadol hydrochloride is cis-2-[(dimethyl amino) methyl]-1-(3-methyoxyphenyl) cyclohexanol hydrochloride. Unless otherwise specified, the term tramadol refers to the racemic mixture of the (±) cis isomers. IV Tramadol (Tramadol Hydrochloride Injection) is a sterile solution formulation of tramadol HCl 50 mg/1 mL, for IV administration. Each unit of IV Tramadol consists of glass ampoules of 50 mg of tramadol HCl and sodium acetate as buffering agent in 1 mL of water for injection or 100 mg of tramadol HCl and sodium acetate as buffering agent in 2 mL of water for injection. The final drug product is stable at room temperature.

We do not own or operate manufacturing facilities for the production of IV Tramadol, nor do we have plans to develop or own manufacturing operations in the foreseeable future. Currently, we have one manufacturer, Polpharma, who subcontracts several activities to another manufacturer, to provide us clinical and commercial supply of IV Tramadol in accordance with cGMP. We also plan to qualify a backup manufacturer. We will be obligated to purchase a minimum amount of final packaged drug product from our current manufacturer over the course of five years commencing upon the approval of our NDA for IV Tramadol. We will pay a fixed per dose unit fee to our current manufacturer in addition to a low single digit royalty on net sales revenue and a milestone payment amount of $2.0 million upon FDA approval of IV Tramadol.

We and our manufacturer, as well as its key subcontractor, are and will be subject to extensive government regulation in connection with the manufacture of any pharmaceutical product, including ongoing periodic and unannounced inspections by the FDA, the DEA and corresponding state, European and other foreign agencies to ensure strict compliance with cGMPs and other applicable state, federal and foreign regulations. We do not have control over third party manufacturers' compliance with these regulations and standards, other than through contractual obligations and audit oversight. If they are deemed out of compliance with cGMPs, product recalls could result, inventory could be destroyed, production could be stopped and supplies could be delayed or otherwise disrupted.

If we need to change manufacturers after commercialization, the FDA and some corresponding foreign regulatory agencies must approve these new manufacturers in advance, which will involve testing and additional inspections to ensure compliance with cGMPs and other FDA regulations and standards and may require significant lead times and delay. Furthermore, switching manufacturers may be difficult because the number of potential manufacturers is limited. It may be difficult or impossible for us to find a replacement manufacturer quickly or on terms acceptable to us, or at all.

Government and Industry Regulations

General

U.S. Drug Development

In the United States, the FDA regulates drugs under the FDCA, and its implementing regulations. Drugs are also subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approval and maintaining subsequent compliance with applicable federal, state and local statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during product development, the approval process or after approval may subject an applicant to administrative or judicial sanctions. These sanctions could include, among other actions, the FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, untitled or warning letters, voluntary product recalls or market withdrawals, product seizures, total or partial suspension of production or distribution injunctions, fines, consent decrees, refusals of government contracts, restitution, disgorgement or civil and criminal penalties. Any agency or judicial enforcement action could have a material adverse effect on us If we fail to manufacture any of our product candidates in sufficient quantities and at acceptable quality and pricing levels, or fail to obtain adequate DEA quotas for controlled substances, or to fully comply with cGMP regulations, we may face delays in the commercialization of this product candidate or be unable to meet market demand, and may be unable to generate potential revenues.

Our product candidates must be approved by the FDA through the NDA process before they may be legally marketed in the United States. We intend to submit our NDAs under the 505(b)(2) regulatory approval pathway. Development and approval of drugs generally involves the following:

- Submission to the FDA of an IND, which must become effective before clinical trials involving humans may begin;
- Approval by an independent institutional review board, or IRB, or ethics committee at each clinical trial site before a trial may be initiated at that site;
- Performance of adequate and well-controlled human clinical trials in accordance with applicable IND regulations and other good clinical practices, or GCPs;
- Submission of an NDA to the FDA;
- The FDA's decision within 60 days of its receipt of an NDA to accept it for filing and review;
- Satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities where the drug is produced to assess compliance with cGMPs and assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;
- Possible FDA audit of the clinical trial sites that generated the data in support of the NDA; and
- FDA review and approval of the NDA.

The nonclinical testing, clinical trials and review process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our product candidates will be granted on a timely basis, if at all. The data required to support an NDA are generated in two distinct developmental stages: nonclinical and clinical. The nonclinical development stage generally involves synthesizing the active component, developing the formulation and control procedures and determining the manufacturing process, as well as carrying out non-human toxicology, pharmacology and drug metabolism studies in the laboratory, which may support subsequent clinical testing in humans. In the case of documentation to support a 505(b)(2) NDA, this nonclinical data may be referenced in literature or the FDA's previous findings of safety and efficacy for a listed drug. The sponsor must submit the results of the nonclinical studies, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. An IND is a request for authorization from the FDA to administer an investigational drug product to humans, and must become effective before clinical trials may begin. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to one or more proposed clinical trials and places the IND on clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. As a result, submission of an IND may not result in the FDA allowing clinical trials to commence.

The clinical stage of development involves the administration of the product candidate to healthy volunteers and patients under the supervision of qualified investigators, generally physicians not employed by or under the sponsor's control, in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the trial, dosing procedures, subject selection and exclusion criteria and the parameters to be used to monitor subject safety and assess efficacy. Each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND. Further, each clinical trial must be reviewed and approved by an independent IRB for each institution where the trial will be conducted to ensure that the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the informed consent form that must be provided to each subject or his or her legal representative and must monitor the clinical trial until completed.

Clinical Trials

Clinical trials are generally conducted in three sequential phases, known as Phase 1, Phase 2 and Phase 3, and may overlap.

- Phase 1 clinical trials generally involve a small number of healthy volunteers who are initially exposed to a single dose and then multiple doses of the product candidate. The primary purpose of these clinical trials is to assess the metabolism, pharmacology, side effect tolerability and safety of the drug.

- Phase 2 clinical trials typically involve studies in disease-affected patients to determine the dose required to produce the desired benefits. At the same time, safety and further pharmacokinetic and pharmacodynamics information is collected, possible adverse effects and safety risks are identified and a preliminary evaluation of efficacy is conducted.

- Phase 3 clinical trials generally involve large numbers of patients at multiple sites and are designed to provide the data necessary to demonstrate the product candidate's safety and effectiveness for its intended use, establish its overall benefit/risk relationship, and provide an adequate basis for approval.

By following the 505(b)(2) regulatory approval pathway, the applicant may reduce some of the burdens of developing a full clinical program by relying on investigations not conducted by the applicant and for which the applicant has not obtained a right of reference, such as prior investigations involving the listed drug. In such cases, some clinical trials may not be required or may be otherwise limited.

Post-approval trials, sometimes referred to as Phase 4, may be conducted after initial marketing approval. These trials are used to gain additional experience from the management of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA.

Before approval, progress reports detailing the results of the clinical trials, among other information, must be submitted at least annually to the FDA, and written IND safety reports must be submitted to the FDA and investigators for serious and unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the same or similar drugs, findings from animal or *in vitro* testing suggesting a significant risk to humans, and any clinically important rate increase of a serious suspected adverse reaction compared to that listed in the protocol or investigator brochure. Phase 1, Phase 2 and Phase 3 clinical trials may not be completed successfully within any specified period, if at all. The FDA or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the trial is not being conducted in accordance with the IRB's requirements or the use of the drug raises any safety concerns. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the sponsor, known as a data safety monitoring board or committee. Depending on its charter, this group may determine whether a trial may move forward at designated check points based on access to certain data from the trial.

There are also requirements governing the reporting of ongoing clinical trials and completed trial results to public registries. Sponsors of certain clinical trials of FDA-regulated products are required to register and disclose specified clinical trial information, which is publicly available at *www.clinicaltrials.gov*. Information related to the product, patient population, phase of investigation, study sites and investigators and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to discuss the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed until the new product or new indication being studied has been approved. However, there are evolving rules and increasing requirements for publication of all trial-related information, and it is possible that data and other information from trials involving drugs that never garner approval could require disclosure in the future.

Concurrent with clinical trials, companies usually develop additional information about the chemistry and physical characteristics of the drug as well as finalize a process for manufacturing it in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate, and, among other things, a drug manufacturer must develop methods for testing the identity, strength, quality and purity of the final drug product. Appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

NDA and FDA Review Process

The results of nonclinical studies and clinical trials, together with other detailed information, including extensive information on manufacturing and drug composition and proposed labeling, are submitted to the FDA in the form of an NDA requesting approval to market the drug for one or more specified indications. The FDA reviews an NDA to determine, among other things, whether a drug is safe and effective for its intended use and whether the product is being manufactured in accordance with cGMPs to assure and preserve the product's identity, strength, quality and purity. FDA approval of an NDA must be obtained before a drug may be legally marketed in the United States.

Under the PDUFA as amended in 2017, each NDA must be accompanied by a user fee. The FDA adjusts the PDUFA user fees on an annual basis. According to the FDA's current fee schedule for fiscal year (FY) 2018, effective through September 30, 2018, the user fee for an application requiring clinical data, such as an NDA, is $2,421,495. Clinical data, as interpreted by the FDA to assess fees under PDUFA, include (1) study reports or literature reports of what are explicitly or implicitly represented by the applicant to be adequate and well-controlled trials for safety or effectiveness or (2) reports of comparative activity (other than bioequivalence and bioavailability studies), immunogenicity, or efficacy, where those reports are necessary to support a claim of comparable clinical effect. The term does not include bioequivalence and bioavailability studies submitted in support of an NDA. NDAs for which clinical data are not required to demonstrate safety and effectiveness are reduced to half of the amount of the prescribed user fee, or $1,210,748 for FY 2018. PDUFA also imposes an annual Prescription Drug Program Fee ($304,162 per approved product for FY 2018) for establishments named as the applicant in a human drug application. An establishment is not to be assessed more than five (5) prescription drug program fees in a given fiscal year. Fee waivers or reductions are available in certain circumstances, including waiver of the application fee for the first application filed by a small business.

The FDA reviews submitted NDAs before it accepts them for filing, and may request additional information rather than accepting the applications. The FDA must make a decision on accepting an NDA for filing within 60 days of receipt. Once the submission is accepted for filing, the FDA begins an in-depth review of the NDA. Under the goals and policies agreed to by the FDA under PDUFA, the FDA has ten months from the filing date in which to complete its initial review of a standard NDA and respond to the applicant, and six months from the filing date for an NDA designated for priority review. The FDA does not always meet its PDUFA goal dates for standard and priority NDAs, and the review process is often significantly extended by FDA requests for additional information or clarification.

Before approving an NDA, the FDA will conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether they comply with cGMPs. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product to specifications. The FDA may also audit data from clinical trials to ensure compliance with GCP requirements. Additionally, the FDA may refer applications for novel drug products or drug products which present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation regarding whether the application should be approved and, if so, under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers them carefully when making decisions. NDAs submitted under Section 505(b)(2) are typically not referred to an Advisory Panel for consideration unless new safety information is revealed in the review cycle. The FDA likely will re-analyze the clinical trial data, which could result in extensive discussions between the FDA and the applicant during the review process. The review and evaluation of an NDA by the FDA is extensive and time consuming and may take longer than originally planned to complete, and we may not receive a timely approval, if at all.

After the FDA evaluates an NDA, it will issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete and the application will not be approved in its present form. A Complete Response Letter usually describes the specific deficiencies in the NDA identified by the FDA, and may require additional clinical data, such as an additional pivotal Phase 3 clinical trial, and other significant and time-consuming requirements related to clinical trials, nonclinical studies or manufacturing. If a Complete Response Letter is issued, the applicant may resubmit the NDA, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information are submitted, the FDA may decide that the NDA does not satisfy the criteria for approval. Data obtained from clinical trials are not always conclusive, and the FDA may interpret data differently than the sponsor interprets the same data.

There is no assurance that the FDA will approve a product candidate for marketing, and the sponsor may encounter significant difficulties or costs during the review process. If a product receives marketing approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling, or it may condition approval on changes to the proposed labeling. The FDA also may condition approval on the development of adequate controls and specifications for manufacturing and a commitment to conduct post-marketing testing and surveillance to monitor the potential effects of approved products. For example, the FDA may require Phase 4 trials designed to further assess a drug's safety and efficacy.

The FDA may also place other conditions on approval including the requirement for a risk evaluation and mitigation strategy, or REMS, to assure the safe use of the drug. If the FDA concludes a REMS is needed, the sponsor of the NDA must submit a proposed REMS. The FDA will not approve the NDA without an approved REMS, if required. A REMS could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Marketing approval may be withdrawn for non-compliance with regulatory requirements or if problems occur following initial marketing.

Section 505(b)(2) Regulatory Approval Pathway

Section 505(b)(2) of the FDCA provides an alternate regulatory pathway for approval of a new drug by allowing the FDA to rely on data not developed by the applicant. Specifically, Section 505(b)(2) permits the submission of an NDA where one or more of the investigations relied upon by the applicant for approval was not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The applicant may rely upon published literature and/or the FDA's findings of safety and effectiveness for an approved drug already on the market. Approval or submission of a 505(b)(2) application, like those for abbreviated new drugs, or ANDAs, may be delayed because of patent and/or exclusivity rights that apply to the previously approved drug.

A 505(b)(2) application may be submitted for a new chemical entity, or NCE, when some part of the data necessary for approval is derived from studies not conducted by or for the applicant and when the applicant has not obtained a right of reference. Such data are typically derived from published studies, rather than FDA's previous findings of safety and effectiveness of a previously approved drug. For changes to a previously approved drug however, an applicant may rely on the FDA's finding of safety and effectiveness of the approved drug, coupled with information needed to support the change from the approved drug, such as new studies conducted by the applicant or published data. When based on an approved drug, the 505(b)(2) drug may be approved for all of the indications permitted for the approved drug, as well as any other indication supported by additional data.

Section 505(b)(2) applications also may be entitled to marketing exclusivity if supported by appropriate data and information. As discussed in more detail below, three-year new data exclusivity may be granted to the 505(b)(2) application if one or more clinical investigations conducted in support of the application, other than bioavailability/bioequivalence studies, were essential to the approval and conducted or sponsored by the applicant. Five years of marketing exclusivity may be granted if the application is for an NCE, and pediatric exclusivity is likewise available.

Orange Book Listing and Paragraph IV Certification

For NDA submissions, including those under Section 505(b)(2), applicants are required to list with the FDA certain patents with claims that cover the applicant's product. Upon approval, each of the patents listed in the application is published in *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly referred to as the Orange Book. Any applicant who subsequently files an ANDA or 505(b)(2) NDA that references a drug listed in the Orange Book must certify to the FDA that (1) no patent information on the drug product that is the subject of the application has been submitted to the FDA; (2) such patent has expired; (3) the date on which such patent expires; or (4) such patent is invalid or will not be infringed upon by the manufacture, use or sale of the drug product for which the application is submitted. This last certification is known as a Paragraph IV certification.

If an applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the holder of the NDA for the approved drug and the patent owner once the application has been accepted for filing by the FDA. The NDA holder or patent owner may then initiate a patent infringement lawsuit in response to notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification prevents the FDA from approving the ANDA or 505(b)(2) application until the earlier of 30 months from the date of the lawsuit, the applicant's successful defense of the suit, or expiration of the patent.

Pediatric Information

Under the Pediatric Research Equity Act, or PREA, an NDA or supplement to an NDA must contain data to assess the safety and efficacy of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation in which the product is safe and effective. The FDA may grant deferrals for submission of pediatric data or full or partial waivers.

The Food and Drug Administration Safety and Innovation Act, or FDASIA, which was signed into law on July 9, 2012, amended the FDCA to require that a sponsor who is planning to submit an NDA for a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration submit an initial Pediatric Study Plan, or PSP, within 60 days of an end-of-Phase 2 meeting or, if there is no such meeting, as early as practicable before the initiation of the Phase 3 or Phase 2/3 trial. The initial PSP must include an outline of the pediatric trial(s) that the sponsor plans to conduct, including objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such information and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric trials. The FDA and the sponsor must reach an agreement on the PSP, but the sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from nonclinical studies, early phase clinical trials and other clinical development programs.

Post-Marketing Requirements

Following approval, the company and the new product are subject to continuing regulation by the FDA, which include monitoring and recordkeeping activities, reporting of adverse experiences and complying with promotion and advertising requirements, which include prohibitions on the promotion of the drugs for unapproved, or "off-label" uses. Although physicians may prescribe legally available drugs for off-label treatments, manufacturers may not promote such non-FDA approved uses. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use on an on-going basis. Further, if there are any modifications to the drug, including changes to indications, labeling, or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a supplemental NDA or new NDA, which may require the applicant to develop additional data or conduct additional nonclinical studies or clinical trials.

The FDA regulations require that products be manufactured in specific approved facilities and in accordance with cGMPs. These regulations require, among other things, quality control and quality assurance, the maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMPs. Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies, and are subject to periodic, unannounced inspections by the FDA and certain state agencies for compliance with cGMPs and other laws. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMPs. The discovery of violative conditions, including failure to conform to cGMPs, could result in enforcement actions, and the discovery of problems with a product after approval may result in restrictions on a product, manufacturer or holder of an approved NDA, including voluntary recalls and product seizures.

Discovery of previously unknown problems with a product or the failure to comply with applicable FDA requirements can have negative consequences, including adverse publicity, judicial or administrative enforcement, untitled or warning letters from the FDA, mandated corrections to advertising or communications to doctors and civil or criminal penalties, among others. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures. New government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our products under development.

U.S. Marketing Exclusivity

The FDCA provides three years of marketing exclusivity for an NDA, or supplement to an existing NDA, for a drug product that contains a previously approved NCE if new clinical investigations, other than bioavailability/bioequivalence studies, were essential to the application's approval (*e.g.*, for new indications, dosages or strengths of an existing drug). This three-year exclusivity for new data covers only the modification for which the drug received approval on the basis of the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the active agent for the original indication. Furthermore, this exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the nonclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and efficacy.

Pediatric exclusivity is another type of regulatory market exclusivity in the United States, which, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protections or patent term, may be granted based on the voluntary completion of a pediatric trial in accordance with an FDA-issued "Written Request." The FDA issues a written request for pediatric clinical trials before approval of an NDA only where it determines that information relating to the use of a drug in a pediatric population, or part of the pediatric population, may produce health benefits in that population.

DEA Regulation

Because our product candidate is subject to the Controlled Substances Act, or CSA, we must comply with various requirements set forth by that legislation, as amended, its implementing regulations and as enforced by the DEA. The CSA imposes various registration, record-keeping and reporting requirements, procurement and manufacturing quotas, labeling and packaging requirements, security controls, prescription and order form requirements and restrictions on prescription refills for certain kinds of pharmaceutical products. A principal factor for determining the particular requirements of the CSA applicable to a product, if any, is its actual or potential abuse profile. A product may be listed as a Schedule I, II, III, IV or V controlled substance, with Schedule I presenting the highest perceived risk of abuse and Schedule V presenting the least. For example, Schedule I controlled substances have no currently accepted medical use in treatment in the United States and a lack of accepted safety for use under medical supervision. The active ingredient in our product candidate is a Schedule IV controlled substance.

Annual registration is required for any facility that manufactures, distributes, dispenses, imports or exports any controlled substance. The registration is specific to the particular location, activity and controlled substance schedule. For example, separate registrations are needed for import and manufacturing, and each registration will specify which schedules of controlled substances are authorized. Similarly, separate registrations are also required for separate facilities.

The DEA typically inspects a facility to review its security measures prior to issuing a registration and on a periodic basis. Security requirements vary by controlled substance schedule, with the most stringent requirements applying to Schedule I and Schedule II controlled substances. Required security measures include background checks on employees and physical control of inventory through measures such as vaults and inventory reconciliations. Records must be maintained for the handling of all controlled substances, and periodic reports made to the DEA, for example distribution reports for Schedule I and II controlled substances. Reports must also be made for thefts or losses of any controlled substance, and to obtain authorization to destroy any controlled substance.

In addition, a DEA quota system controls and limits the availability and production of controlled substances in Schedule I or II. Distributions of any Schedule I or II controlled substance must also be accompanied by special order forms, with copies provided to the DEA. Because our products are, and our product candidates are expected to be, regulated as Schedule II controlled substances, they will be subject to the DEA's production and procurement quota scheme. The DEA establishes annually an aggregate quota for how much of a controlled substance may be produced in total in the United States based on the DEA's estimate of the quantity needed to meet legitimate scientific and medicinal needs. The limited aggregate amount that the DEA allows to be produced in the United States each year is allocated among individual companies, which must submit applications annually to the DEA for individual production and procurement quotas. We must receive an annual quota from the DEA in order to produce or procure any Schedule I or Schedule II controlled substance for use in manufacturing of our product and product candidates. The DEA may adjust aggregate production quotas and individual production and procurement quotas from time to time during the year, although the DEA has substantial discretion in whether or not to make such adjustments.

To enforce these requirements, the DEA conducts periodic inspections of registered establishments that handle controlled substances. Failure to maintain compliance with applicable requirements, particularly as manifested in loss or diversion, can result in administrative, civil or criminal enforcement action. The DEA may seek civil penalties, refuse to renew necessary registrations or initiate administrative proceedings to revoke those registrations. In some circumstances, violations could result in criminal proceedings.

In addition to federal scheduling, some drugs may be subject to state-controlled substance regulation and thus more extensive requirements than those determined by the DEA and FDA.

Other Healthcare Laws and Compliance Requirements

Manufacturing, sales, promotion and other activities following product approval are also subject to regulation by numerous regulatory authorities in addition to the FDA, including the Centers for Medicare & Medicaid Services, other divisions of the Department of Health and Human Services, the U.S. Department of Justice, the DEA, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency and state and local governments.

We will also be subject to various federal and state laws targeting fraud and abuse in the healthcare industry. These laws may impact, among other things, our proposed sales, marketing and educational programs. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

- The federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either (1) the referral of an individual to a person for furnishing any item or service for which payment is available under a federal health care program, or (2) the purchase, lease, order or recommendation thereof of any good, facility, service or item for which payment is available under a federal health care program;

- 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, false or fraudulent claims for payment from the federal government or making or using, or causing to be made or used, a false record or statement material to a false or fraudulent claim;

- The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program, obtaining money or property of the health care benefit program through false representations or knowingly and willingly falsifying, concealing or covering up a material fact, making false statements or using or making any false or fraudulent document in connection with the delivery of, or payment for, health care benefits or services;

- 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;

- The provision under the ACA commonly referred to as the Sunshine Act, which requires applicable manufacturers of covered drugs, devices, biologics and medical supplies to track and annually report to CMS payments and other transfers of value provided to physicians and teaching hospitals and certain ownership and investment interests held by physicians or their immediate family members in applicable manufacturers and group purchasing organizations; and

- State law equivalents of each of the above federal laws, such as the Anti-Kickback Statute and False Claims Act, and state laws concerning security and privacy of health care information, which may differ in substance and application from state-to-state thereby complicating compliance efforts.

The ACA broadened the reach of the fraud and abuse laws by, among other things, amending the intent requirement of the federal Anti-Kickback Statute and the applicable criminal healthcare fraud statutes contained within 42 U.S.C. Section 1320a-7b. Pursuant to the statutory amendment, a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, the ACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act or the civil monetary penalties statute. Many states have adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare items or services reimbursed by any source, not only the Medicare and Medicaid programs.

As noted above, the federal False Claims Act prohibits anyone from, among other things, knowingly presenting, or causing to be presented, false or fraudulent claims for payment from federal programs, including Medicare and Medicaid. 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. 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 prosecuted under the federal False Claims Act in connection with their off-label promotion of drugs. Penalties for such violations could include three times the actual damages sustained by the government, mandatory civil penalties between $10,781 and $21,563 for each separate false claim, exclusion from participation in federal healthcare programs, and the potential implication of various federal criminal statutes. Private individuals also have the ability to bring actions under the federal False Claims Act, or *qui tam* actions, and certain states have enacted laws based on the federal False Claims Act.

Pharmaceutical Coverage, Pricing and Reimbursement

In the United States and markets in other countries, sales of any products for which we receive regulatory approval for commercial sale will depend in part on the availability of reimbursement from third party payors, including government health administrative authorities, managed care providers, private health insurers and other organizations. Third party payors are increasingly examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy, and, accordingly, significant uncertainty exists as to the reimbursement status of newly approved therapeutics. Adequate third-party reimbursement may not be available for our products to enable us to realize an appropriate return on our investment in research and product development. We are unable to predict the future course of federal or state health care legislation and regulations, including regulations that will be issued to implement provisions of the health care reform legislation enacted in 2010, known as the Affordable Care Act. The Affordable Care Act and further changes in the law or regulatory framework could have a material adverse effect on our business.

International Regulation

In addition to regulations in the United States, there are a variety of foreign regulations governing clinical trials and commercial sales and distribution of any product candidates. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval.

Employees

As of December 31, 2018, we had 6 full-time employees. None of our employees are represented by a labor union and we consider our employee relations to be good.

Item 1A. Risk Factors

The following information sets forth risk factors that could cause our actual results to differ materially from those contained in the forward-looking statements we have made in this Form 10-K and those we may make from time to time. You should carefully consider the risks described below, in addition to the other information contained in this Form 10-K, before making an investment decision. Our business, financial condition or results of operations could be harmed by any of these risks. The risks and uncertainties described below are not the only ones we face. Additional risks not presently known to us or other factors not perceived by us to present significant risks to our business at this time also may impair our business operations.

Risks Related to our Potential Merger with InvaGen Pharmaceuticals

If the proposed merger is not completed, our business could be materially and adversely affected and our stock price could decline.

On November 12, 2018, the Company entered into SPMA with InvaGen, Merger Sub and Fortress, pursuant to which, among other things and subject to the satisfaction or waiver of the conditions set forth therein, Merger Sub will merge with and into the Company, with the Company continuing as the surviving entity and becoming a wholly-owned subsidiary of InvaGen. The transaction is valued at $215 million, in addition to certain CVR payments.

Consummation of the Merger Transaction is conditioned upon FDA approval of IV Tramadol, its labeling and usage and the absence of any REMS restrictions in effect with respect to IV Tramadol. Additionally, the SPMA contains customary representations, warranties, covenants and termination rights as well as certain customary conditions, including, among others, the expiration of any waiting period applicable to the acquisition under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended. Therefore, the Merger Transaction may not be completed or may not be completed as quickly as expected. If the SPMA is terminated, the market price of our ordinary shares will likely decline, as we believe that our market price reflects an assumption that the merger will be completed. In addition, our share price may be adversely affected as a result of the fact that we have incurred and will continue to incur significant expenses related to the Merger Transaction that will not be recovered if the Merger Transaction is not completed. If the SPMA is terminated under certain circumstances, we may be obligated to pay InvaGen a termination fee of $10.0 million. As a consequence of the failure of the merger to be completed, as well as of some or all of these potential effects of the termination of the SPMA, our business could be materially and adversely affected.

The fact that there is a merger pending could have an adverse effect on our business and results of operations.

While the merger is pending, it creates uncertainty about our future. We are subject to a number of risks that may adversely affect our business and results of operations, including:

- the diversion of management and employee attention may detract from our ability to obtain regulatory approval for and, if approved, to successfully commercialize IV Tramadol in a timely manner;
- continuing to incur significant expenses related to the merger;
- the merger agreement restricting us from engaging in business advantageous activities outside of our ordinary course of business without InvaGen's consent; and
- being unable to respond effectively to competitive pressures, industry developments and future opportunities.

If the merger occurs, our shareholders will not be able to participate in any upside to our business other than through the CVRs; if the required commercialization milestone under the CVRs is not achieved, shareholders may not realize any value from the CVRs.

Upon consummation of the merger, our shareholders will receive an estimated per share price of $13.92 in cash at closing and a contractual contingent value right, or a CVR, to receive additional consideration in cash if certain milestones related to the commercialization of IV Tramadol are achieved, but will not receive any shares of InvaGen. Even if our business following the merger performs well, our current shareholders will not receive any additional consideration or be able to share in the increased value of our business by virtue of being equity owners.

Risks Related to Our Business and Industry

We currently have no drug products for sale, and only one drug product candidate, IV Tramadol. We are dependent on the success of IV Tramadol and cannot guarantee that we will be able to complete the required studies or that this product candidate will receive regulatory approval or be successfully commercialized.

Our business success depends on our ability to obtain regulatory approval for and to successfully commercialize our only product candidate, IV Tramadol, and any significant delays in obtaining approval for and commercializing IV Tramadol will have a substantial adverse impact on our business and financial condition.

If approved, our ability to generate revenues from IV Tramadol will depend on our ability to:

- hire, train, deploy and support our sales force;
- create market demand for IV Tramadol through our own marketing and sales activities, and any other arrangements to promote this product candidate we may later establish;
- conduct such marketing and sales activities in a manner that is compliant with federal and state laws, including restrictions on off-label promotion and anti-kickback requirements;
- obtain sufficient quantities of IV Tramadol from our third-party manufacturers as required to meet commercial demand at launch and thereafter;
- establish and maintain agreements with wholesalers, distributors and group purchasing organizations on commercially reasonable terms;
- obtain and maintain government and private payer reimbursement for our product; and
- maintain patent protection and regulatory exclusivity for IV Tramadol.

We may not receive regulatory approval for IV Tramadol or future product candidates, or its or their approvals may be delayed, which would have a material adverse effect on our business and financial condition.

IV Tramadol and other future product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by the European Medicines Agency, or the EMA, and similar regulatory authorities outside the United States. Failure to obtain marketing approval for our product candidate IV Tramadol or any future product candidates will prevent us from commercializing the product candidates. We have not received approval to market IV Tramadol from regulatory authorities in any jurisdiction. We have only limited experience in conducting preclinical and clinical studies and filing and supporting the applications necessary to gain marketing approvals and expect to rely on third party contract research organizations as well as consultants and vendors to assist us in this process. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities.

Our product candidate IV Tramadol or any future product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use.

If our product candidate or any future product candidate receives marketing approval, the accompanying label may limit the approved use of our drug, which could limit sales of the product. In addition, our third-party supplier may not pass an inspection by the FDA of its manufacturing facilities and we may be forced to identify, qualify and implement additional suppliers.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive, may take many years if approval is granted at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional preclinical studies or clinical trials. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

If we experience delays in obtaining approval or if we fail to obtain approval of our product candidate or any future product candidates, the commercial prospects for our product candidates may be harmed and our ability to generate revenue will be materially impaired.

In addition, even if we were to obtain approval, regulatory authorities may, among other things, approve our product candidate or any future product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our product, 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. The regulatory authority may also require the label to contain warnings, contraindications, or precautions that limit the commercialization of that product. Any of these scenarios could compromise the commercial prospects for our product candidate or any future product candidates.

If IV Tramadol is approved and our contract manufacturer fails to produce the product in the volumes that we require on a timely basis, to produce the product according to the applicable quality standards and requirements, or to comply with stringent regulations applicable to pharmaceutical drug manufacturers, we may face delays in the commercialization of this product candidate, lose potential revenues or be unable to meet market demand.

The manufacture of pharmaceutical products requires significant expertise and capital investment, including the development of advanced manufacturing techniques and process controls, and the use of specialized processing equipment. We have entered into a development and supply agreement for the completion of pre-commercialization manufacturing development activities and the manufacture of commercial supplies of IV Tramadol. Any termination or disruption of this relationship may materially harm our business and financial condition, and frustrate any commercialization efforts for this product candidate.

In order to meet anticipated demand for IV Tramadol, if this product candidate is approved, we have one manufacturer to provide us clinical and commercial supply of IV Tramadol in accordance with the Current Good Manufacturing Practice, or cGMP. We also plan to qualify a backup manufacturer.

All of our contract manufacturers must comply with strictly enforced federal, state and foreign regulations, including cGMP requirements enforced by the FDA through its facilities inspection program, as well as controlled substance handling and security requirements, and we have little control over their compliance with these regulations. Any failure to comply with applicable regulations may result in fines and civil penalties, suspension of production, suspension or delay in product approval, product seizure or recall, or withdrawal of product approval, and would limit the availability of our product. Any manufacturing defect or error discovered after products have been produced and distributed could result in even more significant consequences, including costly recall procedures, re-stocking costs, damage to our reputation and potential for product liability claims.

If the commercial manufacturers upon whom we rely to manufacture IV Tramadol, and any other product candidates we may in-license, fail to deliver the required commercial quantities on a timely basis at commercially reasonable prices, we would likely be unable to meet demand for our products and we would lose potential revenues.

If serious adverse or unacceptable side effects are identified during the development of IV Tramadol or our future product candidates, we may need to abandon or limit our development of some of our product candidates.

If our product candidate or future product candidates are associated with undesirable side effects in clinical trials or have characteristics that are unexpected, we may need to abandon their development or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. In our industry, many compounds that initially showed promise in early stage testing have later been found to cause side effects that prevented further development of the compound. In the event that our preclinical or clinical trials reveal a high and unacceptable severity and prevalence of side effects, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development or deny approval of our product candidate or future product candidates for any or all targeted indications. The FDA could also issue a letter requesting additional data or information prior to making a final decision regarding whether or not to approve a product candidate. The number of requests for additional data or information issued by the FDA in recent years has increased, and resulted in substantial delays in the approval of several new drugs. Undesirable side effects caused by our product candidate or future product candidates could also result in the inclusion of serious risk information in our product labeling, application of burdensome post-market requirements, or denial of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications, and in turn prevent us from commercializing and generating revenues from the sale of our product candidate. Drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial and could result in potential product liability claims.

For example, some of the adverse events observed in the IV Tramadol clinical trials completed to date include nausea, dizziness, drowsiness, tiredness, sweating, vomiting, dry mouth, somnolence and hypotension.

Additionally, if one or more of our current or future product candidates receives marketing approval, and we or others later identify undesirable side effects caused by this product, a number of potentially significant negative consequences could result, including:

- regulatory authorities may require the addition of serious risk-related labeling statements, specific warnings, precautions, or contraindication;
- regulatory authorities may suspend or withdraw their approval of the product, or require it to be removed from the market;
- regulatory authorities may require implementation of burdensome post-market risk mitigation strategies and practices;
- we may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of the product; or
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining marketing approval and market acceptance of our product candidate or future product candidates or could substantially increase our commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenues from its sale.

Even if IV Tramadol receives regulatory approval, which may not occur, it and any other products we may market will remain subject to substantial regulatory scrutiny.

IV Tramadol and any other product candidates we may license or acquire will also be subject to ongoing requirements and review of the FDA and other regulatory authorities. These requirements include, among others, labeling, packaging, storage, advertising, promotion, record-keeping and submission of safety and other post-market information and reports, registration and listing requirements, ongoing cGMP requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping of the drug.

The FDA may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the product. The FDA closely regulates the post-approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use and off-label information and if we do not market our products for only their approved indications and on-label information, we may be subject to enforcement action for off-label marketing as well as false claims liability. Violations of the FDCA relating to the promotion of prescription drugs may lead to investigations alleging violations of federal and state health care fraud and abuse laws, as well as state consumer protection laws.

In addition, later discovery of previously unknown adverse events or other problems with our products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on such products, operations, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- fines, restitution or disgorgement of profits;
- suspension or withdrawal of marketing or regulatory approvals;
- suspension of any ongoing clinical trials;
- refusal to permit the import or export of our products;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

The FDA's policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained.

We will need to obtain FDA approval of any proposed product brand names, and any failure or delay associated with such approval may adversely impact our business.

A pharmaceutical product candidate cannot be marketed in the United States or many other countries until we have completed a rigorous and extensive regulatory review processes, including obtaining the approval of a brand name. Any brand names we intend to use for our product candidates will require approval from the FDA regardless of whether we have secured a formal trademark registration from the U.S. Patent and Trademark Office, or USPTO. The FDA typically conducts a review of proposed product brand names, including an evaluation of potential for confusion with other product names. The FDA may also object to a product brand name if it believes the name inappropriately implies medical claims. If the FDA objects to any of our proposed product brand names, we may be required to adopt an alternative brand name for our product candidates. If we adopt an alternative brand name, we would lose the benefit of our existing trademark applications for such product candidate and may be required to expend significant additional resources in an effort to identify a suitable product brand name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. We may be unable 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 candidates.

Our current and future relationships with customers and third-party payors in the United States and elsewhere may be subject, directly or indirectly, to applicable anti-kickback, fraud and abuse, false claims, transparency, health information privacy and security and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished prof its and future earnings.

Healthcare providers, physicians and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our future arrangements with third party payors, distributors, retailers, marketers and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Anti-Kickback Statute, the federal False Claims Act, and similar state or foreign laws which may constrain the business or financial arrangements and relationships through which we sell, market and distribute any product candidates for which we obtain marketing approval. In addition, we may be subject to transparency laws and patient privacy regulation by U.S. federal and state governments and by governments in foreign jurisdictions in which we conduct our business. The applicable federal, state and foreign healthcare laws and regulations that may affect our ability to operate include, but are not necessarily limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs, such as Medicare and Medicaid;

- federal civil and criminal false claims laws and civil monetary penalty laws, including the federal False Claims Act, which impose criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment that are false or fraudulent, making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government, or the knowing retention of an overpayment from government health care programs; the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose obligations on covered healthcare providers, health plans, and healthcare clearinghouses, as well as their business associates that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- the federal Open Payments program, which requires manufacturers of certain 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 "payments or other transfers of value" made to physicians, which is defined to include doctors, dentists, optometrists, podiatrists and chiropractors, and certain teaching hospitals and applicable manufacturers to report annually to CMS ownership and investment interests held by the physicians and their immediate family members. Data collection began on August 1, 2013 with requirements for manufacturers to submit reports to CMS by March 31, 2014 and 90 days after the end of each subsequent calendar year. Disclosure of such information was made by CMS on a publicly available website beginning in September 2014; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third party payors, including private insurers; state and foreign 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 otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. 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, including, without limitation, damages, fines, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations, which could have a material adverse effect on our business. If any of the physicians or other healthcare providers or entities with whom we expect to do business, including our collaborators, is found not to be in compliance with applicable laws, it may be subject to criminal, civil or administrative sanctions, including exclusions from participation in government healthcare programs, which could also materially affect our business.

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.

Any regulatory approval 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, our ability to effectively market and sell our products may be reduced and our business may be adversely affected.

While physicians may choose to prescribe drugs for uses that are not described in the product's approved labeling and for uses that differ from those tested in clinical studies and approved by the regulatory authorities, our ability to promote the products is 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 United States 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 or off-label information. If our promotional activities fail to comply with these 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 suspend or withdraw an approved product from the market, require a recall or corrective advertising, institute fines, or could result in disgorgement of money, operating restrictions, injunctions or civil or criminal prosecution by the government, any of which could harm our reputation and business.

Current and future legislation may increase the difficulty and cost for us to obtain marketing approval of, and to commercialize, our product candidates and may affect the prices we are able to obtain.

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 prevent or delay marketing approval of our product candidate, restrict or regulate post-approval activities, and affect our ability to profitably sell any product candidates for which we obtain marketing approval.

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the MMA, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and certain disabled people and introduced a reimbursement methodology based on average sales prices for physician-administered drugs. In addition, this law provided authority for limiting the number of drugs that will be covered in any therapeutic class. Cost reduction initiatives and other provisions of this law and future laws could decrease the coverage and price that we will receive for any approved products. While the MMA only applies to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Therefore, any limitations in reimbursement that results from the MMA may result in reductions in payments from private payors.

In March 2010, the Patient Protection and Affordable Care Act, or the ACA, became law. The ACA is a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms.

Among the provisions of the ACA of importance to our potential product candidate are the following:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic products;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program;
- expansion of healthcare fraud and abuse laws, including the False Claims Act and the Anti-Kickback Statute, new government investigative powers, and enhanced penalties for noncompliance;
- new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices;
- extension of manufacturers' Medicaid rebate liability;
- expansion of eligibility criteria for Medicaid programs;
- expansion of the entities eligible for discounts under the Public Health Service Act's pharmaceutical pricing program;
- new requirements to report financial arrangements with physicians and teaching hospitals;
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

The Supreme Court upheld the ACA in the main challenge to the constitutionality of the law in 2012. Specifically, the Supreme Court held that the individual mandate and corresponding penalty was constitutional because it would be considered a tax by the federal government. The Supreme Court also upheld federal subsidies for purchasers of insurance through federally facilitated exchanges in a decision released in June 2015.

President Trump ran for office on a platform that supported the repeal of the ACA, and one of his first actions after his inauguration was to sign an Executive Order instructing federal agencies to waive or delay requirements of the ACA that impose economic or regulatory burdens on states, families, the health-care industry and others. Modifications to or repeal of all or certain provisions of the ACA have been attempted in Congress as a result of the outcome of the recent presidential and congressional elections, consistent with statements made by the incoming administration and members of Congress during the presidential and congressional campaigns and following the election. In January 2017, Congress voted to adopt a budget resolution for fiscal year 2017, or the Budget Resolution, that authorizes the implementation of legislation that would repeal portions of the ACA. The Budget Resolution is not a law. However, it is widely viewed as the first step toward the passage of legislation that would repeal certain aspects of the ACA. In March 2017, following the passage of the budget resolution for fiscal year 2017, the U.S. House of Representatives passed legislation known as the American Health Care Act of 2017, which, if enacted, would amend or repeal significant portions of the ACA. Attempts in the Senate to pass ACA repeal legislation, including the Better Care Reconciliation Act of 2017, so far have been unsuccessful. At the end of 2017, Congress passed the Tax Cuts and Jobs Act, which repealed the penalty for individuals who fail to maintain minimum essential health coverage as required by the ACA. Following this legislation, Texas and 19 other states filed a lawsuit alleging that the ACA is unconstitutional as the individual mandate was repealed, undermining the legal basis for the Supreme Court's prior decision. This lawsuit is ongoing and the outcome may have a significant impact on our business.

Most recently, the Bipartisan Budget Act of 2018, the "BBA," which set government spending levels for Fiscal Years 2018 and 2019, revised certain provisions of the ACA. Specifically, beginning in 2019, the BBA increased manufacturer point-of-sale discounts off negotiated prices of applicable brand drugs in the Medicare Part D coverage gap from 50% to 70%, ultimately increasing the liability for brand drug manufacturers. Further, this mandatory manufacturer discount applies to biosimilars beginning in 2019.

The Trump Administration has also taken several regulatory steps to redirect ACA implementation. The Department of Health and Human Services, the "HHS",finalized a hospital payment reduction for drugs acquired through the 340B Drug Pricing Program and has proposed to expand this payment reduction to other hospital settings. HHS also has taken steps to increase the availability of cheaper health insurance options, typically with fewer benefits. The Administration has also signaled its intention to address drug prices and to increase competition, including by increasing the availability of biosimilars and generic drugs. As these are regulatory actions, a new administration could undo or modify these efforts.

There have been, and likely will continue to be, legislative and regulatory proposals at the federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare products and services. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare may adversely affect:

- the demand for any products for which we may obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;
- our ability to generate revenues and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

In addition, governments may impose price controls, which may adversely affect our future profitability.

We expect that the ACA, 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 receive for any approved drug. Any reduction in reimbursement from Medicare or other government healthcare 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.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals, if any, of our product candidates, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing conditions and other requirements.

Public concern regarding the safety of opioid drug products such as IV Tramadol could delay or limit our ability to obtain regulatory approval, result in the inclusion of serious risk information in our labeling, negatively impact market performance, or require us to undertake other activities that may entail additional costs.

In light of 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 controlled substance 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. 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 new law 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. It 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 conduct additional preclinical studies or clinical trials prior to approving IV Tramadol, our ability to obtain approval of this product candidate will be delayed. If the FDA requires us to provide additional clinical or preclinical data following the approval of IV Tramadol, the indications for which this product candidate is approved may be limited or there may be specific warnings or limitations on production dosing, and our efforts to commercialize IV Tramadol may be otherwise adversely impacted.

Rising public, medical, Congressional, and agency concern around the prescription of controlled substance drug products to patients and a growing movement to reduce the use of opioid drug products, to develop abuse-deterrent products, and to prevent dependence also could negatively impact our ability to commercialize and generate revenue from IV Tramadol if it is approved for marketing in the United States.

If the DEA decides to reschedule Tramadol from a Schedule IV controlled substance to a more restrictive Schedule, IV Tramadol could lose its competitive advantage, and our related clinical development and regulatory approval could be delayed or prevented.

In July 2014, the U.S. Drug Enforcement Administration, or DEA, classified Tramadol as a Schedule IV controlled substance. In comparison, other opioids, which have a high potential for abuse, are mostly classified as Schedule I and II controlled substances. If approved, IV Tramadol will be the only intravenous Schedule IV opioid on the market. However, in the current environment where the opioid epidemic is a recognized problem in the United States, there is a possibility that the DEA might reschedule Tramadol as a Schedule I, II or III controlled substance. Such a rescheduling would severely impair IV Tramadol's current competitive advantage over traditional opioids and may affect our ability to market IV Tramadol as a safe alternative pain management product.

If we experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented.

We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States. Some of our competitors have ongoing clinical trials for product candidates that treat the same indications as our product candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates. Available therapies for the indications we are pursuing can also affect enrollment in our clinical trials. Patient enrollment is affected by other factors including, but not necessarily limited to:

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

Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidate or future product candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing.

We expect intense competition for IV Tramadol, and new products may emerge that provide different or better therapeutic alternatives for our targeted indications.

The biotechnology and pharmaceutical industries are subject to rapid and intense technological change. We face, and will continue to face, competition in the development and marketing of IV Tramadol from academic institutions, government agencies, research institutions and biotechnology and pharmaceutical companies. There can be no assurance that developments by others will not render IV Tramadol obsolete or noncompetitive. Furthermore, new developments, including the development of other drug technologies and methods of preventing the incidence of disease, occur in the pharmaceutical industry at a rapid pace. These developments may render IV Tramadol obsolete or noncompetitive.

IV Tramadol will compete with well-established products with similar indications. Competing products available for the management of pain include Ofirmev (IV acetaminophen) and IV formulations of NSAIDs such as Dyloject (diclofenac), Toradol (ketorolac), and Caldolor (ibuprofen). In addition, we also expect to compete with agents such as Exparel, a liposome injection of bupivacaine indicated for administration into the surgical site to produce postsurgical analgesia. In addition to approved products, there are a number of product candidates in development for the management of acute pain. The late-stage pain development pipeline is replete with reformulations and fixed-dose combination products of already available therapies. Among specific drug classes, opioid analgesics and NSAIDs represent the greatest number of agents in development. Most investigational opioids that have reached the later stages of clinical development are new formulations of already marketed opioids. Likewise, investigational NSAIDs — mostly lower dose injectable reformulations of already approved compounds — are another significant area of late-stage drug development in the postoperative pain space. There are also several agents with novel mechanisms in clinical development, such as CR845 (Cara Therapeutics, Inc.) and TRV130 (Trevena, Inc.).

Competitors may seek to develop alternative formulations of IV centrally acting synthetic opioid analgesics for our targeted indications that do not directly infringe on our in-licensed patent rights. The commercial opportunity for IV Tramadol could be significantly harmed if competitors are able to develop alternative formulations outside the scope of our in-licensed patents. Compared to us, many of our potential competitors have substantially greater:

- capital resources;
- development resources, including personnel and technology;
- clinical trial experience;
- regulatory experience;
- expertise in prosecution of intellectual property rights; and
- manufacturing, distribution and sales and marketing experience.

As a result of these factors, our competitors may obtain regulatory approval of their products more rapidly than we are able to or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize IV Tramadol. Our competitors may also develop drugs that are more effective, safe, useful and less costly than ours and may be more successful than us in manufacturing and marketing their products.

If IV Tramadol does not achieve broad market acceptance, the revenues that we generate from its sales will be limited.

The commercial success of IV Tramadol, if approved, will depend upon its acceptance by the medical community, our ability to ensure that the drug is included in hospital formularies, and coverage and reimbursement for IV Tramadol by third party payors, including government payors. The degree of market acceptance of IV Tramadol or any other product candidate we may license or acquire would depend on a number of factors, including, but not necessarily limited to:

- the efficacy and safety as demonstrated in clinical trials;
- the timing of market introduction of such product candidate as well as competitive products;
- the clinical indications for which the drug is approved;
- acceptance by physicians, major operators of cancer clinics and patients of the drug as a safe and effective treatment;
- the safety of such product candidate seen in a broader patient group (i.e., real world use);
- the availability, cost and potential advantages of alternative treatments, including less expensive generic drugs;
- the availability of adequate reimbursement and pricing by third party payors and government authorities;
- the relative convenience and ease of administration of the product candidate for clinical practices;
- the product labeling or product insert required by the FDA or regulatory authority in other countries, including any contradictions, warnings, drug interactions, or other precautions;
- the approval, availability, market acceptance and reimbursement for a companion diagnostic, if any;
- the prevalence and severity of adverse side effects;
- the effectiveness of our sales and marketing efforts;
- changes in the standard of care for the targeted indications for our product candidate or future product candidates, which could reduce the marketing impact of any superiority claims that we could make following FDA approval; and
- potential advantages over, and availability of, alternative treatments.

If any product candidate that we develop does not provide a treatment regimen that is as beneficial as, or is not perceived as being as beneficial as, the current standard of care or otherwise does not provide patient benefit, that product candidate, if approved for commercial sale by the FDA or other regulatory authorities, likely will not achieve market acceptance. Our ability to effectively promote and sell IV Tramadol and any other product candidates we may license or acquire in the hospital marketplace will also depend on pricing and cost effectiveness, including our ability to produce a product at a competitive price and achieve acceptance of the product onto hospital formularies, as well as our ability to obtain sufficient third-party coverage or reimbursement. Since many hospitals are members of group purchasing organizations, which leverage the purchasing power of a group of entities to obtain discounts based on the collective buying power of the group, our ability to attract customers in the hospital marketplace will also depend on our ability to effectively promote our product candidates to group purchasing organizations. We will also need to demonstrate acceptable evidence of safety and efficacy, as well as relative convenience and ease of administration. Market acceptance could be further limited depending on the prevalence and severity of any expected or unexpected adverse side effects associated with our product candidates. If our product candidates are approved but do not achieve an adequate level of acceptance by physicians, health care payors and patients, we may not generate sufficient revenue from these products, and we may not become or remain profitable. In addition, our efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may never be successful.

If the government or third-party payors fail to provide adequate coverage and payment rates for IV Tramadol or any future products we may license or acquire in the future, if any, or if hospitals choose to use therapies that are less expensive, our revenue and prospects for profitability will be limited.

In both domestic and foreign markets, our sales of any future products will depend in part upon the availability of coverage and reimbursement from third party payors. Such third-party payors include government health programs such as Medicare, managed care providers, private health insurers and other organizations. In particular, many U.S. hospitals receive a fixed reimbursement amount per procedure for certain surgeries and other treatment therapies they perform. Because this amount may not be based on the actual expenses the hospital incurs, hospitals may choose to use therapies which are less expensive when compared to our product candidate or future product candidates. Accordingly, IV Tramadol or any other product candidates that we may in-license or acquire, if approved, will face competition from other therapies and drugs for these limited hospital financial resources. We may need to conduct post-marketing studies in order to demonstrate the cost-effectiveness of any future products to the satisfaction of hospitals, other target customers and their third-party payors. Such studies might require us to commit a significant amount of management time and financial and other resources. Our future products might not ultimately be considered cost-effective. Adequate third-party coverage and reimbursement might not be available to enable us to maintain price levels sufficient to realize an appropriate return on investment in product development.

If we are unable to establish sales, marketing and distribution capabilities or to enter into agreements with third parties to market and sell our product candidates, we may not be successful in commercializing our product candidates if and when they are approved.

We currently do not have a marketing or sales organization for the marketing, sales and distribution of pharmaceutical products. In order to commercialize any product candidate that receives marketing approval, we would need to build marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. In the event of successful development and regulatory approval of IV Tramadol or another product candidate, we expect to build a targeted specialist sales force to market or co-promote the product. There are risks involved with establishing our own sales, marketing and distribution capabilities. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize our future products, if any, on our own include, but are not necessarily limited to:

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any future products;
- the lack of complementary or other products to be offered by sales personnel, which may put us at a competitive disadvantage from the perspective of sales efficiency relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

As an alternative to establishing our own sales force, we may choose to partner with third parties that have well-established direct sales forces to sell, market and distribute our products. There are risks involved with partnering with third party sales forces, including ensuring adequate training on the product, regulatory, and compliance requirements associated with promotion of the product.

We rely, and expect to continue to rely, on third parties to conduct our preclinical studies and clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials or complying with applicable regulatory requirements.

We rely on third party contract research organizations and clinical research organizations to conduct some of our preclinical studies and all of our clinical trials for IV Tramadol and for any future product candidates. We expect to continue to rely on third parties, such as contract research organizations, clinical research organizations, clinical data management organizations, medical institutions and clinical investigators, to conduct some of our preclinical studies and all of our clinical trials. The agreements with these third parties might terminate for a variety of reasons, including a failure to perform by the third parties. If we need to enter into alternative arrangements, that could delay our product development activities.

Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our legal and regulatory product development responsibilities. For example, we will remain responsible for ensuring that each of our preclinical studies and clinical trials are conducted in accordance with the general investigational plan and protocols for the trial and for ensuring that our preclinical studies are conducted in accordance with good laboratory practice, or GLP, as appropriate. Moreover, the FDA requires us to comply with standards, commonly referred to as good clinical practices, or GCPs, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Regulatory authorities enforce these requirements through periodic inspections of trial sponsors, clinical investigators and trial sites. If we or any of our clinical research organizations fail to comply with applicable GCPs, 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 complies with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within specified timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

The third parties with whom we have contracted to help perform our preclinical studies or clinical trials may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our preclinical studies or clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates.

If any of our relationships with these third-party contract research organizations or clinical research organizations terminates, we may not be able to enter into arrangements with alternative contract research organizations or clinical research organizations or to do so on commercially reasonable terms. Switching or adding additional contract research organizations or clinical research organizations involves additional cost and requires extensive training and management time and focus. In addition, there is a natural transition period when a new contract research organization or clinical research organization commences work. As a result, delays could occur, which could compromise our ability to meet our desired development timelines. Though we carefully manage our relationships with our contract research organizations or clinical research organizations, there can be no assurance that we will not encounter challenges or delays in the future.

We contract with third parties for the manufacture of our product candidates for preclinical and clinical testing and expect to continue to do so for commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not have any manufacturing facilities or personnel. We rely, and expect to continue to rely, on third parties for the manufacture of our product candidates for preclinical and clinical testing, as well as for commercial manufacture if any of our product candidates receive marketing approval. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.

We also expect to rely on third party manufacturers or third-party collaborators for the manufacture of commercial supply of any product candidates for which our collaborators or we obtain marketing approval. We may be unable to establish any agreements with third party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third party manufacturers, reliance on third party manufacturers entails additional risks, including, but not necessarily limited to:

- reliance on the third party for regulatory compliance and quality assurance;
- raw material or active ingredient shortages from suppliers the third party has qualified for our product;
- the possible breach of the manufacturing agreement by the third party;
- manufacturing delays if our third-party manufacturers give greater priority to the supply of other products over our product candidates or otherwise do not satisfactorily perform according to the terms of the agreement between us;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how; and
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit an NDA to the FDA. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturers for compliance with cGMP regulations for manufacture of our product candidates. Third party manufacturers may not be able to comply with the cGMP regulations or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products.

IV Tramadol and any products that we may develop may compete with other product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us. Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. We do not currently have arrangements in place for redundant supply or a second source for bulk drug substance. If our current contract manufacturers cannot perform as agreed, we may be required to replace such manufacturers. We may incur added costs and delays in identifying and qualifying any replacement manufacturers.

The U.S. Drug Enforcement Administration, or the DEA, restricts the importation of a controlled substance finished drug product when the same substance is commercially available in the United States, which could reduce the number of potential alternative manufacturers for IV Tramadol.

Our current and anticipated future dependence upon others for the manufacture of our product candidates or products may adversely affect our future profit margins and our ability to commercialize any products that receive marketing approval on a timely and competitive basis.

We also expect to rely on other third parties to store and distribute drug supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of our product candidates or commercialization of our products, producing additional losses and depriving us of potential product revenue.

We rely on clinical data and results obtained by third parties that could ultimately prove to be inaccurate or unreliable.

As part of our strategy to mitigate development risk, we seek to develop product candidates with validated mechanisms of action and we utilize biomarkers to assess potential clinical efficacy early in the development process. This strategy necessarily relies upon clinical data and other results obtained by third parties that may ultimately prove to be inaccurate or unreliable. Further, such clinical data and results may be based on products or product candidates that are significantly different from our product candidate or future product candidates. If the third-party data and results we rely upon prove to be inaccurate, unreliable or not applicable to our product candidate or future product candidate, we could make inaccurate assumptions and conclusions about our product candidates and our research and development efforts could be compromised and called into question during the review or any marketing applications we submit.

If we breach the agreement under which we license rights to IV Tramadol, we could lose the ability to continue to develop and commercialize this product candidate.

In February 2015, Fortress obtained an exclusive license to IV Tramadol for the U.S. market from Revogenex Ireland Ltd., or Revogenex, pursuant to the License Agreement; Fortress subsequently transferred the License Agreement to us. Because we have in-licensed the rights to this product candidate from a third party, if there is any dispute between us and our licensor regarding our rights under the License Agreement, our ability to develop and commercialize this product candidate may be adversely affected. Any uncured, material breach under the License Agreement could result in our loss of exclusive rights to our product candidate and may lead to a complete termination of our related product development efforts.

We may not be able to manage our business effectively if we are unable to attract and retain key personnel.

We may not be able to attract or retain qualified management and commercial, scientific and clinical personnel in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses. If we are not able to attract and retain necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy.

Our employees, consultants, or third-party partners may engage in misconduct or other improper activities, including those that result in noncompliance with certain regulatory standards and requirements, which could have a material adverse effect on our business.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees, consultants, or third-party partners could include intentional failures to comply with FDA regulations, provide accurate information to the FDA, comply with manufacturing standards we have established, comply with federal and state healthcare fraud and abuse laws and regulations, 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, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee, consultant, or third-party misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation, as well as civil and criminal liability. 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 governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such 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 have a significant impact on our business and results of operations, including the imposition of significant fines or other civil and/or criminal sanctions.

We face potential product liability exposure, and if successful claims are brought against us, we may incur substantial liability for IV Tramadol or other product candidates we may license or acquire and may have to limit their commercialization.

The use of IV Tramadol and any other product candidates we may license or acquire in clinical trials and the sale of any products for which we obtain marketing approval expose us to the risk of product liability claims. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Product liability claims might be brought against us by consumers, health care providers or others using, administering or selling our products. If we cannot successfully defend ourselves against these claims, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- withdrawal of clinical trial participants;
- termination of clinical trial sites or entire trial programs;
- decreased demand for any product candidates or products that we may develop;
- initiation of investigations by regulators;
- impairment of our business reputation;
- costs of related litigation;
- substantial monetary awards to patients or other claimants;
- loss of revenues;
- reduced resources of our management to pursue our business strategy; and
- the inability to commercialize our product candidate or future product candidates.

We have limited product liability insurance coverage for our clinical trials. However, our insurance coverage may not reimburse us or may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. When needed, we intend to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for our product candidate in development, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us could cause our stock price to fall and, if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business.

Our future growth depends on our ability to identify and acquire or in-license products and if we do not successfully identify and acquire or in-license related product candidates or integrate them into our operations, we may have limited growth opportunities.

An important part of our business strategy is to continue to develop a pipeline of product candidates by acquiring or in-licensing products, businesses or technologies that we believe are a strategic fit with our focus on the hospital marketplace. Future in-licenses or acquisitions, however, may entail numerous operational and financial risks, including:

- exposure to unknown liabilities;
- disruption of our business and diversion of our management's time and attention to develop acquired products or technologies;
- difficulty or inability to secure financing to fund development activities for such acquired or in-licensed technologies in the current economic environment;
- incurrence of substantial debt or dilutive issuances of securities to pay for acquisitions;
- higher than expected acquisition and integration costs;
- increased amortization expenses;
- difficulty and cost in combining the operations and personnel of any acquired businesses with our operations and personnel;
- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and
- inability to retain key employees of any acquired businesses.

We have limited resources to identify and execute the acquisition or in-licensing of third party products, businesses and technologies and integrate them into our current infrastructure. In particular, we may compete with larger pharmaceutical companies and other competitors in our efforts to establish new collaborations and in-licensing opportunities. These competitors likely will have access to greater financial resources than us and may have greater expertise in identifying and evaluating new opportunities. Moreover, we may devote resources to potential acquisitions or in-licensing opportunities that are never completed, or we may fail to realize the anticipated benefits of such efforts.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we focus on research programs and product candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. Although we believe that the safety procedures for handling and disposing of these materials comply with the standards prescribed by these laws and regulations, we cannot eliminate the risk of accidental contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Our business and operations would suffer in the event of system failures.

Despite the implementation of security measures, our internal computer systems are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Any system failure, accident or security breach that causes interruptions in our operations could result in a material disruption of our drug development programs. For example, the loss of clinical trial data from completed clinical trials for IV Tramadol 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 results in a loss or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we may incur liability and the further development of our product candidate may be delayed.

Risks Related to Intellectual Property

If we are unable to obtain and maintain patent protection for our technology and products or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our technology and products may be impaired.

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection in the United States with respect to IV Tramadol or any other product candidates that we may license or acquire and the methods we use to manufacture them, as well as successfully defending these patents and trade secrets against third party challenges. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our product candidates. We will only be able to protect our technologies from unauthorized use by third parties to the extent that valid and enforceable patents or trade secrets cover them.

The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. If our licensors or we fail to obtain or maintain patent protection or trade secret protection for IV Tramadol or any other product candidate we may license or acquire, third parties could use our proprietary information, which could impair our ability to compete in the market and adversely affect our ability to generate revenues and achieve profitability. Moreover, should we enter into other collaborations we may be required to consult with or cede control to collaborators regarding the prosecution, maintenance and enforcement of our patents. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. In addition, no consistent policy regarding the breadth of claims allowed in pharmaceutical or biotechnology patents has emerged to date in the United States. The patent situation outside the United States is even more uncertain. The laws of foreign countries may not protect our rights to the same extent as the laws of the United States. For example, European patent law restricts the patentability of methods of treatment of the human body more than United States law does. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after a first filing, or in some cases at all. Therefore, we cannot know with certainty whether we or our licensors were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions. In the event that a third party has also filed a U.S. patent application relating to our product candidates or a similar invention, we may have to participate in interference proceedings declared by the USPTO to determine priority of invention in the United States. The costs of these proceedings could be substantial and it is possible that our efforts would be unsuccessful, resulting in a material adverse effect on our U.S. patent position. As a result, the issuance, scope, validity, enforceability and commercial value of our or any of our licensors' patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. For example, the federal courts of the United States have taken an increasingly dim view of the patent eligibility of certain subject matter, such as naturally occurring nucleic acid sequences, amino acid sequences and certain methods of utilizing same, which include their detection in a biological sample and diagnostic conclusions arising from their detection. Such subject matter, which had long been a staple of the biotechnology and biopharmaceutical industry to protect their discoveries, is now considered, with few exceptions, ineligible in the first place for protection under the patent laws of the United States. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our patents (if any) or in those licensed from third parties.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and affect the validity, enforceability, scope or defense of our issued patents. 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 are prosecuted and may also affect patent litigation. The USPTO recently developed new regulations and procedures to govern administration 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 on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. 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, all of which could have a material adverse effect on our business and financial condition.

Moreover, we may be subject to a third party preissuance submission of prior art to the USPTO, or become involved in opposition, derivation, reexamination, inter parties review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, patent office trial, proceeding or litigation could reduce the scope of, render unenforceable, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner.

The issuance of a patent does not foreclose challenges to its inventorship, scope, validity or enforceability. Therefore, our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

The patent rights that we have in-licensed covering the infusion time and pharmacokinetics, or PK, profile for IV Tramadol are limited to a specific IV formulation of centrally acting synthetic opioid analgesic, and our market opportunity for this product candidate may be limited by the lack of patent protection for the active ingredient itself and other formulations that may be developed by competitors.

The active ingredients in IV Tramadol have been generic in the United States for a number of years. While we believe that the patent estate covering IV Tramadol (including but not limited to U.S. Patent Nos. 8,895,622; 9,561,195, 9,566,253 9,693,949, 9,968,551 and 9,980,900) provides strong protection, our market opportunity would be limited if a generic manufacturer could obtain regulatory approval for another IV formulation of tramadol and commercialize it without infringing on our patent.

Because it is difficult and costly to protect our proprietary rights, we may not be able to ensure their protection.

The degree of future protection for our proprietary rights is uncertain, because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- our licensors might not have been the first to make the inventions covered by each of our pending patent applications and issued patents;
- our licensors might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate our product candidate or any future product candidates technologies;
- it is possible that none of the pending patent applications licensed to us will result in issued patents;
- the issued patents covering our product candidate or any future product candidates may not provide a basis for market exclusivity for active products, may not provide us with any competitive advantages, or may be challenged by third parties;
- we may not develop additional proprietary technologies that are patentable; or
- patents of others may have an adverse effect on our business.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our issued patents or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents. In addition, in a patent infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or 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 proceeding could put one or more of our patents at risk of being invalidated, rendered unenforceable, or interpreted narrowly.

If we are sued for infringing intellectual property rights of third parties, it will be costly and time consuming, and an unfavorable outcome in any litigation would harm our business.

Our ability to develop, manufacture, market and sell IV Tramadol or any other product candidates that we may license or acquire depends upon our ability to avoid infringing the proprietary rights of third parties. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the general fields of pain treatment and cover the use of numerous compounds and formulations in our targeted markets. Because of the uncertainty inherent in any patent or other litigation involving proprietary rights, we and our licensors may not be successful in defending intellectual property claims by third parties, which could have a material adverse effect on our results of operations. Regardless of the outcome of any litigation, defending the litigation may be expensive, time-consuming and distracting to management. In addition, because patent applications can take many years to issue, there may be currently pending applications, unknown to us, which may later result in issued patents that IV Tramadol may infringe. There could also be existing patents of which we are not aware that IV Tramadol may inadvertently infringe.

There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and biopharmaceutical industries generally. If a third-party claims that we infringe on their patents or misappropriated their technology, we could face a number of issues, including:

- infringement and other intellectual property claims which, with or without merit, can be expensive and time consuming to litigate and can divert management's attention from our core business;
- substantial damages for past infringement which we may have to pay if a court decides that our product infringes on a competitor's patent;
- a court prohibiting us from selling or licensing our product unless the patent holder licenses the patent to us, which it would not be required to do;
- if a license is available from a patent holder, we may have to pay substantial royalties or grant cross licenses to our patents; and
- redesigning our processes so they do not infringe, which may not be possible or could require substantial funds and time.

Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace.

We may need to license certain intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms.

A third party may hold intellectual property, including patent rights that are important or necessary to the development and commercialization of our products. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our products, in which case we would be required to obtain a license from these third parties on commercially reasonable terms, or our business could be harmed, possibly materially.

If we fail to comply with our obligations in our intellectual property licenses and funding arrangements with third parties, we could lose rights that are important to our business.

We are currently party to a license agreement for IV Tramadol. In the future, we may become party to licenses that are important for product development and commercialization. If we fail to comply with our obligations under current or future license and funding agreements, our counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture or market any product or utilize any technology that is covered by these agreements or may face other penalties under the agreements. Such an occurrence could materially and adversely affect the value of a product candidate being developed under any such agreement or could restrict our drug discovery activities. Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements with less favorable terms, or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology.

We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

As is common in the biotechnology and pharmaceutical industry, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to seeking patent protection for our product candidate or future product candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position, particularly where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We limit disclosure of such trade secrets where possible but we also seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who do have access to them, such as our employees, our licensors, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of these parties may breach the agreements and may unintentionally or willfully disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. Moreover, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

Risks Related to Our Finances and Capital Requirements

We have incurred significant losses since our inception. We expect to incur losses for the foreseeable future, and may never achieve or maintain profitability.

We are an emerging growth company with a limited operating history. We have focused primarily on in-licensing and developing IV Tramadol, with the goal of supporting regulatory approval for this product candidate. We have incurred losses since our inception in February 2015.

These losses, among other things, have had and will continue to have an adverse effect on our stockholders' equity and working capital. We expect to continue to incur significant operating losses for the foreseeable future. We also do not anticipate that we will achieve profitability for a period of time after generating material revenues, if ever. If we are unable to generate revenues, we will not become profitable and may be unable to continue operations without continued funding. Because of the numerous risks and uncertainties associated with developing pharmaceutical products, we are unable to predict the timing or amount of increased expenses or when or if, we will be able to achieve profitability. Our net losses may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase substantially if:

- IV Tramadol or other future product candidates are approved for commercial sale, due to the necessity in establishing adequate commercial infrastructure to launch such candidate or candidates without substantial delays, including hiring, sales and marketing personnel, and contracting with third parties for warehousing, distribution, cash collection and related commercial activities;
- we are required by the FDA, or foreign regulatory authorities, to perform studies in addition to those currently expected;
- there are any delays in completing our clinical trials or the development of any of our product candidates;
- we execute other collaborative, licensing or similar arrangements and the timing of payments we may make or receive under these arrangements;

- there are variations in the level of expenses related to our future development programs;
- there are any product liability or intellectual property infringement lawsuits in which we may become involved; and
- there are any regulatory developments affecting IV Tramadol or the product candidates of our competitors.

Our ability to become profitable depends upon our ability to generate revenue. To date, we have not generated any revenue from our development stage product, and we do not know when, or if, we will generate any revenue. Our ability to generate revenue depends on a number of factors, including, but not limited to, our ability to:

- obtain regulatory approval for IV Tramadol, or any other product candidates that we may license or acquire;
- manufacture commercial quantities of IV Tramadol or other product candidates, if approved, at acceptable cost levels; and
- develop a commercial organization and the supporting infrastructure required to successfully market and sell IV Tramadol or other product candidates, if approved.

Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress our value and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product offerings or even continue our operations. A decline in our value could also cause you to lose all or part of your investment.

Our short operating history makes it difficult to evaluate our business and prospects.

We were incorporated on February 9, 2015, and have only been conducting operations with respect to IV Tramadol since February 17, 2015. We have not yet demonstrated an ability to successfully complete clinical trials, obtain regulatory approvals, manufacture a commercial scale product, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Consequently, any predictions about our future performance may not be as accurate as they could be if we had a history of successfully developing and commercializing pharmaceutical products.

In addition, as a young business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We will need to expand our capabilities to support commercial activities. We may not be successful in adding such capabilities.

We expect our financial condition and operating results to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any past quarterly period as an indication of future operating performance.

We do not have any products that are approved for commercial sale and therefore do not expect to generate any revenues from product sales in the foreseeable future, if ever.

We have not generated any product related revenues to date, and do not expect to generate any such revenues for at least the next several years, if at all. To obtain revenues from sales of our product candidates, we must succeed, either alone or with third parties, in developing, obtaining regulatory approval for, manufacturing and marketing products with commercial potential. We may never succeed in these activities, and we may not generate sufficient revenues to continue our business operations or achieve profitability.

We will require substantial additional funding, which may not be available to us on acceptable terms, or at all. If we fail to raise the necessary additional capital, we may be unable to raise capital when needed, which would force us to delay, reduce or eliminate our product development programs or commercialization efforts.

Our operations have consumed substantial amounts of cash since inception. We expect to significantly increase our spending to advance the clinical development of IV Tramadol and launch and commercialize any additional product candidates for which we receive regulatory approval, including building our own commercial organizations to address certain markets. We will require additional capital for the further development and commercialization of our product candidates, as well as to fund our other operating expenses and capital expenditures, and cannot provide any assurance that we will be able to raise funds to complete the development of our product.

We cannot be certain that additional funding will be available on acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us we may have to significantly delay, scale back or discontinue the development or commercialization of one or more of our product candidates. We may also seek collaborators for product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available. Any of these events could significantly harm our business, financial condition and prospects.

Our future funding requirements will depend on many factors, including, but not limited to:

- the timing, design and conduct of, and results from, preclinical and clinical trials for our product candidates;
- the potential for delays in our efforts to seek regulatory approval for our product candidates, and any costs associated with such delays;
- the costs of establishing a commercial organization to sell, market and distribute our product candidates;
- the rate of progress and costs of our efforts to prepare for the submission of an NDA for any product candidates that we may in-license or acquire in the future, and the potential that we may need to conduct additional clinical trials to support applications for regulatory approval;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights associated with our product candidates, including any such costs we may be required to expend if our licensors are unwilling or unable to do so;
- the cost and timing of securing sufficient supplies of our product candidates from our contract manufacturers for clinical trials and in preparation for commercialization;
- the effect of competing technological and market developments;
- the terms and timing of any collaborative, licensing, co-promotion or other arrangements that we may establish;
- if one or more of our product candidates are approved, the potential that we may be required to file a lawsuit to defend our patent rights or regulatory exclusivities from challenges by companies seeking to market generic versions of one or more of our product candidates; and
- the success of the commercialization of one or more of our product candidates.

Future capital requirements will also depend on the extent to which we acquire or invest in additional complementary businesses, products and technologies.

In order to carry out our business plan and implement our strategy, we anticipate that we will need to obtain additional financing from time to time and may choose to raise additional funds through strategic collaborations, licensing arrangements, public or private equity or debt financing, bank lines of credit, asset sales, government grants, or other arrangements. We cannot be sure that any additional funding, if needed, will be available on terms favorable to us or at all. Furthermore, any additional equity or equity-related financing may be dilutive to our stockholders, and debt or equity financing, if available, may subject us to restrictive covenants and significant interest costs. If we obtain funding through a strategic collaboration or licensing arrangement, we may be required to relinquish our rights to certain of our product candidates or marketing territories.

Our inability to raise capital when needed would harm our business, financial condition and results of operations, and could cause our stock value to decline or require that we wind down our operations altogether.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish proprietary rights.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings, grants and license and development agreements in connection with any collaborations. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

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

We are a listed and traded public company. As a public company, we incur significant legal, accounting and other expenses under the Sarbanes-Oxley Act of 2002, as well as rules subsequently implemented by the Securities and Exchange Commission, or SEC, and the rules of any stock exchange on which we may become listed. These rules impose various requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and appropriate corporate governance practices. Our management and other personnel have devoted and will continue to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations increase our legal and financial compliance costs and make some activities more time-consuming and costly. For example, these rules and regulations make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified persons to serve on our Board of Directors, our Board committees or as executive officers.

The Sarbanes-Oxley Act of 2002 requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. As a result, we are required to periodically perform an evaluation of our internal controls over financial reporting to allow management to report on the effectiveness of those controls, as required by Section 404 of the Sarbanes-Oxley Act. Additionally, our independent auditors are required to perform a similar evaluation and report on the effectiveness of our internal controls over financial reporting. These efforts to comply with Section 404 and related regulations have required, and continue to require, the commitment of significant financial and managerial resources. While we anticipate maintaining the integrity of our internal controls over financial reporting and all other aspects of Section 404, we cannot be certain that a material weakness will not be identified when we test the effectiveness of our control systems in the future. If a material weakness is identified, we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources, costly litigation or a loss of public confidence in our internal controls, which could have an adverse effect on the market price of our stock.

We are an "emerging growth company" and a "smaller reporting company," and the reduced disclosure requirements applicable to emerging growth companies and smaller reporting companies may make our common stock less attractive to investors.

We are an "emerging growth company" as that term is used in the JOBS Act, and may 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 the initial public offering of our common stock, (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 outstanding common stock that are held by non-affiliates exceeds $700 million as of the prior June 30, and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three year period. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure in this Annual Report on Form 10-K;
- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of these accounting standards until they would otherwise apply to private companies. We have elected to take advantage of this extended transition period.

We are also a smaller reporting company, and we will remain a smaller reporting company until the fiscal year following the determination that our voting and non-voting common shares held by non-affiliates is more than $250 million measured on the last business day of our second fiscal quarter, or our annual revenues are more than $100 million during the most recently completed fiscal year and our voting and non-voting common shares held by non-affiliates is more than $700 million measured on the last business day of our second fiscal quarter. Similar to emerging growth companies, smaller reporting companies are able to provide simplified executive compensation disclosure, are exempt from the auditor attestation requirements of Section 404, and have certain other reduced disclosure obligations, including, among other things, being required to provide only two years of audited financial statements and not being required to provide selected financial data, supplemental financial information or risk factors.

We have elected to take advantage of certain of the reduced reporting obligations. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be reduced or more volatile.

Our results of operations and liquidity needs could be materially negatively affected by market fluctuations and economic downturn.

Our results of operations could be materially negatively affected by economic conditions generally, both in the United States and elsewhere around the world. Continuing concerns over inflation, energy costs, geopolitical issues, the availability and cost of credit, the U.S. mortgage market and residential real estate market in the United States have contributed to increased volatility and diminished expectations for the economy and the markets going forward. These factors, combined with volatile oil prices, declining business and consumer confidence and increased unemployment, have precipitated an economic recession and fears of a possible depression. Domestic and international equity markets continue to experience heightened volatility and turmoil. These events and the continuing market upheavals may have an adverse effect on us. In the event of a continuing market downturn, our results of operations could be adversely affected by those factors in many ways, including making it more difficult for us to raise funds if necessary, and our stock price may further decline.

Risks Relating to Securities Markets and Investment in Our Stock

Our stock may be subject to substantial price and volume fluctuations due to a number of factors, many of which are beyond our control and may prevent our stockholders from reselling our common stock at a profit.

The market prices for securities of biotechnology and pharmaceutical companies have historically been highly volatile, and the market has from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies.

The market price of our common stock is likely to be highly volatile and may fluctuate substantially due to many factors, including:

- announcements concerning the progress of our efforts to obtain regulatory approval for and commercialize IV Tramadol or future product candidates, including any requests we receive from the FDA for additional studies or data that result in delays in obtaining regulatory approval or launching this product candidate, if approved;
- market conditions in the pharmaceutical and biotechnology sectors or the economy as a whole;
- price and volume fluctuations in the overall stock market;
- the failure of IV Tramadol or future product candidates, if approved, to achieve commercial success;
- announcements of the introduction of new products by us or our competitors;
- developments concerning product development results or intellectual property rights of others;
- litigation or public concern about the safety of our potential products;
- actual fluctuations in our quarterly operating results, and concerns by investors that such fluctuations may occur in the future;
- deviations in our operating results from the estimates of securities analysts or other analyst comments;
- additions or departures of key personnel;
- health care reform legislation, including measures directed at controlling the pricing of pharmaceutical products, and third party coverage and reimbursement policies;
- developments concerning current or future strategic collaborations; and
- discussion of us or our stock price by the financial and scientific press and in online investor communities.

Fortress controls a voting majority of our common stock.

Pursuant to the terms of the Class A Preferred Stock held by Fortress, Fortress will be entitled to cast, for each share of Class A Preferred Stock held by Fortress, the number of votes that is equal to 1.1 times a fraction, the numerator of which is the sum of (A) the aggregate number of shares of outstanding common stock and (B) the whole shares of common stock into which the shares of outstanding the Class A Preferred Stock are convertible and the denominator of which is the aggregate number of shares of outstanding Class A Preferred Stock, or the Class A Preferred Stock Ratio. Thus, Fortress will at all times have voting control of us. Further, for a period of ten years from the date of the first issuance of shares of Class A Preferred Stock, the holders of record of the shares of Class A Preferred Stock (or other capital stock or securities issued upon conversion of or in exchange for the Class A Preferred Stock), exclusively and as a separate class, shall be entitled to appoint or elect the majority of our directors. This concentration of voting power may delay, prevent or deter a change in control, even when such a change may be in the best interests of all stockholders, could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of us or our assets, and might affect the prevailing market price of our common stock.

Fortress has the right to receive a significant grant of shares of our common stock annually, which will result in the dilution of your holdings of common stock upon each grant, which could reduce their value.

Under the terms of the Amended and Restated Founders Agreement, which became effective September 13, 2016, Fortress will receive a grant of shares of our common stock equal to 2.5% of the gross amount of any equity or debt financing. Additionally, the holders of Class A Preferred Stock, as a class, will receive an annual dividend, payable in shares of common stock in an amount equal to 2.5% of our fully-diluted outstanding capital stock as of the business day immediately prior to the date such dividend is payable. Fortress currently owns all outstanding shares of Class A Preferred Stock. At our Annual Meeting of the Stockholder's held on June 13, 2018, the Company's shareholders approved an amendment to the Company's Third Amended and Restated Certificate of Incorporation, amending the Class A Preferred dividend payment date from February 17 to January 1 of each year. These share issuances to Fortress and any other holder of Class A Preferred Stock will dilute your holdings in our common stock and, if our value has not grown proportionately over the prior year, would result in a reduction in the value of your shares. The Amended and Restated Founders Agreement has a term of 15 years and renews automatically for subsequent one-year periods unless terminated by Fortress or upon a Change in Control (as defined in the Amended and Restated Founders Agreement).

We are a "controlled company" within the meaning of NASDAQ listing standards and, as a result, qualify for, and rely on, exemptions from certain corporate governance requirements. You will not have the same protections afforded to stockholders of companies that are subject to such requirements.

We are a "controlled company" within the meaning of NASDAQ listing standards. Under these rules, a company of which more than 50% of the voting power is held by an individual, a group or another company is a "controlled company" and may elect not to comply with certain corporate governance requirements of NASDAQ, including (i) the requirement that a majority of the Board of Directors consist of independent directors, (ii) the requirement that we have a nominating and corporate governance committee that is composed entirely of independent directors with a written charter addressing the committee's purpose and responsibilities and (iii) the requirement that we have a compensation committee that is composed entirely of independent directors with a written charter addressing the committee's purpose and responsibilities. We intend to rely on some or all of these exemptions.

Accordingly, you will not have the same protections afforded to stockholders of companies subject to all of the corporate governance requirements of NASDAQ.

We might have received better terms from unaffiliated third parties than the terms we receive in our agreements with Fortress.

The agreements we entered into with Fortress in connection with the separation include the Management Services Agreement, or the MSA, and the Founders Agreement. While we believe the terms of these agreements are reasonable, they might not reflect terms that would have resulted from arm's-length negotiations between unaffiliated third parties. The terms of the agreements relate to, among other things, payment of a royalty on product sales and the provision of employment and transition services. We might have received better terms from third parties because, among other things, third parties might have competed with each other to win our business.

The ownership by our executive officers and some of our directors of equity securities of Fortress and/or rights to acquire equity securities of Fortress might create, or appear to create, conflicts of interest.

Because of their current or former positions with Fortress, some of our executive officers and directors own shares of Fortress common stock and/or options to purchase shares of Fortress common stock. Their individual holdings of common stock and/or options to purchase common stock of Fortress may be significant compared to their total assets. Ownership by our directors and officers, after our separation, of common stock and/or options to purchase common stock of Fortress create might appear to create conflicts of interest when these directors and officers are faced with decisions that could have different implications for Fortress than for us. For instance, and by way of example, if there were to be a dispute between Fortress and us regarding the calculation of the royalty fee due to Fortress under the terms of the Founders Agreement, then certain of our senior employees may have and will appear to have a conflict of interest with regard to the outcome of such dispute.

Certain of our officers and directors serve in similar roles with our parent company, affiliates, related parties and other parties with whom we transact business; ongoing and future relationships and transactions between these parties could result in conflicts of interest.

We share directors and/or officers with certain of our parent company, affiliates, related parties or other companies with which we transact business, and such arrangements could create conflicts of interest in the future, including with respect to the allocation of corporate opportunities. While we believe that we have put in place policies and procedures to identify such conflicts and that any existing agreements that may give rise to such conflicts and any such policies or procedures were negotiated at arm's length in conformity with fiduciary duties, such conflicts of interest may nonetheless arise. The existence and consequences of such potential conflicts could expose us to lost profits, claims by our investors and creditors, and harm to our results of operations.

We may become involved in securities class action litigation that could divert management's attention and harm our business.

The stock markets have from time to time experienced significant price and volume fluctuations that have affected the market prices for the common stock of biotechnology and pharmaceutical companies. These broad market fluctuations may cause the market price of our stock to decline. In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and biopharmaceutical companies have experienced significant stock price volatility in recent years. We may become involved in this type of litigation in the future. Litigation often is expensive and diverts management's attention and resources, which could adversely affect our business.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Our corporate and executive office is located at 2 Gansevoort Street, 9th Floor, New York, NY 10014. We are not currently under a lease agreement at 2 Gansevoort Street. We believe that our existing facilities are adequate to meet our current requirements. We do not own any real property.

Item 3. Legal Proceedings

In connection with the SPMA, two putative class action lawsuits were filed in the United States District Court for the District of Delaware. The two lawsuits are captioned *Bushansky v. Avenue Therapeutics, Inc. et al, Docket No. 1:19-cv-00085 (D. Del. Jan 15, 2019)* and *Krause v. Avenue Therapeutics, Inc. et al, Docket No. 1:19-cv-00107 (D. Del. Jan 17, 2019)* (collectively, the "Merger Litigation"). The complaints, which were filed by purported Company stockholders, generally allege that the preliminary and definitive proxy statements that the Company filed with the SEC on December 11, 2018 and December 21, 2018, respectively, omitted certain material information in connection with the Stock Purchase Transaction and the Merger Transaction in violation of Sections 14(a) and 20(a) of the Securities Exchange Act of 1934, and SEC Rule 14a-9 thereunder. These complaints include demands for, among other things, an order enjoining defendants from closing the Stock Purchase Transaction and the Merger Transaction absent certain disclosures of information identified in the complaints.

The Company believes that the claims asserted in the Merger Litigation are without merit and that no supplemental disclosure was required under applicable law. However, in order to avoid the risk of the Merger Litigation delaying or adversely affecting the SPMA and to minimize the costs, risks and uncertainties inherent in litigation, and without admitting any liability or wrongdoing, the Company determined to voluntarily supplement the Proxy Statement it filed with the SEC on December 21, 2018. Nothing in the supplement to the proxy was deemed an admission of the legal necessity or materiality under applicable laws of any of the disclosures set forth within the supplement to the Proxy Statement. To the contrary, the Company specifically denied all allegations in the Merger Litigation that any additional disclosure was required.

Item 4. Mine Safety Disclosures

Not applicable

PART II

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

Market information

Our common stock has been trading on the NASDAQ Global Market since June 26, 2017, under the symbol "ATXI." Prior to this, there was no public market for our common stock.

The following table sets forth the high and low closing sale prices of our common stock for the periods indicated:

Fiscal Year Ended December 31, 2018	High	Low
First Quarter	$ 5.75	$ 3.64
Second Quarter	$ 4.96	$ 3.58
Third Quarter	$ 4.21	$ 2.75
Fourth Quarter	$ 5.60	$ 2.10

Fiscal Year Ended December 31, 2017	High	Low
Second Quarter (beginning June 26)	$ 8.25	$ 7.88
Third Quarter	$ 8.00	$ 5.08
Fourth Quarter	$ 5.64	$ 3.53

Reverse stock split

On June 26, 2017, the Company effected a 3.0-to-1.0 reverse stock split of Company's common stock. No fractional shares were issued in connection with the stock split. The par value and other terms of these classes of stock were not affected by the reverse stock split.

All share and per share amounts, including stock options, have been retroactively adjusted in these condensed financial statements for all periods presented to reflect the 3.0-to-1.0 reverse stock split. Further, the fair value of stock issuances has been retroactively adjusted in these unaudited condensed financial statements for all periods presented to reflect the 3.0-to-1.0 reverse stock split.

Equity Compensation Plans

On August 15, 2017, we filed a registration statement on Form S-8 under the Securities Act registering the common stock issued, issuable or reserved for issuance under our 2015 Incentive Plan ("2015 Plan"). The registration statement became effective immediately upon filing, and shares covered by the registration statement are eligible for sale in the public markets, subject to grant of the underlying awards, vesting provisions and Rule 144 limitations applicable to our affiliates.

Holders

As of December 31, 2018, there were approximately 10.7 million shares of common stock outstanding held by 22 record stockholders.

Dividends

We have never paid or declared any cash dividends on our common stock, and we do not anticipate paying any cash dividends on our common stock in the foreseeable future. We intend to retain all available funds and any future earnings to fund the development and expansion of our business. Any future determination to pay dividends will be at the discretion of our board of directors and will depend upon a number of factors, including our results of operations, financial condition, future prospects, contractual restrictions, restrictions imposed by applicable law and other factors our board of directors deems relevant.

Securities Authorized for Issuance under Equity Compensation Plans

Subject to adjustment as provided in the 2015 Plan, the aggregate number of shares of our common stock reserved and available for issuance pursuant to awards granted under the 2015 Plan is 2,000,000.

Recent Sales of Unregistered Securities.

On February 8, 2019, the Company and InvaGen completed the First Stage Closing under the SPMA. In connection with the First Stage Closing, the Company received $35 million from InvaGen and InvaGen received 5,833,333 shares of the Company's common stock, resulting in an ownership interest in the Company by InvaGen of 33.3% on a fully diluted basis.

The above transaction was conducted pursuant to the exemption provided by Regulation D under the Securities Act.

Description of Registrant's Securities to be Registered.

Not applicable.

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

Forward-Looking Statements

Statements in the following discussion and throughout this report that are not historical in nature are "forward-looking statements." You can identify forward-looking statements by the use of words such as "expect," "anticipate," "estimate," "may," "will," "should," "intend," "believe," and similar expressions. Although we believe the expectations reflected in these forward-looking statements are reasonable, such statements are inherently subject to risk and we can give no assurances that our expectations will prove to be correct. Actual results could differ from those described in this report because of numerous factors, many of which are beyond our control. These factors include, without limitation, those described under Item 1A "Risk Factors." We undertake no obligation to update these forward-looking statements to reflect events or circumstances after the date of this report or to reflect actual outcomes. Please see "Forward-Looking Statements" at the beginning of this Form 10-K.

The following discussion of our financial condition and results of operations should be read in conjunction with our financial statements and the related notes thereto and other financial information appearing elsewhere in this Form 10-K. We undertake no obligation to update any forward-looking statements in the discussion of our financial condition and results of operations to reflect events or circumstances after the date of this report or to reflect actual outcomes.

Overview

We are a specialty pharmaceutical company that seeks to acquire, license, develop and commercialize products principally for use in the acute/intensive care hospital setting. Our current product candidate is intravenous (IV) Tramadol, for the treatment of moderate to moderately severe post-operative pain. In 2016, we completed a pharmacokinetic (PK) study for IV Tramadol in healthy volunteers as well as an end of phase 2 (EOP2) meeting with the U.S. Food and Drug Administration (FDA). In the third quarter of 2017, we initiated a Phase 3 development program of IV Tramadol for the management of post-operative pain. Under the terms of certain agreements described herein, we have an exclusive license to develop and commercialize IV Tramadol in the United States. To date, we have not received approval for the sale of our product candidate in any market and, therefore, have not generated any sales revenue from our product candidates.

On June 26, 2017, we completed an initial public offering (IPO) of our common stock, resulting in net proceeds of approximately $34.2 million after deducting underwriting discounts, and other offering costs.

We have used the proceeds from our IPO to initiate our first Phase 3 trial of IV Tramadol in patients with moderate-to-severe pain following bunionectomy, which had its first patient dosed in September 2017. In May 2018, we announced the study met its primary endpoint and all key secondary endpoints.

Further, in December 2018, we initiated the second Phase 3 trial in patients with moderate-to-severe pain following abdominoplasty upon successful completion of the bunionectomy study. Based on the enrollment pace of similar studies, we anticipate that we will have topline data from this second Phase 3 trial as early as mid-2019.

In December 2017, we initiated an open-label safety study, which will run concurrently with the two Phase 3 trials.

If these studies meet their primary endpoints, we plan to submit a new drug application, or an NDA, for IV Tramadol to treat moderate to moderately severe postoperative pain pursuant to Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act, or FDCA, by the end of 2019.

On November 12, 2018, we entered into a Stock Purchase and Merger Agreement (SPMA) with InvaGen Pharmaceuticals Inc. (InvaGen), Madison Pharmaceuticals Inc. (Merger Sub), and Fortress Biotech, Inc. (Fortress), pursuant to which InvaGen agreed to purchase, for $35 million, common shares representing 33.3% of the fully diluted capitalization of the Company (the Stock Purchase Transaction) and subsequently acquire the remaining issued and outstanding capital stock of the Company for $180 million, subject to certain reductions, in a reverse subsidiary merger transaction (the Merger Transaction). Pursuant to the terms and subject to the conditions set forth in the SPMA, InvaGen will, at second closing, hold 100% of the issued and outstanding equity interests of the Company. Consummation of the Merger Transaction is conditioned, among other things, upon FDA approval of IV Tramadol, its labeling and scheduling and the absence of any Risk Evaluation and Mitigation Strategy ("REMS") restrictions in effect with respect to IV Tramadol, as well as the expiration of any waiting period applicable to the acquisition under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended.

The aggregate consideration to be paid by InvaGen under the SPMA is $215 million in cash, subject to certain potential reductions, which InvaGen intends to have sufficient immediately available funds to pay. In addition, we are subject to certain lock-up restrictions and agreed not to (subject to customary exceptions), during the period commencing at the signing of the SPMA until the Merger Transaction, issue, buy, sell, or otherwise subject to a security interest, pledge, hypothecation, mortgage or lien, any securities of the Company.

The SPMA was approved by a majority of our stockholders, including a majority of our non-affiliated stockholders, at our special shareholder meeting on February 6, 2019. On February 8, 2019, the Company and InvaGen consummated the Stock Purchase Transaction whereby InvaGen acquired 5,833,333 shares of our common stock at $6.00 per share for total gross consideration of $35.0 million, representing a 33.3% stake in our capital stock on a fully diluted basis.

Our net loss for the years ended December 31, 2018 and 2017 was approximately $21.5 million and $12.3 million, respectively. As of December 31, 2018, we had an accumulated deficit of approximately $42.2 million. Substantially all our net losses resulted from costs incurred in connection with our research and development program of IV Tramadol and from general and administrative costs associated with our operations.

We expect to continue to incur increased research and development costs and increased general and administration related costs and incur operating losses for at least the next several years as we develop and seek regulatory approval for IV Tramadol in the U.S.

We may need to obtain additional capital through the sale of debt or equity financings or other arrangements to fund our operations and research and development activity; however, there can be no assurance that we will be able to raise needed capital under acceptable terms, if at all. The sale of additional equity may dilute existing stockholders and newly issued shares may contain senior rights and preferences compared to currently outstanding shares of common stock. Issued debt securities may contain covenants and limit our ability to pay dividends or make other distributions to stockholders. If we are unable to obtain such additional financing, future operations would need to be scaled back or discontinued.

We are a majority controlled subsidiary of Fortress. For related party transactions, see Note 5.

Avenue Therapeutics, Inc. was incorporated in Delaware on February 9, 2015. Our executive offices are located at 2 Gansevoort Street, 9th Floor, New York, NY 10014. Our telephone number is (781) 652-4500, and our email address is info@avenuetx.com.

Critical Accounting Policies and Use of Estimates

Our discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States (GAAP). The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and the disclosure of contingent assets and liabilities in our financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued expenses and stock-based compensation. We base our estimates on historical experience, known trends and events and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Research and Development

Research and development costs are expensed as incurred. Advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made. Upfront and milestone payments due to third parties that perform research and development services on our behalf will be expensed as services are rendered or when the milestone is achieved. Costs incurred in obtaining technology licenses are charged to research and development expense if the technology licensed has not reached technological feasibility and has no alternative future use.

Research and development costs primarily consist of personnel related expenses, including salaries, benefits, travel, and other related expenses, stock-based compensation, payments made to third parties for license and milestone costs related to in-licensed products and technology, payments made to third party contract research organizations for preclinical and clinical studies, investigative sites for clinical trials, consultants, the cost of acquiring and manufacturing clinical trial materials, costs associated with regulatory filings and patents, laboratory costs and other supplies.

Costs incurred in obtaining technology licenses are charged to research and development expense if the technology licensed has not reached commercial feasibility and has no alternative future use. The licenses purchased by us require substantial completion of research and development, regulatory and marketing approval efforts in order to reach commercial feasibility and has no alternative future use. Accordingly, the total purchase price for the licenses acquired are reflected as research and development — licenses acquired on our Statement of Operations.

Annual Stock Dividend

In September 2016, in connection with the Amended and Restated Articles of Incorporation, we issued 250,000 Class A preferred shares to Fortress. The Class A preferred shares entitle the holder to a stock dividend equal to 2.5% of our fully diluted outstanding equity (The Annual Stock Dividend). On June 13, 2018, our Stockholders adopted an amendment to our Third Amended and Restated Certificate of Incorporation amending the payment date going forward to January 1 of each year. Concurrently with the execution and delivery of the SPMA, we, InvaGen and Fortress entered into a waiver agreement (“the Waiver Agreement”), pursuant to which, among other things, Fortress irrevocably waived its right to receive dividends of our common shares under the terms of the Class A Preferred Stock and any fees, payments, reimbursements or other distributions under a certain management services agreement between us and Fortress and the Founders Agreement (as defined in the SPMA), for the period November 12, 2018 to the termination of InvaGen’s rights under Section 4 of the Stockholders Agreement that was signed between us, certain stockholders of ours, and InvaGen.

We recorded the Annual Stock Dividend due to Fortress as contingent consideration. Contingent consideration is recorded when probable and reasonably estimable. Our future share prices cannot be estimated due to the nature of our assets and our stage of development. Due to these uncertainties, we concluded that we could not reasonably estimate the contingent consideration until shares were actually issued on February 17, 2018. Because the issuance of shares on February 17, 2018 occurred prior to the issuance of the December 31, 2017 financial statements, we recorded approximately $1.1 million in research and development - licenses acquired for the year ended December 31, 2017. Due to the Waiver Agreement, we recorded $0 in research and development - licenses acquired for the year ended December 31, 2018.

Stock-Based Compensation

We expense stock-based compensation to employees and board members over the requisite service period based on the estimated grant-date fair value of the awards. Stock-based awards with graded-vesting schedules are recognized on a straight-line basis over the requisite service period for each separately vesting portion of the award. For stock-based compensation awards to non-employees, we measure the fair value of the non-employee awards at each reporting period prior to vesting and finally at the vesting date of the award. Changes in the estimated fair value of these non-employee awards are recognized as compensation expense in the period of change.

The assumptions used in calculating the fair value of stock-based awards represent management's best estimates and involve inherent uncertainties and the application of management's judgment.

Fair Value Option

As permitted under ASC 825, *Financial Instruments*, (ASC 825), we have elected the fair value option to account for our convertible notes that were issued during 2016. In accordance with ASC 825, we record these convertible notes at fair value with changes in fair value recorded in the Statement of Operations. As a result of applying the fair value option, direct costs and fees related to the convertible notes were recognized in earnings as incurred and were not deferred.

Valuation of Warrant Related to NSC Note

In accordance with ASC 815 *Derivatives and Hedging*, we classified the fair value of the warrant (Contingently Issuable Warrants) that we may be obligated to issue to National Securities, Inc. (NSC), in connection with the transfer on October 31, 2015 of $3.0 million of indebtedness to NSC, as a derivative liability as there was a potential that we would not have a sufficient number of authorized common shares available to settle this instrument. We valued these Contingently Issuable Warrants using a Black-Scholes model and used estimates for an expected dividend yield, a risk-free interest rate, and expected volatility together with management's estimate of the probability of issuance of the Contingently Issuable Warrants. At each reporting period, as long as the Contingently Issuable Warrants were potentially issuable and there was a potential for an insufficient number of authorized shares available to settle the Contingently Issuable Warrants, the Contingently Issuable Warrants had to be revalued and any difference from the previous valuation date would be recognized as a change in fair value in our statement of operations. On June 26, 2017, the warrants were issued.

Income Taxes

No income tax expense or benefit was recognized in the accompanying financial statements. Our deferred tax assets are comprised primarily of net operating loss carryforwards. We maintain a full valuation allowance on our deferred tax assets since we have not yet achieved sustained profitable operations. As a result, we have not recorded any income tax benefit since our inception.

Results of Operations

Comparison of the Years Ended December 31, 2018 and 2017

	For The Year Ended		Change	
($ in thousands)	December 31, 2018	December 31, 2017	$	%
Operating expenses:				
Research and development	$ 17,696	$ 6,698	$ 10,998	164%
Research and development - licenses acquired	-	1,103	(1,103)	(100)%
General and administrative	4,120	3,620	500	14%
Loss from operations	(21,816)	(11,421)	(10,395)	91%
Interest income	(93)	(88)	(5)	6%
Interest expense	-	294	(294)	(100)%
Interest expense - related party	-	81	(81)	(100)%
Change in fair value of convertible notes payable	-	99	(99)	(100)%
Change in fair value of warrant liabilities	-	451	(451)	(100)%
Other income	(175)	-	(175)	*
Net Loss	**$ (21,548)**	**$ (12,258)**	**$ (9,290)**	**76%**

* Comparison to prior period not meaningful

Research and Development Expenses

For the years ended December 31, 2018 and 2017, research and development expenses were $17.7 million and $6.7 million, respectively. The $11.0 million increase primarily reflects an increase of $10.2 million in clinical trial costs associated with the completion of the bunionectomy study in May 2018, the ongoing safety study and the initiation of the abdominoplasty study in December 2018. There were also increases of $0.4 million in personnel costs and $0.4 million in stock compensation costs associated with increased headcount.

Research and Development Expenses – Licenses Acquired

For the years ended December 31, 2018 and 2017, research and development expenses – licenses acquired were $0 and $1.1 million, respectively. The $1.1 million expense in 2017 represents the payment of the annual Class A Preferred Stock dividend of 2.5% of the fully dilutive shares. There was no payment for the year ended December 31, 2018 due to the SPMA with InvaGen.

General and Administrative Expenses

For the years ended December 31, 2018 and 2017, general and administrative expenses were $4.1 million and $3.6 million, respectively. The $0.5 million increase primarily reflects increases of $0.2 million for personnel costs, $0.4 million for legal costs, $0.1 million for marketing research cost and $0.2 million for professional fees partially offset by a decrease of $0.4 million for stock compensation costs associated with the 2.5% financing fee due to Fortress from the IPO in 2017.

Interest Income

Interest income was $0.1 million for the years ended December 31, 2018 and 2017, respectively. Interest income was earned from our proceeds from our IPO in June 2017.

Interest Expense

Interest expense was $0 and $0.3 million for the years ended December 31, 2018 and 2017, respectively. Interest expense was primarily related to our note payable with NSC which was repaid in July 2017.

Interest Expense - Related Party

Interest expense - related party was $0 and $0.1 million for the years ended December 31, 2018 and 2017, respectively. Interest expense - related party was primarily related to our note payable with Fortress. The note payable to Fortress was repaid in full in July 2017.

Change in Fair Value of Convertible Notes Payable

The change in fair value of convertible notes payable was $0 and $0.1 million for the years ended December 31, 2018 and 2017, respectively. The notes were converted into shares upon the IPO on June 26, 2017.

Change in Fair Value of Warrant Liabilities

We are required to account for the Contingently Issuable Warrants to NSC under ASC 815, *Derivatives and Hedging*, for each reporting period as long as the Contingently Issuable Warrants were potentially issuable and there was a potential for an insufficient number of authorized shares available to settle the Contingently Issuable Warrants. The difference in fair value from the previous valuation date needs to be marked to market through our statement of operations. We recorded an expense of $0 and $0.5 million for the years ended December 31, 2018 and 2017, respectively. The Contingently Issuable Warrants were issued upon the IPO on June 26, 2017.

Other

Other income was $0.2 million and $0 for the years ended December 31, 2018 and 2017, respectively. The source of the other income for 2018 was the receipt of the New York City Biotech Tax Credit.

Liquidity and Capital Resources

We have incurred substantial operating losses since our inception and expect to continue to incur significant operating losses for the foreseeable future and may never become profitable. As of December 31, 2018, we had an accumulated deficit of $42.2 million.

On June 26, 2017, we completed an IPO of our common stock, which resulted in the issuance of 6,325,000 shares of its common stock, inclusive of 825,000 shares which were subject to an underwriter over-allotment. The shares were issued at $6.00 per share, resulting in net proceeds of approximately $34.2 million after deducting underwriting discounts, and other offering costs. On February 8, 2019, InvaGen acquired 5,833,333 shares of our common stock at $6.00 per share for net proceeds of $31.5 million after deducting commission fees and other offering costs, representing a 33.3% stake in our Company's capital stock on a fully diluted basis.

We expect to use the net proceeds from the above transactions primarily for general corporate purposes, which may include financing our growth, developing new or existing product candidates, and funding capital expenditures and investments. We currently anticipate that our cash and cash equivalent balances at December 31, 2018, in conjunction with $31.5 million net proceeds received in February 2019 from InvaGen in connection with the SPMA are sufficient to fund our anticipated operating cash requirements for approximately the next 12 months. If we cannot generate significant cash from our operations, we intend to obtain any additional funding we require through strategic relationships, public or private equity or debt financings, grants or other arrangements.

Cash Flows for the Years Ended December 31, 2018 and 2017

	For The Years Ended December 31,	
($ in thousands)	**2018**	**2017**
Total cash (used in)/provided by:		
Operating activities	$ (18,216)	$ (6,802)
Investing activities	10,000	(10,000)
Financing activities	(895)	28,387
Net (decrease) increase in cash	$ (9,111)	$ 11,585

Operating Activities

Net cash used in operating activities was approximately $18.2 million for the year ended December 31, 2018, primarily comprised of our $21.5 million net loss, partially offset by: $1.8 million increase in operating assets and liabilities, and $1.5 million in share based compensation.

Net cash used in operating activities was approximately $6.8 million for the year ended December 31, 2017, primarily comprised of our $12.3 million net loss, partially offset by: $0.9 million issuance of common shares, $2.1 million increase in operating assets and liabilities, $1.1 million common shares issuable, $0.5 million in change in fair value of warrant liabilities, $0.6 million in share based compensation, $0.2 million in debt discount amortization and $0.1 million in change in fair value of convertible notes payable.

Investing Activities

Net cash provided by investing activities for the year ended December 31, 2018 was $10.0 million. The Company's short-term investments of certificates of deposits consisting of $10.0 million matured in the year ended December 31, 2018.

Net cash used in investing activities for the year ended December 31, 2017 was $10.0 million. The Company purchased short-term investments of certificates of deposits consisting of $10.0 million in the year ended December 31, 2017.

Financing Activities

Net cash used by financing activities for the year ended December 31, 2018 was $0.9 million which was from the payments for deferred financing costs.

Net cash provided by financing activities for the year ended December 31, 2017 was $28.4 million. The source of the net cash provided in 2017 was mostly from the net proceeds of our initial public offering of $34.2 million partially offset by our repayments of notes payable of $5.8 million.

Recently Adopted Accounting Standards

See Note 2 to the financial statements for a full description of recent accounting pronouncements including the respective expected dates of adoption and expected effects on results of operations and financial condition.

Off-Balance Sheet Arrangements

We are not party to any off-balance sheet transactions. We have no guarantees or obligations other than those which arise out of normal business operations.

Item 8. Financial Statements and Supplementary Data.

The information required by this Item is set forth in the financial statements and notes thereto beginning at page F-1 of this Annual Report on Form 10-K.

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

Not applicable.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures. As of December 31, 2018, management carried out, under the supervision and with the participation of our principal executive officer and principal financial officer, an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Our disclosure controls and procedures are designed to provide reasonable assurance that information we are required to disclose in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in applicable rules and forms. Based upon that evaluation, our principal executive officer and principal financial officer concluded that, as of December 31, 2018, our disclosure controls and procedures were effective.

Management's Report on Internal Control over Financial Reporting. Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rule 13a-15(f) or Rule 15d-15(f) under the Exchange Act). Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2018. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission, known as COSO, in Internal Control-Integrated Framework (2013). Our management has concluded that, as of December 31, 2018, our internal control over financial reporting was effective based on these criteria.

Changes in Internal Control Over Financial Reporting. There were no changes in our internal control over financial reporting during the most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on the Effectiveness of Controls. Our management, including our principal executive officer and principal financial officer, does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within our company have been detected.

Item 9B. Other Information

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this Item is incorporated herein by reference from our Proxy Statement for our 2019 Annual Meeting of Stockholders.

Item 11. Executive Compensation

The information required by this Item is incorporated herein by reference from our Proxy Statement for our 2019 Annual Meeting of Stockholders.

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

The information required by this Item is incorporated herein by reference from our Proxy Statement for our 2019 Annual Meeting of Stockholders.

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

The information required by this Item is incorporated herein by reference from our Proxy Statement for our 2019 Annual Meeting of Stockholders.

Item 14. Principal Accounting Fees and Services

The information required by this Item is incorporated herein by reference from our Proxy Statement for our 2019 Annual Meeting of Stockholders.

PART IV

Item 15. Exhibits, Financial Statement Schedules

(a) Financial Statements.

The following financial statements are filed as part of this report:

(b) Exhibits.

Exhibit No.	Description
3.1	Third Amended and Restated Certificate of Incorporation of Avenue Therapeutics, Inc., filed as Exhibit 3.1 to Form 8-K filed on June 27, 2017 (File No. 001-38114) and incorporated herein by reference.
3.2	Certificate of Amendment of the Third Amended and Restated Certificate of Incorporation of Avenue Therapeutics, Inc., filed as Exhibit 3.1 to Form 10-Q filed on August 14, 2018 (File No. 001-38114) and incorporated herein by reference.
3.3	Amended and Restated Bylaws of Avenue Therapeutics, Inc., filed as Exhibit 3.1 to Form 8-K filed on February 11, 2019 (File No. 000-38114) and incorporated herein by reference.
4.1	Specimen certificate evidencing shares of Common Stock, filed as Exhibit 4.1 to Form 10-12G filed on January 12, 2017 (File No. 000-55556) and incorporated herein by reference.
4.2	Form of warrant agreement, filed as Exhibit 4.2 to Form 10-12G filed on January 12, 2017 (File No. 000-55556) and incorporated herein by reference.
10.1	Asset Transfer and License Agreement between Fortress Biotech, Inc. and Revogenex Ireland Limited dated February 17, 2015, filed as Exhibit 10.1 to Form 10-12G/A filed on March 13, 2017 (File No. 000-55556) and incorporated herein by reference.*

10.2	First Amendment to Asset Transfer and License Agreement between Fortress Biotech, Inc. and Revogenex Ireland Limited dated June 23, 2016, filed as Exhibit 10.11 to Form 10-12G/A filed on March 13, 2017 (File No. 000-55556) and incorporated herein by reference.
10.3	Second Amendment to Asset Transfer and License Agreement between Fortress Biotech, Inc. and Revogenex Ireland Limited dated May 4, 2017, filed as Exhibit 10.3 to Form S-1/A filed on May 22, 2017 (File No. 333-217552) and incorporated herein by reference.
10.4	Amended and Restated Founders Agreement between Fortress Biotech, Inc. and Avenue Therapeutics, Inc. dated September 13, 2016, filed as Exhibit 10.2 to Form 10-12G filed on January 12, 2017 (File No. 000-55556) and incorporated herein by reference.
10.5	Promissory Note from Avenue Therapeutics, Inc. to NSC Biotech Venture Fund I, LLC, effective as of October 31, 2015, filed as Exhibit 10.3 to Form 10-12G filed on January 12, 2017 (File No. 000-55556) and incorporated herein by reference.
10.6	Promissory Note from Avenue Therapeutics, Inc. to Fortress Biotech, Inc., effective as of March 15, 2015, filed as Exhibit 10.4 to Form 10-12G filed on January 12, 2017 (File No. 000-55556) and incorporated herein by reference.
10.7	Management Services Agreement between Fortress Biotech, Inc. and Avenue Therapeutics, Inc. effective as of February 17, 2015, filed as Exhibit 10.5 to Form 10-12G filed on January 12, 2017 (File No. 000-55556) and incorporated herein by reference.
10.8	Employment Agreement with Dr. Lucy Lu, MD, dated June 10, 2015, filed as Exhibit 10.6 to Form 10-12G filed on January 12, 2017 (File No. 000-55556) and incorporated herein by reference.#
10.9	Avenue Therapeutics, Inc. 2015 Incentive Plan, filed as Exhibit 10.7 to Form 10-12G filed on January 12, 2017 (File No. 10.7 000-55556) and incorporated herein by reference.
10.10	Consulting Agreement with Dr. Scott A. Reines, dated July 22, 2015, filed as Exhibit 10.8 to Form 10-12G filed on January 12, 2017 (File No. 000-55556) and incorporated herein by reference.#
10.11	First Amendment to Consulting Agreement with Dr. Scott A. Reines, dated January 25, 2016, filed as Exhibit 10.9 to 10.7 Form 10-12G filed on January 12, 2017 (File No. 000-55556) and incorporated herein by reference.#
10.12	Second Amendment to Consulting Agreement with Dr. Scott A. Reines, dated August 2, 2016, filed as Exhibit 10.10 to Form 10-12G/A filed on March 13, 2017 (File No. 000-55556) and incorporated herein by reference.#
10.13	Third Amendment to Consulting Agreement with Dr. Scott A. Reines, dated February 28, 2017, filed as Exhibit 10.12 to Form 10-12G/A filed on March 13, 2017 (File No. 000-55556) and incorporated herein by reference.#
10.14	Letter Agreement with Joseph Vazzano, dated July 28, 2017, filed as Exhibit 10.1 to Form 8-K filed on August 15, 2017 (File No. 001-38114) and incorporated herein by reference.#
10.15	Stock Purchase and Merger Agreement, dated as of November 12, 2018, by and between Avenue Therapeutics, Inc., InvaGen Pharmaceuticals Inc. and Madison Pharmaceuticals Inc., incorporated herein by reference from the Company's Form 8-K filed on November 14, 2018.
10.16	Stockholders Agreement, dated as of November 12, 2018, by and between Avenue Therapeutics, Inc., Fortress Biotech, Inc., Dr. Lucy Lu, M.D. and InvaGen Pharmaceuticals Inc., incorporated herein by reference from the Company's Form 8-K filed on November 14, 2018.
10.17	Credit Agreement, dated as of November 12, 2018, by and between Avenue Therapeutics, Inc. and InvaGen Pharmaceuticals Inc., incorporated herein by reference from the Company's Form 8-K filed on November 14, 2018.
10.18	Guaranty, dated as of November 12, 2018, by and between Fortress Biotech, Inc. and InvaGen Pharmaceuticals Inc., incorporated herein by reference from the Company's Form 8-K filed on November 14, 2018.
10.19	Voting and Support Agreement, dated as of November 12, 2018, by and between Avenue Therapeutics, Inc., Fortress Biotech, Inc., Dr. Lucy Lu, M.D. and InvaGen Pharmaceuticals Inc., incorporated herein by reference from the Company's Form 8-K filed on November 14, 2018.

10.20	Waiver Agreement, dated as of November 12, 2018, by and between Avenue Therapeutics, Inc., Fortress Biotech, Inc. and InvaGen Pharmaceuticals Inc., incorporated herein by reference from the Company's Form 8-K filed on November 14, 2018.
10.21	Restrictive Covenant Agreement, dated as of November 12, 2018, by and between Fortress Biotech, Inc. and InvaGen Pharmaceuticals Inc., incorporated herein by reference from the Company's Form 8-K filed on November 14, 2018.
10.22	Indemnification Agreement, dated as of November 12, 2018, by and between Fortress Biotech, Inc. and InvaGen Pharmaceuticals Inc., incorporated herein by reference from the Company's Form 8-K filed on November 14, 2018.
10.23	Restrictive Covenant Agreement, dated as of November 12, 2018, by and between Dr. Lucy Lu, M.D. and InvaGen Pharmaceuticals Inc., incorporated herein by reference from the Company's Form 8-K filed on November 14, 2018.
10.24	First Amendment to Executive Employment Agreement, dated as of November 12, 2018, by and between Avenue Therapeutics, Inc. and Dr. Lucy Lu, M.D., incorporated herein by reference from the Company's Form 8-K filed on November 14, 2018.
23.1	Consent of Independent Registered Public Accounting Firm, BDO USA, LLP.
24.1	Power of Attorney (included on signature page)
31.1	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Principal Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	The following financial information from Avenue Therapeutics, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2018, formatted in XBRL (eXtensible Business Reporting Language): (i) Balance Sheets, (ii) Statement of Operations, (iii) Statement of Stockholders' Equity (Deficit), (iv) Statements of Cash Flows, and (v) the Notes to Financial Statements

* Subject to a request for confidential treatment.
# Management Compensation Arrangement.

Item 16. Form 10-K Summary

None.

INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Stockholders and Board of Directors
Avenue Therapeutics, Inc.
New York, New York

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Avenue Therapeutics, Inc. (the "Company") as of December 31, 2018 and 2017, the related statements of operations, stockholders' equity (deficit), and cash flows for the years then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2018 and 2017, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. 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 financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ BDO USA, LLP

We have served as the Company's auditor since 2016.

New York, NY
March 12, 2019

AVENUE THERAPEUTICS, INC.
BALANCE SHEETS
(In thousands, except share and per share amounts)

	December 31, 2018	December 31, 2017
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 2,671	$ 11,782
Short-term investments	-	10,000
Deferred financing costs	1,702	-
Prepaid expenses and other current assets	152	388
Total Assets	**$ 4,525**	**$ 22,170**
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current Liabilities:		
Accounts payable and accrued expenses	$ 4,669	$ 2,737
Accounts payable and accrued expenses - related party	487	53
Total current liabilities	5,156	2,790
Total Liabilities	5,156	2,790
Commitments and Contingencies		
Stockholders' Equity (Deficit)		
Preferred Stock ($0.0001 par value), 2,000,000 shares authorized		
Class A Preferred Stock, 250,000 shares issued and outstanding as of December 31, 2018 and 2017, respectively	-	-
Common Stock ($0.0001 par value), 50,000,000 shares authorized		
Common shares; 10,667,714 and 10,265,083 shares issued and outstanding as of December 31, 2018 and 2017, respectively	1	1
Common stock issuable, 0 and 273,837 shares as of December 31, 2018 and 2017, respectively	-	1,103
Additional paid-in capital	41,577	38,937
Accumulated deficit	(42,209)	(20,661)
Total Stockholders' Equity (Deficit)	(631)	19,380
Total Liabilities and Stockholders' Equity (Deficit)	**$ 4,525**	**$ 22,170**

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

AVENUE THERAPEUTICS, INC.
STATEMENTS OF OPERATIONS
(In thousands, except share and per share amounts)

	For the Years Ended	
	December 31, 2018	**December 31, 2017**
Operating expenses:		
Research and development	$ 17,696	$ 6,698
Research and development - licenses acquired	-	1,103
General and administrative	4,120	3,620
Loss from operations	(21,816)	(11,421)
Interest income	(93)	(88)
Interest expense	-	294
Interest expense - related party	-	81
Change in fair value of convertible notes payable	-	99
Change in fair value of warrant liabilities	-	451
Other income	(175)	-
Net Loss	**$ (21,548)**	**$ (12,258)**
Net loss per common share outstanding, basic and diluted	$ (2.10)	$ (1.85)
Weighted average number of common shares outstanding, basic and diluted	10,239,169	6,634,937

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

AVENUE THERAPEUTICS, INC.
STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT)
(In thousands, except share amounts)

	Class A Preferred Shares		Common Shares		Common Shares Issuable		Additional paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Shares	Amount	capital	deficit	equity (deficit)
Balance at December 31, 2016	**250,000**	**$ -**	**3,257,937**	**$ 1**	**83,532**	**$ 49**	**$ 105**	**$ (8,403)**	**$ (8,248)**
Share based compensation	-	-	220,000	-	-	-	604	-	604
Issuance of common shares - Founders Agreement	-	-	241,657	-	(83,532)	(49)	997	-	948
Common shares issuable to Fortress - Founders	-	-	-	-	273,837	1,103	-	-	1,103
Issuance of common shares, net of costs	-	-	6,325,000	-	-	-	34,235	-	34,235
Conversion of MSA fees into common shares	-	-	166,666	-	-	-	1,000	-	1,000
Issuance of warrants under the NSC Note	-	-	-	-	-	-	750		750
Exercise of warrants under the NSC Note	-	-	4,075	-	-	-	-	-	-
Conversion of notes payable	-	-	49,748	-	-	-	299	-	299
Change in fair value of convertible notes warrants	-	-	-	-	-	-	15	-	15
Modification to interest on fortress note	-	-	-	-	-	-	300	-	300
Contribution of capital - extinguishment of Fortress compensation accrual	-	-	-	-	-	-	632	-	632
Net loss	-	-	-	-	-	-	-	(12,258)	(12,258)
Balance at December 31, 2017	**250,000**	**$ -**	**10,265,083**	**$ 1**	**273,837**	**$ 1,103**	**$ 38,937**	**$ (20,661)**	**$ 19,380**
Issuance of common shares - Founders Agreement	-	-	273,837	-	(273,837)	(1,103)	1,103	-	-
Exercise of warrants under the NSC Note	-	-	20,816	-	-	-	-	-	-
Share based compensation	-	-	107,978	-	-	-	1,537	-	1,537
Net loss	-	-	-	-	-	-	-	(21,548)	(21,548)
Balance at December 31, 2018	**250,000**	**$ -**	**10,667,714**	**$ 1**	**-**	**$ -**	**$ 41,577**	**$ (42,209)**	**$ (631)**

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

AVENUE THERAPEUTICS, INC.
STATEMENTS OF CASH FLOWS
(In thousands)

	For the Years Ended	
	December 31, 2018	**December 31, 2017**
Cash flows from operating activities:		
Net loss	$ (21,548)	$ (12,258)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share based compensation	1,537	604
Change in fair value of convertible notes payable	-	99
Change in fair value of warrant liabilities	-	451
Debt discount amortization	-	174
Issuance of common shares - Founders Agreement	-	948
Common shares issuable - Founders Agreement	-	1,103
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	236	(388)
Accounts payable and accrued expenses	1,125	2,231
Accounts payable and accrued expenses - related party	434	337
Interest payable	-	(57)
Accrued interest - related party	-	(46)
Net cash used in operating activities	(18,216)	(6,802)
Cash flows from investing activities:		
Maturity (purchase) of Short-term investments (certificates of deposits)	10,000	(10,000)
Net cash provided by (used in) investing activities	10,000	(10,000)
Cash flows from financing activities:		
Issuance of common shares	-	37,950
Offering costs	(895)	(3,715)
Repayment of NSC Note	-	(3,000)
Proceeds from notes payable - related party	-	637
Repayments of notes payable - related party	-	(3,485)
Net cash (used in) provided by financing activities	(895)	28,387
Net change in cash	(9,111)	11,585
Cash and cash equivalents, beginning of period	11,782	197
Cash and cash equivalents, end of period	**$ 2,671**	**$ 11,782**
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ -	$ 303
Non-cash financing activities:		
Unpaid deferred financing costs	$ 807	$ -
Conversion of MSA fees into common shares	$ -	$ 1,000
Issuance of warrants	$ -	$ 750
Extinguishment of Fortress compensation accrual	$ -	$ 632
Modification to interest on fortress note	$ -	$ 300
Conversion of notes payable	$ -	$ 200
Change in fair value of convertible notes warrants	$ -	$ 15

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

Note 1 — Organization, Plan of Business Operations

Avenue Therapeutics, Inc. (the "Company" or "Avenue") was incorporated in Delaware on February 9, 2015, as a wholly owned subsidiary of Fortress Biotech, Inc. ("Fortress"), to develop and market pharmaceutical products for the acute care setting in the United States. The Company will focus on developing its product candidate, an intravenous ("IV") formulation of tramadol HCI ("IV Tramadol"), for moderate to moderately severe post-operative pain.

Stock Purchase and Merger Agreement (the "SPMA")

On November 12, 2018, the Company and InvaGen Pharmaceuticals Inc. ("InvaGen"), entered into definitive agreements with two closing stages for a proposed acquisition of the Company for a total aggregate consideration of $215.0 million. The SPMA was approved by a majority of the Company's stockholders, including a majority of its non-affiliated stockholders, at its special shareholder meeting on February 6, 2019. On February 8, 2019, InvaGen acquired 5,833,333 shares of the Company's common stock at $6.00 ("the Stock Purchase Transaction") per share for net proceeds of $31.5 million after deducting commission fees and other offering costs, representing a 33.3% stake in the Company's capital stock on a fully diluted basis.

At the second stage closing, InvaGen will acquire the remaining shares of Avenue's common stock, pursuant to a reverse triangular merger with Avenue remaining as the surviving entity, for up to $180.0 million in the aggregate ("the Merger Transaction"). The second stage closing is subject to the satisfaction of certain closing conditions, including conditions pertaining to U.S. Food and Drug Administration approval, labeling, scheduling and the absence of any Risk Evaluation and Mitigation Strategy ("REMS") or similar restrictions in effect with respect to IV Tramadol, as well as the expiration of any waiting period applicable to the acquisition under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended.

Concurrently with the execution and delivery of the SPMA, the Company and InvaGen entered into a credit agreement (the "Credit Agreement"), pursuant to which InvaGen will provide initial financing to the Company in an amount of up to $3.0 million in the form of a line of credit, up to the closing of the Stock Purchase Transaction which occurred on February 8, 2019. Any amounts drawn on the line of credit will be deducted from the aggregate consideration payable to the Company pursuant to the Stock Purchase Transaction. As of December 31, 2018, no amounts were drawn on this line of credit. Subject to the terms and conditions described in the SPMA, the Buyer may also provide interim financing to the Company in an amount of up to $7.0 million during the time period between the Stock Purchase Transaction (which occurred on February 8, 2019) and the Merger Transaction. Any amounts drawn on the interim financing will be deducted from the aggregate consideration payable to Company stockholders by virtue of the Merger Transaction.

Concurrently with the execution and delivery of the Credit Agreement, Fortress and InvaGen entered into a guaranty (the "Guaranty"), pursuant to which Fortress guaranteed the full payment to InvaGen, when due, of all amounts of (x) all obligations of the Company to InvaGen under the Credit Agreement, whether for principal interest, fees, charges, expenses or otherwise, and (y) any and all costs and expenses incurred by InvaGen in enforcing any of its rights under the Guaranty.

Liquidity and Capital Resources

The Company has incurred substantial operating losses since its inception and expects to continue to incur significant operating losses for the foreseeable future as it executes on its product development plan and may never become profitable. As of December 31, 2018, the Company had an accumulated deficit of $42.2 million.

Note 2 — Significant Accounting Policies

Basis of Presentation

The Company's financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP") and are stated in U.S. dollars. The Company has no subsidiaries.

The financial statements may not be indicative of future performance and may not reflect what their results of operations, financial position, and cash flows would have been had Avenue operated as an independent entity. Certain estimates, including allocations from Fortress, have been made to provide financial statements for stand-alone reporting purposes. Avenue became a stand-alone entity following the Initial Public Offering ("IPO") on June 26, 2017. All inter-company transactions between Fortress and Avenue are classified as Accounts Payable and Accrued Expenses — Related Party in the financial statements. The Company believes that the assumptions underlying the financial statements are reasonable. The cost allocation methods used prior to the IPO in June 2017 applied to certain common costs include the following:

- Specific identification. Where the amounts were specifically identified to Avenue, they were classified accordingly.
- Reasonable allocation. Where the amounts were not clearly or specifically identified, management determined if a reasonable allocation method could be applied.

Reverse stock split

On June 26, 2017, the Company effected a 3.0-to-1.0 reverse stock split of Company's common stock. No fractional shares were issued in connection with the stock split. The par value and other terms of these classes of stock were not affected by the reverse stock split.

All share and per share amounts, including stock options, have been retroactively adjusted in these financial statements for all periods presented to reflect the 3.0-to-1.0 reverse stock split. Further, the fair value of stock issuances has been retroactively adjusted in these financial statements for all periods presented to reflect the 3.0-to-1.0 reverse stock split.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates.

Cash and Cash Equivalents

The Company considers all short-term investments with an original maturity of three months or less when purchased to be cash equivalents. Cash and cash equivalents at December 31, 2018 and at December 31, 2017 consisted of cash, money market funds and certificates of deposit in institutions in the United States. Balances at certain institutions have exceeded Federal Deposit Insurance Corporation ("FDIC") insured limits and U.S. government agency securities.

Short-term Investments

The Company classifies its certificates of deposit as short-term investments in accordance with the Financial Accounting Standards Board ("FASB") ASC 320, *Investments - Debt and Equity Securities*. The Company considers all short-term investments with an original maturity in excess of three months but less than a year when purchased to be short-term investments. There were no investments as of December 31, 2018. In July 2017 and in September 2017, the Company purchased $5.0 million of certificates of deposit with an original maturity of six months. At December 31, 2017, the Company had approximately $10.0 million in certificates of deposit with an original maturity of greater than three months. The Company reassesses the appropriateness of the classification of its investments at the end of each reporting period. The Company has determined that its certificates of deposits with an original maturity of six months should be classified as short-term investments as of December 31, 2017. This classification was based upon management's determination that it has the positive intent and ability to hold the securities until their maturity dates, as its investments mature within one year and the underlying cash invested in these securities is not required for current operations.

Investments consist of short-term FDIC insured certificates of deposit carried at amortized cost using the effective interest method. The cost of the Company's certificates of deposit approximated fair value.

Research and Development

Research and development costs are expensed as incurred. Advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made. Upfront and milestone payments due to third parties that perform research and development services on the Company's behalf will be expensed as services are rendered or when the milestone is achieved.

Research and development costs primarily consist of personnel related expenses, including salaries, benefits, travel, and other related expenses, stock-based compensation, payments made to third parties for license and milestone costs related to in-licensed products and technology, payments made to third party contract research organizations for preclinical and clinical studies, investigative sites for clinical trials, consultants, the cost of acquiring and manufacturing clinical trial materials, costs associated with regulatory filings and patents, laboratory costs and other supplies.

Costs incurred in obtaining technology licenses are charged to research and development expense if the technology licensed has not reached commercial feasibility and has no alternative future use. The licenses purchased by the Company require substantial completion of research and development, regulatory and marketing approval efforts in order to reach commercial feasibility and have no alternative future use. Accordingly, the total purchase price for the licenses acquired are reflected as research and development — licenses acquired on the Company's Statements of Operations.

Annual Stock Dividend

In September 2016, in connection with the Amended and Restated Articles of Incorporation, the Company issued 250,000 Class A preferred shares to Fortress. The Class A preferred shares entitled the holder to a stock dividend equal to 2.5% of the fully diluted outstanding equity of the Company ("The Annual Stock Dividend") to be paid on February 17 of each year. On June 13, 2018, the Company's Stockholders adopted an amendment to the Company's Third Amended and Restated Certificate of Incorporation amending the payment date going forward to January 1 of each year. Concurrently with the execution and delivery of the SPMA, the Company, InvaGen and Fortress entered into a waiver agreement ("the Waiver Agreement"), pursuant to which, among other things, Fortress irrevocably waived its right to receive dividends of the Company's common shares under the terms of the Class A Preferred Stock and any fees, payments, reimbursements or other distributions under a certain management services agreement between the Company and Fortress and the Founders Agreement (as defined in the SPMA), for the period November 12, 2018 to the termination of InvaGen's rights under Section 4 of the Stockholders Agreement that was signed between the Company, certain stockholders of the Company, and InvaGen.

The Company recorded the Annual Stock Dividend due to Fortress as contingent consideration. Contingent consideration is recorded when probable and reasonably estimable. The Company's future share prices cannot be estimated due to the nature of its assets and the Company's stage of development. Due to these uncertainties, the Company concluded that it could not reasonably estimate the contingent consideration until shares were actually issued on February 17, 2018. Because the issuance of shares on February 17, 2018 occurred prior to the issuance of the December 31, 2017 financial statements, the Company recorded approximately $1.1 million in research and development - licenses acquired for the year ended December 31, 2017. Due to the Waiver Agreement, the Company recorded $0 in research and development - licenses acquired for the year ended December 31, 2018.

Fair Value Measurement

The Company follows accounting guidance on fair value measurements for financial assets and liabilities measured at fair value on a recurring basis. Under the accounting guidance, fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or a liability.

The accounting guidance requires fair value measurements be classified and disclosed in one of the following three categories:

Level 1: Quoted prices in active markets for identical assets or liabilities.

Level 2: Observable inputs other than Level 1 prices, for similar assets or liabilities that are directly or indirectly observable in the marketplace.

Level 3: Unobservable inputs which are supported by little or no market activity and that are financial instruments whose values are determined using pricing models, discounted cash flow methodologies, or similar techniques, as well as instruments for which the determination of fair value requires significant judgment or estimation.

The fair value hierarchy also requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires management to make judgments and consider factors specific to the asset or liability.

Stock-Based Compensation

The Company expenses stock-based compensation to employees and board members over the requisite service period based on the estimated grant-date fair value of the awards. Stock-based awards with graded-vesting schedules are recognized on a straight-line basis over the requisite service period for each separately vesting portion of the award. For stock-based compensation awards to non-employees, the Company measures the fair value of the non-employee awards at each reporting period prior to vesting and finally at the vesting date of the award. Changes in the estimated fair value of these non-employee awards are recognized as compensation expense in the period of change.

The assumptions used in calculating the fair value of stock-based awards represent management's best estimates and involve inherent uncertainties and the application of management's judgment.

Fair Value Option

As permitted under ASC 825, *Financial Instruments*, ("ASC 825"), the Company has elected the fair value option to account for its convertible notes that were issued during 2016. In accordance with ASC 825, the Company records these convertible notes at fair value with changes in fair value recorded in the Statement of Operations. As a result of applying the fair value option, direct costs and fees related to the convertible notes were recognized in earnings as incurred and were not deferred.

Valuation of Warrant Related to NSC Note

In accordance with ASC 815 *Derivatives and Hedging*, the Company classified the fair value of the warrant ("Contingently Issuable Warrants") that it may be obligated to issue to National Securities, Inc. ("NSC"), in connection with the transfer on October 31, 2015 of $3.0 million of indebtedness to NSC, as a derivative liability as there was a potential that the Company would not have a sufficient number of authorized common shares available to settle this instrument. The Company valued these Contingently Issuable Warrants using a Black-Scholes model and used estimates for an expected dividend yield, a risk-free interest rate, and expected volatility together with management's estimate of the probability of issuance of the Contingently Issuable Warrants. At each reporting period, as long as the Contingently Issuable Warrants were potentially issuable and there was a potential for an insufficient number of authorized shares available to settle the Contingently Issuable Warrants, the Contingently Issuable Warrants had to be revalued and any difference from the previous valuation date would be recognized as a change in fair value in the Company's statement of operations. On June 26, 2017, the warrants were issued (See Note 9).

Income Taxes

The Company accounts for income taxes under ASC 740, *Income Taxes* ("ASC 740"). ASC 740 requires the recognition of deferred tax assets and liabilities for both the expected impact of differences between the financial statement and tax basis of assets and liabilities and for the expected future tax benefit to be derived from tax loss and tax credit carry forwards. ASC 740 additionally requires a valuation allowance to be established when it is more likely than not that all or a portion of deferred tax assets will not be realized.

ASC 740 also clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements and prescribes a recognition threshold and measurement process for financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. For those benefits to be recognized, a tax position must be more-likely-than-not to be sustained upon examination by taxing authorities. ASC 740 also provides guidance on de-recognition, classification, interest and penalties, accounting in interim period, disclosure and transition. Based on the Company's evaluation, it has been concluded that there are no significant uncertain tax positions requiring recognition in the Company's financial statements. Since the Company was incorporated on February 9, 2015, the 2015 through 2018 tax years are the only periods subject to examination upon filing of appropriate tax returns. The Company believes that its income tax positions and deductions would be sustained on audit and does not anticipate any adjustments that would result in a material change to its financial position.

The Company's policy for recording interest and penalties associated with audits is to record such expense as a component of income tax expense. There were no amounts accrued for penalties or interest as of or during the years ended December 31, 2018 and 2017. Management is currently unaware of any issues under review that could result in significant payments, accruals or material deviations from its position.

Net loss per Share

Loss per share is computed by dividing net loss by the weighted-average number of common shares outstanding, excluding unvested restricted stock and stock options, during the period. Since dividends are declared paid and set aside among the holders of shares of common stock and Class A common stock pro-rata on an as-if-converted basis, the two-class method of computing net loss per share is not required.

The following table sets forth the potential common shares that could potentially dilute basic income per share in the future that were not included in the computation of diluted income (loss) per share because to do so would have been anti-dilutive for the periods presented:

	For the Years Ended	
	December 31, 2018	**December 31, 2017**
Restricted stock units/awards	1,104,643	714,999
Preferred shares	250,000	250,000
Options	20,000	20,000
Total potential dilutive effect	1,374,643	984,999

Comprehensive Loss

The Company has no components of other comprehensive loss, and therefore, comprehensive loss equals net loss.

Recently Adopted Accounting Standards

In January 2017, the FASB issued ASU No. 2017-01, *Business Combinations (Topic 805) Clarifying the Definition of a Business* ("ASU 2017-01"). The amendments in this ASU clarify the definition of a business with the objective of adding guidance to assist entities with evaluating whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. The definition of a business affects many areas of accounting including acquisitions, disposals, goodwill, and consolidation. The guidance is effective for annual periods beginning after December 15, 2017, including interim periods within those periods. The Company adopted ASU 2017-01 in the first quarter of 2018 and its adoption did not have a material impact on the Company's financial statements.

In May 2017, the FASB issued ASU No. 2017-09, *Compensation-Stock Compensation (Topic 718): Scope of Modification Accounting*, ("ASU 2017-09") which clarifies when to account for a change to the terms or conditions of a share-based payment award as a modification. Under the new guidance, modification accounting is required only if the fair value, the vesting conditions, or the classification of the award (as equity or liability) changes as a result of the change in terms or conditions. It is effective prospectively for the annual period ending December 31, 2018 and interim periods within that annual period. Early adoption is permitted. The Company early adopted ASU 2017-09 in the first quarter of 2018 and its adoption did not have a material impact on the Company's financial statements.

In June 2018, the FASB issued ASU No. 2018-07, *Improvements to Nonemployee Share-Based Payment Accounting*, ("ASU 2018-07") which simplifies the accounting for share-based payments granted to nonemployees for goods and services. Under the ASU, most of the guidance on such payments to nonemployees would be aligned with the requirements for share-based payments granted to employees. The changes take effect for public companies for fiscal years starting after December 15, 2018, including interim periods within that fiscal year. For all other entities, the amendments are effective for fiscal years beginning after December 15, 2019, and interim periods within fiscal years beginning after December 15, 2020. Early adoption is permitted, but no earlier than an entity's adoption date of Topic 606. The Company adopted ASU 2018-07 in the first quarter of 2019 and its adoption did not have a material impact on the Company's financial statements and related disclosures.

Note 3 — Allocation

The expense allocations to Avenue, which represent Lucy Lu's executive compensation, have been paid by Fortress and allocated by the Company between Avenue and Fortress based on time spent on Avenue projects versus time spent on Fortress projects. The allocations were based on assumptions that management believes are reasonable; however, these allocations are not necessarily indicative of the costs and expenses that would have resulted if Avenue had been operating as a stand-alone entity. Since Lucy Lu became a full-time employee for Avenue in June 2017, the allocations ceased as her time spent was 100% devoted to Avenue. For the years ended December 31, 2018 and 2017, the allocated expenses related to Lucy Lu were approximately $0 and $0.2 million, respectively, and were recorded 50% to research and development and 50% to general and administration expenses. Upon the IPO, Fortress and Avenue agreed to extinguish the total amount accrued under these expense allocations. Therefore, the Company recorded the $0.6 million related to the allocation of Lucy Lu's compensation as a contribution of capital on June 26, 2017.

Note 4 — License/Supplier Agreements

Effective as of February 17, 2015, Fortress transferred the Revogenex license and all other rights and obligations under the License Agreement to Avenue, pursuant to the terms of the Founders Agreement. In connection with the terms of the License Agreement, Fortress purchased an exclusive license to IV Tramadol for the U.S. market from Revogenex, a privately held company in Dublin, Ireland. Tramadol is a centrally acting synthetic opioid analgesic for moderate to moderately severe pain and is available as immediate release or extended-release tablets in the United States. Fortress made an upfront payment of $2.0 million to Revogenex upon execution of the exclusive license, and on June 17, 2015, Fortress paid an additional $1.0 million to Revogenex after receiving all the assets specified in the agreement. The $3.0 million cumulative payment was included in research and development-licenses acquired in the statements of operations. In addition, under the terms of the agreement, Revogenex is eligible to receive additional milestone payments totaling $4.0 million upon the achievement of certain development milestones, as well as royalty payments for sales of the product.

On October 29, 2018, the Company and Zaklady Farmaceutyczne Polpharma ("Polpharma") extended the term of the supply agreement to eight years from the date of the launch of the product. In addition, under the terms of the amended agreement, Polpharma is eligible to receive a milestone payment totaling $2.0 million upon the achievement of a certain development milestone, as well as royalty payments for sales of the product.

Note 5 — Related Party Agreements

Founders Agreement and Management Services Agreement with Fortress

Fortress entered into a Founders Agreement with Avenue in February 2015, pursuant to which Fortress assigned to Avenue all of its rights and interest under Fortress's license agreement with Revogenex for IV Tramadol (the "License Agreement"). As consideration for the Founders Agreement, Avenue assumed $3.0 million in debt (see Note 7) that Fortress accumulated to NSC for expenses and costs of forming Avenue and obtaining the IV Tramadol license, of which $3.0 million represents the acquisition of the License Agreement. As additional consideration for the transfer of rights under the Founders Agreement, Avenue shall also: (i) issue annually to Fortress, on the anniversary date of the Founders Agreement, shares of common stock equal to two and one half percent (2.5%) of the fully-diluted outstanding equity of Avenue at the time of issuance; (ii) pay an equity fee in shares of Avenue common stock, payable within five (5) business days of the closing of any equity or debt financing for Avenue or any of its respective subsidiaries that occurs after the effective date of the Founders Agreement and ending on the date when Fortress no longer has majority voting control in Avenue's voting equity, equal to two and one half percent (2.5%) of the gross amount of any such equity or debt financing; and (iii) pay a cash fee equal to four and one half percent (4.5%) of Avenue's annual net sales, payable on an annual basis, within ninety (90) days of the end of each calendar year. In the event of a change in control (as it is defined in the Founders Agreement), Fortress will be paid a one-time change in control fee equal to five (5x) times the product of (i) net sales for the twelve (12) months immediately preceding the change in control and (ii) four and one-half percent (4.5%). This additional consideration was waived on November 12, 2018 with the Waiver Agreement signed between Avenue, Fortress and InvaGen.

On September 13, 2016, the Company entered into an Amended and Restated the Founders Agreement ("A&R Founders Agreement") with Fortress. The A&R Founders Agreement eliminated the Annual Equity Fee in connection with the original agreement and added a term of 15 years, which upon expiration automatically renews for successive one-year periods unless terminated by Fortress or a Change in Control occurs. Concurrently with the A&R Founders Agreement the Company entered into an Exchange Agreement whereby the Company exchanged Fortress' 2.3 million Class A common shares for approximately 2.5 million common shares and 250,000 Class A Preferred shares (see Note 9).

On June 26, 2017, the Company issued 158,125 common shares to Fortress representing 2.5% of common shares issued in connection with the IPO (see Note 9). The Company recorded expense of approximately $0.9 million related to the financing fee in general and administrative expenses in the Statement of Operations for the year ended December 31, 2017.

Effective as of February 17, 2015, Fortress entered into a Management Services Agreement (the "MSA") with Avenue and each of Avenue's current directors and officers who are directors or officers of Fortress, excluding services provided by Dr. Lucy Lu, the Company's current Chief Executive Officer as of June 26, 2017 and the former Chief Financial Officer of Fortress (resigned as of June 26, 2017), to provide services to Avenue pursuant to the terms of the MSA. Pursuant to the terms of the MSA, for a period of five (5) years, Fortress will render advisory and consulting services to Avenue. Services provided under the MSA may include, without limitation, (i) advice and assistance concerning any and all aspects of Avenue's operations, clinical trials, financial planning and strategic transactions and financings and (ii) conducting relations on behalf of Avenue with accountants, attorneys, financial advisors and other professionals (collectively, the "Services"). Avenue is obligated to utilize clinical research services, medical education, communication and marketing services and investor relations/public relation services of companies or individuals designated by Fortress, provided those services are offered at market prices. However, Avenue is not obligated to take or act upon any advice rendered from Fortress and Fortress shall not be liable for any of Avenue's actions or inactions based upon their advice. Fortress and its affiliates, including all members of Avenue's Board of Directors, have been contractually exempt from fiduciary duties to Avenue relating to corporate opportunities. In consideration for the Services, Avenue will pay Fortress an annual consulting fee of $0.5 million (the "Annual Consulting Fee"), payable in advance in equal quarterly installments on the first business day of each calendar quarter in each year, provided, however, that such Annual Consulting Fee shall be increased to $1.0 million for each calendar year in which Avenue has net assets in excess of $100.0 million at the beginning of the calendar year.

On May 15, 2017, the Company and Fortress amended the MSA to allow for payment of the Annual Consulting Fee in the Company's common stock in increments of $0.5 million, prior to the launch of the Company's IPO (see Note 9). On June 26, 2017, the Company repaid $1.0 million of the outstanding 2015 and 2016 Annual Consulting fees by issuing 166,666 shares of the Company's common stock at the offering price of $6.00 per share.

For the years ended December 31, 2018 and 2017, the Company had expenses related to the MSA of approximately $0.4 million and $0.5 million, respectively. Effective November 12, 2018, the MSA fee was waived with the Waiver Agreement signed between Avenue, Fortress and InvaGen.

Fortress Note

Effective March 15, 2015, the Company and Fortress entered into a future advance promissory note (the "Fortress Note"), in which Fortress agreed to provide a working capital line of credit until the Company has a third-party financing. Interest on the Fortress Note accrued at 8% per annum and shall be payable to Fortress on the day after the end of each calendar quarter following the first third-party financing. All principal and accrued interest under the Fortress Note is payable on demand following the first third-party financing. This Fortress Note can be pre-paid at any time in cash or through the assumption of Fortress' indebtedness NSC or other similar indebtedness.

In May 2017, in anticipation of the Company's IPO, the Company and Fortress amended the FBIO Note (the "FBIO Note Amendment"), to reduce interest on the FBIO Note from 8% to 2% from inception, effective the closing date of the Company's IPO. Accordingly, on June 26, 2017, the interest rate was reduced and resulted in a reduction of interest of approximately $0.3 million ($0.4 million at 8% versus $0.1 million at 2%). In accordance with ASC 470-50, *Debt, Modifications and Extinguishments*, the Company determined that since the change in interest rate did not materially change the nature of the note, it was accounted for as a modification and recorded as a reduction in interest expense of $0.3 million in additional paid in capital on the Statement of Stockholders' Equity (Deficit).

On July 25, 2017, the Company repaid the outstanding principal and interest balance of the Fortress Note of approximately $3.5 million and $0.1 million, respectively. For the years ended December 31, 2018 and 2017, the Company had interest expense related to the Fortress Note of approximately $0 and $74,000, respectively.

NSC Note and Financings

In September 2016, Fortress acquired through a tender offer 56.6% of National Holdings, Inc. ("National" or "NHLD"). The Company held an approximate $3.0 million NSC Note ("NSC Note") (see Note 7) for which NSC, a subsidiary of National, received a 10% placement fee upon issuance of the Note to Fortress. As of February 11, 2019, Fortress completed a two stage sale of its entire ownership in National and as such, National is no longer a related party. On June 26, 2017, the Company completed an IPO and NSC acted as co-manager in this offering and earned commissions and fees of approximately $2.3 million. On July 5, 2017, the Company repaid the outstanding NSC Note of approximately $3.0 million and accrued interest of approximately $2,000.

On June 26, 2017, pursuant to the terms of the Company's $3.0 million NSC Note, upon the closing of the Company's IPO, the Company issued to National the Contingently Issuable Warrants for 125,000 common shares at par, relating to its aggregate gross proceeds from its third-party offerings exceeding five times the value of the debt. Upon the issuance of the Contingently Issuable Warrants, Fortress was removed as the guarantor on the note (see Note 7).

Note 6 — Accounts Payable and Accrued Expenses

Accounts payable, accrued expenses and other liabilities consisted of the following (in thousands):

	As of December 31,	
	2018	**2017**
Accounts payable	$ 3,089	$ 1,545
Accrued employee compensation	463	215
Accrued contracted services and other	1,117	977
Accounts payable and accrued expenses	$ 4,669	$ 2,737

Note 7 — Notes Payable

NSC Note

In February 2015, Fortress closed a private placement of a promissory note for $10.0 million in favor of NSC Biotech Venture Fund I, LLC. Fortress used the proceeds from this promissory note to acquire medical technologies and products. The note matures in 36 months, provided that during the first 24 months Fortress can extend the maturity date by six months. No principal amount will be due for the first 24 months (or the first 30 months if the maturity date is extended). Thereafter, the note will be repaid at the rate of 1/12 of the principal amount per month for a period of 12 months. Interest on the note is 8% payable quarterly during the first 24 months (or the first 30 months if the note is extended) and monthly during the last 12 months. NSC acted as the sole placement agent for the this note. The NSC Note, was amended and restated on July 29, 2015, to provide that any time a Fortress Company receives from Fortress any proceeds from this note, Fortress may, in its sole discretion, cause the Fortress Company to issue to NSC Biotech Venture Fund I, LLC a new promissory note (the NSC Note) on identical terms as the original note (giving effect to the passage of time with respect to maturity). The NSC Note will equal the dollar amount of the Fortress Company's share of the original note and reduce the Fortress' obligations under the original note by such amount.

Fortress will guarantee the NSC Note until the Company either completes an initial public offering of its securities or raises sufficient equity capital so that it has cash equal to five times the NSC Note. If the Company has an initial public offering and raises sufficient equity capital so that it has cash equal to five times the amount of the portion of the proceeds of the NSC Note transferred to it, then NSC will receive a Contingently Issuable Warrant to purchase the Company's stock equal to 25% of the outstanding note divided by the lowest price the Company sells its equity in its first third party financing. The warrants were issued on June 26, 2017 and have a term of 10 years and an exercise price equal to the par value of the Company's common stock.

In January 2017, the Company notified NSC Biotech Venture Fund I, LLC, of its election to extend the maturity date to September 30, 2018.

As of December 31, 2016, the Company's NSC Note totaled $3.0 million, with a debt discount related to the Company's pro rata share of Fortress' debt issuance costs of approximately $0.2 million. The effective interest rate of the NSC Note approximates 13.1%. The original fair value of the Contingently Issuable Warrants in connection with the NSC Note in the amount of approximately $0.1 million was recorded as a debt discount based on its fair value (see Note 9). The Contingently Issuable Warrants were recorded at fair value at each reporting period (see Note 10).

On June 26, 2017, pursuant to the terms of the Company's $3.0 million NSC Note, upon the closing of the Company's IPO, the Company issued to National warrants for 125,000 common shares at par with a fair value of $0.8 million, relating to its aggregate gross proceeds from its third-party offerings exceeding five times the value of the debt. Upon the issuance of the warrant, Fortress was removed as the guarantor on the note.

On July 5, 2017, the Company repaid the outstanding NSC Note of approximately $3.0 million and accrued interest of approximately $2,000. At December 31, 2017, the Company had $0 outstanding under its NSC Note.

For the years ended December 31, 2018 and 2017, the Company recorded interest expense of approximately $0 and $0.3 million, respectively.

The following table summarizes NSC Note activities as of December 31, 2018 (in thousands):

	Note Payable	Discount	Note Payable, Net
December 31, 2016 balance	$ 3,000	$ (174)	$ 2,826
Repayments	(3,000)	-	(3,000)
Amortization of debt discount	-	174	174
December 31, 2017 balance	$ -	$ -	$ -
December 31, 2018 balance	$ -	$ -	$ -

Westpark Convertible Note

On December 30, 2016, Avenue held a closing of the sale of convertible promissory notes. Avenue sold three convertible promissory notes to investors for an aggregate of $0.2 million. The notes have an initial term of 18 months, which can be extended at the option of the holder, on one or more occasions, for up to 180 days and accrue simple interest at the rate of 5% per annum for the first 12 months and 8% per annum simple interest thereafter. The notes are guaranteed by Fortress. The outstanding principal and interest of the notes automatically converts into the type of equity securities sold by Avenue in the next sale of equity securities in which Avenue realizes aggregate gross cash proceeds of at least $10.0 million (before commissions or other expenses and excluding conversion of the notes) at a conversion price equal to the lesser of (a) the lowest price per share at which equity securities of Avenue are sold in such sale less a 33% discount and (b) a per share price based on a pre-offering valuation of $30.0 million divided by the number of common shares outstanding on a fully-diluted basis. The outstanding principal and interest of the notes may be converted at the option of the holder in any sale of equity securities that does not meet the $10.0 million threshold for automatic conversion using the same methodology. The notes also automatically convert upon a "Sale" of Avenue, defined as (a) a transaction or series of related transactions where one or more non-affiliates acquires (i) capital stock of Avenue or any surviving successor entity possessing the voting power to elect a majority of the board of directors or (ii) a majority of the outstanding capital stock of Avenue or the surviving successor entity (b) the sale, lease or other disposition of all or substantially all of Avenue's assets or any other transaction resulting in substantially all of Avenue's assets being converted into securities of another entity or cash. Upon a Sale of Avenue, the outstanding principal and interest of the notes automatically converts into common shares at a price equal to the lesser of (a) a discount to the price per share being paid in the Sale of Avenue equal to 33% or (b) the quotient resulting from dividing (x) $30.0 million by (y) the fully-diluted common stock of Avenue outstanding immediately prior to the Sale of Avenue (excluding the notes).

In the closing, Avenue realized net proceeds of $0.1 million after paying WestPark Capital, Inc., the placement agent, placement agent fees of $30,000 and escrow fees of $4,000 and paying approximately $14,000 in legal fees. Additionally, WestPark received a warrant ("Avenue Warrant") to purchase the number of shares of Avenue's common stock equal to $10,000 divided by the price per share at which any note sold to investors first converts into Avenue's common stock. The Avenue Warrant has a ten-year term and has a per share exercise price equal to the price per share at which any note sold to investors first converts into Avenue's common stock.

The fair value of these convertible notes amounted to $0.2 million.

Due to the complexity and number of embedded features within each convertible note, and as permitted under accounting guidance, the Company elected to account for the convertible notes and all the embedded features (collectively, the "hybrid instrument") under the fair value option.

On June 26, 2017, in connection with the closing of the Company's IPO, these convertible notes were converted into 49,748 shares of Avenue's common stock.

Note 8 — Commitments and Contingencies

Leases

The Company is not a party to any leases for office space or equipment.

Litigation

The Company recognizes a liability for a contingency when it is probable that liability has been incurred and when the amount of loss can be reasonably estimated. When a range of probable loss can be estimated, the Company accrues the most likely amount of such loss, and if such amount is not determinable, then the Company accrues the minimum of the range of probable loss.

In connection with the SPMA, two putative class action lawsuits were filed in the United States District Court for the District of Delaware. The two lawsuits are captioned Bushansky v. Avenue Therapeutics, Inc. et al, Docket No. 1:19-cv-00085 (D. Del. Jan 15, 2019) and Krause v. Avenue Therapeutics, Inc. et al, Docket No. 1:19-cv-00107 (D. Del. Jan 17, 2019) (collectively, the "Merger Litigation"). The complaints, which were filed by purported Company stockholders, generally allege that the preliminary and definitive proxy statements that the Company filed with the SEC on December 11, 2018 and December 21, 2018, respectively, omitted certain material information in connection with the Stock Purchase Transaction and the Merger Transaction in violation of Sections 14(a) and 20(a) of the Securities Exchange Act of 1934, and SEC Rule 14a-9 thereunder. These complaints include demands for, among other things, an order enjoining defendants from closing the Stock Purchase Transaction and the Merger Transaction absent certain disclosures of information identified in the complaints.

The Company believes that the claims asserted in the Merger Litigation are without merit and that no supplemental disclosure was required under applicable law. However, in order to avoid the risk of the Merger Litigation delaying or adversely affecting the SPMA and to minimize the costs, risks and uncertainties inherent in litigation, and without admitting any liability or wrongdoing, the Company determined to voluntarily supplement the Proxy Statement it filed with the SEC on December 21, 2018. Nothing in the supplement to the proxy was deemed an admission of the legal necessity or materiality under applicable laws of any of the disclosures set forth within the supplement to the Proxy Statement. To the contrary, the Company specifically denied all allegations in the Merger Litigation that any additional disclosure was required.

Note 9 — Stockholders' Equity (Deficit)

Class A Preferred Shares

Pursuant to the Company's Third Amended and Restated Certificate of Incorporation, filed September 13, 2016, Class A Common Stock was eliminated and 2,000,000 shares of Preferred Stock were authorized, of which 250,000 have been designated as Class A Preferred Stock and the remainder are undesignated preferred stock. The Class A Preferred Stock, with a par value of $0.0001 per share, is identical to undesignated Common Stock other than as to voting rights, conversion rights, and the PIK Dividend right (as described below). The undesignated Preferred Stock may be issued from time to time in one or more series. The Company's Board of Directors is authorized to determine or alter the dividend rights, dividend rate, conversion rights, voting rights, rights and terms of redemption (including sinking fund provisions, if any), the redemption price or prices, the liquidation preferences and other designations, powers, preferences and relative, participating, optional or other special rights, if any, and the qualifications, limitations and restrictions granted to or imposed upon any wholly unissued series of Preferred Stock, and to fix the number of shares of any series of Preferred Stock (but not below the number of shares of any such series then outstanding).

Pursuant to the Company's Second Amended and Restated Certificate of Incorporation, the holders of the outstanding shares of Class A Preferred Stock shall receive on each February 17 (each a "PIK Dividend Payment Date") after the original issuance date of the Class A Preferred Stock until the date all outstanding Class A Preferred Stock is converted into Common Stock or redeemed (and the purchase price is paid in full), pro rata per share dividends paid in additional fully paid and nonassessable shares of Common Stock (such dividend being herein called "PIK Dividends") such that the aggregate number of shares of Common Stock issued pursuant to such PIK Dividend is equal to two and one-half percent (2.5%) of the Corporation's fully-diluted outstanding capitalization on the date that is one (1) business day prior to any PIK Dividend Payment Date ("PIK Record Date"). In the event the Class A Preferred Stock converts into Common Stock, the holders shall receive all PIK Dividends accrued through the date of such conversion. No dividend or other distribution shall be paid, or declared and set apart for payment (other than dividends payable solely in capital stock on the capital stock of the Company) on the shares of Common Stock until all PIK Dividends on the Class A Preferred Stock shall have been paid or declared and set apart for payment. All dividends are non-cumulative. On June 13, 2018, the Company's Stockholders adopted an amendment to the Company's Third Amended and Restated Certificate of Incorporation amending the PIK Dividend Payment Date going forward to January 1 of each year. This PIK Dividend was waived in connection with the Waiver Agreement signed on November 12, 2018. (see Note 5).

On any matter presented to the stockholders of the Company for their action or consideration at any meeting of stockholders of the Company (or by written consent of stockholders in lieu of meeting), each holder of outstanding shares of Class A Preferred Stock shall be entitled to cast for each share of Class A Preferred Stock held by such holder as of the record date for determining stockholders entitled to vote on such matter, the number of votes that is equal to one and one-tenth (1.1) times a fraction, the numerator of which is the sum of (A) the number of shares of outstanding Common Stock and (B) the whole shares of Common Stock in to which the shares of outstanding Class A Common Stock and the Class A Preferred Stock are convertible, and the denominator of which is number of shares of outstanding Class A Preferred Stock (the "Class A Preferred Stock Ratio"). Thus, the Class A Preferred Stock will at all times constitute a voting majority.

Each share of Class A Preferred Stock is convertible, at the option of the holder, into one fully paid and nonassessable share of Common Stock (the "Conversion Ratio"), subject to certain adjustments. If the Company, at any time effects a subdivision or combination of the outstanding Common Stock (by any stock split, stock dividend, recapitalization, reverse stock split or otherwise), the applicable Conversion Ratio in effect immediately before that subdivision is proportionately decreased or increased, as applicable, so that the number of shares of Common Stock issuable on conversion of each share of Class A Preferred Stock shall be increased or decreased, a applicable, in proportion to such increase or decrease in the aggregate number of shares of Common Stock outstanding. Additionally, if any reorganization, recapitalization, reclassification, consolidation or merger involving the Company occurs in which the Common Stock (but not the Class A Preferred Stock) is converted into or exchanged for securities, cash or other property, then each share of Class A Preferred Stock becomes convertible into the kind and amount of securities, cash or other property which a holder of the number of shares of Common Stock of the Company issuable upon conversion of one share of the Class A Preferred Stock immediately prior to such reorganization, recapitalization, reclassification, consolidation or merger would have been entitled to receive pursuant to such transaction.

Common Stock

As of December 31, 2018, the Company's authorized capital stock consists of 50,000,000 shares of common stock, with $0.0001 par value, and 2,000,000 shares of Preferred Stock, with $0.0001 par value, of which 250,000 have been designated as Class A Preferred Stock and the remainder are undesignated Preferred Stock.

Holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders and do not have cumulative voting rights. An election of directors by our stockholders shall be determined by a plurality of the votes cast by the stockholders entitled to vote on the election. Holders of common stock are entitled to receive proportionately any dividends as may be declared by our Board of Directors, subject to any preferential dividend rights of outstanding preferred stock.

In the event of our liquidation or dissolution, the holders of common stock are entitled to receive proportionately all assets available for distribution to stockholders after the payment of all debts and other liabilities and subject to the prior rights of any outstanding preferred stock. Holders of common stock have no preemptive, subscription, redemption or conversion rights. The rights, preferences and privileges of holders of common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future.

On September 13, 2016, the Company entered into the A&R Founders Agreement with Fortress. The A&R Founders Agreement eliminated the Annual Equity Fee in connection with the original agreement and added a term of 15 years, which upon expiration automatically renews for successive one-year periods unless terminated by Fortress or a Change in Control occurs. Concurrently with the A&R Founders Agreement the Company entered into an Exchange Agreement whereby the Company exchanged Fortress' 2.3 million Class A common shares for approximately 2.5 million common shares and 250,000 Class A Preferred shares.

Initial Public Offering

On June 26, 2017, the Company completed an IPO of its common stock, which resulted in the issuance of 6,325,000 shares of its common stock, inclusive of 825,000 shares which were subject to an underwriter over-allotment. The shares were issued at $6.00 per share, resulting in net proceeds of approximately $34.2 million after deducting underwriting discounts, and other offering costs.

In conjunction with the closing of the IPO, the Company issued warrants in connection with its NSC Debt and its Convertible Notes.

Awards to Fortress

Pursuant to the Company's Third and Second Amended and Restated Certificates of Incorporation, on February 17, 2018 and 2017, the Company issued 273,837 and 83,532, respectively, shares of common stock to Fortress, which equaled to 2.5% of the fully diluted outstanding equity of Avenue at the time of issuance for the annual stock dividend. The Company recorded an expense of approximately $1.1 million and $49,000, in research and development licenses-acquired related to these stock grants during the years ended December 31, 2017 and 2016, respectively.

On June 26, 2017, pursuant to the terms of the Founders Agreement with Fortress, the Company issued to Fortress 158,125 shares of common stock at $6.00 per share, representing the 2.5% financing fee Fortress receives on third-party financings. The Company recorded expense of approximately $0.9 million related to the financing fee in general and administrative expenses in the Statement of Operations for the year ended December 31, 2017.

On June 26, 2017, the Company repaid $1.0 million of the outstanding 2015 and 2016 Annual Consulting fees by issuing 166,666 shares of the Company's common stock at the offering price of $6.00 per share. The 2017 Annual Consulting fee of $0.5 million was paid in cash in the year ended December 31, 2017.

Equity Incentive Plan

The Company has in effect the 2015 Incentive Plan ("2015 Incentive Plan'). The 2015 Incentive Plan was adopted in January 2015 by our stockholders. Under the 2015 Incentive Plan, the compensation committee of the Company's board of directors is authorized to grant stock-based awards to directors, officers, employees and consultants. The plan authorizes grants to issue up to 2,000,000 shares of authorized but unissued common stock and expires 10 years from adoption and limits the term of each option to no more than 10 years from the date of grant.

Total shares available for the issuance of stock-based awards under the Company's 2015 Incentive Plan was 647,022 shares at December 31, 2018.

Restricted Stock Units and Restricted Stock Awards

The following table summarizes restricted stock unit and award activity for the year ended December 31, 2018:

	Number of Units and Awards	Weighted Average Grant Date Fair Value
Unvested balance at December 31, 2017	714,999	$ 5.00
Granted	467,978	$ 3.48
Vested	(78,334)	$ 2.05
Unvested balance at December 31, 2018	1,104,643	$ 4.45

For the years ended December 31, 2018 and 2017 stock-based compensation expenses associated with the amortization of restricted stock units and restricted stock awards for employees and non-employees were approximately $1.5 million and $0.6 million, respectively.

For the years ended December 31, 2018, and 2017, the weighted average grant date fair value of restricted stock units and awards granted was $3.48 and $6.77, respectively. The total fair value of restricted stock units and awards that vested during the years ended December 31, 2018 and 2017 was $0.1 million and $33,000, respectively.

At December 31, 2018, the Company had unrecognized stock-based compensation expense related to restricted stock units and restricted stock awards of $3.3 million, which is expected to be recognized over the remaining weighted-average vesting period of 2.0 years.

On November 12, 2018, the Company and Dr. Lucy Lu entered into an amendment to the Executive Employment Agreement, dated June 10, 2015 ("the Employment Agreement"), pursuant to which the Dr. Lu. shall be vested in one hundred percent (100%) of all unvested equity rewards in the event of the termination of the Executive Employment Agreement upon her death, complete disability, termination without cause or resignation for good reason not in connection with a change of control (other than certain equity awards which may be granted following the SPMA). Pursuant to the amendment, the Executive's separation benefits following her termination without cause or resignation for good reason in connection with a change of control (100% vesting) is subject to an additional condition that Dr. Lu has not entered into a new employment agreement with the Company's acquirer or an affiliate thereof. Dr. Lu's original Employment Agreement provided for accelerated vesting of only those unvested shares that would have vested in the upcoming year upon death or disability, termination without cause outside of a change in control, or resignation for good reason outside of a change in control. As this modification does not affect the fair value of the award, no adjustment to compensation cost is necessary. Any acceleration of vesting upon the events described above will result in a recognition of the remaining compensation cost associated with the award.

Stock Options

On August 15, 2017, 20,000 stock options were granted to a consultant under the 2015 Incentive Plan with a $6.29 exercise price and a five-year life. The stock options vest upon achievement of certain milestones based on the price of the Company's stock in relation to the exercise price of $6.29. The stock options were valued using a Black-Scholes model with the following assumptions; volatility of 80%, risk free rate of 1.83% and effective life of 5 years. The fair value of each stock option was $1.85. The entire value of the stock option grant of $37,000 was expensed on the grant date in accordance with ASC 505 *Equity-based Payments to Non-employees* as "no specific performance is required by the grantee to retain those equity instruments, then, because of the elimination of any obligation on the part of the counterparty to earn the equity instruments, a measurement date has been reached."

The following table summarizes stock option award activity for the year ended December 31, 2018:

	Stock Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)
Outstanding, December 31, 2017	20,000	$ 6.29	4.63
Granted	-	-	-
Outstanding, December 31, 2018	20,000	$ 6.29	3.63

Stock Warrants

On June 26, 2017, sufficient equity capital was raised so that the Company had cash equal to five times the amount of the portion of the proceeds of the NSC Note transferred to it. As a result, the Company issued warrants for 125,000 common shares with an exercise price of par value and a ten-year term. As a result of this transaction, the Company recorded the fair value of the Contingently Issuable Warrants of approximately $0.8 million as an increase to additional paid in capital on the Statement of Stockholders' Equity (Deficit).

On June 26, 2017, in connection with the automatic conversion of the WestPark Convertible Notes, which automatically converted upon the closing of the IPO, the Company issued 2,488 warrants at an exercise price of $4.02 and a ten-year term. Pursuant to the terms of the note agreement, the exercise price represents the price at which the notes converted, which is equal to a 33% discount to the IPO price of $6.00 per share.

The following table summarizes the warrant activity for the year ended December 31, 2018:

	Warrants	Weighted Average Exercise Price	Aggregate Intrinsic Value (in thousands)
Outstanding, December 31, 2017	123,413	$ 0.0811	$ 438
Exercised	(20,816)	$ 0.0001	-
Outstanding, December 31, 2018	102,597	$ 0.0976	$ 544

Note 10 — Fair Value Measurement

Financial instruments measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. At December 31, 2018 and 2017, the warrant balance of $0 was classified as Level 3 instruments.

The following table sets forth the changes in the estimated fair value for the Company's Level 3 classified derivative warrant liability (in thousands):

	NSC Contingently Issuable Warrants	Westpark Contingently Issuable Warrants	Total
Fair value, December 31, 2016	$ 302	$ 12	$ 314
Change in fair value	448	3	451
Conversion into common shares	(750)	-	(750)
Change in fair value of convertible notes warrants	-	(15)	(15)
Fair value, December 31, 2017	-	-	-
Change in fair value	-	-	-
Fair value, December 31, 2018	$ -	$ -	$ -

On June 26, 2017, pursuant to the terms of the Company's $3.0 million NSC Note, upon the closing of the Company's IPO, the Company issued to National warrants for 125,000 common shares at par with a fair value of $0.8 million, relating to its aggregate gross proceeds from its third-party offerings exceeding five times the value of the debt. Upon the issuance of the warrant, Fortress was removed as the guarantor on the note (see Note 7).

Additionally, on June 26, 2017, the Company issued 2,488 warrants to purchase common shares of the Company at $4.02, to Westpark, in connection with their role as placement agent.

The following table sets forth the changes in the estimated fair value for our Level 3 classified convertible notes payable (in thousands):

	Westpark Convertible Notes
Fair value, December 31, 2016	$ 200
Change in fair value	99
Conversion into common shares	(299)
Fair value, December 31, 2017	$ -
Change in fair value	-
Fair value, December 31, 2018	$ -

Note 11 — Income Taxes

For financial reporting purposes, the Company calculated income tax provision and deferred income tax balances as if it was a separate entity and had filed its own separate tax return under Sub-Chapter C of the Internal Revenue Code.

A reconciliation of the statutory U.S. federal rate to the Company's effective tax rate is as follows:

	For the years ended December 31,	
	2018	2017
Statutory federal income tax rate	21%	35%
State taxes, net of federal tax benefit	9%	8%
Federal tax rate change	0%	(20)%
State tax rate change	0%	1%
Non-deductible items	0%	(3)%
Other	0%	(1)%
Credits	5%	1%
Change in valuation allowance	(35)%	(21)%
Income taxes provision (benefit)	0%	0%

The components of the net deferred tax asset as of December 31, 2018 and 2017 are the following (in thousands):

	As of December 31,	
	2018	2017
Deferred tax assets:		
Net operating loss carryovers	$ 10,160	$ 4,220
Stock compensation and other	658	70
Change in warrant liabilities	-	226
Amortization of license	1,006	1,064
Accruals and reserves	221	8
Tax credits	1,294	154
Total deferred tax assets	13,339	5,742
Less valuation allowance	(13,339)	(5,742)
Deferred tax assets, net of valuation allowance	$ -	$ -

The Company has determined, based upon available evidence, that it is more likely than not that the net deferred tax asset will not be realized and, accordingly, has provided a full valuation allowance against it. A valuation allowance of approximately $13.3 million and $5.7 million was recorded for the years ended December 31, 2018 and 2017, respectively.

On December 22, 2017, "H.R.1", formerly known as the "Tax Cuts and Jobs Act," was signed into law. Among other items, H.R.1 reduced the federal corporate tax rate to 21% from the existing maximum rate of 35%, effective January 1, 2018. As a result, the Company recorded a decrease related to its deferred tax assets and valuation allowance of $2.5 million, with a corresponding net adjustment to deferred income tax expense of zero for the year ended December 31, 2017.

As of December 31, 2018, the Company had federal and state net operating loss carryforwards of approximately $34.5 million and $43.1 million, respectively. The federal and state net operating loss carryforwards will begin to expire, if not utilized, by 2035 and 2035, respectively. The Company has $1.3 million of research and development credit carryforwards, which will begin to expire, if not utilized, in 2035. Utilization of the net operating loss and credit carryforwards may be subject to an annual limitation due to the ownership change limitations provided by Section 382 of the Internal Revenue Code of 1986 ("IRC"), as amended and similar state provisions. Certain tax attributes are subject to an annual limitation as a result of the Company's June 2017 initial public offering, which constitutes an ownership change under Section 382. Certain tax attributes may be subject to an annual limitation as a result of the SPMA with InvaGen, which could constitute an ownership change under Section 382.

There are no significant matters determined to be unrecognized tax benefits taken or expected to be taken in a tax return, in accordance with ASC 740 "Income Taxes" ("ASC 740"), which clarifies the accounting for uncertainty in income taxes recognized in the financial statements, that have been recorded on the Company's financial statements for the periods ended December 31, 2018 and 2017. The Company does not anticipate a material change to unrecognized tax benefits in the next twelve months.

Additionally, ASC 740 provides guidance on the recognition of interest and penalties related to income taxes. There were no interest or penalties related to income taxes that have been accrued or recognized as of and for the periods ended December 31, 2018 and 2017.

The federal and state tax returns for the period ended December 31, 2015 and the years ended December 31, 2016, 2017, and 2018 are currently open for examination under the applicable federal and state income tax statues of limitations.

Note 12 – Subsequent Events

Litigation

In connection with the SPMA, two putative class action lawsuits were filed in the United States District Court for the District of Delaware. The two lawsuits are captioned *Bushansky v. Avenue Therapeutics, Inc. et al, Docket No. 1:19-cv-00085 (D. Del. Jan 15, 2019)* and *Krause v. Avenue Therapeutics, Inc. et al, Docket No. 1:19-cv-00107 (D. Del. Jan 17, 2019)* (collectively, the "Merger Litigation"). The complaints, which were filed by purported Company stockholders, generally allege that the preliminary and definitive proxy statements that the Company filed with the SEC on December 11, 2018 and December 21, 2018, respectively, omitted certain material information in connection with the Stock Purchase Transaction and the Merger Transaction in violation of Sections 14(a) and 20(a) of the Securities Exchange Act of 1934, and SEC Rule 14a-9 thereunder. These complaints include demands for, among other things, an order enjoining defendants from closing the Stock Purchase Transaction and the Merger Transaction absent certain disclosures of information identified in the complaints.

The Company believes that the claims asserted in the Merger Litigation are without merit and that no supplemental disclosure was required under applicable law. However, in order to avoid the risk of the Merger Litigation delaying or adversely affecting the SPMA and to minimize the costs, risks and uncertainties inherent in litigation, and without admitting any liability or wrongdoing, the Company determined to voluntarily supplement the Proxy Statement it filed with the SEC on December 21, 2018. Nothing in the supplement to the proxy was deemed an admission of the legal necessity or materiality under applicable laws of any of the disclosures set forth within the supplement to the Proxy Statement. To the contrary, the Company specifically denied all allegations in the Merger Litigation that any additional disclosure was required.

SPMA

The SPMA was approved by a majority of the Company's stockholders, including a majority of its non-affiliated stockholders, at its special shareholder meeting on February 6, 2019. On February 8, 2019, InvaGen acquired 5,833,333 shares of the Company's common stock at $6.00 per share for net proceeds of $31.5 million after deducting commission fees and other offering costs, representing a 33.3% stake in the Company's capital stock on a fully diluted basis.

SIGNATURES

Pursuant to the requirements of Section 12 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.

Avenue Therapeutics, Inc.

By: /s/ Lucy Lu, M.D.
Name: Lucy Lu, M.D.
Title: President and Chief Executive Officer

March 12, 2019

POWER OF ATTORNEY

We, the undersigned directors and/or executive officers of Avenue Therapeutics, Inc., hereby severally constitute and appoint Lucy Lu, M.D., acting singly, his or her true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for him or her in any and all capacities, to sign this report and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent full power and authority to do and perform each and every act and thing necessary or appropriate to be done in connection therewith, as fully for all intents and purposes as he or she might or could do in person, hereby approving, ratifying and confirming all that said attorney-in-fact and agent, or his substitute, may lawfully do or cause to be done by virtue hereof.

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 capacities and on the dates indicated.

Signature	Title	Date
/s/ Lucy Lu, M.D. Lucy Lu, M.D.	President and Chief Executive Officer (Principal Executive Officer)	March 12, 2019
/s/ Joseph Vazzano Joseph Vazzano	Chief Financial Officer (Principal Financial Officer)	March 12, 2019
/s/ Lindsay A. Rosenwald, M.D. Lindsay A. Rosenwald, M.D.	Executive Chairman of the Board	March 12, 2019
/s/ Scott A. Reines, M.D., Ph.D. Scott A. Reines, M.D., Ph.D.	Interim Chief Medical Officer	March 12, 2019
/s/ Nishant Saxena Nishant Saxena	Director	March 12, 2019
/s/ Neil Herskowitz Neil Herskowitz	Director	March 12, 2019
/s/ Jeffrey Paley, M.D. Jeffrey Paley, M.D.	Director	March 12, 2019
/s/ Jaideep Gogtay, M.D., Ph.D. Jaideep Gogtay, M.D., Ph.D.	Director	March 12, 2019
/s/ Jay Kranzler, M.D., Ph.D. Jay Kranzler, M.D., Ph.D.	Director	March 12, 2019

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

Avenue Therapeutics, Inc.
New York, New York

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (No. 333-224276) and Form S-8 (No. 333-219972) of Avenue Therapeutics, Inc. of our report dated March 12, 2019, relating to the financial statements which appears in this Form 10-K.

/s/ BDO USA, LLP
New York, New York

March 12, 2019

Exhibit 31.1

Certification of
Principal Executive Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Lucy Lu, M.D., certify that:

1. I have reviewed this Annual Report on Form 10-K of Avenue 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, 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 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.

/s/ Lucy Lu, M.D.
Lucy Lu, M.D.
President and Chief Executive Officer
(Principal Executive Officer)
March 12, 2019

Exhibit 31.2

Certification of
Principal Financial Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Joseph Vazzano, certify that:

1. I have reviewed this Annual Report on Form 10-K of Avenue 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, 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 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.

/s/ Joseph Vazzano
Joseph Vazzano
Chief Financial Officer
(Principal Financial Officer)
March 12, 2019

Exhibit 32.1

Certification of
Principal Executive Officer
Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

I, Lucy Lu, M.D., Chief Executive Officer of Avenue Therapeutics, Inc. (the "Company"), in compliance with Section 906 of the Sarbanes-Oxley Act of 2002, hereby certify that, to the best of my knowledge, the Company's Annual Report on Form 10-K for the period ended December 31, 2018 (the "Report") filed with the Securities and Exchange Commission:

· Fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

· The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Lucy Lu, M.D.
Lucy Lu, M.D.
President and Chief Executive Officer
(Principal Executive Officer)
March 12, 2019

Exhibit 32.2

Certification of
Principal Financial Officer
Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

I, Joseph Vazzano, Principal Financial Officer of Avenue Therapeutics, Inc. (the "Company"), in compliance with Section 906 of the Sarbanes-Oxley Act of 2002, hereby certify that, to the best of my knowledge, the Company's Annual Report on Form 10-K for the period ended December 31, 2018 (the "Report") filed with the Securities and Exchange Commission:

· Fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

· The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Joseph Vazzano
Joseph Vazzano
Chief Financial Officer
(Principal Financial Officer)
March 12, 2019