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

AMENDMENT NO. 1
TO
FORM 10

GENERAL FORM FOR REGISTRATION OF SECURITIES
Pursuant to Section 12(b) or (g) of the Securities Exchange Act of 1934

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, New York**	**10014**
(Address of Principal Executive Offices)	(Zip Code)

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

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

(Title of Class)	(Name of exchange on which registered)
n/a	**n/a**

Securities registered pursuant to section 12(g) of the Act:

(Title of Class)
Common Stock, par value $0.0001 per share

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒ (Do not check if a smaller reporting company)	Smaller reporting company	☐

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SPECIAL CAUTIONARY NOTICE REGARDING FORWARD-LOOKING STATEMENTS

Certain matters discussed in this registration statement 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 registration statement. 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 candidate 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 drug 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 registration statement reflect our views and assumptions as of the effective date of this registration statement. 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.

References in this registration statement to "Avenue Therapeutics," "Avenue," "we," "us" and "our" refer to Avenue Therapeutics, Inc., a Delaware corporation.

Item 1: Business

OVERVIEW

We are a specialty pharmaceutical company that acquires, licenses, develops and commercializes products principally for use in the acute/intensive care hospital setting. Avenue's product candidate is an intravenous (" **IV**") formulation of tramadol HCI ("**IV Tramadol**"), for the treatment of moderate to moderately severe post-operative pain. In 2016, we completed a pharmacokinetics ("**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 (the "**FDA**"). We plan to initiate a Phase 3 development program of IV Tramadol for the management of post-operative pain in 2017. Under the terms of certain agreements described herein, we have an exclusive license to develop and commercialize IV Tramadol in the United States. Avenue plans to seek additional products to develop in the acute/intensive care hospital market in addition to IV Tramadol. Avenue Therapeutics is a Delaware corporation, which is currently majority-owned by Fortress Biotech, Inc. ("**Fortress**").

Market Overview – Postoperative Pain & the U.S. Hospital Market

We formed Avenue to develop and market pharmaceutical products for the acute care setting in the United States. Our initial focus will be on developing our proprietary product candidate, IV Tramadol, for moderate to moderately severe post-operative pain. Even though the post-operative pain market is entrenched with low cost, generic pain relievers, we believe 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 (the "**2014 Pain Report**"), sales of analgesics delivered via parenteral routes (IV, subcutaneous, and intramuscular injections) for the treatment of acute pain totaled $965 million in the U.S. in 2013. According to the 2014 Pain Report, there were over ten million select common inpatient procedures performed, all of which likely required post-operative pain management, in the U.S. in 2013.

The Current Standard of Care in the U.S.

The major goal in the management of postoperative pain is minimizing the dose of medications to lessen side effects while still providing adequate analgesia. This goal 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 treat post-operative pain, hospitals and even hospital units have their own practice guidelines that are often well entrenched in 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 ("**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 are essential to safe and effective pain management. The general consensus among pain management practitioners is that more than one modality (i.e., molecules with different mechanisms or with different routes of administration) is optimal for successful post-operative pain management. The most commonly prescribed agents in the immediate postoperative pain market are typically acetaminophen ("**APAP**"), nonsteroidal anti-inflammatory drugs ("**NSAIDS**") and opioid analgesics. Opioids offer inexpensive, safe and effective postoperative pain control and can be used in combination with other agents and techniques. As a result, they are a mainstay in post-operative pain management. 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 issue for patients and physicians to address.

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. Immune dysfunction, in particular, can slow the postoperative rehabilitation process and compound the risk inherent in any surgical procedure. The most common side effects of opioid usage are constipation (which has a very high incidence) and nausea. These side effects can be difficult to manage and patients do not seem to develop tolerance to them, especially in the case of constipation. NSAIDS have their own serious side effects, including increased post-surgery bleeding, peptic ulcer disease and renal impairment.

CORPORATE INFORMATION

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

We are currently filing for registration under this Form 10 under the Exchange Act, and we are not subject to the reporting requirements of section 13(a) or 15(d).

PRODUCT UNDER DEVELOPMENT

Tramadol, a synthetic dual-acting opioid, is a centrally acting analgesic with weak opioid agonist properties. It also works through a number of different mechanisms including inhibition of serotonin and noradrenaline re-uptake. These opioid and non-opioid modes of action are synergistic, essentially providing "multimodal therapy" with the use of a single drug. It is also commonly combined with APAP or NSAIDS in clinical practice. Tramadol has established a well-known efficacy and safety profile as it has been used throughout the world for decades. The efficacy of oral and parenteral tramadol in relieving moderate to moderately severe postoperative pain associated with surgery was demonstrated in several comparative, well designed human clinical studies.

In clinical studies, the overall analgesic efficacy of parenteral tramadol is similar to that of morphine and meperidine and comparable or superior to that of pentazocine.

In a study 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.

In a study 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 tramadol, meperidine or saline. The conclusion of the study was that meperidine and tramadol produced comparable analgesia.

In a study 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.

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 April 1995, under the trade name Ultram ® immediate release tablet, and is available as 50 mg, 100 mg, and 200 mg dosage forms (Ortho-McNeil-Janssen). Ultracet®, a combination product containing tramadol and acetaminophen, is also marketed in the United States (Ortho-McNeil-Janssen). Notably, the data from its extensive use as well as specific clinical pharmacology studies have demonstrated that, as compared to other opioids, tramadol use is associated with less respiratory depression, results in minimal delay in gastric emptying and gastrointestinal motility, and has minimal effect on hemodynamic function. Moreover, it has minimal gastrointestinal adverse effects, including reduced constipation compared to other opioids and does not impair immune function. Its most common side effects are nausea and vomiting and, importantly, it has low abuse potential as the risk of addiction is negligible (it is currently listed in the United States as a Class IV controlled substance). Compared to NSAIDs, tramadol does not increase bleeding risk, aggravate hypertension, cause gastrointestinal mucosal damage, impact renal function or aggravate congestive heart failure. Oral Tramadol was generally well tolerated in clinical trials evaluating its analgesic 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.

Although parenteral tramadol (i.v./i.m./s.c.) is approved and used for the management of moderate to moderately severe postoperative pain throughout much of the world, including Europe, India and Australia/New Zealand, there is no parenteral formulation currently available in the United States. We anticipate that the introduction of an intravenous formulation in the United States will address many of the short comings of opioids, APAP and NSAIDs currently used in the post-operative setting.

Advantages of IV Tramadol over the currently available oral formulations in the United States and other analgesics used in the post-operative setting likely include:

- More rapid onset of action than orally delivered tramadol;
- Tolerability to patients who cannot take oral medications;

- Based upon various studies and other available information, a favorable side effect profile compared to current standard-of-care opioids and injectable NSAIDs, including a reduced risk of respiratory depression, excessive sedation, hemodynamic effects (such as hypotension), dependency, bleeding risk, renal toxicity and gastrointestinal irritation, and immune system depression;

- Favorable safety compared to the current standard-of-care injectable pain products (opioids and NSAIDs) in some special populations, including patients who cannot tolerate the side effects of morphine, elderly patients, patients with a history of opioid addiction, patients who have peptic ulcer disease, and patients with susceptibility to perioperative bleeding; and

- Less costs associated with oversight of patients that may be high risk for opioid dependence;

We believe that IV Tramadol will be a useful and effective tool in the management of acute postoperative pain. Its advantages compared to current standard-of-care agents, along with the known efficacy, safety and tolerability profile for tramadol support the use of IV Tramadol in this setting. The risks associated with the use of IV Tramadol, benign compared to other opioids, are consistent with that of the currently marketed oral tramadol products. Consequently, with the industry trend toward multimodal therapy, we believe 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 treatment of post-operative pain.

COSTS AND TIME TO COMPLETE PRODUCT DEVELOPMENT

Based on the outcome of the EOP2 meeting, we provide the following program overview and estimates regarding the costs associated with the completion of the current development plan and our current estimated range of the time that will be necessary to complete that development plan for IV Tramadol. We also direct your attention to the Risk Factors (see Item 1A), which could significantly affect our ability to meet these cost and time estimates.

Product Candidate	Target Indication	Clinical Development Plan and Timing	NDA Submission	Estimated Cost to Complete Development
IV Tramadol HCI	Moderate to Moderately Severe Post-Operative Pain	Phase 3 Program to begin in 2017	2019	Approximately $30 million

Completion dates and costs in the above table are estimates due to the uncertainties associated with clinical trials and the related requirements of development. In the cases where the requirements for clinical trials and development programs have not been fully defined, or are dependent on the success of other trials, we cannot estimate trial completion or cost with any certainty. The actual spending on each trial during the year is also dependent on funding.

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 U.S. Patent and Trademark Office 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. 8,895,622 "Intravenous Administration of Tramadol" issued on November 25, 2014 (the "**622 Patent**"). The 622 Patent is directed to and claims a method of treating pain by administering a therapeutically effective dose of tramadol intravenously over a time period from about 10 minutes to about 45 minutes (i.e., the rate of intravenous tramadol administration). This method of treatment is different and may provide significant benefits (e.g., reduced side effects) over previously approved methods of administration of intravenous tramadol, in which the dose was typically accomplished over a 2-3 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 intravenous tramadol formulations, such as Tramal® solution for injection (available outside the U.S.). This patent is scheduled to expire in 2032.

Also pursuant to the License Agreement, we have exclusive, worldwide commercialization rights to two continuation patents of the 622 Patent, U.S. Patent No. 9,561,195 (the "**195 Patent**") issued on February 7, 2017 and U.S. Patent No. 9,566,253 (the "**253 Patent**") issued on February 14, 2017, both 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 and 253 patents contain claims which patentably differentiate over additional prior art discovered after the issuance of the 622 patent. Both of these patents contain claims directed to the administration of a 50 mg dose of tramadol intravenously over about 10 -20 minutes, and administering further doses of tramadol from approximately two- to six-hour time intervals to treat moderate to severe acute pain. The tramadol dose is preferably administered over 15 (±2) minutes. The 195 and 253 Patents are scheduled to expire in 2032.

Additionally, the License Agreement grants us the rights to a further patent filing to an intravenous tramadol dosing regimen which was recently filed with the USPTO and granted prioritized examination. This new patent application describes and claims a dosing regimen in which the Company's intravenous tramadol product is dosed to a human patient(s) 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 6 hours at steady state. 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 intravenous tramadol dosing regimen to an oral dosing regimen with less concern about deleterious effects which might occur from a switch from intravenous 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 intravenous dose provides at steady state). This new dosing regimen is the result of considerable experimentation by the Company, and a prior art search has not revealed any similar dosing regimen being used or published with respect to tramadol intravenous infusions. This application has been assigned to an Examiner, who has recently issued a non-substantive action. We expect substantive review to begin shortly. We believe that the subject matter of this new patent application is new and unobvious and are hopeful of obtaining a new U.S. patent based on this invention sometime in 2017. This patent, if issued, is expected to expire in 2036.

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.

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.

LICENSING AGREEMENTS AND COLLABORATIONS

Revogenex Ireland Ltd.

Effective as of February 17, 2015, Fortress obtained a worldwide (with the exception of 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 as amended as of June 23, 2016 (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 the 622 Patent and the 729 and 775 Applications (with the exception of 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 ("**IND**") pertaining to IV Tramadol, as well as all supporting documentation and relevant correspondence with the U.S. Food and Drug Administration ("**FDA**"). Further, under the License Agreement, Fortress assumed the rights and obligations of Revogenex under its current manufacturing agreement as amended on April 4, 2016 (the "**Manufacturing Agreement**"). Fortress transferred all its rights and obligations under the License Agreement and the Manufacturing Agreement to Avenue Therapeutics in May of 2015, under an agreement that has been super-ceded by the Amended and Restated Founders Agreement dated September 13, 2016. The Company evaluated the License Agreement and determined that it constituted an asset acquisition, as among other things, the Company had to perform additional studies in order to commence a Phase 3 study. Accordingly the payments under the License Agreement of $3.0 million were recorded, as an immediate expense, in research and development for the year ended December 31, 2015, as there was no alternative future use.

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: (i) by Revogenex if the NDA has not been filed by August 17, 2019 and Avenue has failed to use commercially reasonable efforts to carry out all of the product development, (ii) by Revogenex if the FDA does not issue an approval or otherwise issues a "not approvable" notice for the NDA within 15 months after the NDA has been filed with the FDA, although this termination right will be tolled if Avenue is using commercial reasonable efforts in its negotiations with the FDA for approval and if Avenue receives a "not approvable" notice, it will have a 15 month period to correct any issues and re-file the NDA for approval, (iii) by Avenue if it reasonably determines prior to NDA approval that the development of IV Tramadol is not economically viable, or (iv) by either Revogenex or Avenue (provided Avenue is using or has used commercially reasonable efforts to commercialize IV Tramadol) if, after the third anniversary date of the commercial launch, Avenue fails to achieve annual net sales with respect to IV Tramadol of at least $20 million in any given calendar year, with certain exceptions.

COMPETITION

Competition in the pharmaceutical and biotechnology industries is intense. Our competitors include pharmaceutical companies and biotechnology companies, as well as universities and public and private 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 in advance of our competitors.

We believe that IV Tramadol will compete with a number of opioid and non-opioid drugs that are currently available for acute pain or in development. The most commonly used opioids in the post-operative and acute pain settings are morphine, hydromorphone and fentanyl. The non-opioid drugs used in this setting include Ofirmev (IV acetaminophen) and intravenous formulations of non-steroidal anti-inflammatory drugs (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 treatment 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 post-operative pain space. There are also several agents with novel mechanisms in clinical development, such as CR845 (Cara Therapeutics, Inc.) and TRV130 (Trevena, Inc.).

EMPLOYEES

As of the date of this registration statement, we have no full-time employees and three part-time employees. Dr. Lucy Lu serves as our Interim President and Chief Executive Officer. Once this registration statement becomes effective, Dr. Lu will serve in a full-time capacity as our President and Chief Executive Officer. In addition, David Horin serves in a part-time capacity as our Interim Chief Financial Officer, pursuant to an agreement between us and Chord Advisors, LLC. Dr. Scott A. Reines serves in a part-time capacity as our Interim Chief Medical Officer. Please see *Item 6. Executive Compensation* for more 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.

Currently, we have one manufacturer to provide us clinical and commercial supply of IV Tramadol in accordance with current Good Manufacturing Practices ("**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 (5) years commencing upon the approval of our U.S. 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.

Contract manufacturers are subject to ongoing periodic and unannounced inspections by the FDA, the Drug Enforcement Administration and corresponding state and European agencies to ensure strict compliance with cGMPs and other state and federal regulations. We do not have control over third-party manufacturers' compliance with these regulations and standards, other than through contractual obligations. 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 corresponding foreign regulatory agencies must approve these new manufacturers in advance, which will involve testing and additional inspections to ensure compliance with 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

Numerous governmental authorities, principally the FDA and corresponding state and foreign regulatory agencies, impose substantial regulations upon the clinical development, manufacture and marketing of our product candidate, as well as our ongoing research and development activities. Our product candidate has not been approved for sale in any market in which we have marketing rights. Before marketing in the U.S., any drug that we develop must undergo rigorous pre-clinical testing and clinical trials and an extensive regulatory approval process implemented by the FDA under the FDCA. The FDA regulates, among other things, the pre-clinical and clinical testing, safety, efficacy, approval, manufacturing, record keeping, adverse event reporting, packaging, labeling, storage, advertising, promotion, export, sale and distribution of biopharmaceutical products.

The regulatory review and approval process is lengthy, expensive and uncertain. We are required to submit extensive pre-clinical and clinical data and supporting information to the FDA for each indication or use to establish a drug candidate's safety and efficacy before we can secure FDA approval to market or sell a product in the U.S. The approval process takes many years, requires the expenditure of substantial resources and may involve ongoing requirements for post-marketing studies or surveillance. Before commencing clinical trials in humans, we must submit an IND to the FDA containing, among other things, pre-clinical data, chemistry, manufacturing and control information, and an investigative plan. Our submission of an IND may not result in FDA authorization to commence a clinical trial.

The FDA may permit expedited development, evaluation, and marketing of new therapies intended to treat persons with serious or life-threatening conditions for which there is an unmet medical need under its fast track drug development programs. A sponsor can apply for fast track designation at the time of submission of an IND, or at any time prior to receiving marketing approval of the new drug application, or NDA. To receive fast track designation, an applicant must demonstrate:

- that the drug is intended to treat a serious or life-threatening condition;

- that the drug is intended to treat a serious aspect of the condition; and

- that the drug has the potential to address unmet medical needs, and this potential is being evaluated in the planned drug development program.

The FDA must respond to a request for fast track designation within 60 calendar days of receipt of the request. Over the course of drug development, a product in a fast track development program must continue to meet the criteria for fast track designation. Sponsors of products in fast track drug development programs must be in regular contact with the reviewing division of the FDA to ensure that the evidence necessary to support marketing approval will be developed and presented in a format conducive to an efficient review. Sponsors of products in fast track drug development programs ordinarily are eligible for priority review of a completed application in six months or less and also may be permitted to submit portions of an NDA to the FDA for review before the complete application is submitted.

Sponsors of drugs designated as fast track also may seek approval under the FDA's accelerated approval regulations. Under this authority, the FDA may grant marketing approval for a new drug product on the basis of adequate and well-controlled clinical trials establishing that the drug product has an effect on a surrogate endpoint that is reasonably likely, based on epidemiologic, therapeutic, pathophysiologic, or other evidence, to predict clinical benefit or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity. Approval will be subject to the requirement that the applicant study the drug further to verify and describe its clinical benefit where there is uncertainty as to the relation of the surrogate endpoint to clinical benefit or uncertainty as to the relation of the observed clinical benefit to ultimate outcome. Post-marketing studies are usually underway at the time an applicant files the NDA. When required to be conducted, such post-marketing studies must also be adequate and well-controlled. The applicant must carry out any such post-marketing studies with due diligence. Many companies who have been granted the right to utilize an accelerated approval approach have failed to obtain approval. Moreover, negative or inconclusive results from the clinical trials we hope to conduct or adverse medical events could cause us to have to repeat or terminate the clinical trials. Accordingly, we may not be able to complete the clinical trials within an acceptable time frame, if at all, and, therefore, could not submit the NDA to the FDA or foreign regulatory authorities for marketing approval.

Clinical testing must meet requirements for institutional review board oversight, informed consent and good clinical practices, and must be conducted pursuant to an IND, unless exempted.

For purposes of NDA approval, clinical trials are typically conducted in the following sequential phases:

- *Phase 1*: The drug is administered to a small group of humans, either healthy volunteers or patients, to test for safety, dosage tolerance, absorption, metabolism, excretion and clinical pharmacology.

- *Phase 2*: Studies are conducted on a larger number of patients to assess the efficacy of the product, to ascertain dose tolerance and the optimal dose range, and to gather additional data relating to safety and potential adverse events.

- *Phase 3*: Studies establish safety and efficacy in an expanded patient population.

- *Phase 4*: The FDA may require Phase 4 post-marketing studies to find out more about the drug's long-term risks, benefits, and optimal use, or to test the drug in different populations.

The length of time necessary to complete clinical trials varies significantly and may be difficult to predict. Clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. Additional factors that can cause delay or termination of our clinical trials, or that may increase the costs of these trials, include:

- slow patient enrollment due to the nature of the clinical trial plan, the proximity of patients to clinical sites, the eligibility criteria for participation in the study or other factors;

- inadequately trained or insufficient personnel at the study site to assist in overseeing and monitoring clinical trials or delays in approvals from a study site's review board;

- longer treatment time required to demonstrate efficacy or determine the appropriate product dose;

- insufficient supply of the drug candidates;

- adverse medical events or side effects in treated patients; and

- ineffectiveness of the drug candidates.

In addition, the FDA, equivalent foreign regulatory authority, or a data safety monitoring committee for a trial may place a clinical trial on hold or terminate it if it concludes that subjects are being exposed to an unacceptable health risk, or for futility. Any drug is likely to produce some toxicity or undesirable side effects in animals and in humans when administered at sufficiently high doses and/or for a sufficiently long period of time. Unacceptable toxicity or side effects may occur at any dose level at any time in the course of studies in animals designed to identify unacceptable effects of a drug candidate, known as toxicological studies, or clinical trials of drug candidates. The appearance of any unacceptable toxicity or side effect could cause us or regulatory authorities to interrupt, limit, delay or abort the development of any of our drug candidates and could ultimately prevent approval by the FDA or foreign regulatory authorities for any or all targeted indications.

Sponsors of drugs may apply for a special protocol assessment ("**SPA**") from the FDA. The SPA process is a procedure by which the FDA provides official evaluation and written guidance on the design and size of proposed protocols that are intended to form the basis for an NDA. However, final marketing approval depends on the results of efficacy, the adverse event profile and an evaluation of the benefit/risk of treatment demonstrated in the Phase 3 trial. The SPA may only be changed through a written agreement between the sponsor and the FDA, or if the FDA becomes aware of a substantial scientific issue essential to product safety or efficacy.

Before receiving FDA approval to market a product, we must demonstrate that the product is safe and effective for its intended use by submitting to the FDA an NDA containing the pre-clinical and clinical data that have been accumulated, together with chemistry and manufacturing and controls specifications and information, and proposed labeling, among other things. The FDA may refuse to accept an NDA for filing if certain content criteria are not met and, even after accepting an NDA, the FDA may often require additional information, including clinical data, before approval of marketing a product.

It is also becoming more common for the FDA to request a Risk Evaluation and Mitigation Strategy, or REMS, as part of a NDA. The REMS plan contains post-market obligations of the sponsor to train prescribing physicians, monitor off-label drug use, and conduct sufficient Phase 4 follow-up studies and registries to ensure the continued safe use of the drug.

As part of the approval process, the FDA must inspect and approve each manufacturing facility. Among the conditions of approval is the requirement that a manufacturer's quality control and manufacturing procedures conform to cGMP. Manufacturers must expend significant time, money and effort to ensure continued compliance, and the FDA conducts periodic inspections to certify compliance. It may be difficult for our manufacturers or us to comply with the applicable cGMP, as interpreted by the FDA, and other FDA regulatory requirements. If we, or our contract manufacturers, fail to comply, then the FDA may not allow us to market products that have been affected by the failure.

If the FDA grants approval, the approval will be limited to those conditions and patient populations for which the product is safe and effective, as demonstrated through clinical studies. Further, a product may be marketed only in those dosage forms and for those indications approved in the NDA. Certain changes to an approved NDA, including, with certain exceptions, any significant changes to labeling, require approval of a supplemental application before the drug may be marketed as changed. Any products that we manufacture or distribute pursuant to FDA approvals are subject to continuing monitoring and regulation by the FDA, including compliance with cGMP and the reporting of adverse experiences with the drugs. The nature of marketing claims that the FDA will permit us to make in the labeling and advertising of our products will generally be limited to those specified in FDA approved labeling, and the advertising of our products will be subject to comprehensive monitoring and regulation by the FDA. Drugs whose review was accelerated may carry additional restrictions on marketing activities, including the requirement that all promotional materials are pre-submitted to the FDA. Claims exceeding those contained in approved labeling will constitute a violation of the Federal Food, Drug and Cosmetic Act ("**FDCA**"). Violations of the FDCA or regulatory requirements at any time during the product development process, approval process, or marketing and sale following approval may result in agency enforcement actions, including withdrawal of approval, recall, seizure of products, warning letters, injunctions, fines and/or civil or criminal penalties. Any agency enforcement action could have a material adverse effect on our business.

Failure to comply with applicable federal, state and foreign laws and regulations would likely have a material adverse effect on our business. In addition, federal, state and foreign laws and regulations regarding the manufacture and sale of new drugs are subject to future changes.

Other Healthcare Laws and Compliance Requirements

In the U.S., our activities are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including the Centers for Medicare and Medicaid Services (formerly the Health Care Financing Administration), other divisions of the United States Department of Health and Human Services (e.g., the Office of Inspector General), the United States Department of Justice and individual United States Attorney offices within the Department of Justice, and state and local governments.

Pharmaceutical Coverage, Pricing and Reimbursement

In the U.S. 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 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 U.S., 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.

OUR DEVELOPMENT AND REGULATORY STRATEGY FOR IV TRAMADOL

Revogenex completed two nonclinical PK and toxicology studies in dogs, a Phase I dose proportionality study and a TQT study of IV Tramadol. 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" ("**QTc**") interval in healthy volunteers. The QTc interval represents electrical depolarization and repolarization of the heart ventricles. A lengthened QTc interval is a marker for the potential of ventricular arrhythmias.

In 2016, we completed a PK study for IV Tramadol in healthy volunteers as well as an EOP2 meeting with the FDA. We plan to initiate a Phase 3 development program of IV Tramadol for the management of post-operative pain in 2017. The purpose of the PK study was to determine a dosing regimen for IV Tramadol that provides a similar exposure profile to that of oral tramadol at steady state. We expect to utilize this dosing regimen in our Phase 3 program. 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.

In general, Phase II studies 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 II clinical studies for IV tramadol because tramadol is a known analgesic, and oral tramadol is labeled for "moderate to moderately severe pain" in the U.S. Instead, per FDA request, we completed pharmacokinetic simulations and conducted a pharmacokinetic and safety study in healthy volunteers, in order to select a Phase III dose based on achieving exposure to tramadol, and its primary metabolite, similar to that provided by oral tramadol.

We held an End-of-Phase II (EOP2) meeting with the FDA in 2016. At this meeting, we discussed Phase III program requirements for IV tramadol and confirmed the key elements of the Phase III study designs. As a result of the discussion at the meeting, we plan to conduct two Phase III safety and efficacy studies and an additional safety study in patients who require IV analgesia following surgery. The first Phase III safety and efficacy study will be conducted in patients undergoing bunionectomy surgery. Approximately 405 patients will be randomized 1:1:1 to one of two doses of IV tramadol, or placebo, for 48 hours. The primary efficacy endpoint is Sum of Pain Intensity Difference over 48 hours (SPID 48) – i.e. a measure of the overall effectiveness of the drug in reducing pain intensity during the 48-hour period. The second Phase III safety and efficacy study will be conducted in patients undergoing abdominoplasty surgery. 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). Approximately 250 patients will be enrolled into the safety study which has an open label, single arm design.

The Phase 3 development program of IV Tramadol for the management of post-operative pain will consist of three studies: an efficacy and safety study in an orthopedic model, an efficacy and safety study in a soft tissue model, and an open label safety study. We plan to initiate the Phase 3 development program in 2017. We anticipate that approximately 1,000 patients will be enrolled in the Phase 3 program.

If these studies are successful, we would expect to submit an NDA for approval of IV Tramadol to treat moderate to moderately severe post-operative pain pursuant to Section 505(b)(2) of the Federal, Food, Drug and Cosmetic Act.

Section 505(b)(2) New Drug Applications

As an alternate path to FDA approval for new indications or improved formulations of previously-approved products, a company may file a Section 505(b)(2) NDA, instead of a "stand-alone" or "full" NDA. Section 505(b)(2) of the FDCA was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984, otherwise known as the Hatch-Waxman Act. Section 505(b)(2) permits the submission of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. For example, the Hatch-Waxman Act permits the applicant to rely upon the FDA's findings of safety and effectiveness for an approved product. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product. The FDA may then approve the new formulation for all or some of the label indications for which the referenced product has been approved, or the new indication sought by the Section 505(b)(2) applicant.

To the extent that a Section 505(b)(2) applicant is relying on the FDA's findings for an already-approved product, the applicant is required to make certain certifications to the FDA regarding any patents listed for the approved product in the FDA's Orange Book publication. Specifically, the applicant must certify that: (1) the required patent information has not been filed; (2) the listed patent has expired; (3) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (4) the listed patent is invalid or will not be infringed by the manufacture, use or sale of the new product. A certification that the new product will not infringe the already approved product's Orange Book-listed patents or that such patents are invalid is called a paragraph IV certification. If the applicant does not challenge the listed patents, the Section 505(b)(2) application will not be approved until all the listed patents claiming the referenced product have expired. The Section 505(b)(2) application also may not be approved until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the referenced product has expired.

If the applicant has provided a paragraph IV certification to the FDA, the applicant must also send notice of the paragraph IV certification to the NDA and patent holders once the NDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a legal challenge to the paragraph IV certification. The filing of a patent infringement lawsuit within forty-five (45) days of their receipt of a paragraph IV certification automatically prevents the FDA from approving the Section 505(b)(2) NDA until the earlier of the expiration of a thirty (30) month period, the expiration of the patent, the entry of a settlement order or consent decree stating that the patents are invalid or not infringed, a decision in the case concerning infringement or validity that is favorable to the Section 505(b)(2) applicant. For drugs with five-year exclusivity, if an action for patent infringement is initiated after year four of that exclusivity period, then the thirty (30) month stay period is extended by such amount of time so that seven and a half (7.5) years have elapsed since the approval of the NDA with five (5) year exclusivity. This period could be extended by six (6) months if the NDA sponsor obtains pediatric exclusivity. Thus, the Section 505(b)(2) applicant may invest a significant amount of time and expense in the development of its products only to be subject to significant delay and patent litigation before its products may be commercialized. Alternatively, if the listed patent holder does not file a patent infringement lawsuit within the required forty-five (5) day period, the applicant's NDA will not be subject to the 30-month stay.

Notwithstanding the approval of many products by the FDA pursuant to Section 505(b)(2), over the last few years certain brand-name pharmaceutical companies and others have objected to the FDA's interpretation of Section 505(b)(2), and one pharmaceutical company has sued the FDA over the matter. Although the issues in that litigation are specific to the products involved, if the FDA does not prevail, it may be required to change its interpretation of Section 505(b)(2), which could delay or even prevent the FDA from approving any Section 505(b)(2) NDA that we submit.

Item 1A. Risk Factors

The following information sets forth risk factors that could cause our actual results to differ materially from those contained in forward-looking statements we have made in this registration statement 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 registration statement, 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 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 this product candidate will receive regulatory approval or be successfully commercialized.

Our business success depends on our ability to obtain regulatory approval for and 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;

- 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; 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 further 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 (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 filing and supporting the applications necessary to gain marketing approvals and expect to rely on third-party contract research organizations 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 in this way, which could limit sales of the product.

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 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. 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, 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 ("**cGMP**"). We also plan to qualify a backup manufacturer, although we currently only have a single 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, 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 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 unfavorable information in our product labeling, 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, 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 unfavorable labeling statements, specific warnings or a contraindication;
- regulatory authorities may suspend or withdraw their approval of the product, or require it to be removed from the market;
- 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 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, 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 labeling, packaging, storage, advertising, promotion, record-keeping and submission of safety and other post-market information and reports, registration and listing requirements, 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 provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use and if we do not market our products for only their approved indications, we may be subject to enforcement action for off-label marketing. Violations of the Federal Food, Drug and Cosmetic Act (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 other countries until we have completed a rigorous and extensive regulatory review processes, including 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 PTO. 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 profits 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 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 and the federal False Claims Act, 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 or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government; 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 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 teaching hospitals and applicable manufacturers and applicable group purchasing organizations 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 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 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 U.S. generally do not regulate the behavior of physicians in their choice of treatments. Regulatory authorities do, however, restrict communications by pharmaceutical companies on the subject of off-label use. If our promotional activities fail to comply with 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 institute fines, or could result in disgorgement of money, operating restrictions, injunctions or criminal prosecution, any of which could harm our business.

We are subject to new legislation, regulatory proposals and managed care initiatives that may increase our costs of compliance and adversely affect our ability to market our products, obtain collaborators and raise capital.

In the United States and some foreign jurisdictions, there have been a number of proposed and enacted legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any products for which we obtain marketing approval.

Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively the PPACA, 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 PPACA of importance to our potential product candidates are:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively;
- 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 non-compliance;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for a manufacturer's outpatient drugs to be covered under Medicare Part D;
- extension of a manufacturer's Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for certain individuals with income at or below 133% of the federal poverty level beginning in 2014, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- the new requirements under the federal Open Payments program and its implementing regulations;
- 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.

In addition, other legislative changes have been proposed and adopted since the PPACA was enacted. These changes include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year that started in 2013. On March 1, 2013, President Obama signed an executive order implementing the 2% Medicare payment reductions, and on April 1, 2013, these reductions went into effect. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for our drugs, if approved, and, accordingly, our financial operations.

We expect that the PPACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and 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 drugs. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, 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 testing and other requirements.

Public concern regarding the safety of drug products such as IV Tramadol could delay or limit our ability to obtain regulatory approval, result in the inclusion of unfavorable information in our labeling, 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 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 dosing, and our efforts to commercialize IV Tramadol may be otherwise adversely impacted.

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 treatment of pain include Ofirmev (IV acetaminophen) and intravenous formulations of non-steroidal anti-inflammatory drugs (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 treatment 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 post-operative 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 intravenous 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 will 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, including its use outside the approved indications;
- 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;
- 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;
- limitations or warnings contained in the product's FDA-approved labeling;
- 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, 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 candidates that receive 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.

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 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 ("**GLP**") as appropriate. Moreover, the FDA requires us to comply with standards, commonly referred to as good clinical practices ("**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 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 similar 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;
- 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 (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.

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 pursuant to the License Agreement; Fortress 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 our License Agreement, our ability to develop and commercialize this product candidate may be adversely affected. Any uncured, material breach under our 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 may engage in misconduct or other improper activities, including noncompliance with 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 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 health-care 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 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. 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 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 will obtain limited product liability insurance coverage for any and all of our upcoming 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 and other countries 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 U.S. The patent situation outside the U.S. 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 eighteen (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 U.S. Patent and Trademark Office to determine priority of invention in the U.S. 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 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 the enforcement 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 PTO 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 PTO, 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 PK profile for IV Tramadol are limited to a specific intravenous 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 U.S. for a number of years. While we believe that the 622 Patent provides strong protection, our market opportunity would be limited if a generic manufacturer could obtain regulatory approval for another intravenous 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 product candidates are approved for commercial sale, due to the necessity in establishing adequate commercial infrastructure to launch this product candidate 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 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 preclinical and clinical development of our product candidates and launch and commercialize any 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, pre-clinical 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 intend to become a listed and traded public company. As a public company, we will incur significant legal, accounting and other expenses under the Sarbanes-Oxley Act of 2002, as well as rules subsequently implemented by the 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.

Compliance with the Sarbanes-Oxley Act of 2002 will require substantial financial and management resources and may increase the time and costs of completing an acquisition.

A business that we identify as a potential acquisition target may not be in compliance with the provisions of the Sarbanes-Oxley Act regarding the adequacy of internal controls. The development of the internal controls of any such entity to achieve compliance with the Sarbanes-Oxley Act may increase the time and costs necessary to complete any such acquisition. Furthermore, any failure to implement required new or improved controls, or difficulties encountered in the implementation of adequate controls over our financial processes and reporting in the future, could harm our operating results or cause us to fail to meet our reporting obligations. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our securities.

We are an "emerging growth company" and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make our securities less attractive to investors.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act (the "**JOBS Act**"). We will remain an "emerging growth company" for up to five (5) years. However, if our non-convertible debt issued within a three-year period or revenues exceeds $1 billion, or the market value of our ordinary shares that are held by non-affiliates exceeds $700 million on the last day of the second fiscal quarter of any given fiscal year, we would cease to be an emerging growth company as of the following fiscal year. As an emerging growth company, we are not being required to comply with the auditor attestation requirements of section 404 of the Sarbanes-Oxley Act, we have reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and we are exempt from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. Additionally, as an emerging growth company, we have elected to delay the adoption of new or revised accounting standards that have different effective dates for public and private companies until those standards apply to private companies. As such, our financial statements may not be comparable to companies that comply with public company effective dates. We cannot predict if investors will find our shares less attractive because we may rely on these provisions. If some investors find our shares less attractive as a result, there may be a less active trading market for our shares and our share price may be more volatile.

Further, Section 102(b)(1) of the JOBS Act exempts emerging growth companies from being required to comply with new or revised financial accounting standards until private companies (that is, those that have not had a Securities Act registration statement declared effective or do not have a class of securities registered under the Exchange Act) are required to comply with the new or revised financial accounting standards. The JOBS Act provides that a company can elect to opt out of the extended transition period and comply with the requirements that apply to non-emerging growth companies but any such an election to opt out is irrevocable. We have elected not to opt out of such extended transition period which means that when a standard is issued or revised and it has different application dates for public or private companies, we, as an emerging growth company, will not adopt the new or revised standard until the time private companies are required to adopt the new or revised standard. This may make comparison of our financial statements with another public company which is neither an emerging growth company nor an emerging growth company which has opted out of using the extended transition period difficult or impossible because of the potential differences in accountant standards used.

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 U.S. 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 U.S. 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.

Our independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern.

The report of our independent auditors dated March 6, 2017, on our financial statements for the periods ended December 31, 2016 and 2015, included an explanatory paragraph indicating that there is substantial doubt about our ability to continue as a going concern. The substantial doubts are based on our working capital deficit of approximately $6.2 million and $2.4 million respectively and our stockholders' deficit of approximately $8.2 million $5.2 million respectively, and the Company has incurred losses of approximately $3.2 million for the year ended December 31, 2016 and $5.2 million for the period from inception to December 31, 2015. Further, the Company expects to continue to incur significant costs in pursuit of its financing plans and product development. Our ability to continue as a going concern will be determined by our ability to raise additional capital in the form of debt or equity financing. Our financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or amounts and classification of liabilities that might be necessary should we be unable to continue as a going concern.

Risks Relating to Securities Markets and Investment in Our Stock

There is not now and there may not ever be an active market for our Common Stock. There are restrictions on the transferability of these securities.

There currently is no market for our Common Stock and, except as otherwise described herein, we have no plans to file any registration statement or otherwise attempt to create a market for the shares. Even if an active market develops for the shares, Rule 144, which provides for an exemption from the registration requirements under the Securities Act under certain conditions, requires, among other conditions, a holding period prior to the resale (in limited amounts) of securities acquired in a non-public offering without having to satisfy the registration requirements under the Securities Act. There can be no assurance that we will fulfill any reporting requirements in the future under the Exchange Act or disseminate to the public any current financial or other information concerning us, as is required by Rule 144 as part of the conditions of its availability.

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 continue 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 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 number of shares of outstanding Class A Preferred Stock (the "**Class A Preferred Stock Ratio**"). Thus, Fortress will at all times have voting control of Avenue. Further, for a period of ten (10) 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 the directors of Avenue. This concentration of voting power may delay, prevent or deter a change in control of us 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 Avenue or our assets, and might affect the prevailing market price of our Common Stock.

We might not realize the potential benefits from our separation from Fortress.

We might not realize the potential benefits that we expect from our separation from Fortress. By separating from Fortress, there is a risk that we might be more susceptible to market fluctuations and other adverse events than we would have been were we still a part of Fortress. In addition, we will incur significant costs, which might exceed our estimates, and we will incur some negative effects from our separation from Fortress as we will likely have substantially less resources than Fortress.

Our separation from Fortress might present significant challenges.

There is a significant degree of difficulty and management distraction inherent in the process of our separating from Fortress and our separation from Fortress might not be completed as successfully and cost-effectively as we anticipate. This could have an adverse effect on our business, financial condition and results of operations. For instance, these difficulties may include:

- The challenge of effecting the separation while carrying on the ongoing operations of each business;

- The potential difficulty in retaining key officers and personnel of each company; and

- Separating corporate infrastructure, including but not limited to systems, insurance, accounting, legal, finance, tax and human resources, for each of the two companies.

Concerns about our prospects as a stand-alone company could affect our ability to retain employees.

The separation represents a substantial organizational and operational change and our employees might have concerns about our prospects as a stand-alone company, including our ability to successfully operate the new entity and our ability to maintain our independence after the separation. If we are not successful in assuring our employees of our prospects as an independent company, our employees might seek other employment, which could materially adversely affect our business.

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 (See Item 7 - Certain Relationships and Related Transactions, and Director Independence), 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. These share issuances to Fortress and any other holder of Class A Preferred Stock will dilute your holdings in our Common Stock and, if the value of Avenue 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 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 an 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 shares 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.

The dual roles of our officers and directors who also serve in similar roles with Fortress could create a conflict of interest and will require careful monitoring by our independent directors.

We share some directors with Fortress, and in addition, under the Management Services Agreement, we will also share some officers with Fortress. This could create conflicts of interest between the two companies in the future. While we believe that the Founders Agreement and the Management Services Agreement were negotiated by independent parties on both sides on arm's length terms, and the fiduciary duties of both parties were thereby satisfied, in the future situations may arise under the operation of both agreements that may create a conflict of interest. We will have to be diligent to ensure that any such situation is resolved by independent parties. In particular, under the Management Services Agreement, Fortress and its affiliates are free to pursue opportunities which could potentially be of interest to Avenue, and they are not required to notify Avenue prior to pursuing the opportunity. Any such conflict of interest or pursuit by Fortress of a corporate opportunity independent of Avenue could expose us to claims by our investors and creditors, and could harm 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 2. Financial Information.

Management's Discussion and Analysis of the Results of Operations

Forward-Looking Statements

Statements in the following discussion and throughout this registration statement 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 registration statement 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 registration statement or to reflect actual outcomes. Please see "Forward Looking Statements" at the beginning of this Form 10.

The following discussion of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and the related notes thereto and other financial information appearing elsewhere in this Form 10. 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 registration statement or to reflect actual outcomes.

Overview

We are a specialty pharmaceutical company that acquires, licenses, develops and commercializes products principally for use in the acute/intensive care hospital setting. Our initial product candidate is IV Tramadol, for the treatment of moderate to moderately severe post-operative pain. In the first quarter of 2016, we completed a PK study for IV Tramadol in healthy volunteers as well as an EOP2 meeting with the FDA. We plan to initiate a Phase 3 development program of IV Tramadol for the management of post-operative pain in 2017. Under the terms of certain agreements described herein, we have an exclusive license to develop and commercialize IV Tramadol in the United States. We plan to seek additional products to develop in the acute/intensive care hospital market in addition to IV Tramadol. To date, we have not received approval for the sale of our product candidate in any market and, therefore, have not generated any product sales from our product candidates.

We are a majority controlled subsidiary of Fortress.

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.

Our significant accounting policies are described in more detail in the notes to our financial statements.

Results of Operations

Comparison of Year Ended December 31, 2016 to Period Ended December 31, 2015 from February 9, 2015 (Inception)

General

At December 31, 2016, we had an accumulated deficit of $8.4 million, primarily as a result of expenditures for licenses acquired, for research and development and for general and administrative purposes. While we may in the future generate revenue from a variety of sources, including license fees, milestone payments, research and development payments in connection with strategic partnerships and/or product sales, our product candidate is in early stages of development and may never be successfully developed or commercialized. Accordingly, we expect to continue to incur substantial losses from operations for the foreseeable future, and there can be no assurance that we will ever generate significant revenues.

Research and Development Expenses

Research and development expenses 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, laboratory costs and other supplies.

For the year ended December 31, 2016 and for the period from February 9, 2015 (inception) to December 31, 2015, research and development expenses were approximately $1.3 million and $1.0 million, respectively. For the year ended December 31, 2016, $1.3 million of costs were related to the development of IV Tramadol of which, $0.9 million relates to the PK Study we conducted in the first half of 2016, $250,000 relates to our Management Services Agreement with Fortress, and $0.2 million relates personnel costs. From inception February 9, 2015 through December 31, 2015, $0.7 million relates to activities in connection with the development of IV Tramadol, $208,000 relates to our management Services Agreement with Fortress and $0.1 million for personnel costs.

For the year ended December 31, 2016 and the period from February 9, 2015 (inception) to December 31, 2015, research and development licenses acquired were $49,000 and $3.0 million. The $49,000 represent the annual Preferred A stock dividend and the $3.0 million represents the upfront payment for the IV Tramadol license we acquired in 2015 and $40,000 represents the 2.5% equity fee pursuant to the Founders' Agreement. In 2016, the annual equity fee was replaced with the Preferred A stock dividend.

We expect our research and development activities to increase as we develop our existing product candidates and potentially acquire new product candidates, reflecting increasing costs associated with the following:

- employee-related expenses, which include salaries and benefits, and rent expense;
- license fees and milestone payments related to in-licensed products and technology;
- expenses incurred under agreements with contract research organizations, investigative sites and consultants that conduct our clinical trials and a substantial portion of our preclinical activities;
- the cost of acquiring and manufacturing clinical trial materials; and
- costs associated with non-clinical activities, and regulatory approvals.

General and Administrative Expenses

General and administrative expenses consist principally of professional fees for legal and consulting services, personnel-related costs, and other general operating expenses not otherwise included in research and development expenses.

For the year ended December 31, 2016 and for the period from February 9, 2015 (inception) to December 31, 2015 general and administrative expenses were approximately $1.0 million and $0.8 million, respectively. For the year ended December 31, 2016, $250,000 relates to our Management Services Agreement with Fortress, $0.6 million relates to professional fees and $0.2 million relates personnel costs. From inception February 9, 2015 through December 31, 2015, $0.6 million was for professional fees in connection with the acquisition of the license from Revogenex as well as formation costs, $208,000 related to the Management Services Agreement with Fortress, effective as of February 17, 2015, and approximately $0.1 million related to personnel costs.

We anticipate general and administrative expenses will increase in future periods, reflecting continued and increasing costs associated with:

- support of our expanded research and development activities;
- stock compensation granted to key employees and non-employees;
- support of business development activities; and
- increased professional fees and other costs associated with the regulatory requirements and increased compliance associated with being a public reporting company.

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, 2016, we had an accumulated deficit of $8.4 million.

In February 2015, Fortress closed a private placement of a promissory note for $10 million through National Securities Corporation (the "**NSC Note**"). Fortress used the proceeds from the NSC Note to acquire medical technologies, products and for activities related to the formation of its subsidiaries. The NSC Note matures 36 months after issuance, 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 after issuance (or the first 30 months after issuance if the maturity date is extended). Thereafter, the NSC 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 NSC Note is 8%, payable quarterly during the first 24 months after issuance (or the first 30 months after issuance if the NSC Note is extended) and monthly during the last 12 months. National Securities Corporation ("**NSC**"), a wholly owned subsidiary of National Holdings, Inc., acted as the sole placement agent for the NSC Note.

On January 3, 2017, in accordance with the terms of the NSC Note, we notified NSC of our intention to extend the maturity date of the original note by six months to September 30, 2018.

Fortress used some of the proceeds from the NSC Note to acquire our license agreement, by transferring this indebtedness to us. Since the NSC Note allows Fortress to transfer a portion of the proceeds from the NSC Note to us. As of October 31, 2015 we executed an identical NSC Note of $3.0 million in favor of NSC, representing a transfer of Fortress indebtedness. Further, we have recorded interest expense of approximately $349,000 and $215,000 related to this note in interest expense (includes discount amortization) in our Statements of Operations for the year ended December 31, 2016 and for the period from February 9, 2015 (inception) to December 31, 2015, respectively.

Further, in accordance with the terms of the NSC Note, we issued a warrant to NSC equal to twenty-five percent (25%) of the amount of NSC Note proceeds we received from Fortress divided by the lowest price at which we next sold common stock. The warrant issued has a term of 10 years and an exercise price equal to the par value of our common stock.

Through December 31, 2016, we had an Intercompany Working Capital Promissory Note ("**Fortress Note**"), which approximates $2.8 million December 31, 2016. Further, we have recorded interest expense of $178,000 and $168,000 related to this note in interest expense - due related in our Statements of Operations for the year ended December 31, 2016 and for the period from February 9, 2015 (inception) to December 31, 2015, respectively.

To date, our operations have been funded by the NSC Note and the Fortress Note and may continue to be funded by the Fortress Note or, if necessary, by the NSC Note, until we are able to raise capital. We will need to raise capital in order to proceed with the Phase 3 development program for IV Tramadol in 2017, which is estimated to cost approximately $30 million. Our plans to raise capital may not be successful. These factors, among others, raise substantial doubt about our ability to continue as a going concern.

In December 2016, we raised approximately $200,000 of convertible notes.

Recently Issued Accounting Pronouncements

In January 2017, the Financial Accounting Standards Board ("**FASB**") issued Accounting Standards Update ("**ASU**") No. 2017-04, *Intangibles - Goodwill and Other* (Topic 350): Simplifying the Test for Goodwill Impairment ("**ASU 2017-04**"), which eliminates the second step of the previous FASB guidance for testing goodwill for impairment and is intended to reduce cost and complexity of goodwill impairment testing. The amendments in this ASU modify the concept of impairment from the condition that exists when the carrying amount of goodwill exceeds its implied fair value to the condition that exists when the carrying amount of a reporting unit exceeds its fair value. After determining if the carrying amount of a reporting unit exceeds its fair value, the entity should take an impairment charge of the same amount to the goodwill for that reporting unit, not to exceed the total goodwill amount for that reporting unit. This eliminates the second step of calculating the implied fair value of goodwill by assigning the fair value of a reporting unit to all of its assets and liabilities as if that reporting unit had been acquired in a business combination. ASU 2017-04 is effective for annual periods beginning after December 15, 2019, including interim periods within those annual periods. Early adoption is permitted for interim or annual goodwill impairment tests performed on testing dates after January 1, 2017. The Company is currently evaluating the impact of adopting the new guidance on its financial statements.

In January 2017, FASB issued ASU 2017-01, "*Business Combinations (Topic 805) Clarifying the Definition of a Business*". The amendments in this Update is to 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 is currently evaluating the impact of adopting this guidance.

In August 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows - Classification of Certain Cash Receipts and Cash Payments*, which addresses eight specific cash flow issues with the objective of reducing the existing diversity in practice in how certain cash receipts and cash payments are presented and classified in the statement of cash flows. The standard is effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. Early adoption is permitted, including adoption in an interim period. The Company is currently in the process of evaluating the impact of this new pronouncement on its statements of cash flows.

In April 2016, the FASB issued ASU No. 2016-10, *Revenue from Contracts with Customer* ("**ASU 2016-10**"). The new guidance is an update to ASC 606 and provides clarity on: identifying performance obligations and licensing implementation. For public companies, ASU 2016-10 is effective for annual periods, including interim periods within those annual periods, beginning after December 15, 2016. The Company is currently evaluating the impact that ASU 2016-10 will have on its financial statements.

In March 2016, the FASB issued ASU No. 2016-09 *Compensation-Stock Compensation (Topic 718), Improvements to Employee Share-Based Payment Accounting* ("**ASU 2016-09**"). Under ASU 2016-09, companies will no longer record excess tax benefits and certain tax deficiencies in additional paid-in capital ("**APIC**"). Instead, they will record all excess tax benefits and tax deficiencies as income tax expense or benefit in the income statement and the APIC pools will be eliminated. In addition, ASU 2016-09 eliminates the requirement that excess tax benefits be realized before companies can recognize them. ASU 2016-09 also requires companies to present excess tax benefits as an operating activity on the statement of cash flows rather than as a financing activity. Furthermore, ASU 2016-09 will increase the amount an employer can withhold to cover income taxes on awards and still qualify for the exception to liability classification for shares used to satisfy the employer's statutory income tax withholding obligation. An employer with a statutory income tax withholding obligation will now be allowed to withhold shares with a fair value up to the amount of taxes owed using the maximum statutory tax rate in the employee's applicable jurisdiction(s). ASU 2016-09 requires a company to classify the cash paid to a tax authority when shares are withheld to satisfy its statutory income tax withholding obligation as a financing activity on the statement of cash flows. Under current GAAP, it was not specified how these cash flows should be classified. In addition, companies will now have to elect whether to account for forfeitures on share-based payments by (1) recognizing forfeitures of awards as they occur or (2) estimating the number of awards expected to be forfeited and adjusting the estimate when it is likely to change, as is currently required. The Amendments of this ASU are effective for reporting periods beginning after December 15, 2016, with early adoption permitted but all of the guidance must be adopted in the same period. The Company is currently assessing the impact the adoption of ASU 2016-09 will have on its financial statements.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)* ("**ASU 2016-02**") which supersedes FASB Accounting Standards Codification ("**ASC**") Topic 840, *Leases (Topic 840)* and provides principles for the recognition, measurement, presentation and disclosure of leases for both lessees and lessors. The new standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight-line basis over the term of the lease, respectively. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than twelve months regardless of classification. Leases with a term of twelve months or less will be accounted for similar to existing guidance for operating leases. The standard is effective for annual and interim periods beginning after December 15, 2018, with early adoption permitted upon issuance. The Company is currently evaluating the method of adoption and the impact of adopting ASU 2016-02 on its financial statements. When adopted, the Company does not expect this guidance to have a material impact on its financial statements.

In January 2016, the FASB issued ASU No. 2016-01, *Recognition and Measurement of Financial Assets and Financial Liabilities* ("**ASU 2016-01**"). ASU 2016-01 requires equity investments to be measured at fair value with changes in fair value recognized in net income; simplifies the impairment assessment of equity investments without readily determinable fair values by requiring a qualitative assessment to identify impairment; eliminates the requirement for public business entities to disclose the method(s) and significant assumptions used to estimate the fair value that is required to be disclosed for financial instruments measured at amortized cost on the balance sheet; requires public business entities to use the exit price notion when measuring the fair value of financial instruments for disclosure purposes; requires an entity to present separately in other comprehensive income the portion of the total change in the fair value of a liability resulting from a change in the instrument-specific credit risk when the entity has elected to measure the liability at fair value in accordance with the fair value option for financial instruments; requires separate presentation of financial assets and financial liabilities by measurement category and form of financial assets on the balance sheet or the accompanying notes to the financial statements and clarifies that an entity should evaluate the need for a valuation allowance on a deferred tax asset related to available-for-sale securities in combination with the entity's other deferred tax assets. ASU 2016-01 is effective for financial statements issued for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. We are currently evaluating the impact that ASU 2016-01 will have on our balance sheet or financial statement disclosures. When adopted, we do not expect this guidance to have a material impact on our financial statements.

In November 2015, the FASB issued ASU No. 2015-17, *Balance Sheet Classification of Deferred Taxes* ("**ASU 2015-17**"). ASU 2015-17 requires that deferred tax liabilities and assets be classified as noncurrent in a classified statement of financial position. ASU 2015-17 is effective for financial statements issued for fiscal years beginning after December 15, 2016, and interim periods within those fiscal years. We are currently evaluating the impact that ASU 2015-17 will have on our balance sheet or financial statement disclosures. When adopted, we do not expect this guidance to have a material impact on our financial statements.

In April 2015, the FASB issued ASU No. 2015-03, *Simplifying the Presentation of Debt Issuance Costs* ("**ASU 2015-03**"), which requires debt issuance costs to be presented in the balance sheet as a direct deduction from the carrying value of the associated debt liability, consistent with the presentation of a debt discount. ASU 2015-03 is effective for the interim and annual periods ending after December 15, 2015, with early adoption permitted. We adopted ASU 2015-03 and such adoption resulted in debt issuance costs presented as an offset against notes payable, long-term, in the accompanying balance sheet.

In August 2014, the FASB issued ASU No. 2014-15, *Presentation of Financial Statements-Going Concern* ("**ASU 2014-15**"), which defines management's responsibility to assess an entity's ability to continue as a going concern, and to provide related footnote disclosures if there is substantial doubt about its ability to continue as a going concern. ASU 2014-15 is effective for annual reporting periods ending after December 15, 2016, with early adoption permitted. We are currently evaluating the impact of adopting ASU 2014-15 and its related disclosures. When adopted, we do not expect this guidance to have a material impact on our financial statements.

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 3. Properties.

Our corporate and executive office is located 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 4. Security Ownership of Certain Beneficial Owners and Management.

The following table sets forth certain information with respect to the beneficial ownership of our common stock, and, as indicated, our Class A preferred stock and vested warrants, as of December 31, 2016, for:

- each of our named executive officers;
- each of our directors;
- all of our current executive officers and directors as a group; and
- each person, or group of affiliated persons, known by us to be the beneficial owner of more than 5% of our outstanding shares of common stock.

Except as indicated in footnotes to this table, we believe that the stockholders named in this table will have sole voting and investment power with respect to all shares of common stock shown to be beneficially owned by them, based on information provided to us by such stockholders. Unless otherwise indicated, the address for each director and executive officer listed is: c/o Avenue Therapeutics, Inc., 2 Gansevoort Street, 9th Floor, New York, NY 10014.

	Common Stock BeneficiallyOwned	
Name and Address of Beneficial Owner	**Number of Shares and Nature of Beneficial Ownership**	**Percentage of Total Common Stock**
Lucy Lu, M.D.	1,000,000	10.2%
Michael S. Weiss	500,000(1)	5.1%(1)
Lindsay A. Rosenwald, M.D.	500,000(1)	5.1%(1)
David J. Horin	0	0.0%
Scott A. Reines, M.D., Ph.D.	0	0.0%
Neil Herskowitz	0	0.0%
Jeffrey Paley	0	0.0%
Akhtar Samad, M.D., PhD	0	0.0%
Jay Kranzler, MD, PhD	0	0.0%
All executive officers and directors as a group	1,000,000(2)	10.2%(2)
5% or Greater Stockholders:		
Fortress Biotech, Inc.	8,723,810	89.3%
Other Stockholders:		
Robert Niecestro	50,000	0.5%

(1) Mr. Weiss and Dr. Rosenwald each have warrants convertible into 500,000 shares of our common stock. These warrants were issued by Fortress and are convertible into shares of our common stock that are owned by Fortress. These do not represent equity compensation by us to either Mr. Weiss or Dr. Rosenwald.

(2) The total calculation for all executive officers and directors as a group does not include Mr. Weiss' and Dr. Rosenwald's warrants, which have not yet been exercised. The shares underlying the warrants are currently held by Fortress.

	Class A Preferred Stock Beneficially Owned	
Name and Address of Beneficial Owner	Number of Shares and Nature of Beneficial Ownership	Percentage of Total Class A Preferred Stock
Fortress Biotech, Inc.	250,000	100.0%

Item 5. Directors and Executive Officers.

The following table sets forth certain information about our directors and our executive officers.

Name	Age	Position
Lindsay A. Rosenwald, M.D.	61	Executive Chairman of the Board of Directors
Lucy Lu, M.D.	41	Interim President, Chief Executive Officer and Director
Scott A. Reines, M.D., Ph.D.	70	Interim Chief Medical Officer
David Horin, CPA	48	Interim Chief Financial Officer
Michael S. Weiss	50	Director
Neil Herskowitz	59	Director
Jeffrey Paley, MD	49	Director
Akhtar Samad, MD, PhD	57	Director
Jay Kranzler, MD, PhD	59	Director

Executive Officers

Lindsay A. Rosenwald, M.D. – Executive Chairman of the Board of Directors

Dr. Rosenwald has served as a member of our Board of Directors since inception. Dr. Rosenwald has been a member of the Board of Directors of Fortress since October 2009 and has served as its Chairman, President and Chief Executive Officer since December 2013. He also served as Co-Chairman of the Board of Directors of CB Pharma Acquisition Corp. from their inception in 2014 to June 2016. Dr. Rosenwald also is Co-Portfolio Manager and Partner of Opus Point Partners Management, LLC, an asset management firm in the life sciences industry, which he co-founded in 2009. Prior to that, from 1991 to 2008, he served as the Chairman of Paramount BioCapital, Inc. Over the last 23 years, Dr. Rosenwald has acted as a biotechnology entrepreneur and has been involved in the founding and recapitalization of numerous public and private biotechnology and life sciences companies. Dr. Rosenwald received his B.S. in finance from Pennsylvania State University and his M.D. from Temple University School of Medicine. Based on Dr. Rosenwald's biotechnology and pharmaceutical industry experience and in-depth understanding of our business, the Board of Directors believes that Dr. Rosenwald has the appropriate set of skills to serve as a member of the Board in light of our business and structure.

Lucy Lu, M.D. – Interim President and Chief Executive Officer and Director

Dr. Lu has been our Interim President and Chief Executive Officer since inception. From February 2012 to the date hereof, Dr. Lu has been the Executive Vice President and Chief Financial Officer of Fortress Biotech, Inc. Prior to working in the biotech industry, Dr. Lu had 10 years of experience in healthcare-related equity research and investment banking. From February 2007 through January 2012, Dr. Lu was a senior biotechnology equity analyst with Citigroup Investment Research. From 2004 until joining Citigroup, she was with First Albany Capital, serving as Vice President from April 2004 until becoming a Principal of the firm in February 2006. Dr. Lu holds an M.D. degree from the New York University School of Medicine and an M.B.A. from the Leonard N. Stern School of Business at New York University. Dr. Lu obtained a B.A. from the University of Tennessee's College of Arts and Science.

Scott A. Reines, M.D., Ph.D. - Interim Chief Medical Officer

Dr. Reines has served as our Interim Chief Medical Officer since January 2016. Dr. Reines has led the clinical development of important new drugs in five different therapeutic areas. As Senior Vice President for CNS, Pain, and Translational Medicine at Johnson & Johnson, he oversaw the development and approval of INVEGA and INVEGA SUSTENNA for schizophrenia, NUCYNTA for moderate to severe pain, REMINYL ER for Alzheimer's disease, RISPERDAL CONSTA for schizophrenia and bipolar disorder, RISPERDAL for treatment of the autism, and TOPAMAX for prevention of migraine and seizures. At Johnson & Johnson, he was responsible for all CNS and Pain products, as well as for Clinical Pharmacology and Pharmacogenomics, and was a member of the Johnson & Johnson Pharmaceutical R&D Board of Directors.

Previously, Dr. Reines was Vice President, Clinical Research at Merck, with responsibilities for Psychopharmacology, Neuropharmacology, Gastroenterology, and Ophthalmology. There he led the development of EMEND for prevention of chemotherapy-induced nausea and vomiting, MAXALT for treatment of migraine headache, SINEMET-CR for Parkinson's disease, and TRUSOPT, COSOPT, and TIMOPTIC-XE for prevention of glaucoma.

Currently, Dr. Reines consults for biotech, pharmaceutical, and venture firms, is a member of two Scientific Advisory Boards, and Chair of a Data Safety Monitoring Board. He is also a member of two non-profit boards, serving as Vice Chair of the Board of Directors of KidsPeace, a large children's psychiatric healthcare provider, and as a member of the Board of Directors of Heritage Conservancy, which is directed toward land preservation.

Dr. Reines also served for two years as co-chair of the Neuroscience Steering Committee, Foundation for NIH Biomarkers Consortium, and spent five years on the National Drug Abuse Advisory Council. He holds a bachelor's degree in chemistry from Cornell University, a PhD in chemistry/molecular biology from Columbia University, and an MD from Albert Einstein College of Medicine. He is Board Certified in Psychiatry and Neurology.

David Horin, CPA – Interim CFO

Mr. Horin has served as our Interim Chief Financial Officer under our agreement with Chord Advisors, LLC ("**Chord**") since June 2015. Pursuant to such agreement, we pay Chord $7,500 per month for its back office accounting support and accounting policy and financial reporting services that it provides to us, including the services of Mr. Horin. Mr. Horin provides services of approximately 25 hours per month. We do not have information, nor any influence over Mr. Horin's direct compensation from Chord. Mr. Horin has been a Managing Partner of Chord since June 2012. Chord provides accounting advisory services, SEC reporting advisory services, and IPO-readiness services. While at Chord, Mr. Horin has gained extensive experience in financial accounting and SEC reporting for complex business transactions and issues arising from the application of existing or proposed financial accounting guidance. From March 2008 to June 2012, Mr. Horin was the Chief Financial Officer of Rodman & Renshaw Capital Group, Inc., a full-service investment bank dedicated to providing corporate finance, strategic advisory, sales and trading and related services to public and private companies across multiple sectors and regions. From March 2003 through March 2008, Mr. Horin was the Chief Accounting Officer at Jefferies Group, Inc., a full-service global investment bank and institutional securities firm focused on growth and middle-market companies and their investors. Prior to his employment at Jefferies Group, Inc., from 2000 to 2003, Mr. Horin was a Senior Manager in KPMG's Department of Professional Practice in New York, where he advised firm members and clients on technical accounting and risk management matters for a variety of public, international and early growth stage entities. Mr. Horin's education as well as his years of experience as a senior finance executive provide an excellent foundation for his service as the interim Chief Financial Officer of the Company. Mr. Horin has a Bachelor of Science degree in Accounting from Baruch College, City University of New York. Mr. Horin is also a Certified Public Accountant.

Non-Executive Directors

Michael S. Weiss

Mr. Weiss has served as both a director and member of senior management in public and private companies over the past two decades. He has served as Chief Executive Officer and Executive Chairman of our Board of Directors since March 2015 and has served as a director and Executive Vice Chairman of our parent company, Fortress, since February 2014. He also served as Co-Chairman of the Board of Directors of CB Pharma Acquisition Corp. from their inception in 2014 to June 2016. He has also served as Executive Chairman, Interim Chief Executive Officer and President of TG Therapeutics, Inc., a company he founded in 2011. Mr. Weiss is also currently Co-Portfolio Manager and Partner of Opus Point Partners, LLC, which he co-founded in 2009. From 2002 to 2009, Mr. Weiss was the Chairman and Chief Executive Officer of Keryx Biopharmaceuticals, Inc., where he helped the company acquire and develop its lead drug, Auryxia, as well as executed a strategic alliance for Auryxia with Japan Tobacco, Inc. and Torii Pharmaceutical Co., Ltd. worth more than $100 million. Mr. Weiss also served as Chairman of the board of directors of National Holdings Corporation from 2011 to 2012. Mr. Weiss' extensive experience founding and managing early stage life science companies makes is the ideal background for a member of our Board. Mr. Weiss began his professional career as a lawyer with Cravath, Swaine & Moore LLP. He earned his J.D. from Columbia Law School and his B.S. in Finance from The University at Albany.

Neil Herskowitz

Mr. Herskowitz joined our Board of Directors in December 2015. Mr. Herskowitz has been a Managing Member of the ReGen Group of Companies since 1998, which include Riverside Contracting LLC, Riverside Claims LLC, ReGen Capital I LLC, ReGen Partners LLC, ReGen Partners I L.P. and, most recently, ReGen Capital Investments LLC and Riverside Claims Investments LLC. He has extensive board membership experience, including as: (1) a director of TG Therapeutics, Inc., a public company, from July 2004 to June 2015; (2) Chairman of the Board of Directors of Starting Point Services for Children, a not-for-profit corporation; (3) a Non-Executive Director at Checkpoint Therapeutics, Inc. since August 2015; (4) a Non-Executive Director of Avenue Therapeutics, Inc. since December 2015; (5) an Independent Director and Audit Committee Chairman at CB Pharma Acquisition Corporation from November 2014 to May 2016; and (6) previous director positions on the boards of CytRx Oncology Corporation, Alacrity Biosciences, Inc, Innovive Pharmaceuticals and Chelsea Therapeutics International Ltd. (formerly, Ivory Capital Corp). Mr. Herskowitz acquired a B.B.A. in Finance from Bernard M. Baruch College in 1978.

Jeffrey Paley, MD.

Dr. Paley joined our Board of Directors in December 2015. Dr. Paley has been an Active Clinician and Consultant in the healthcare industry for the past 18 years, during which time Dr. Paley has consulted for over 30 analysts and portfolio managers in the biotechnology, pharmaceutical, specialty pharmaceutical and medical technology arenas, reviewing the clinical, preclinical and regulatory pedigrees of numerous therapeutics and devices. Prior to his work for the buy-side, Dr. Paley consulted directly for several biotechnology and specialty pharmaceutical companies. Dr. Paley founded Access Medical Associates in 2003, after spending five years on the full-time academic faculty of Weill Cornell Medical College, where he served as a Director of Clinical Research at the Cornell Internal Medicine Associates. At Weill Cornell, Dr. Paley was a Principal or Co-Principal Investigator on several studies of diabetes, hypertension, and cholesterol disorders, including the landmark ACCORD study of intensive hyperglycemia, hypertension and hyperlipidemia management. He has served as a Director of Kellbenx, Retrophin and Remote Radiology Inc., Dr. Paley trained at Harvard Medical School and completed a residency in Internal Medicine at Massachusetts General Hospital. Dr. Paley has been selected to serve on our Board of Directors based on his experience, including his experience in medicine and clinical trials and in serving as a director of other public companies.

Akhtar Samad, MD, PhD

Dr. Samad joined our Board of Directors in December 2015. Dr. Samad established Symbios Partners in 2008 to address what he perceived as an unmet need in the advisory space – a hybrid strategic advisory and IR consultancy, offering a variety of proprietary services across such areas as clinical and business development, investment thesis and positioning, market intelligence, investor/analyst outreach and financing strategies. He works closely with senior members of client management teams, including CEO, CBO, CMO/CSO, CFO and Director of Communications, to formulate and revise client corporate strategy. Prior to launching Symbios, Dr. Samad was a Managing Director at Bear Stearns where he directed the small/mid-cap biotechnology equity research team from 2000-2008. He is a former academic cancer and genomics researcher, who trained with the co-discoverer of VEGF at Harvard, and completed his medical residency and fellowship at Cornell and the National Cancer Institute. He has been an invited moderator at the Annual Cancer Progress Conferences, and has moderated other oncology and genomics conferences. He received his MD/PhD training at NYU Medical School. Dr. Samad has been selected to serve on our Board of Directors based on his experience, including his experience in biopharmaceutical equity research, strategy and finance.

Jay Kranzler, MD, PhD

Dr. Kranzler joined our Board of Directors in February 2017. Dr. Kranzler has been a Founder, CEO, Board Member, and Advisor to leading life science companies for over 30 years. He is currently acting as Chief Executive Officer of Regenovation, a regenerative medicine company, and is a Board Member of Methylation Sciences, Pastorus, and ImmunoBrain Checkpoint, all companies focused on developing therapeutics for psychiatric or neurological disorders. Dr. Kranzler started his career at McKinsey & Company where he established the Firm's pharmaceutical practice. He served as Chief Executive Officer (CEO) of Cytel Corporation, a company focused on the development of immunomodulatory drugs. Following Cytel, Dr. Kranzler became the CEO of Cypress Bioscience, where he was credited for the development of Savella™ (milnacipran) for the treatment of fibromyalgia. Dr. Kranzler was also Vice President, Head of External R&D Innovation and Worldwide R&D Strategic Investments at Pfizer. During his career, Dr. Kranzler has developed drugs, medical devices, as well as diagnostics, and is the inventor on over 30 patents. Dr. Kranzler graduated from Yale University School of Medicine with MD and PhD degrees with a focus in psychopharmacology.

Family Relationships

There is no family relationship between any director, executive officer or person nominated to become a director or executive officer.

Composition of our board of directors of Directors

Our Bylaws provide that our board of directors must consist of between one (1) and nine (9) directors, and such number of directors within this range may be determined from time to time by resolution of our board of directors or our stockholders. Currently, we have six (6) directors.

Our Bylaws also provide that our directors may be removed with or without cause by the affirmative vote of the holders of at least a majority of the shares then entitled to vote at an election of directors. An election of our directors by our stockholders will be determined by a plurality of the votes cast by the stockholders entitled to vote on the election.

Our current and future executive officers and significant employees serve at the discretion of our board of directors. Our board of directors may also choose to form certain committees, such as a compensation and an audit committee.

Director Compensation

We have not paid any of our non-executive directors any compensation for serving on our board.

Communicating with the Board of Directors

Our Board has established a process by which stockholders can send communications to the Board. You may communicate with the Board as a group, or to specific directors, by writing to our Corporate Secretary, at our offices located at 2 Gansevoort Street, 9 th Floor, New York, NY 10014. The Corporate Secretary will review all such correspondence and regularly forward to our Board a summary of all correspondence and copies of all correspondence that, in the opinion of the Corporate Secretary, deals with the functions of the Board or committees thereof or that he otherwise determines requires their attention. Directors may at any time review a log of all correspondence we receive that is addressed to members of our Board and request copies of any such correspondence. Concerns relating to accounting, internal controls, or auditing matters may be communicated in this manner. These concerns will be immediately brought to the attention of our Board and handled in accordance with procedures established by our Board.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires our executive officers, directors and persons who beneficially own more than ten percent (10%) of a registered class of our equity securities to file with the SEC initial reports of ownership and reports of changes in ownership of our Common Stock and other equity securities. These executive officers, directors, and greater than ten percent (10%) beneficial owners are required by SEC regulation to furnish us with copies of all Section 16(a) forms filed by such reporting persons.

Based solely on our review of such forms furnished to us, we believe that during the prior fiscal year, all of our executive officers and directors and every person who is directly or indirectly the beneficial owner of more than ten percent (10%) of any class of our security complied with the filing requirements of Section 16(a) of the Exchange Act.

Code of Ethics

We adopted a Code of Ethics that applies to all directors, officers and employees. Our Code of Ethics is available on our website atwww.avenuetx.com. A copy of our code of ethics will also be provided to any person without charge, upon written request sent to us at our offices located at 2 Gansevoort Street, 9 th Floor, New York, NY 10014.

Item 6. Executive Compensation.

2016 and 2015 Summary Compensation Table

As an emerging growth company, we are required to disclose the compensation earned by or paid to our named executive officers during 2016 and 2015 from inception.

Name and Principal Position	Year	Salary ($)	Stock Awards ($) (1)	Total ($)
Lucy Lu(2)	2016	316,932(2)	27,875	344,807
Interim Chief Executive Officer, President and Director	2015	40,155	20,047	60,202
Scott A. Reines				
Interim Chief Medical Officer	2016	43,175	-	43,175
	2015	16,040(3)	-	16,040
David J. Horin	2016	50,000	-	50,000
Interim Chief Financial Officer	2015	13,500(4)	-	13,500

(1) Reflects the aggregate grant date fair value of restricted stock granted during the fiscal year calculated in accordance with FASB ASC Topic 718. See Note 8 to our audited financial statements for the year ended December 31, 2015, included elsewhere in this Form 10, for a discussion of the assumptions made by us in determining the grant date fair value of our equity awards.

(2) Dr. Lu's employment will commence upon the Company going public. The amount reported represents the pro rata portion of Dr. Lu's annual salary at Fortress based the percentage of her time devoted to us. From February 2015 through December 31, 2015 Dr. Lu spent approximately 27% of her time devoted to us and from January 1, 2016 through December 31, 2016 Dr. Lu spent approximately 53% of her time. 2016 salary includes Dr. Lu's 2016 bonus of approximately $135,800.

(3) This represents the amount paid to Dr. Reines during 2015 and for the twelve months ended December 31, 2016 for services rendered. He provided us with approximately 40 hours of work in 2015 and for the twelve months ended December 31, 2016 approximately 106 hours. We pay him a per hour rate of $400 per hour for his work pursuant to our Consulting Agreement with him.

(4) This represents the amount paid to Chord during 2015 and 2016 for the twelve months ended December 31, 2016, 2016 for services rendered for services rendered, including those of Mr. Horin. We do not have information or any influence over Mr. Horin's direct compensation from Chord. Mr. Horin spends approximately 10% of his time on matters related to us.

Compensation Arrangements for Executive Officers

Lucy Lu, M.D. entered into an Employment Agreement to serve as our President and Chief Executive Officer upon the Company going public. Under the terms of Dr. Lu's Employment Agreement, dated as of June 10, 2015 (the "**Employment Agreement**") upon the Company becoming a public company, Dr. Lu's base salary will be equal to three hundred and ninety-five thousand dollars ($395,000) per year. Dr. Lu's base salary may be reduced only in connection with a company-wide decrease in executive compensation. Dr. Lu is also eligible to receive an annual discretionary bonus, not to exceed fifty percent (50%) of her base salary, if certain financial, clinical development, and/or business milestones are met in the discretion of Board. Prior to her execution of the Employment Agreement, Ms. Lu was granted one million (1,000,000) shares of our Common Stock pursuant to a Restricted Stock Issuance Agreement between us and Ms. Lu, dated June 10, 2015. Dr. Lu's employment with us is at will and may be terminated by us at any time and for any reason. However, under the terms of the Employment Agreement, Dr. Lu will be entitled to cash severance payments if we terminate her employment without cause (as defined in the Employment Agreement) or if Dr. Lu resigns her employment for good reason (as defined in the Employment Agreement). Dr. Lu is also the Chief Financial Officer of Fortress. The term of the Employment Agreement begins when this registration statement is declared effective.

Although no formal written agreement has been entered into with Dr. Rosenwald, our Executive Chairman, we will pay Dr. Rosenwald a cash salary equal to $50,000 per year, provided that no payments will be made to Dr. Rosenwald until we complete our first third-party financing.

On January 25, 2016, we entered into a First Amendment to our Consulting Agreement with Dr. Reines, which we originally entered into on July 22, 2015. Pursuant to such agreement, Dr. Reines will serve as our Interim Chief Medical Officer and will also serve as a consultant to us. Dr. Reines will remain an independent contractor. Pursuant to the agreement, Avenue pays Dr. Reines $400.00 per hour for all services provided for Avenue. The company entered into a Second Amendment with Dr. Reines in August 2016 that extends the agreement by two years, followed by automatic renewal for successive one-year periods, unless earlier terminated.

On June 12, 2015, we entered into an agreement with Chord, under which Mr. Horin will serve as our Interim Chief Financial Officer and Chord will provide back office accounting support as well as accounting policy and financial reporting for us. We paid Chord an advisory fee of five thousand dollars ($5,000) per month prior to the public filing of this Registration Statement and seven thousand five hundred dollars ($7,500) per month thereafter. The arrangement can be terminated by either party upon thirty (30) days written notice. Chord also provides advisory services to Fortress. We do not have information or any influence over Mr. Horin's direct compensation from Chord.

Employee Benefit and Incentive Plans

We do not maintain any deferred compensation, retirement, pension or profit sharing plans. Our board of directors have adopted an incentive plan, the material terms of which are described below, allowing for the grant of equity and cash-based awards to our employees and directors.

2015 Director Compensation

None of our directors received any compensation for their service as a director since our inception February 9, 2015 through December 31, 2016.

Compensation Committee Interlocks and Insider Participation

We do not currently have a compensation committee and, for the year ended December 31, 2015, the compensation, if any, of our executive officers was recommended by our Chief Executive Officer and Chairman and such recommendations were approved by our board of directors. None of our executive officers currently serves as a member of the compensation committee or as a director with compensation duties of any entity that has executive officers serving on our board of directors. None of our executive officers has served in such capacity in the past 12 months.

Equity Incentive Plan

2015 Incentive Plan

Our board of directors adopted the Avenue Therapeutics, Inc. 2015 Incentive Plan (the '**2015 Plan**"). The material terms of the 2015 Plan are described below. As set forth below, the 2015 Plan will be administered by the Compensation Committee. The Compensation Committee has not yet been formed, but it will be formed before any necessary actions to be taken by the Compensation Committee with respect to the 2015 Plan are taken.

The 2015 Plan will be administered by the Compensation Committee

Purpose. The purpose of the 2015 Plan is to promote our success by linking the personal interests of our employees, officers, directors and consultants to those of our stockholders, and by providing participants with an incentive for outstanding performance.

Permissible Awards. The 2015 Plan authorizes the Compensation Committee to grant awards in any of the following forms:

- options to purchase shares of our common stock, which may be nonstatutory stock options or incentive stock options under the Internal Revenue Code. The exercise price of an option granted under the 2015 Plan may not be less than the fair market value of our common stock on the date of grant. Stock options granted under the 2015 Plan may not have a term longer than ten (10) years;
- stock appreciation rights, or SARs, which give the holder the right to receive the excess, if any, of the fair market value of one (1) share of our common stock on the date of exercise, over the base price of the stock appreciation right. The base price of a SAR may not be less than the fair market value of our common stock on the date of grant. SARs granted under the 2015 Plan may not have a term longer than ten years;
- restricted stock, which is subject to restrictions on transferability and subject to forfeiture on terms set by the Compensation Committee;
- restricted stock units, which represent the right to receive shares of our common stock (or an equivalent value in cash or other property) in the future, based upon the attainment of stated vesting or performance goals set by the Compensation Committee;
- deferred stock units, which represent the right to receive shares of our common stock (or an equivalent value in cash or other property) in the future, generally without any vesting or performance restrictions;
- other stock-based awards in the discretion of the Compensation Committee, including unrestricted stock grants; and
- cash-based awards in the discretion of the Compensation Committee, including cash-based performance awards.

All awards will be evidenced by a written award certificate between us and the participant, which will include such provisions as may be specified by the Compensation Committee. Dividend equivalent rights, which entitle the participant to payments in cash or property calculated by reference to the amount of dividends paid on the shares of stock underlying an award, may be granted with respect to awards other than options or SARs.

Awards to Non-Employee Directors. Awards granted under the 2015 Plan to our non-employee directors will be made only in accordance with the terms, conditions and parameters of a plan, program or policy for the compensation of non-employee directors as in effect from time to time. The Compensation Committee may not make discretionary grants under the 2015 Plan to non-employee directors. The maximum aggregate number of shares associated with any award granted under the 2015 Plan in any calendar year to any one non-employee director is 100,000.

Shares Available for Awards; Adjustments. 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. Shares subject to awards that are canceled, terminated, forfeited, settled in cash, withheld to satisfy exercise prices or tax withholding obligations or otherwise not issued for any reason, including by reason of failure to achieve maximum performance goals, will again be available for awards under the 2015 Plan. In the event of a nonreciprocal transaction between us and our stockholders that causes the per share value of our common stock to change (including, without limitation, any stock dividend, stock split, spin-off, rights offering, or large nonrecurring cash dividend), the share authorization limits under the 2015 Plan will be adjusted proportionately, and the Compensation Committee must make such adjustments to the 2015 Plan and awards as it deems necessary, in its sole discretion, to prevent dilution or enlargement of rights immediately resulting from such transaction.

Administration. The 2015 Plan will be administered by the Compensation Committee. The Compensation Committee will have the authority to grant awards; designate participants; determine the type or types of awards to be granted to each participant and the number of awards to be granted and the number of shares or dollar amount to which an award will relate and the terms and conditions thereof; prescribe the form of award; establish, adopt or revise any rules and regulations as it may deem advisable to administer the 2015 Plan; make all other decisions and determinations that may be required under the 2015 Plan and amend the 2015 Plan. Our Board of Directors may at any time administer the 2015 Plan. If it does so, it will have all the powers of the Compensation Committee under the 2015 Plan. In addition, our Board of Directors or Compensation Committee may expressly delegate to a special committee some or all of the Compensation Committee's authority, within specified parameters, to grant awards to eligible participants who, at the time of grant, are not executive officers or directors.

Limitations on Transfer; Beneficiaries. No award will be assignable or transferable by a participant other than by will or the laws of descent and distribution; provided, however, that nonstatutory stock options may be transferred without consideration to members of a participant's immediate family, to trusts in which such immediate family members have more than fifty percent (50%) of the beneficial interest, to foundations in which such immediate family members (or the participant) control the management of assets, and to any other entity (including limited partnerships and limited liability companies) in which the immediate family members (or the participant) own more than fifty percent (50%) of the voting interest; and provided, further, that the Compensation Committee may permit other transfers (other than transfers for value) where the Compensation Committee concludes that such transferability does not result in accelerated taxation, does not cause any option intended to be an incentive stock option to fail to qualify as such, and is otherwise appropriate and desirable, taking into account any factors deemed relevant, including without limitation, any state or federal tax or securities laws or regulations applicable to transferable awards. A participant may, in the manner determined by the Compensation Committee, designate a beneficiary to exercise the rights of the participant and to receive any distribution with respect to any award upon the participant's death.

Treatment of Awards upon a Change in Control. Unless otherwise provided in an award certificate or any special plan document governing an award, upon the occurrence of a change in control of our company, (i) all outstanding options, SARs and other awards in the nature of rights that may be exercised will become fully exercisable, (ii) all time-based vesting restrictions on outstanding awards will lapse; and (iii) the payout opportunities attainable under all outstanding performance-based awards will vest based on target performance and the awards will pay out on a pro rata basis, based on the time elapsed prior to the change in control.

Discretionary Acceleration. The Compensation Committee may, in its discretion, accelerate the vesting and/or payment of any awards for any reason, subject to certain limitations under Section 409A of the Internal Revenue Code. The Compensation Committee may discriminate among participants or among awards in exercising such discretion.

Certain Transactions. Upon the occurrence or in anticipation of certain corporate events or extraordinary transactions, the Compensation Committee may also make discretionary adjustments to awards, including settling awards for cash, providing that awards will become fully vested and exercisable, providing for awards to be assumed or substituted, or modifying performance targets or periods for awards.

Termination and Amendment. The 2015 Plan will terminate on the tenth (10^{th}) anniversary of its adoption, or, if the stockholders approve an amendment to the 2015 Plan that increases the number of shares subject to the 2015 Plan, the tenth (10^{th}) anniversary of the date of such approval, unless earlier terminated by our Board of Directors or Compensation Committee. Our Board or Compensation Committee may, at any time and from time to time, terminate or amend the 2015 Plan, but if an amendment to the 2015 Plan would constitute a material amendment requiring stockholder approval under applicable listing requirements, laws, policies or regulations, then such amendment will be subject to stockholder approval. No termination or amendment of the 2015 Plan may adversely affect any award previously granted under the 2015 Plan without the written consent of the participant. Without the prior approval of our stockholders, and except as otherwise permitted by the antidilution provisions of the 2015 Plan, the 2015 Plan may not be amended to permit us to directly or indirectly reprice, replace or repurchase "underwater" options or SARs.

The Compensation Committee may amend or terminate outstanding awards. However, such amendments may require the consent of the participant and, unless approved by the stockholders or otherwise permitted by the antidilution provisions of the 2015 Plan, (i) the exercise price or base price of an option or SAR may not be reduced, directly or indirectly, (ii) an option or SAR may not be cancelled in exchange for cash, other awards, or options or SARS with an exercise price or base price that is less than the exercise price or base price of the original option or SAR, or otherwise, (iii) we may not repurchase an option or SAR for value (in cash or otherwise) from a participant if the current fair market value of the shares of our common stock underlying the option or SAR is lower than the exercise price or base price per share of the option or SAR, and (iv) the original term of an option or SAR may not be extended.

Prohibition on Repricing. As indicated above under "Termination and Amendment," outstanding stock options and SARs cannot be repriced, directly or indirectly, without the prior consent of our stockholders. The exchange of an "underwater" option or stock appreciation right (i.e., an option or stock appreciation right having an exercise price or base price in excess of the current market value of the underlying stock) for cash or for another award would be considered an indirect repricing and would, therefore, require the prior consent of our stockholders.

Certain Federal Tax Effects

The following discussion is limited to a summary of the U.S. federal income tax provisions relating to the grant, exercise and vesting of awards under the 2015 Plan and the subsequent sale of common stock acquired under the 2015 Plan. The tax consequences of awards may vary depending upon the particular circumstances, and it should be noted that the income tax laws, regulations and interpretations thereof change frequently. Participants should rely upon their own tax advisors for advice concerning the specific tax consequences applicable to them, including the applicability and effect of state, local, and foreign tax laws.

Nonstatutory Stock Options. There typically will be no federal income tax consequences to the optionee or to us upon the grant of a nonstatutory stock option under the 2015 Plan. When the optionee exercises a nonstatutory option, however, he or she will recognize ordinary income in an amount equal to the excess of the fair market value of our common stock received upon exercise of the option at the time of exercise over the exercise price, and we will typically be allowed a corresponding deduction. Any gain that the optionee realizes when he or she later sells or disposes of the option shares will be short-term or long-term capital gain, depending on how long the shares were held.

Incentive Stock Options. There typically will be no federal income tax consequences to the optionee or to us upon the grant or exercise of an incentive stock option. If the optionee holds the option shares for the required holding period of at least two (2) years after the date the option was granted or one (1) year after exercise, the difference between the exercise price and the amount realized upon sale or disposition of the option shares will be long-term capital gain or loss, and we will not be entitled to a federal income tax deduction. If the optionee disposes of the option shares in a sale, exchange, or other disqualifying disposition before the required holding period ends, he or she will recognize taxable ordinary income in an amount equal to the excess of the fair market value of the option shares at the time of exercise (or, if less, the amount realized on the disposition of the shares) over the exercise price, and we would typically be allowed a federal income tax deduction equal to such amount. While the exercise of an incentive stock option does not result in current taxable income, the excess of the fair market value of the option shares at the time of exercise over the exercise price will be an item of adjustment for purposes of determining the optionee's alternative minimum taxable income.

Stock Appreciation Rights. A participant receiving a stock appreciation right typically will not recognize income, and we will not be allowed a tax deduction, at the time the award is granted. When the participant exercises the stock appreciation right, the amount of cash and the fair market value of any shares of our common stock received will be ordinary income to the participant and we will typically be allowed as a corresponding federal income tax deduction at that time.

Restricted Stock. Unless a participant makes an election to accelerate recognition of income to the date of grant as described below, the participant will not recognize income, and we will not be allowed a tax deduction, at the time a restricted stock award is granted, provided that the award is subject to restrictions on transfer and is subject to a substantial risk of forfeiture. When the restrictions lapse, the participant will recognize ordinary income equal to the fair market value of our common stock as of that date (less any amount he or she paid for the stock), and we will typically be allowed a corresponding federal income tax deduction at that time, subject to limitations in certain circumstances. If the participant files an election under Code Section 83(b) within thirty (30) days after the date of grant of the restricted stock, he or she will recognize ordinary income as of the date of grant equal to the fair market value of the stock as of that date (less any amount paid for the stock), and we will typically be allowed a corresponding federal income tax deduction, subject to limitations in certain circumstances at that time. Any future appreciation in the stock will be taxable to the participant at capital gains rates. However, if the stock is later forfeited, the participant will not be able to recover the tax previously paid pursuant to the Section 83(b) election. To the extent unrestricted dividends are paid during the restricted period under the applicable award agreement, any such dividends will be taxable to the participant at ordinary income tax rates and will be deductible by us unless the participant has made a Section 83(b) election, in which case the dividends will thereafter be taxable to the participant as dividends and will not be deductible by us.

Stock Units. A participant typically will not recognize income, and we will not be allowed a tax deduction, at the time a stock unit award is granted. Upon receipt of shares of our common stock (or the equivalent value in cash) in settlement of a stock unit award, a participant will recognize ordinary income equal to the fair market value of our common stock or other property as of that date, and we will typically be allowed a corresponding federal income tax deduction at that time, subject to limitations in certain circumstances.

Cash-Based Performance Awards. A participant will not recognize income, and we will not be allowed a tax deduction, at the time a cash-based performance award is granted (for example, when the performance goals are established). Upon receipt of cash in settlement of the award, the participant will recognize ordinary income equal to the cash received, and we will typically be allowed a corresponding federal income tax deduction at that time, subject to limitations in certain circumstances.

Item 7. Certain Relationships and Related Transactions, and Director Independence.

The following is a summary of each transaction or series of similar transactions since the inception of Avenue to which it was or is a party and that:

- the amount involved exceeded or exceeds $120,000 or is greater than 1% of our total assets; and
- any of our directors or executive officers, any holder of 5% of our capital stock or any member of their immediate family had or will have a direct or indirect material interest.

We entered into a founders agreement with Fortress, effective February 17, 2015 and amended and restated on September 13, 2016 (the "**Founders Agreement**"), pursuant to which Fortress assigned to Avenue the Revogenex license and all other rights and obligations of Fortress under the License Agreement and the Manufacturing Agreement.

In exchange for the assignment of the License Agreement and the Manufacturing Agreement, we issued Fortress 250,000 shares of our Class A Preferred Stock and 8,417,250 shares of our Common Stock. As additional consideration for the Founders Agreement, we assumed $3 million in debt that Fortress accumulated under the NSC Note (described below), for the initial license payment in February 2015 for $2 million and the additional payment in June 2015 of $1 million related to obtaining the License Agreement. As further consideration for the transfer of rights under the Founders Agreement, we shall also: (i) pay an equity fee in shares of 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 2.50% of the gross amount of any such equity or debt financing; and (ii) pay a cash fee equal to 4.5% of our 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), we will pay a one-time change in control fee equal to five (5x) times the product of (i) Net Sales (as it is defined in the Founders Agreement) for the twelve (12) months immediately preceding the Change in Control and (ii) four and one-half percent (4.5%). The Founders Agreement has a fifteen (15) year term with automatic one (1) year renewals unless terminated by Fortress or upon a Change in Control.

Effective February 17, 2015, we entered into a Management Services Agreement (the "**MSA**") with Fortress, whereby Fortress agreed to provide certain management, advisory and consulting services to us pursuant to the terms of the MSA for a period of five (5) years (subject to extension). Each of our current directors and officers who are directors or officers of Fortress provide their services to us pursuant to the terms of the MSA. Services provided under the MSA may include, without limitation, (i) advice and assistance concerning any and all aspects of our operations, clinical trials, financial planning and strategic transactions and financings and (ii) conducting relations on behalf of our Company with accountants, attorneys, financial advisors and other professionals (collectively, the "**Services**"). At Fortress' request, we are 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, we are not obligated to take or act upon any advice rendered to us from Fortress, and Fortress will not be liable for any of our actions or inactions based upon their advice. Fortress and its affiliates, including some members of our Board of Directors, have been contractually exempted from their fiduciary duties to our Company relating to corporate opportunities. As consideration for the Services, we are obligated to remit Fortress an annual cash fee of five hundred thousand dollars ($500,000) (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 $1,000,000 for each calendar year in which the Company has net assets in excess of $100,000,000 at the beginning of the calendar year. The first payment of the Annual Consulting Fee will be due following the completion of our first equity financing in excess of $10,000,000 and will include all amounts accrued since entry into the MSA, as well as an advance payment for the next quarter.

Since our inception in February 2015, Fortress has funded our operations pursuant to the terms of the Fortress Note. The Fortress Note is a future advance promissory note under which Fortress provides funds to support our operations. Interest on the Fortress Note is being 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. For the period from February 9, 2015 (inception) to December 31, 2016, the principal balance of the Fortress Note approximated $2.8 million and the Company recognized approximately $346,000 in interest expense related to the Fortress Note.

Lindsay A. Rosenwald, our Executive Chairman of the Board of Directors, is currently Chief Executive Officer of Fortress and Lucy Lu, our Interim President and Chief Executive Officer is currently Chief Financial Officer of Fortress. The MSA and Founders Agreements were negotiated with Fortress.

On June 12, 2015, we entered into an agreement with Chord under which Chord provides back office accounting support as well as accounting policy and financial reporting for us. In addition to these services, Mr. Horin, a Managing Partner of Chord, will serve as our Interim Chief Financial Officer. We will pay Chord an advisory fee of five thousand dollars ($5,000) per month prior to the public filing of this Registration Statement and seven thousand five hundred dollars ($7,500) per month thereafter. The arrangement can be terminated by either party upon thirty (30) days written notice. Chord, of which Mr. Horin is a Managing Partner, also provides advisory accounting services to Fortress under a separate agreement.

Fortress Financing Arrangements Affecting Avenue

On February 27, 2015, Fortress executed a Note Purchase Agreement (the "**Fortress Note Purchase Agreement**") with NSC Biotech Venture Fund I, LLC ("**Investor**") and issued the NSC Note in favor of the Investor. See "Liquidity and Capital Resources" for a description of the NSC Note. In connection with the Founders Agreement, we are assuming $3.0 million under the NSC Note and will be obligated to issue warrants to purchase our common stock equal to twenty-five (25%) of the amount of NSC Note proceeds we receive from Fortress divided by the lowest price at which we sell our common stock in our first third party financing. Until we complete an initial public offering of our securities registered under the Securities Act of 1933, as amended, or we raise sufficient equity capital so that we have cash equal to five (5) times our portion of the NSC Note, Fortress will continue to be obligated to repay the portion of NSC Note allocated to us.

Further, until February 26, 2016, upon any proposed issuance by us of capital stock or debt, including common stock or similar forms of capital stock, as well as securities that may be convertible into or exercisable or exchangeable for such capital stock (including convertible and non-convertible debt), in a private financing, other than equity or convertible debt securities, units or other combinations or securities that include equity or convertible debt securities issued in connection with a strategic partnership, acquisition of another company or a merger and/or acquisition of substantially all of our or Fortress's assets (a "**Subsequent Financing**"), NSC shall have the right, but not the obligation, to participate for twenty percent (20%) of the Subsequent Fortress Financing on the same terms, conditions and price provided for in the Subsequent Financing. We must provide NSC reasonable written notice of our intention to affect a Subsequent Financing which must include the terms and conditions of such Subsequent Financing. NSC then has five (5) business days to respond to our written notice with NSC's election to participate in the Subsequent Financing.

On January 3, 2017, in accordance with the terms of the NSC Note, Fortress notified the Investor on our behalf of its intention to extend the maturity date of the original note by six months to September 30, 2018.

Director Independence

Though not a listed company, we intend to adhere to the corporate governance standards adopted by NASDAQ. NASDAQ rules require our Board to make an affirmative determination as to the independence of each director. Consistent with these rules, our Board conducted its annual review of director independence. During the review, our Board considered relationships and transactions since incorporation between each director or any member of his immediate family, on the one hand, and us and our subsidiaries and affiliates, on the other hand. The purpose of this review was to determine whether any such relationships or transactions were inconsistent with a determination that the director is independent. Based on this review, our Board determined that of the current members of our Board, three directors, Neil Herskowitz, Dr. Jeffrey Paley and Akhtar Samad, M.D. PhD, are independent directors under the criteria established by NASDAQ and by our Board.

Our board of directors has a chairman, Lindsay A. Rosenwald, who has authority, among other things, to call and preside over board meetings, to set meeting agendas and to determine materials to be distributed to the board of directors. Accordingly, the chairman has substantial ability to shape the work of the board of directors.

Item 8. Legal Proceedings.

We are not involved in any litigation that we believe could have a material adverse effect on our financial position or results of operations. There is no action, suit, proceeding, inquiry or investigation before or by any court, public board, government agency, self-regulatory organization or body pending or, to the knowledge of our executive officers, threatened against or affecting our company or our officers or directors in their capacities as such.

Item 9. Market Price of and Dividends on the Registrant's Common Equity and Related Stockholder Matters.

Market information

There is no established public trading market in our common stock. Our securities are not listed for trading on any national securities exchange nor are bid or asked quotations reported in any over-the-counter quotation service.

Equity Compensation Plans

We expect that in the future we will file a registration statement on Form S-8 under the Securities Act registering the common stock subject to outstanding options or reserved for issuance under our 2015 Plan. That registration statement will become effective immediately upon filing, and shares covered by that registration statement will thereupon be 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, 2016, there were 9,773,810 shares of Common Stock outstanding held by three record holders, and 250,000 shares of Class A Preferred Stock outstanding held by one record holder.

Dividends

We have never paid cash dividends on any of our capital stock and currently intend to retain our future earnings, if any, to fund the development and growth of our business.

Our Class A Preferred Stock pays a stock dividend equal to 2.5% of our common stock on the anniversary date of the Founders Agreement.

Stock Not Registered Under the Securities Act; Rule 144 Eligibility

Our Common Stock has not been registered under the Securities Act. Accordingly, the shares of Common Stock issued and outstanding may not be resold absent registration under the Securities Act and applicable state securities laws or an available exemption thereunder.

Rule 144

Shares of our common stock that are restricted securities will be eligible for resale in compliance with Rule 144 (**Rule 144**") or Rule 701 ("**Rule 701**") of the Securities Act, subject to the requirements described below. "Restricted Securities," as defined under Rule 144, were issued and sold by us in reliance on exemptions from the registration requirements of the Securities Act. These shares may be sold in the public market only if registered or if they qualify for an exemption from registration, such as Rule 144 or Rule 701. Below is a summary of the requirements for sales of our common stock pursuant to Rule 144, as in effect on the date of this Form 10, after the effectiveness of this Form 10.

Affiliates

Affiliates will be able to sell their shares under Rule 144 beginning 90 days after the effectiveness of this Form 10, subject to all other requirements of Rule 144. In general, under Rule 144, an affiliate would be entitled to sell within any three-month period a number of shares that does not exceed one percent of the number of shares of our common stock then outstanding. Sales under Rule 144 are also subject to manner of sale provisions and notice requirements and to the availability of current public information about us.

Persons who may be deemed to be our affiliates generally include individuals or entities that control, or are controlled by, or are under common control with, us and may include our directors and officers, as well as our significant stockholders.

Non-Affiliates

For a person who has not been deemed to have been one of our affiliates at any time during the 90 days preceding a sale, sales of our shares of common stock held longer than six months, but less than one year, will be subject only to the current public information requirement and can be sold under Rule 144 beginning 90 days after the effectiveness of this Form 10. A person who is not deemed to have been one of our affiliates at any time during the 90 days preceding a sale, and who has beneficially owned the shares proposed to be sold for at least one year, is entitled to sell the shares without complying with the manner of sale, public information, volume limitation or notice provisions of Rule 144 upon the effectiveness of this Form 10.

Rule 701

Rule 701 under the Securities Act, as in effect on the date of this Form 10, permits resales of shares in reliance upon Rule 144 but without compliance with certain restrictions of Rule 144, including the holding period requirement. Most of our employees, executive officers, directors or consultants who purchased shares under a written compensatory plan or contract may be entitled to rely on the resale provisions of Rule 701, but all holders of Rule 701 shares are required to wait until 90 days after the effective date of this Form 10 before selling their shares under Rule 701.

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.

Item 10. Recent Sales of Unregistered Securities.

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 $142,000 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.

Item 11. Description of Registrant's Securities to be Registered.

The following description summarizes the material terms of Avenue capital stock as of the date of this registration statement. Because it is only a summary, it does not contain all the information that may be important to you. For a complete description of our capital stock, you should refer to our Second Amended and Restated Certificate of Incorporation and our Bylaws, and to the provisions of applicable Delaware law.

The authorized capital stock of Avenue 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. Only our Common Stock is being registered hereby. The description of our Class A Preferred Stock in this Item is for informational purposes only.

Class A Preferred Stock

Class A Preferred Stock is identical to Common Stock other than as to voting rights, the election of directors for a definite period, conversion rights and the PIK Dividend right (as described below). On any matter presented to our stockholders for their action or consideration at any meeting of our stockholders (or by written consent of stockholders in lieu of meeting), each holder of outstanding shares of Class A Preferred Stock will 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 shares of outstanding Common Stock and (B) the whole shares of Common Stock in to which the shares of outstanding Class A Preferred Stock are convertible and the denominator of which is the 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.

For a period of ten (10) years from the date of the first issuance of shares of Class A Preferred Stock (the "**Class A Director Period**"), 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 the directors of Avenue (the "**Class A Directors**"). Thus, the Class A Preferred Stock will be entitled to elect the majority of the Board of Directors during the Class A Director Period.

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 Avenue'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.

Finally, 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.

Undesignated Preferred Stock

The undesignated Preferred Stock may be issued from time to time in one or more series. Avenue'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).

Other Features of Our Capital Stock

- *Dividend Rights*. The holders of outstanding shares of our capital stock, including Common Stock and Class A Preferred Stock, are entitled to receive dividends out of funds legally available at the times and in the amounts that our Board of Directors may determine; provided, however, that 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 Avenue) 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.

- *Voting Rights*. The holders of our Common Stock are entitled to one vote for each share of Common Stock held and the holders of our Class A Preferred Stock are entitled to the number of votes equal to the Class A Preferred Stock Ratio for each share of Class A Preferred Stock held on all matters submitted to a vote of the stockholders, including the election of directors except as to the Class A Directors during the Class A Director Period. Our Second Amended and Restated Certificate of Incorporation and Bylaws do not provide for cumulative voting rights.

- *No Preemptive or Similar Rights.* The holders of our Common Stock and Class A Preferred Stock have no preemptive, conversion, or subscription rights, and there are no redemption or sinking fund provisions applicable thereto.

- *Right to Receive Liquidation Distributions.* Upon our liquidation, dissolution, or winding-up, the assets legally available for distribution to our stockholders would be distributable ratably among the holders of our capital stock, including Common Stock and Class A Preferred Stock, outstanding at that time after payment of other claims of creditors, if any.

- *Adjustment to Class A Preferred Stock Conversion Ratio* If Avenue, 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 for the Class A Preferred Stock 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, as 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 Avenue 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.

Item 12. Indemnification of Directors and Officers.

We have adopted provisions in our Second Amended and Restated Certificate of Incorporation that limit the liability of our directors for monetary damages for breach of their fiduciary duties, except for liability that cannot be eliminated under the Delaware General Corporation Law ("**DGCL**"). Delaware law provides that directors of a corporation will not be personally liable for monetary damages for breach of their fiduciary duties as directors, except liability for any of the following:

- any breach of their duty of loyalty to the corporation or the stockholder;

- acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;

- unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the DGCL; or

- any transaction from which the director derived an improper personal benefit.

This limitation of liability does not apply to liabilities arising under the federal securities laws and does not affect the availability of equitable remedies such as injunctive relief or rescission.

Our Second Amended and Restated Certificate of Incorporation and our Bylaws also provide that we will indemnify our directors and executive officers and may indemnify our other officers and employees and other agents to the fullest extent permitted by law. We believe that indemnification under our Bylaws covers at least negligence and gross negligence on the part of indemnified parties. Our Bylaws also permit us to secure insurance on behalf of any officer, director, employee or other agent for any liability arising out of his or her actions in this capacity, regardless of whether our Bylaws would permit indemnification. We have secured such insurance.

Item 13. Financial Statements and Supplementary Data.

The information required by this item may be found beginning on page F-1 of this Form 10.

Item 14. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

Effective July 1, 2016, we dismissed EisnerAmper LLP ("**EisnerAmper**") as the independent registered public accounting firm for Fortress and the Fortress Companies, including Avenue. The Fortress Board of Directors participated in and approved this decision.

The reports of EisnerAmper on the consolidated financial statements of the Company for the fiscal period from February 9, 2015 (inception) to October 31, 2015 (previous fiscal year end), did not contain an adverse opinion or a disclaimer of opinion, nor were such reports qualified or modified as to uncertainty, audit scope, or accounting principles.

During the fiscal period from February 9, 2015 (inception) to October 31, 2015, and through June 30, 2016, we did not have any disagreements with EisnerAmper on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure, which disagreements, if not resolved to the satisfaction of EisnerAmper, would have caused it to make reference to the subject matter of the disagreements in connection with its reports on the consolidated financial statements for such time periods.

During the fiscal period from February 9, 2015 (inception) to October 31, 2015, and through June 30, 2016, no "reportable events" as defined in Item 304(a)(1)(v) of Regulation S-K have occurred.

EisnerAmper has indicated to the Company that it concurs with the foregoing statements contained in the second, third and fourth paragraphs above as they relate to EisnerAmper and has furnished a letter to the Securities and Exchange Commission to this effect. A copy of the letter from EisnerAmper is attached to this registration statement as Exhibit 16.1.

Effective October 11, 2016, Fortress and the Company engaged BDO USA, LLP ("**BDO**") as its new independent registered public accounting firm. The Company's Board of Directors approved this decision.

During the fiscal period from February 9, 2015 (inception) to December 31, 2015, and through June 30, 2016, we did not consult with BDO regarding any matters described in Items 304(a)(2)(i) or 304(a)(2)(ii) of Regulation S-K under the Securities Act of 1933.

Item 15. Financial Statements and Exhibits

(a) Financial Statements.

The following financial statements are filed as part of this registration statement:

(b) Exhibits.

Exhibit No.	Description
3.1	Second Amended and Restated Certificate of Incorporation of Avenue Therapeutics, Inc. #
3.2	Bylaws of Avenue Therapeutics, Inc. #
4.1	Specimen certificate evidencing shares of Common Stock. #
4.2	Form of warrant agreement. #
10.1	Asset Transfer and License Agreement between Fortress Biotech, Inc. and Revogenex Ireland Limited dated February 17, 2015.* #
10.2	Amended and Restated Founders Agreement between Fortress Biotech, Inc., and Avenue Therapeutics, Inc. dated September 13, 2016. #
10.3	Promissory Note from Avenue Therapeutics, Inc. to NSC Biotech Venture Fund I, LLC, effective as of October 31, 2015. #
10.4	Promissory Note from Avenue Therapeutics, Inc. to Fortress Biotech, Inc. #
10.5	Management Services Agreement between Fortress Biotech, Inc. and Avenue Therapeutics, Inc. effective as of February 17, 2015. #
10.6	Employment Agreement with Dr. Lucy Lu, MD, dated June 10, 2015. #
10.7	Avenue Therapeutics, Inc. 2015 Incentive Plan. #
10.8	Consulting Agreement with Dr. Scott A. Reines, dated July 22, 2015. #
10.9	First Amendment to Consulting Agreement with Dr. Scott A. Reines, dated January 25, 2016. #
10.10	Second Amendment to Consulting Agreement with Dr. Scott A. Reines, dated August 2, 2016. #
10.11	First Amendment to Asset Transfer and License Agreement between Fortress Biotech, Inc. and Revogenex Ireland Limited dated June 23, 2016. #
16.1	Letter from EisnerAmper LLP to the SEC.

* Subject to a request for confidential treatment.
# Previously filed.

INDEX TO FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

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

We have audited the accompanying balance sheets of Avenue Therapeutics, Inc. as of December 2016 and 2015 and the related statements of operations, stockholders' deficit, and cash flows for the year ended December 31, 2016 and the period from February 9, 2015 (inception) to December 31, 2015. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States) and in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, 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. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Avenue Therapeutics, Inc. at December 31, 2016 and 2015, and the results of its operations and its cash flows for the year ended December 31, 2016 and the period from February 9, 2015 (inception) to December 31, 2015**,** in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As described in Note 1 to the financial statements, the Company has suffered recurring losses from operations and has a net capital deficiency that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ BDO USA, LLP
Boston, Massachusetts
March 6, 2017

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

	December 31, 2016	December 31, 2015
ASSETS		
Current Assets:		
Cash	$ 197	$ 14
Total Assets	**$ 197**	**$ 14**
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current Liabilities:		
Accounts payable and accrued expenses	$ 506	$ 491
Accrued expenses - related party	1,348	511
Interest payable	57	-
Accrued interest - related party	346	165
Notes payable - related party	2,848	1,165
NSC notes payable, short-term	1,000	-
Derivative warrant liability	314	114
Total current liabilities	6,419	2,446
Convertible notes payable, at fair value	200	-
NSC notes payable, long-term (net of debt discount of $174 and $297, respectively)	1,826	2,703
Total Liabilities	8,445	5,149
Commitments and Contingencies		
Stockholders' Deficit		
Preferred Stock ($0.0001 par value), 2,000,000 shares authorized		
Class A Preferred Stock, 250,000 and 0 shares issued and outstanding as of December 31, 2016 and 2015, respectively	-	-
Common Stock ($0.0001 par value), 50,000,000 shares authorized		
Class A Common Stock, 0 and 7,000,000 shares issued and outstanding as of December 31, 2016 and 2015, respectively	-	1
Common shares; 9,773,810 and 2,150,000 shares issued and outstanding as of December 31, 2016 and 2015, respectively	1	-
Common stock issuable, 250,595 and 228,750 shares as of December 31, 2016 and 2015, respectively	49	40
Additional paid-in capital	105	50
Accumulated deficit	(8,403)	(5,226)
Total Stockholders' Deficit	(8,248)	(5,135)
Total Liabilities and Stockholders' Deficit	**$ 197**	**$ 14**

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

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

	For The Year Ended December 31, 2016	For The Period from February 9, 2015 (Inception) through December 31, 2015
Operating expenses:		
Research and development	$ 1,331	$ 961
Research and development – licenses acquired	49	3,040
General and administration	997	842
Loss from operations	(2,377)	(4,843)
Interest expense	420	215
Interest expense - related party	192	168
Change in fair value of warrant liabilities	188	-
Net Loss	**$ (3,177)**	**$ (5,226)**
Net loss per common share outstanding, basic and diluted	$ (0.37)	$ (0.64)
Weighted average number of common shares outstanding, basic and diluted	8,581,578	8,107,209

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

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

	Class A Preferred Shares		Class A Common Shares		Common Shares		Common shares issuable	Additional paid-in capital	Accumulated deficit	Total Stockholders' deficit
	Shares	**Amount**	**Shares**	**Amount**	**Shares**	**Amount**				
Issuance of Class A common shares to Fortress on February 9, 2015	-	$ -	7,000,000	$ 1	-	$ -	$ -	$ (1)	$ -	$ -
Issuance of common shares to Fortress on February 9, 2015	-	-	-	-	1,000,000	-	-	-	-	-
Issuance of common shares for services	-	-	-	-	150,000	-	-	22	-	22
Share based compensation	-	-	-	-	1,000,000	-	-	29	-	29
Common shares issuable to Fortress per Founders Agreement	-	-	-	-	-	-	40	-	-	40
Net loss	-	-	-	-	-	-	-	-	(5,226)	(5,226)
Balance at December 31, 2015	**-**	**$ -**	**7,000,000**	**$ 1**	**2,150,000**	**$ -**	**$ 40**	**$ 50**	**$ (5,226)**	**$ (5,135)**
Share based compensation	-	-	-	-	-	-	-	28	-	28
Issuance of common shares - Founders Agreement	-	-	-	-	252,560	-	(40)	45	-	5
Conversion Class A common shares to Class A preferred shares and common shares	250,000	-	(7,000,000)	(1)	7,471,250	1	-	-	-	-
Common shares issuable to Fortress per Founders Agreement	-	-	-	-	-	-	49	-	-	49
Retirement of common shares	-	-	-	-	(100,000)	-	-	(18)		(18)
Net loss	-	-	-	-	-	-	-	-	(3,177)	(3,177)
Balance at December 31, 2016	**250,000**	**$ -**	**-**	**$ -**	**9,773,810**	**$ 1**	**$ 49**	**$ 105**	**$ (8,403)**	**$ (8,248)**

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

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

	For The Year Ended December 31, 2016	For The Period from February 9, 2015 (Inception) through December 31, 2015
Cash flows from operating activities:		
Net loss	$ (3,177)	$ (5,226)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share based compensation	28	29
Issuance of common shares for services	-	22
Research and development-licenses acquired, expensed	-	3,000
Common shares issuable - Founders Agreement	49	40
Common shares issued - Founders Agreement	5	-
Change in fair value of warrant liabilities	188	-
Financing fees expensed related to convertible notes, at fair value	58	-
Non-cash financing fees expensed related to convertible notes, at fair value	12	-
Debt discount amortization	123	73
Changes in operating assets and liabilities :		
Accounts payable and accrued expenses	15	491
Accrued expenses - related party	829	511
Interest payable	57	-
Accrued interest - related party	181	165
Net cash used in operating activities	(1,632)	(895)
Cash flows from investing activities:		
Purchase of research and development licenses	-	(3,000)
Net cash used in investing activities	-	(3,000)
Cash flows from financing activities:		
Proceeds from convertible note, at fair value	200	-
Financing fees expensed related to convertible notes, at fair value	(58)	-
Proceeds from NSC notes payable	-	3,000
Payment of debt issue costs associated with NSC Note	-	(256)
Proceeds from notes payable - related party	1,673	1,165
Net cash provided by financing activities	1,815	3,909
Net change in cash	183	14
Cash, beginning of period	14	-
Cash, end of period	**$ 197**	**$ 14**
Non-cash investing and financing activities:		
Issuance of Class A common shares to Fortress on February 9, 2015	$ -	$ 1
Warrant liability associated with NCS debt	$ -	$ 114
Retirement of common shares	$ 18	$ -
Conversion Class A common shares to Class A preferred shares and common shares	$ 1	$ -
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 183	$ 60

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

Note 1 - Organization, Plan of Business Operations and Going Concern Consideration

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.

Intravenous formulation of Tramadol HCI ("IV Tramadol")

In February 2015, Fortress purchased an exclusive license to an intravenous ("**IV**") formulation of Tramadol for the U.S. market from Revogenex Ireland Ltd ("**Revogenex**"), a privately held company in Dublin, Ireland. Fortress made an upfront payment of $2.0 million to Revogenex upon execution of the exclusive license, with an additional $1.0 million paid 120 days later, on June 17, 2015. Under the terms of the agreement, Revogenex is eligible to receive additional milestone payments upon the achievement of certain development milestones, in addition to royalty payments for sales of the product. 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 transferred the Revogenex license and all other rights and obligations of Fortress under the License Agreement to Avenue pursuant to the Assignment and Assumption Agreement effective as of February 17, 2015. Per the terms of the agreement, the Company assumed $3.0 million in debt (see Note 6).

Avenue plans to initiate a Phase 3 development program of IV Tramadol for the management of post-operative pain in 2016 following completion of a pharmacokinetics or PK study.

On February 9, 2015, Lucy Lu, M.D. was appointed to serve as the Company's Interim President and Chief Executive Officer. Under the terms of Dr. Lu's Employment Agreement, dated as of June 10, 2015 (the "**Employment Agreement**"), upon the Company becoming a public company, Dr. Lu will serve as the Company's full-time President and Chief Executive Officer and receive base salary equal to $395,000 per year. Dr. Lu's base salary may be reduced only in connection with a Company-wide decrease in executive compensation. Dr. Lu is also eligible to receive an annual discretionary bonus, not to exceed 50% of her base salary, if certain financial, clinical development, and/or business milestones are met at the discretion of the Board. Prior to her execution of the Employment Agreement, Dr. Lu was granted 1,000,000 shares of the Company's common stock pursuant to a Restricted Stock Issuance Agreement between the Company and Dr. Lu, dated June 10, 2015. Dr. Lu's employment with the Company is at will and may be terminated by the Company at any time and for any reason. However, under the terms of the Employment Agreement, Dr. Lu will be entitled to cash severance payments if the Company terminates her employment without cause (as defined in the Employment Agreement) or if Dr. Lu resigns her employment for good reason (as defined in the Employment Agreement). Dr. Lu also serves as the Chief Financial Officer for Fortress.

The expense allocations to Avenue, which represent Lucy Lu's executive compensation in accordance with the terms of her employment agreement with Fortress, have been paid by Fortress and allocated by the Company between Avenue and Fortress by allocating 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. For the year ended December 31, 2016 and the period from February 9, 2015 (Inception) through December 31, 2015, the allocated expenses related to Lucy Lu were approximately $336,800 and $94,500, respectively.

Going Concern Consideration

As of December 31, 2016, the Company's working capital deficit was approximately $6.2 million, and the Company's stockholders' deficit was approximately $8.2 million. Further, the Company expects to continue to incur significant costs in pursuit of its financing plans, developments plans and acquisition plans. The Company will need to raise capital in order to proceed with its plans to conduct a Phase 3 development program. The Company's plan to raise capital may not be successful. These factors, among others, raise substantial doubt about the Company's ability to continue as a going concern. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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 ("**GAAP**"). 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. All inter-company transactions between Fortress and Avenue are classified as accrued expenses - related party in the financial statements. The Company believes that the assumptions underlying the financial statements are reasonable. The cost allocation methods 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.

The financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("**U.S. GAAP**") and are stated in U.S. dollars.

The acquisition of the IV Tramadol license and the assumption of liabilities in connection with this license was accounted for as a transaction among businesses under common control. Because the license and assumption of liabilities met the definition of a business (as defined in ASC 805), the transfer of the business represented a transfer among entities under common control which should be accounted for at carrying amount with retrospective adjustment of prior period financial statements similar to the manner in which a pooling-of-interest was accounted for under APB 16*, Business Combinations.* Given this, the acquisition of the license by Fortress (and transferred to Avenue) represented a Research and Development expenditure which should be expensed pursuant to ASC 730 *Research and Development*.

Results of operations for the period in which the acquisition occurred are reported as though the acquisition had occurred at the beginning of the period. Accordingly, results of operations, presented in the financial statements, for period February 9, 2015 (Inception) through December 31, 2015 are comprised of operations of the Company.

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. There were no cash equivalents at December 31, 2016 and 2015.

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.

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. 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 the Company 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 the Company's Statement of Operations.

Annual Equity Fee

Prior to the September 2016 amendment to the Founder's Agreement (the "**Amended and Restated the Founders Agreement**"), Fortress was entitled to an annual fee on each anniversary date equal to 2.5% of the fully diluted outstanding equity of the Company, payable in Avenue Common Stock (" **Annual Equity Fee**"). The annual equity fee was part of consideration payable for formation of the Company and identification of certain assets.

The Company recorded the Annual Equity Fee in connection with the Founders Agreement with Avenue 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 has concluded that it is unable to reasonably estimate the contingent consideration until shares are actually issued on February 17 of each year. Because the issuance of shares on February 17, 2016 occurred prior to the issuance of the December 31, 2015 financial statements, the Company recorded approximately $40,000 in research and development - licenses acquired and a credit to Common shares issuable - Founders Agreement during the period ended December 31, 2015. Because the issuance of shares on February 17, 2017 occurred prior to the issuance of the December 31, 2016 financial statements, the Company recorded approximately $49,000 in research and development - licenses acquired and a credit to Common shares issuable - Founders Agreement during the period ended December 31, 2016, in connection with the stock dividend payable to holders of Class A Preferred shares, of which Fortress is the sole holder.

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 over the requisite service period based on the estimated grant-date fair value of the awards. 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 the Financial Accounting Standards Board ("**FASB**"), Accounting Standards Codification ("**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 – Related Party

In accordance with ASC 815, the Company classified the fair value of the warrant ("**Contingently Issuable Warrants**") that it may be obligated to issue to NSC Biotech Venture Fund I, LLC ("**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 should 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.

Income Taxes

The Company accounts for income taxes under ASC Topic 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 and 2016 tax years are will be 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 year ended December 31, 2016 and the period from February 9, 2015 (inception) through December 31, 2015. Management is currently unaware of any issues under review that could result in significant payments, accruals or material deviations from its position.

Licenses Acquired

In accordance with ASC 730-10-25-1, *Research and Development*, 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 has no alternative future use. Accordingly, the total purchase price of $3.0 million was reflected as research and development - licenses acquired in the Company's statement of operations for the period from February 9, 2015 (Inception) through December 31, 2015.

Net loss per Share

Loss per share is computed by dividing net loss by the weighted-average number of common shares outstanding (excluding the impacted of unvested restricted stock) 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. Diluted net loss per share does not reflect the effect of shares of common stock to be issued upon the exercise of warrants or outstanding Class A preferred shares, as their inclusion would be anti-dilutive. There are 50,000 warrants outstanding as of December 31, 2016 and 2015, respectively and 250,000 Class A preferred shares outstanding as of December 31, 2016 and none outstanding as of December 31, 2015, respectively which are excluded from the computations of net loss per share.

Comprehensive Loss

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

Recently Issued Accounting Standards

In January 2017, the Financial Accounting Standards Board ("**FASB**") issued Accounting Standards Update ("**ASU**") No. 2017-04, *Intangibles - Goodwill and Other* (Topic 350): Simplifying the Test for Goodwill Impairment ("**ASU 2017-04**"), which eliminates the second step of the previous FASB guidance for testing goodwill for impairment and is intended to reduce cost and complexity of goodwill impairment testing. The amendments in this ASU modify the concept of impairment from the condition that exists when the carrying amount of goodwill exceeds its implied fair value to the condition that exists when the carrying amount of a reporting unit exceeds its fair value. After determining if the carrying amount of a reporting unit exceeds its fair value, the entity should take an impairment charge of the same amount to the goodwill for that reporting unit, not to exceed the total goodwill amount for that reporting unit. This eliminates the second step of calculating the implied fair value of goodwill by assigning the fair value of a reporting unit to all of its assets and liabilities as if that reporting unit had been acquired in a business combination. ASU 2017-04 is effective for annual periods beginning after December 15, 2019, including interim periods within those annual periods. Early adoption is permitted for interim or annual goodwill impairment tests performed on testing dates after January 1, 2017. The Company is currently evaluating the impact of adopting the new guidance on its consolidated financial statements.

In January 2017, the FASB issued an ASU 2017-01, "*Business Combinations (Topic 805) Clarifying the Definition of a Business*". The amendments in this Update is to 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 is currently evaluating the impact of adopting this guidance.

In August 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows - Classification of Certain Cash Receipts and Cash Payments*, which addresses eight specific cash flow issues with the objective of reducing the existing diversity in practice in how certain cash receipts and cash payments are presented and classified in the statement of cash flows. The standard is effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. Early adoption is permitted, including adoption in an interim period. The Company is currently in the process of evaluating the impact of this new pronouncement on its statements of cash flows.

In April 2016, the FASB issued ASU No. 2016-10, *Revenue from Contracts with Customer* ("**ASU 2016-10**"). The new guidance is an update to ASC 606 and provides clarity on: identifying performance obligations and licensing implementation. For public companies, ASU 2016-10 is effective for annual periods, including interim periods within those annual periods, beginning after December 15, 2016. The Company is currently evaluating the impact that ASU 2016-10 will have on its financial statements.

In March 2016, the FASB issued ASU No. 2016-09 *Compensation-Stock Compensation (Topic 718), Improvements to Employee Share-Based Payment Accounting* ("**ASU 2016-09**"). Under ASU 2016-09, companies will no longer record excess tax benefits and certain tax deficiencies in additional paid-in capital ("**APIC**"). Instead, they will record all excess tax benefits and tax deficiencies as income tax expense or benefit in the income statement and the APIC pools will be eliminated. In addition, ASU 2016-09 eliminates the requirement that excess tax benefits be realized before companies can recognize them. ASU 2016-09 also requires companies to present excess tax benefits as an operating activity on the statement of cash flows rather than as a financing activity. Furthermore, ASU 2016-09 will increase the amount an employer can withhold to cover income taxes on awards and still qualify for the exception to liability classification for shares used to satisfy the employer's statutory income tax withholding obligation. An employer with a statutory income tax withholding obligation will now be allowed to withhold shares with a fair value up to the amount of taxes owed using the maximum statutory tax rate in the employee's applicable jurisdiction(s). ASU 2016-09 requires a company to classify the cash paid to a tax authority when shares are withheld to satisfy its statutory income tax withholding obligation as a financing activity on the statement of cash flows. Under current GAAP, it was not specified how these cash flows should be classified. In addition, companies will now have to elect whether to account for forfeitures on share-based payments by (1) recognizing forfeitures of awards as they occur or (2) estimating the number of awards expected to be forfeited and adjusting the estimate when it is likely to change, as is currently required. The Amendments of this ASU are effective for reporting periods beginning after December 15, 2016, with early adoption permitted but all of the guidance must be adopted in the same period. The Company is currently assessing the impact the adoption of ASU 2016-09 will have on its financial statements.

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)* ("**ASU 2016-02**") which supersedes FASB Accounting Standards Codification ("**ASC**") Topic 840, *Leases (Topic 840)* and provides principles for the recognition, measurement, presentation and disclosure of leases for both lessees and lessors. The new standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight-line basis over the term of the lease, respectively. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than twelve months regardless of classification. Leases with a term of twelve months or less will be accounted for similar to existing guidance for operating leases. The standard is effective for annual and interim periods beginning after December 15, 2018, with early adoption permitted upon issuance. The Company is currently evaluating the method of adoption and the impact of adopting ASU 2016-02 on its financial statements. When adopted, the Company does not expect this guidance to have a material impact on its financial statements.

In January 2016, the FASB issued ASU No. 2016-01, *Recognition and Measurement of Financial Assets and Financial Liabilities* ("**ASU 2016-01**") . ASU 2016-01 requires equity investments to be measured at fair value with changes in fair value recognized in net income; simplifies the impairment assessment of equity investments without readily determinable fair values by requiring a qualitative assessment to identify impairment; eliminates the requirement for public business entities to disclose the method(s) and significant assumptions used to estimate the fair value that is required to be disclosed for financial instruments measured at amortized cost on the balance sheet; requires public business entities to use the exit price notion when measuring the fair value of financial instruments for disclosure purposes; requires an entity to present separately in other comprehensive income the portion of the total change in the fair value of a liability resulting from a change in the instrument-specific credit risk when the entity has elected to measure the liability at fair value in accordance with the fair value option for financial instruments; requires separate presentation of financial assets and financial liabilities by measurement category and form of financial assets on the balance sheet or the accompanying notes to the financial statements and clarifies that an entity should evaluate the need for a valuation allowance on a deferred tax asset related to available-for-sale securities in combination with the entity's other deferred tax assets. ASU 2016-01 is effective for financial statements issued for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. The Company is currently evaluating the impact that ASU 2016-01 will have on its balance sheet or financial statement disclosures. When adopted, the Company does not expect this guidance to have a material impact on its financial statements.

Recently Adopted Accounting Pronouncements

As of October 2015, the Company adopted a sequencing policy whereby all future instruments may be classified as a derivative liability with the exception of instruments related to share-based compensation issued to employees or directors.

In April 2015, the Financial Accounting and Reporting Standards ("**FASB**") issued Accounting Standard Update ("**ASU**") 2015-03, Simplifying the Presentation of Debt Issuance Costs ("**ASU 2015-03**"), which requires debt issuance costs to be presented in the balance sheet as a direct deduction from the carrying value of the associated debt liability, consistent with the presentation of a debt discount. ASU 2015-03 is effective for the interim and annual periods ending after December 15, 2015. The Company adopted ASU 2015-03 on March 31, 2015. The adoption did not have an impact on the financial statements and related disclosures.

In August 2014, the FASB issued ASU No. 2014-15, Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern ("**ASU No. 2014-15**") that will require management to evaluate whether there are conditions and events that raise substantial doubt about the Company's ability to continue as a going concern within one year after the financial statements are issued on both an interim and annual basis. Management will be required to provide certain footnote disclosures if it concludes that substantial doubt exists or when its plans alleviate substantial doubt about the Company's ability to continue as a going concern. The Company adopted ASU No. 2014-15 in the fourth quarter of 2016, and its adoption did not have a material impact on the Company's financial statements.

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. For the period from February 9, 2015 (Inception) through December 31, 2015, the allocated expenses related to Lucy Lu were approximately $95,000 and were recorded 50% to research and development and 50% to general and administration expenses. For the year ended December 31, 2016, the allocated expenses related to Lucy Lu were approximately $336,000, of which $136,000 represent a 2016 bonus payable and were recorded 50% to research and development and 50% to general and administration expenses.

Note 4 - License Agreement

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 has been included in research and development- licenses acquired on the statements of operations. In addition, under the terms of the agreement, Revogenex is eligible to receive additional milestone payments upon the achievement of certain development milestones, as well as royalty payments for sales of the product.

Additionally, on March 10, 2015, the Company entered into a consulting agreement with the CEO of Revogenex (the "**Consultant**") to provide consulting services to the Company. Under the terms of the agreement the Company will pay $25,000 per calendar quarter to the Consultant throughout the initial one year term of the agreement. Either party upon 30-days written notice can terminate the agreement. From March 10, 2015 through December 31, 2015, the Company paid the Consultant approximately $83,000. For the year ended December 31, 2016, the Company had expenses related to the Consultant of approximately $16,000.

Note 5 - Related Party Agreements

Founders Agreement and Management Services Agreement with Fortress

Effective as of February 17, 2015, Fortress and the Company entered into a Founders Agreement pursuant to which Fortress assigned to Avenue all of its right and interest under Fortress' license agreement with Revogenex for IV Tramadol. As consideration for the Founders Agreement, the Company assumed $3.0 million in debt that Fortress accumulated under the NSC Note (See Note 6) for the IV Tramadol license, of which $2.0 million represents the initial payment in February 2015 and $1.0 million the payment made in June 2015. As additional consideration for the transfer of rights under the Founders Agreement, the Company will also: (i) issue annually to Fortress, on the anniversary date of the Founders Agreement, shares of common stock equal to 2.50% of the fully-diluted outstanding equity of Avenue at the time of issuance; (ii) pay an equity fee in shares of 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 (2.50%) 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 our 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), we will pay a one-time change in control fee equal to five (5x) times the product of (i) monthly net sales for the twelve (12) months immediately preceding the change in control and (ii) four and one-half percent (4.5%).

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's 7.0 million Class A common shares for approximately 7.5 million common shares and 250,000 Class A Preferred shares. In connection with the issuance of Class A Preferred shares, Fortress will receive an annual stock dividend (see below).

Effective as of February 17, 2015, the Company entered into a Management Services Agreement (the "**MSA**") with Fortress and each of the Company's current directors and officers who are directors or officers of Fortress to provide services to the Company 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 the Company. Services provided under the MSA may include, without limitation, (i) advice and assistance concerning any and all aspects of our operations, clinical trials, financial planning and strategic transactions and financings and (ii) conducting relations on behalf of our Company with accountants, attorneys, financial advisors and other professionals (collectively, the "**Services**"). The Company 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, the Company is not obligated to take or act upon any advice rendered from Fortress and Fortress shall not be liable for any of our actions or inactions based upon their advice. Fortress and its affiliates, including all members of the Company's Board of Directors, have been contractually exempt from fiduciary duties to the Company relating to corporate opportunities. In consideration for the Services, the Company 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 the Company has net assets in excess of $100 million at the beginning of the calendar year. For the year ended December 31, 2016 and the period from February 9, 2015 (Inception) to December 31, 2015, the Company recognized approximately $500,000 and $417,000, respectively, in expense on the Statement of Operations related to the MSA.

Issuance of Common Shares to Fortress

In connection with the Founders Agreement with Fortress, for the period ended December 31, 2015, the Company recorded an annual equity fee of $40,000 representing the 228,750 shares of our common stock at $0.176 per share. The annual equity fee represents 2.5% of the outstanding shares of the Company, issuable on the anniversary date of the Founders Agreement. As such, on February 17, 2016, the shares were issued. On September 13, 2016, in connection with the Amended and Restated Founders Agreement, the Equity Fee was eliminated.

For the period ended December 31, 2016, in connection with the 250,000 Class A Preferred shares, the Company recorded an expense of $49,000, representing the expense related to the Preferred A stock dividend. The expense is related to the 250,595 common shares issuable to Fortress on the anniversary date of the Amended and Restated Founders Agreement, representing 2.5% of the outstanding shares of the Company at December 31, 2016, at $0.194 per share or $49,000.

For the year ended December 31, 2016, and from inception to December 31, 2015, the Company recorded expenses of $49,000 and $40,000 in research and development licenses acquired.

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 is being 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.

As of December 31, 2016, the Fortress Note totaled approximately $2.8 million. For the year ended December 31, 2016 and the period from February 9, 2015 (Inception) to December 31, 2015, the Company had interest expense related to the Fortress Note of $178,000 and $164,000, respectively.

Consulting Agreement with Chord Advisors, LLC ("Chord")

On June 12, 2015, the Company entered into a full-service consulting agreement with Chord to provide advisory accounting services to the Company. Under the terms of the agreement, the Company will pay Chord five thousand dollars ($5,000) per month prior to becoming a public company and seven thousand five hundred dollars ($7,500) per month thereafter to perform back office accounting functions, accounting analysis and financial reporting. Either party upon 30-days written notice can terminate the agreement. In addition to these services, Mr. Horin, a Managing Partner of Chord, will serve as the Company's Interim Chief Financial Officer. Chord also provides advisory accounting services to Fortress under a separate agreement.

For the year ended December 31, 2016 and the period from February 9, 2015 (Inception) to December 31, 2015, the Company recognized approximately $50,000 and $35,000, respectively, in expense on the Statement of Operations.

NSC Note and Financings

In September 2016, Fortress acquired through a tender offer 56.1% of National Holdings, Inc. ("**National**" or "**NHLD**"). The Company holds a $3.0 million note in favor of NSC Biotech Venture Fund I, LLC for which National Securities, Inc. ("**NSC**"), a subsidiary of National, received a 10% placement fee upon issuance of the Note to Fortress. In addition, upon the completion of a third party raise of five times the NSC Note, the Company will issue a warrant to NSC as the placement agent equal to 25% of the outstanding debt. At December 31, 2016 and 2015 the Company recorded a derivate liability of $302,000 and $114,000 respectively on the Company's balance sheet.

Note 6 - Notes Payable

NSC Note

In February 2015, Fortress closed a private placement of a promissory note for $10 million in favor of NSC Biotech Venture Fund I, LLC, (the **NSC Note**"). Fortress used the proceeds from the NSC 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. National Securities Corporation ("**NSC**"), a wholly owned subsidiary of National Holdings, Inc., acted as the sole placement agent for the NSC Note. In January 2017, the Company notified NSC Biotech Venture Fund I, LLC, of its election to extend the maturity date to September 30, 2018.

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 the NSC 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 "**Amended NSC Note**") on identical terms as the NSC Note (giving effect to the passage of time with respect to maturity). The Amended NSC Note will equal the dollar amount of the Fortress Company's share of the NSC Note and reduce the Fortress' obligations under the NSC Note by such amount. Fortress will guarantee the Amended 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 Amended 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 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 issued will have a term of 10 years and an exercise price equal to the par value of the Company's common stock.

As of December 31, 2016, the Company's Amended 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 $174,000. For the year ended December 31, 2016 and the period from February 9, 2015 (Inception) to December 31, 2015, the Company recorded costs of approximately $123,000 and $73,000, respectively, related to the amortization of the debt discount and approximately $241,000, of which $14,000 is payable to a related party and $145,000 of which $3,500 is payable to a related party, respectively, of interest expense at 8%, both recorded in interest expense on the Statement of Operations. The effective interest rate of the NSC Note approximates 13.1%. The warrant contingently issuable in connection with NSC Note in the amount of approximately $114,000 was recorded as a debt discount based on its fair value (see Note 9). The following table summarizes NSC Note activities as of December 31, 2015 (in thousands).

	Note Payable	Discount	Note Payable, Net
February 9, 2015 balance	$ -	$ -	$ -
Proceeds from issuance of NSC Note	3,000	(256)	2,744
Amortization of debt discount	-	73	73
Derivative warrant liability	-	(114)	(114)
December 31, 2015 balance	$ 3,000	$ (297)	$ 2,703
Amortization of debt discount	-	123	123
December 31, 2016 balance	$ 3,000	$ (174)	$ 2,826

Fortress Note

As of December 31, 2016, the Company's Note from Fortress used to fund it working capital totaled $2.8 million. The note accrues interest at 8% (see Note 5). For the year ended December 31, 2016 and the period from February 9, 2015 (Inception) to December 31, 2015, the Company recognized approximately $178,000 and $168,000, respectively, in expense on the Statement of Operations.

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 $200,000. 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 $142,000 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 $200,000.

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.

Note 7 - 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. As of December 31, 2016, there was no litigation against the Company.

Note 8 - Stockholders' Deficit

Class A Preferred Shares

Pursuant to the Company's Second Amended and Restated Certificate of Incorporation, filed September 13, 2016, Class A Common Stock was eliminated and 2,000,000 shares are 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).

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 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

The Company was authorized to issue 50,000,000 common shares with a par value of $0.0001 per share, of which, 15,000,000 shares were designated as "Class A Common Stock". Fortress subscribed for 7,000,000 of the Class A Common Stock and 1,000,000 shares of the Common Stock. Fortress paid the par value of $800. Dividends are to be distributed pro-rata to the Class A Common Stock and common stock holders. The holders of common stock are entitled to one vote per share of common stock held. The Class A Common Stock holders are entitled to a number of votes equal to 1.1 times a fraction the numerator of which is the sum of (A) the shares of outstanding common stock and (B) the whole shares of common stock into which the shares of outstanding Class A Common Stock are convertible and the denominator of which is the number of shares of Class A Common Stock. Each share of Class A Common Stock shall be convertible, at the option of the holder thereof, into one (1) full paid and non-assessable share of common stock subject to adjustment for stock splits and combinations.

Pursuant to the Founders Agreement, on February 17, 2016, the Company issued 228,750 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 equity fee. The Company recorded an expense of approximately $40,000, in research and development licenses-acquired related to this stock grant during the period ended December 31, 2015.

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' 7.0 million Class A common shares for 7.4 million common shares and 250,000 Class A Preferred shares. The Company also eliminated its Class A Common Stock in July 2016, in connection with the transactions above.

On September 15, 2016, the Company retired the 100,000 shares of restricted stock issued to a consultant in connection with a May 2015 subscription agreement.

Stock Grants

On May 13, 2015, the Company granted 100,000 shares to a consultant, an employee of Fortress. These shares were granted in connection with services provided to the Company by a consultant. These shares are vested. The stock price was determined utilizing a discounted cash flow model prepared by the Company to determine the weighted market value of invested capital, discounted by a lack of marketability of 44.8%, weighted average cost of capital of 30%, and net of debt utilized, resulting in a value of $0.146 per share.

On May 13, 2015, the Company granted 50,000 shares to a consultant, also an employee of TG Therapeutics, Inc., of which Mr. Michael Weiss is Executive Chairmen, Interim President and Chief Executive Officer. These shares were granted in connection with services provided to the Company by the consultant. These shares are immediately vested and have a value of $0.146 per share in accordance with a valuation performed by the Company.

On June 10, 2015, the Company granted 1,000,000 shares to Dr. Lu, the Company's President and Chief Executive Officer. Half of these shares cliff vest in four tranches over 4 years and the other half vest based upon achievement of performance milestones. The shares have a value of $0.146 per share in accordance with a valuation performed by the Company.

The following table summarizes restricted stock award activity for the period from February 9, 2015 (Inception) through December 31, 2015 and the year ended December 31, 2016.

	Number of Units	Weighted Average Grant Day Fair Value
Nonvested at February 9, 2015 (Inception)	-	$ -
Granted	1,150,000	0.15
Vested	(150,000)	0.15
Nonvested at December 31, 2015	1,000,000	$ 0.15
No activity	-	-
Nonvested at December 31, 2016	1,000,000	$ 0.15

For the period from February 9, 2015 (Inception) through December 31, 2015, stock-based compensation expenses associated with the amortization of restricted stock award for employees and non-employees were approximately $29,000 and $22,000, respectively.

For the year ended December 31, 2016, stock-based compensation expenses associated with the amortization of restricted stock award for employees and non-employees were approximately $28,000 and $nil, respectively.

At December 31, 2016, the Company had unrecognized stock-based compensation expense related to restricted stock awards of $24,000, which is expected to be recognized over the remaining weighted-average vesting period of 1.63 years.

Note 9 - 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, 2016 and 2015, the warrant balance of approximately $314,000 and $114,000, respectively, were classified as Level 3 instruments.

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

	[(1)]NSC Contingently Issuable Warrants	Westpark Contingently Issuable Warrants	Total
Fair value, February 9, 2015 (Inception)	$ -	$ -	$ -
Issuance of derivative warrant liabilities	114	-	114
Fair value, December 31, 2015	114	-	114
Issuable derivative warrant liabilities	-	12	12
Change in fair value	188	-	188
Fair value, December 31, 2016	$ 302	$ 12	$ 314

(1) NSC, as the placement agent, is a Related Party.

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 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 issued will have a term of 10 years and an exercise price equal to the par value of the Company's common stock. In accordance with ASC 815 - "*Derivatives and Hedging (Topic 815)*", the Company classified the fair value of the warrant that maybe granted in connection with the NSC Note transferred to the Company on December 31, 2016 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 this warrant using a Black-Scholes model and 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 warrant. Management's estimate of probability of issuance of the warrant was based upon market participant data related to levels of common stock financings in comparison to market capitalizations of comparable companies. At each reporting period, as long as the warrant was potentially issuable and there was a potential for an insufficient number of authorized shares available to settle the warrant, the warrant will be revalued and any difference from the previous valuation date will be recognized as a change in fair value in the Company's statement of operations.

The fair value of the NSC Contingently Issuable Warrants was determined at December 31, 2016 for approximately $302,000 by applying management's estimate of the probability of issuance of the Contingently Issuable Warrants together with the Black-Scholes option pricing model with the following key assumptions:

	December 31, 2016	December 31, 2015
Risk-free interest rate	2.45%	2.27%
Expected dividend yield	-	-
Expected term in years	10.00	10.00
Expected volatility	83%	83%
Probability of issuance of the warrant	50%	25%

The fair value of Westpark warrant liability was measured at fair value using a Monte Carlo simulation valuation methodology. A summary of the weighted average (in aggregate) significant unobservable inputs (level 3 inputs) used in measuring the Company's warrant liabilities that are categorized within Level 3 of the fair value hierarchy for the year ended December 31, 2016 is as follows:

	December 31, 2016
Risk-free interest rate	2.45%
Expected dividend yield	-
Expected term in years	10.00
Expected volatility	87%

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, 2015	$ -
Additions	200
Change in fair value	-
Fair value, December 31, 2016	$ 200

Note 10 - 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,	
	2016	2015
Statutory federal income tax rate	35%	35%
State taxes, net of federal tax benefit	4%	5%
Rate change	(1%)	-
Change in valuation allowance	(38%)	(40%)
Income taxes provision (benefit)	-	-

The components of the net deferred tax asset as of December 31, 2016 and 2015 are the following (in thousands):

	As of December 31,	
	2016	2015
Deferred tax assets:		
Net operating loss carryovers	$ 2,080	$ 887
Change in warrant liabilities	73	-
Amortization of license	1,064	1,136
Accruals and reserves	78	95
Tax credits	33	19
Total deferred tax assets	3,328	2,137
Less valuation allowance	(3,318)	(2,090)
Stock compensation and other	(10)	(47)
Deferred tax asset, 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 $3.3 million and $2.1 million was recorded for the period ended December 31, 2016 and 2015, respectively.

As of December 31, 2016, the Company had federal and state net operating loss carryforwards of approximately $5.3 million and $4.1 million, respectively. The federal and state net operating loss carryforwards will begin to expire, if not utilized, by 2035 and 2025, respectively. Utilization of the net operating loss carryforward may be subject to an annual limitation due to the ownership change limitations provided by Section 382 of the Internal Revenue Code of 1986, as amended and similar state provisions.

The Company is included in the consolidated income tax returns of Fortress Biotech, Inc. and Subsidiaries. The Company's federal and state net operating loss carryforwards may be utilized to offset income of other members included in the consolidated income tax returns for which the Company may be compensated pursuant to outstanding tax-sharing agreements.

There are no significant matters determined to be unrecognized tax benefits taken or expected to be taken in a tax return, in accordance with 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 period ended December 31, 2016. 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 period ended December 31, 2016.

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

SIGNATURES

Pursuant to the requirements of Section 12 of the Securities Exchange Act of 1934, the registrant has duly caused this registration statement 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: Interim President, Chief Executive Officer and Director
March 6, 2017

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 registration statement 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 registration statement 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/ Lindsay A. Rosenwald, M.D. Lindsay A. Rosenwald, M.D.	Executive Chairman of the Board	March 6, 2017
/s/ Lucy Lu, M.D. Lucy Lu, M.D.	Interim President, Chief Executive and Director	March 6, 2017
/s/ Scott A. Reines, M.D., Ph.D. Scott A. Reines, M.D., Ph.D.	Interim Chief Medical Officer	March 6, 2017
/s/ David J. Horin David J. Horin	Interim Chief Financial Officer	March 6, 2017
/s/ Michael S. Weiss Michael S. Weiss	Director	March 6, 2017
/s/ Neil Herskowitz Neil Herskowitz	Director	March 6, 2017
/s/ Jeffrey Paley, M.D. Jeffrey Paley, M.D.	Director	March 6, 2017
/s/ Akhtar Samad, M.D., PhD. Akhtar Samad, M.D., PhD.	Director	March 6, 2017
/s/ Jay Kranzler, MD, PhD. Jay Kranzler, MD, PhD.	Director	March 6, 2017

Exhibit 16.1

March 6, 2017

Securities and Exchange Commission
100 F Street, N.E.
Washington, DC 20549

Ladies and Gentlemen:

We have read Item 14 of Amendment No. 1 to the Registration Statement on Form 10 dated March 6, 2017 of Avenue Therapeutics, Inc. and are in agreement with the statements contained therein as it regards our firm. We have no basis to agree or disagree with other statements of the registrant contained in Item 14.

Sincerely,

/s/ EisnerAmper LLP
EisnerAmper LLP