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

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 patent applications of the 622 Patent, U.S. Patent Application Serial No. 14/550,279 (the "**279 Application**") and U.S. Patent Application Serial No. 14/713,775 (the "**775 Application**"), both of which are entitled "Intravenous Administration of Tramadol" and both of which contain the same disclosure (specification) as that of the 622 Patent. In view of additional prior art discovered after the issuance of the 622 Patent, we have focused efforts on obtaining new patent claims in the 279 and 775 Applications, which patentably differentiate over such prior art. Currently, both of these patent applications 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 pain. The tramadol dose is preferably administered over 15 (±2) minutes. Both of these applications have been allowed by the United States Patent and Trademark Office (the "**USPTO**"), and issuance of patents from these two applications is expected in the first quarter of 2017.

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.

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 pursuant to an Asset Transfer Agreement, dated as of May 13, 2015. 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.

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 January 6, 2017, on our financial statements for the period ended December 31, 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 $2.4 million and our shareholders' deficit of approximately $5.2 million, and the Company has incurred losses of approximately $2.4 million for the nine months ended September 30, 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 the Nine Months Ended September 30, 2016 and from February 9, 2015 (inception) to September 30, 2015

General

At September 30, 2016, we had an accumulated deficit of $7.6 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 nine months ended September 30, 2016 and for the period from February 9, 2015 (inception) to September 30, 2015, research and development expenses were $1.2 million and $0.5 million, respectively. For the nine months ended September 30, 2016, $0.9 million relates costs related to the development of IV Tramadol of which, $0.8 million relates to the PK Study we conducted in the first half of 2016, $0.2 million relates to our Management Services Agreement with Fortress, and $0.1 million relates personnel costs. From inception February 9, 2015 through September 30, 2015 $0.5 million of expenses were primarily related to $0.2 million to the Management Services Agreement with Fortress, and $0.3 million related to professional services.

For the nine months ended September 30, 2016 and for the period from February 9, 2015 (inception) to September 30, 2015, research and development licenses acquired were nil and $3.0 million, respectively. The $3.0 million represents the upfront payment for the IV Tramadol license we acquired in 2015.

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 nine months ended September 30, 2016 and for the period from February 9, 2015 (inception) to September 30, 2015 general and administrative expenses were $0.7 million and $0.4 million, respectively. For the nine months ended September 30, 2016, $0.2 million relates to our Management Services Agreement with Fortress, $0.3 million relates to professional fees and $0.1 million relates personnel costs. From inception February 9, 2015 through September 30, 2015 $0.4 million of expenses were primarily related to $0.1 million to the Management Services Agreement with Fortress, and $0.3 million related to professional services.

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 September 30, 2016, we had an accumulated deficit of $7.6 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.

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 $261,300 and $0 related to this note in interest expense in our Statements of Operations for the nine months ended September 30, 2016 and for the period from February 9, 2015 (inception) to September 30, 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 September 30, 2016, we funded all of our operations through Intercompany Working Capital Promissory Note ("Fortress Note"), which approximates $2.7 million September 30, 2016. Further, we have recorded interest expense of $122,000 and $126,000 related to this note in interest expense - due related in our Statements of Operations for the nine months ended September 30, 2016 and for the period from February 9, 2015 (inception) to September 30, 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 $0.2 million of convertible notes.

Period Ended December 31, 2015 from February 9, 2015 (Inception)

General

At December 31, 2015 we had an accumulated deficit of $5.2 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 is central to our business. For the period from February 9, 2015 through December 31, 2015, research and development expenses were $4.0 million, of which $3.0 million was related to the acquisition of the license and rights to IV Tramadol and an additional $0.7 million relates to activities in connection with the development of IV Tramadol, $0.2 million relates to our management Services Agreement with Fortress and $0.1 million for personnel costs.

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 period from February 9, 2015 through December 31, 2015, general and administrative expenses were $0.9 million, which consisted of expense of $0.6 million for professional fees in connection with the acquisition of the license from Revogenex as well as formation costs , $0.2 million 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

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 and products. 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.

The NSC Note allows Fortress to transfer a portion of the proceeds from the NSC Note to us pursuant to which we will execute an identical NSC Note in favor of NSC. In connection with this transfer, NSC will receive a warrant to purchase our stock equal to 25% of the NSC Note proceeds we receive from Fortress divided by the lowest price at which we sell our equity in our first third party financing. The warrant issued will have a term of 10 years and an exercise price equal to the par value of our common stock. Upon transfer, Fortress will remain a guarantor on the NSC Note until the completion of an initial public offering in which we raise sufficient equity capital so that we have cash equal to five times the amount of the portion of the proceeds of the NSC Note so transferred.

To date, our operations have been funded by the NSC Note of $3.0 million and the Fortress Note of $1.2 million and may continue to be funded by the Fortress Note or, if necessary, by the NSC Note, until we are able to raise capital. Further, we have recorded interest expense of $142,000, related NSC Note, $74,000 in connection with the amortization of debt discount and $167,000 in related party interest expense in our Statements of Operations for the period from February 9, 2015 (inception) to December 31, 2015. 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.

Recently Issued Accounting Pronouncements

In August 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("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 condensed 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 condensed 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 condensed 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 condensed 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 July 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 Beneficially Owned	
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	10.3%
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%
All executive officers and directors as a group	1,000,000(2)	10.3%(2)
5% or Greater Stockholders:		
Fortress Biotech, Inc.	8,700,000	89.2%
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.

Name and Address of Beneficial Owner	Class A Preferred Stock Beneficially Owned	
	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

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 since November 2014; 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. Jeffrey 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. Akhtar 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, Akhtar 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.

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, 9th 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 at www.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, 9th Floor, New York, NY 10014.

Item 6. Executive Compensation.

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 2015.

Name and Principal Position	Year	Salary ($)	Stock Awards ($)[1]	Total ($)
Lucy Lu[2]	2016	138,658	22,901	161,559
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	35,500	—	35,500
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 approximately19% of her time devoted to us and January 1,2016 through September 30,2016 Dr. Lu spent approximately 54% of her time.

(3) This represents the amount paid to Dr. Reines during 2015 and 2016 for the nine months ended September 30, 2016 for services rendered. He provided us with approximately 40 hours of work in 2015 and through September 30, 2016 approximately 108 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 nine months ended September 30, 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 has 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 September 30, 2016.

Compensation Committee Interlocks and Insider Participation

We do not currently have a compensation committee and, for the year ended October 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 September 30, 2016, the principal balance of the Fortress Note approximated $2.8 million and the Company recognized approximately $286,000 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.

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 July 31, 2016, there were 9,950,000 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.

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 $186,000 after paying WestPark Capital, Inc., the placement agent, placement agent fees of $10,000 and escrow fees of $4,000. 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.

We engaged BDO USA, LLP to audit our initial financial statements on November 29, 2016. There have been no changes since or any disagreements with BDO USA, LLP regarding any accounting or financial disclosure matter.

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.

* Subject to a request for confidential treatment.

INDEX TO FINANCIAL STATEMENTS

AVENUE THERAPEUTICS, INC.
BALANCE SHEETS
($ in thousands, except per share amounts)

	September 30, 2016 (Unaudited)	December 31, 2015
ASSETS		
Current Assets:		
Cash	$ 30	$ 14
Prepaid expenses and other current assets	31	-
Total Assets	**$ 61**	**$ 14**
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current Liabilities:		
Accounts payable and accrued expenses	$ 396	$ 491
Accrued expenses - related party	1,096	511
Accrued interest - related party	286	165
Notes payable - related party	2,758	1,165
Derivative warrant liability	222	114
Total current liabilities	4,758	2,446
NSC notes payable, long-term (net of debt discount of $205 and $297, respectively)	2,795	2,703
Total Liabilities	7,553	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 September 30, 2016 and December 31, 2015, respectively	-	-
Common Stock ($0.0001 par value), 50,000,000 shares authorized		
Class A Common Stock, 0 and 7,000,000 shares issued and outstanding as of September 30, 2016 and December 31, 2015, respectively	-	1
Common shares; 9,850,000 and 2,150,000 shares issued as of September 30, 2016 and December 31, 2015, respectively; 9,750,000 and 2,150,000 shares outstanding as of September 30, 2016 and December 31, 2015, respectively	1	-
Common stock issuable, 0 and 228,750 shares as of September 30, 2016 and December 31, 2015, respectively	-	40
Treasury stock, at cost, 100,000 and 0 shares as of September 30, 2016 and December 31, 2015, respectively	(18)	-
Additional paid-in capital	113	50
Accumulated deficit	(7,588)	(5,226)
Total Stockholders' Deficit	(7,492)	(5,135)
Total Liabilities and Stockholders' Deficit	**$ 61**	**$ 14**

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

AVENUE THERAPEUTICS, INC.
STATEMENT OF OPERATIONS
($ in thousands, except per share amounts)
(Unaudited)

	For The Nine Months Ended September 30, 2016	For The Period from February 9, 2015 (Inception) through September 30, 2015
Operating expenses:		
Research and development	$ 1,168	$ 465
Research and development – licenses acquired	-	3,000
General and administration	693	354
Loss from operations	(1,861)	(3,819)
Interest expense	261	-
Interest expense - related party	132	126
Change in fair value of warrant liabilities	108	-
Net Loss	**$ (2,362)**	**$ (3,945)**
Net loss per common share outstanding, basic and diluted	$ (0.28)	$ (0.49)
Weighted average number of common shares outstanding, basic and diluted	8,466,182	8,090,385

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

AVENUE THERAPEUTICS, INC.
STATEMENT OF STOCKHOLDERS' EQUITY
($ in thousands, except share amounts)
(Unaudited)

	Class A Preferred Shares		Class A Common Shares		Common Shares		Treasury Stock		Common shares issuable	Additional paid-in capital	Accumulated deficit	Total Stockholders' deficit
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
Balance at December 31, 2015	**-**	**$ -**	**7,000,000**	**$ 1**	**2,150,000**	**$ -**	**-**	**$ -**	**$ 40**	**$ 50**	**$ (5,226)**	**$ (5,135)**
Share based compensation	-	-	-	-	-	-	-	-	-	23	-	23
Issuance of common shares - Founders Agreement	-	-	-	-	228,750	-	-	-	(40)	40	-	-
Conversion Class A common shares to Class A preferred shares and common shares	250,000	-	(7,000,000)	(1)	7,471,250	1	-	-	-	-	-	-
Repurchase common shares	-	-	-	-	(100,000)	-	100,000	(18)	-	-	-	(18)
Net loss	-	-	-	-	-	-	-	-	-	-	(2,362)	(2,362)
Balance at September 30, 2016	**250,000**	**$ -**	**-**	**$ -**	**9,750,000**	**$ 1**	**100,000**	**$ (18)**	**$ -**	**$ 113**	**$ (7,588)**	**$ (7,492)**

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

AVENUE THERAPEUTICS, INC.
STATEMENT OF CASH FLOWS
(Unaudited)
($ in thousands)

	For The Nine Months Ended September 30, 2016	For The Period from February 9, 2015 (Inception) through September 30, 2015
Cash flows from operating activities:		
Net loss	$ (2,362)	$ (3,945)
Adjustments to reconcile net loss to net cash used in operating activities:		
Share based compensation	23	15
Issuance of common shares for services	-	23
Research and development-licenses acquired, expensed	-	3,000
Change in fair value of warrant liabilities	108	-
Debt discount amortization	92	-
Changes in operating assets and liabilities :		
Prepaid consulting	(31)	(161)
Accounts payable and accrued expenses	(95)	90
Accrued expenses - related party	585	333
Accrued interest - related party	121	126
Net cash used in operating activities	(1,559)	(519)
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 notes payable - related party	1,583	3,524
Repurchase common shares, net of non-cash portion	(8)	-
Net cash provided by financing activities	1,575	3,524
Net change in cash	16	5
Cash, beginning of period	14	-
Cash, end of period	**$ 30**	**$ 5**
Non-cash investing and financing activities:		
Issuance of common shares - Founders Agreement	$ 40	$ -
Repurchase common shares	$ 10	$ -
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	$ -

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.

Going Concern Consideration

As of September 30, 2016, the Company's working capital deficit was approximately $4.7 million and the Company's stockholders' deficit was $7.5 million. Further, the Company expects to continue to incur significant costs in pursuit of its financing and acquisition plans. These conditions 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

Avenue has not been operating as a separate legal entity within Fortress for the full period presented. Accordingly, the financial statements have been prepared on a "separate" basis from Fortress accounts and reflect the historical accounts directly attributable to Avenue together with allocations of costs and expenses. The financial statements have been prepared in accordance with Regulation S-X, Article 3, "General instructions as to financial statements" and Staff Bulletin ("SAB") Topic 1-B, "Allocations of Expenses and Related Disclosure in Financial Statements of Subsidiaries, Divisions or Lesser Business Components of Another Entity".

The financial statements may not be indicative of future performance and may not reflect what the 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.

Unaudited Interim Financial Information

The accompanying interim financial statements and the notes to the financial statements are unaudited. These unaudited interim financial statements have been prepared on the same basis as the audited statements. In the opinion of management, the unaudited interim financial statements reflect all adjustments, which include only normal recurring adjustments necessary for the fair statement of the balances and results for the periods presented. These financial statements results are not necessarily indicative of results to be expected for the full fiscal year or any future period.

The preparation of the Company's unaudited financial statements 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 the unaudited financial statements and the reported amounts of expenses during the period.

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 September 30, 2016 and December 31, 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 probable. 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, 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.

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.

Valuation of Warrant Related to NSC Note

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

For purposes of these financial statements, the Company's income tax expense and deferred tax balances have been recorded as if it filed tax returns on a stand-alone basis separate from Fortress.

Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities measured at the enacted tax rates in effect for the year in which these items are expected to reverse. Deferred tax assets are reduced by valuation allowances if, based on the consideration of all available evidence, it is more likely than not that some portion or all of the deferred tax asset will not be realized.

Net loss per Share

Loss per share is computed by dividing net loss by the weighted-average number of common shares outstanding, excluding unvested restricted stock, 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. In the calculation of diluted loss per share, since there was no option or warrants as well as the conversion of rights, the diluted loss per share equaled the basic loss per share during the period.

Recently Issued Accounting Standards

In August 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("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.

In August 2014, the FASB issued ASU 2014-15, Presentation of Financial Statements - Going Concern (Topic 915): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern ("ASU 2014-15"). ASU 2014-15 states that in connection with preparing financial statements for each annual and interim reporting period, an entity's management should evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued (or within one year after the date that the financial statements are available to be issued when applicable). ASU 2014-15 will be effective for annual and interim periods beginning on or after December 15, 2016. Early adoption is permitted. The Company is currently evaluating the impact, if any, of the adoption of this update.

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.

Note 3 – Allocation

The expense allocations to Avenue, represents 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 nine months ended September 30, 2016 and for the period from February 9, 2015 (Inception) through September 30, 2015, the allocated expenses related to Lucy Lu were approximately $210,000 and $42,000, respectively, and were recorded 50% to research and development and 50% to general and administration expenses.

Note 4 – Consulting Agreement

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. On January 19, 2016, the Company terminated its agreement with the Consultant, effective March 10, 2016. For the nine months ended September 30, 2016, the Company had expenses related to the Consultant of approximately $16,700.

Note 5 – Related Party Agreements

Founders Agreement and Management Services Agreement with Fortress

Effective as of February 17, 2015, Fortress entered into a Founders Agreement with Avenue pursuant to which Fortress assigned to Avenue all of its rights and interest under Fortress's license agreement with Revogenex for IV Tramadol (the "License Agreement"). As consideration for the Founders Agreement, Avenue assumed $3.0 million in debt that Fortress accumulated to NSC for expenses and costs of forming Avenue and obtaining the IV Tramadol license, of which $3.0 million represents the acquisition of the License Agreement. As additional consideration for the transfer of rights under the Founders Agreement, Avenue shall also: (i) issue annually to Fortress, on the anniversary date of the Founders Agreement, shares of common stock equal to two and one half percent (2.5%) of the fully-diluted outstanding equity of Avenue at the time of issuance; (ii) pay an equity fee in shares of Avenue common stock, payable within five (5) business days of the closing of any equity or debt financing for Avenue or any of its respective subsidiaries that occurs after the effective date of the Founders Agreement and ending on the date when Fortress no longer has majority voting control in Avenue's voting equity, equal to two and one half percent (2.5%) of the gross amount of any such equity or debt financing; and (iii) pay a cash fee equal to four and one half percent (4.5%) of Avenue's annual net sales, payable on an annual basis, within ninety (90) days of the end of each calendar year. In the event of a change in control (as it is defined in the Founders Agreement), Fortress will be paid a one-time change in control fee equal to five (5x) times the product of (i) net sales for the twelve (12) months immediately preceding the change in control and (ii) four and one-half percent (4.5%).

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 approximately 7.4 million common shares and 250,000 Class A Preferred shares (see Note 8).

Effective as of February 17, 2015, Fortress entered into a Management Services Agreement (the "MSA") with Avenue and each of Avenue's current directors and officers who are directors or officers of Fortress, excluding services provided by Dr. Lucy Lu our Interim Chief Executive Officer and Chief Financial Officer of Fortress, to provide services to Avenue pursuant to the terms of the MSA. Pursuant to the terms of the MSA, for a period of five (5) years, Fortress will render advisory and consulting services to Avenue. Services provided under the MSA may include, without limitation, (i) advice and assistance concerning any and all aspects of Avenue's operations, clinical trials, financial planning and strategic transactions and financings and (ii) conducting relations on behalf of Avenue with accountants, attorneys, financial advisors and other professionals (collectively, the "Services"). Avenue is obligated to utilize clinical research services, medical education, communication and marketing services and investor relations/public relation services of companies or individuals designated by Fortress, provided those services are offered at market prices. However, Avenue is not obligated to take or act upon any advice rendered from Fortress and Fortress shall not be liable for any of Avenue's actions or inactions based upon their advice. Fortress and its affiliates, including all members of Avenue's Board of Directors, have been contractually exempt from fiduciary duties to Avenue relating to corporate opportunities. In consideration for the Services, Avenue will pay Fortress an annual consulting fee of $0.5 million (the "Annual Consulting Fee"), payable in advance in equal quarterly installments on the first business day of each calendar quarter in each year, provided, however, that such Annual Consulting Fee shall be increased to $1.0 million for each calendar year in which Avenue has net assets in excess of $100 million at the beginning of the calendar year.

For the nine months ended September 30, 2016 and 2015, the Company had expenses related to the Management Services Agreement of $375,000 and $292,000, respectively.

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 September 30, 2016, the Fortress Note totaled approximately $2.8 million. For the nine months ended September 30, 2016 and 2015, the Company had interest expense related to the Fortress Note of $122,000 and $126,000, 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 nine months ended September 30, 2016 and 2015, the Company had expenses related to the consulting agreement with Chord of approximately $35,000 and $13,500, respectively.

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.

Note 6 – Notes Payable

NSC Note

Effective February 17, 2015, the Company issued a promissory note to NSC Biotech Venture Fund I, LLC in the principal amount of $3.0 million (the "NSC Note"). The NSC Note matures thirty-six months from February 17, 2015, provided that during the first twenty-four months, the Company can elect to extend the maturity date by six months. The NSC Note bears interest at 8.0% per annum payable quarterly during the first twenty-four months (or the first thirty months, if the maturity date is extended) and monthly thereafter until maturity. No principal amounts are due from the Company for the first twenty-four months (or the first thirty months if the maturity date is extended). Thereafter, the NSC Note must be repaid at the rate of 1/12th of the principal amount per month for a period of 12 months.

The following table summarizes NSC Note activities for the nine months ended September 30, 2016 ($ in thousands).

	Note Payable	Discount	Note Payable, Net
December 31, 2015 balance	$ 3,000	$ (297)	$ 2,703
Amortization of debt discount	-	92	92
September 30, 2016 balance	$ 3,000	$ (205)	$ 2,795

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 September 30, 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 Shares

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.

Treasury Shares

On August 3, 2016, the Company entered into a stock repurchase agreement with a consultant whereby the Company agreed to repurchase the 100,000 shares of common stock issued to the consultant in connection with a May 2015 subscription agreement. Pursuant to the terms of the subscription agreement, the Company agreed to repurchase the shares at fair value of $0.176 per share or $17,600. The shares were repurchased on September 15, 2016, for cash paid of $7,420 and the repayment of the consultant's short-term loan to Fortress of $10,180. Since the Company's working capital is funded by Fortress, the Consultant's loan repayment is reflected as a reduction of the Company's Fortress Note. The repurchase of the shares was recorded as Treasury Stock on the Company's balance sheets.

Restricted Stock Awards

The following table summarizes unvested restricted stock award activity for the nine months ended September 30, 2016.

	Number of Units	Weighted Average Grant Day Fair Value
Unvested balance at December 31, 2015	1,000,000	$ 0.15
Vested	(175,000)	0.15
Unvested balance at September 30, 2016	825,000	$ 0.15

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

For the nine months ended September 30, 2016 and 2015, stock-based compensation expenses associated with the amortization of restricted stock awards for employees and non-employees were approximately $23,000 and $15,000, respectively.

At September 30, 2016, the Company had unrecognized stock-based compensation expense related to restricted stock awards of $29,000, which is expected to be recognized over the remaining weighted-average vesting period of 1.69 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 September 30, 2016, the Contingently Issuable Warrant balance of approximately $0.2 million was classified as Level 3 instruments.

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

	Contingently Issuable Warrants
Fair value, December 31, 2015	$ 114
Change in fair value	108
Fair value, September 30, 2016	$ 222

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, the Company classifies the fair value of the warrant that may have been granted in connection with the NSC Note transferred to the Company 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 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 warrant. 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 was 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.

The fair value of the Contingently Issuable Warrants was determined 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:

	September 30, 2016	December 31, 2015
Risk-free interest rate	1.60%	1.46%
Expected dividend yield	-	-
Expected term in years	9.09	10.00
Expected volatility	83%	83%
Probability of issuance of the warrant	50%	25%

Note 10 – Subsequent Event

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 $186,000 after paying WestPark Capital, Inc., the placement agent, placement agent fees of $10,000 and escrow fees of $4,000. 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.

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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 sheet of Avenue Therapeutics, Inc. as of December 31, 2015 and the related statements of operations, stockholders' deficit, and cash flows for 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, 2015, and the results of its operations and its cash flows for 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
January 11, 2017

AVENUE THERAPEUTICS, INC.
BALANCE SHEET
As of December 31, 2015
(In thousands, except share and per share amounts)

	December 31, 2015
ASSETS	
Current Assets:	
Cash	$ 14
Total Assets	**$ 14**
LIABILITIES AND STOCKHOLDERS' DEFICIT	
Current Liabilities:	
Accounts payable and accrued expenses	$ 491
Accrued expenses - related party	511
Accrued interest - related party	165
Notes payable - related party	1,165
Derivative warrant liability	114
Total current liabilities	2,446
NSC notes payable, long-term (net of debt discount of $297)	2,703
Total Liabilities	5,149
Commitments and Contingencies	
Stockholders' Deficit	
Common Stock ($0.0001 par value), 50,000,000 shares authorized	
Class A common shares; 7,000,000 shares issued and outstanding as of December 31, 2015	1
Common shares; 2,150,000 shares issued and outstanding as of December 31, 2015	-
Common stock issuable, 228,750 shares as of December 31, 2015	40
Additional paid-in capital	50
Accumulated deficit	(5,226)
Total Stockholders' Deficit	(5,135)
Total Liabilities and Stockholders' Deficit	**$ 14**

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

AVENUE THERAPEUTICS, INC.
STATEMENT OF OPERATIONS
For the Period from February 9, 2015 (Inception) through December 31, 2015
(In thousands, except share and per share amounts)

	For The Period from February 9, 2015 (Inception) through December 31, 2015
Operating expenses:	
Research and development	$ 961
Research and development – licenses acquired	3,000
General and administration	882
Loss from operations	(4,843)
Interest expense	215
Interest expense - related party	168
Net Loss	**$ (5,226)**
Net loss per common share outstanding, basic and diluted	$ (0.64)
Weighted average number of common shares outstanding, basic and diluted	8,107,209

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

AVENUE THERAPEUTICS, INC.
STATEMENT OF STOCKHOLDERS' DEFICIT
For the Period from February 9, 2015 (Inception) through December 31, 2015
(In thousands, except share amounts)

	Class A Common Shares		Common Shares		Common Stock	Additional paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Issuable	capital	deficit	deficit
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 - 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)**	**$ (5,136)**

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

AVENUE THERAPEUTICS, INC.
STATEMENT OF CASH FLOWS
For the Period from February 9, 2015 (Inception) through December 31, 2015
(In thousands)

	For The Period from February 9, 2015 (Inception) through December 31, 2015
Cash flows from operating activities:	
Net loss	$ (5,226)
Adjustments to reconcile net loss to net cash used in operating activities:	
Share based compensation	29
Issuance of common shares for services	22
Research and development-licenses acquired, expensed	3,000
Common shares issuable - Founders Agreement	40
Debt discount amortization	73
Changes in operating assets and liabilities :	
Accounts payable and accrued expenses	491
Accrued expenses - related party	511
Accrued interest - related party	165
Net cash used in operating activities	(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 NSC notes payable	3,000
Payment of debt issue costs associated with NSC Note	(256)
Proceeds from notes payable - related party	1,165
Net cash provided by financing activities	3,909
Net change in cash	14
Cash, beginning of year	-
Cash, end of year	**$ 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
Supplemental disclosure of cash flow information:	
Cash paid for interest	$ 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"). Avenue was formed as a specialty pharmaceutical company that acquires, licenses, develops and commercializes products principally for use in the acute/intensive care hospital setting.

Avenue issued 7,000,000 shares of Class A common stock and 1,000,000 shares of common stock to Fortress. Fortress paid the par value of $800, due from Fortress as of December 31, 2015. The shares were issued pursuant to the Founders Agreement.

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 period from February 9, 2015 (Inception) through December 31, 2015, the allocated expenses related to Lucy Lu were approximately $94,500.

Going Concern Consideration

As of December 31, 2015, the Company's working capital deficit was approximately $2.4 million, and the Company's stockholders' deficit was approximately $5.1 million. Further, the Company expects to continue to incur significant costs in pursuit of its financing plans, developments plans and acquisition plans. These conditions 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, 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.

Annual Equity Fee

Under the Founder's Agreement with Avenue dated February 17, 2015, Fortress is entitled to an annual fee on each anniversary of the Agreement equal to 2.5% of fully diluted outstanding equity, payable in Avenue common shares ("Annual Equity Fee"). The Annual Equity Fee was part of the consideration payable for formation of the Company, identification of certain assets, including the license contributed to Avenue by Fortress (see Note 5).

The Company recorded the Annual Equity Fee in connection with the Founders Agreement with Fortress as contingent consideration. Contingent consideration is recorded when probable and reasonably estimable. The Company's future share prices and shares outstanding cannot be estimated prior to the issuance of the Annual Equity Fee 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 from February 9, 2015 (Inception) through December 31, 2015.

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.

Valuation of Warrant Related to NSC Note

In accordance with ASC 815, the Company classified the fair value of the warrant ("Contingently Issuable Warrants") that may have been granted in connection with the NSC Note transferred to the Company on December 31, 2015 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 with 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 evaluation was performed for the upcoming 2015 tax year, which will be the only period 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 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. In the calculation of diluted loss per share, since there was no option or warrants outstanding as well as the conversion of rights, the diluted loss per share equaled the basic loss per share during the period.

Comprehensive Loss

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

Recently Issued Accounting Standards

In August 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("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.

In August 2014, the FASB issued ASU 2014-15, Presentation of Financial Statements - Going Concern (Topic 915): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern ("ASU 2014-15"). ASU 2014-15 states that in connection with preparing financial statements for each annual and interim reporting period, an entity's management should evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued (or within one year after the date that the financial statements are available to be issued when applicable). ASU 2014-15 will be effective for annual and interim periods beginning on or after December 15, 2016. Early adoption is permitted. The Company is currently evaluating the impact, if any, of the adoption of this update.

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.

Subsequent Events

The Company evaluates events that have occurred after the balance sheet date through the date, which these financial statements were available to be issued.

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 $94,500 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.

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%).

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 period from February 9, 2015 (Inception) to December 31, 2015, the Company recognized approximately $417,000 in expense on the Statement of Operations related to the MSA.

Since the Company's inception in February 2015, Fortress has funded the Company's operations pursuant to the terms of the Fortress Note. Interest on the Fortress Note is being accrued at 8% 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, 2015, the loan approximated $1.2 million and the Company recognized approximately $168,000 in interest expense on the Statement of Operations related to the Fortress Note.

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 $5,000 per month 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 period from February 9, 2015 (Inception) to December 31, 2015, the Company recognized $35,000 in expense on the Statement of Operations.

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.

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, 2015, 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 $297,000. For the period from February 9, 2015 (Inception) to December 31, 2015, the Company recorded costs of approximately $73,000 related to the amortization of the debt discount and approximately $142,000 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

Fortress Note

As of December 31, 2015, the Fortress Note totaled approximately $1.2 million. For the period from February 9, 2015 (Inception) to December 31, 2015, the Company recorded costs of approximately $168,000 of interest expense at 8%, recorded in interest expense on the Statement of Operations.

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, 2015, there was no litigation against the Company.

Note 8 – Stockholders' Deficit

Common Stock

The Company was authorized to issue 50,000,000 common shares with a par value of $0.0001 per share, of which, 7,000,000 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 will pay the par value of $800 to the Company. On February 9,2015, the fair value of the Company's common shares approximated par value as the license had not been transferred. Dividends are to be distributed pro-rata to the Class A 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 the shares of outstanding common stock 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.

Stock Grants

On May 13, 2015, the Company granted 100,000 shares to Andrew Scott, an employee of Fortress. These shares were granted in connection with services Mr. Scott provided to the Company. 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 Robert Niecestro, 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 Mr. Niecestro provided to the Company. 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.

	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

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.

At December 31, 2015, the Company had unrecognized stock-based compensation expense related to restricted stock awards of $52,000, which is expected to be recognized over the remaining weighted-average vesting period of 1.77 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, 2015, the Contingently Issuable Warrant balance of approximately $114,000 was classified as Level 3 instruments.

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

	Contingently Issuable Warrants
Fair value, February 9, 2015 (Inception)	$ -
Issuance of derivative warrant liabilities	114
Fair value, December 31, 2015	$ 114

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, 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, 2015 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 Contingently Issuable Warrants was determined at December 31, 2015 for approximately $114,000 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, 2015
Risk-free interest rate	2.27%
Expected dividend yield	-
Expected term in years	10.00
Expected volatility	83%
Probability of issuance of the warrant	25%

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:

	As of December 31, 2015
Statutory federal income tax rate	(35.0)%
State taxes, net of federal tax benefit	(5.0)%
Change in valuation allowance	40.0%
Income tax provision (benefit)	0.0%

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

	As of December 31, 2015
Deferred tax assets:	
Net operating loss carryovers	$ 887
Amortization of license fee	1,136
Accruals and reserves	95
Tax credit	19
Total deferred tax assets	2,137
Valuation allowance	(2,090)
Stock based compensation	(47)
Deferred tax asset, net of 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 $2.1 million for the period ended December 31, 2015 was recorded.

As of December 31, 2015, the Company had federal and state net operating loss carryforwards of approximately $2.2 million and $2.1 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, 2015. 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, 2015.

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.

Note 11 – Subsequent Event

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 7.4 million common shares and 250,000 Class A Preferred shares.

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
January 11, 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	January 11, 2017
/s/ Lucy Lu, M.D. Lucy Lu, M.D.	Interim President, Chief Executive and Director	January 11, 2017
/s/ Scott A. Reines, M.D., Ph.D. Scott A. Reines, M.D., Ph.D.	Interim Chief Medical Officer	January 11, 2017
/s/ David J. Horin David J. Horin	Interim Chief Financial Officer	January 11, 2017
/s/ Michael S. Weiss Michael S. Weiss	Director	January 11, 2017
/s/ Neil Herskowitz Neil Herskowitz	Director	January 11, 2017
/s/ Jeffrey Paley, M.D. Jeffrey Paley, M.D.	Director	January 11, 2017
/s/ Akhtar Samad, M.D., PhD. Akhtar Samad, M.D., PhD.	Director	January 11, 2017

Exhibit 3.1

SECOND AMENDED AND RESTATED
CERTIFICATE OF INCORPORATION
OF
AVENUE THERAPEUTICS INC.

(Pursuant to Sections 242 and 245 of the
General Corporation Law of the State of Delaware)

Avenue Therapeutics, Inc., a corporation organized and existing under and by virtue of the General Corporation Law of the State of Delaware (the***"Corporation"),*** does hereby certify as follows:

1. That the name of the Corporation is Avenue Therapeutics, Inc., and that this Corporation's original Certificate of Incorporation was filed on February 9, 2015, the Amended and Restated Certificate of Incorporation was filed on May 12, 2015 and the First Amendment to the Amended and Restated Certificate of Incorporation was filed on December 11, 2015.

2. That the duly adopted resolutions proposing to amend and restate the Amended and Restated Certificate of Incorporation of this corporation, declaring said amendment and restatement to be advisable and in the best interests of this corporation and its stockholders, and authorizing the appropriate officers of this corporation to solicit the consent of the stockholders therefor, which resolution setting forth the proposed amendment and restatement is as follows:

RESOLVED, that the Amended and Restated Certificate of Incorporation of this corporation be amended and restated in its entirety to read as follows:

ARTICLE I

The name of the corporation is Avenue Therapeutics, Inc. (the***"Corporation").***

ARTICLE II

The address of the Corporation's registered office in the State of Delaware is 3500 South DuPont Highway, in the City of Dover, Kent County, Delaware 19901. The name of its registered agent at such address is Incorporating Services, Ltd.

ARTICLE III

The nature of the business or purposes to be conducted or promoted is to engage in any lawful act or activity for which corporations may be organized under the Delaware General Corporation Law (as amended from time to time, the *"DGCL"),* and to possess and exercise all of the powers and privileges granted by such law and any other law of the State of Delaware.

ARTICLE IV

Authorized Stock. The total number of shares of all classes of capital stock that the Corporation shall have the authority to issue is (i) fifty million (50,000,000) shares of Common Stock, with $0.0001 par value, and (ii) 2,000,000 shares of Preferred Stock, with $.0001 par value (the ***"Preferred Stock"),*** 250,000 of which are designated as Class A Preferred Stock (the ***"Class A Preferred Stock")*** and the remainder are undesignated Preferred Stock. The undesignated Preferred Stock may be issued from time to time in one or more series. The Board of Directors of the Corporation 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 powers, preferences and relative participating, optional and other special rights of the respective classes of the Corporation's capital stock or the holders thereof and the qualifications, limitations and restrictions thereof are as follows:

1. Dividends.

1 . 1 Class A Preferred. The record 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 PIK Record Date. Notwithstanding the foregoing, a holder of Class A Preferred Stock entitled to receive a PIK Dividend may waive its rights to receive such dividend for any annual period, and such waiver shall not operate as a waiver of any future PIK Dividends. The ***"PIK Record Date"*** shall mean the date that is one (1) business day prior to any PIK Dividend Payment Date.

On the PIK Record Date immediately preceding a PIK Dividend Payment Date, the Board of Directors of the Corporation shall be deemed to have declared PIK Dividends on the Class A Preferred Stock in accordance with the above, payable on the next PIK Dividend Payment Date. PIK Dividends shall be payable in arrears on each PIK Dividend Payment Date, commencing on the first PIK Dividend Payment Date. If any PIK Dividend Payment Date occurs on a day that is not a business day, any accrued PIK Dividends otherwise payable on such PIK Dividend Payment Date shall be paid on the next succeeding business day. PIK Dividends shall be paid to holders of record of the Class A Preferred Stock on each PIK Dividend Payment Date as their names shall appear on the share register of the Corporation on the PIK Record Date immediately preceding such PIK Dividend Payment Date. Unpaid PIK Dividends may be paid at any time to holders of record on the PIK Record Date therefor. 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. The record date for such payment on conversion shall be the date immediately prior to the effective date of such conversion.

1 . 2 Other Distributions. The Corporation shall declare, pay and set aside dividends among the holders of the shares of Common Stock and Class A Preferred Stock pro rata based on the number of shares of Common Stock held by each such holder, treating for this purpose all such shares of Class A Preferred Stock as if they had been converted to Common Stock pursuant to the terms of this Second Amended and Restated Certificate of Incorporation immediately prior to such declarations, payment or setting aside of dividends. 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 Corporation) on the shares of Common Stock of the Corporation until all dividends (set forth in Section IV.1.1 above) on the Class A Preferred Stock shall have been paid or declared and set apart for payment.

2. Voting.

2.1 General.

2.1.1 Subject to Subsection IV.2.2.1, the holders of the Common Stock are entitled to one vote for each share of Common Stock held at all meetings of stockholders (and written actions in lieu of meetings). There shall be no cumulative voting. The number of authorized shares of Common Stock and Preferred Stock may be increased or decreased (but not below the number of shares thereof then outstanding) by the affirmative vote of the holders of shares of capital stock of the Corporation representing a majority of the votes represented by all outstanding shares of capital stock of the Corporation entitled to vote, irrespective of the provisions of Section 242(b)(2) of the DGCL.

2.1.2 Subject to Subsection IV.2.2.1, on any matter presented to the stockholders of the Corporation for their action or consideration at any meeting of stockholders of the Corporation (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 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 number of shares of outstanding Class A Preferred Stock.

2.1.3 Except as provided by law or by the other provisions of this Second Amended and Restated Certificate of Incorporation, holders of Class A Preferred Stock shall vote together with the holders of Common Stock as a single class.

2.2 Election of Directors.

2.2.1 Notwithstanding any provision of the Bylaws of this Corporation, 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 the Corporation (the ***"Class A Directors").***

2.2.2 The holders of record of the shares of Common Stock and Preferred Stock (including Class A Preferred Stock) and of any other class or series of voting stock, exclusively and voting together as a single class, shall be entitled to elect the balance of the total number of directors of the Corporation, if any.

Any director may be removed without cause by, and only by, the affirmative vote of the holders of the shares of the class(es) of capital stock entitled to elect such director or directors, given either at a special meeting of such stockholders duly called for that purpose or pursuant to a written consent of stockholders. At any meeting held for the purpose of electing a director, the presence in person or by proxy of the holders of a majority of the outstanding shares of the class or series entitled to elect such director shall constitute a quorum for the purpose of electing such director. A vacancy in any directorship filled by the holders of any class or series shall be filled only by vote or written consent in lieu of a meeting of the holders of such class or series or by any remaining director or directors elected by the holders of such class or series pursuant to this Subsection 1V.2.2.

3. Conversion.

The holders of the Class A Preferred Stock shall have conversion rights as follows (the ***"Conversion Rights")*:**

3.1 Right to Convert; Conversion Ratio. Each share of Class A Preferred Stock shall be convertible, at the option of the holder thereof, at any time and from time to time, and without the payment of additional consideration by the holder thereof, into one (1) fully paid and nonassessable share of Common Stock (the ***"Conversion Ratio"),*** subject to adjustment as provided below.

3.2 Fractional Shares. No fractional shares of Common Stock shall be issued upon conversion of the Class A Preferred Stock. In lieu of any fractional shares to which the holder would otherwise be entitled, the Corporation shall pay cash equal to such fraction multiplied by the fair market value of a share of Common Stock as determined in good faith by the Board of Directors of the Corporation. Whether or not fractional shares would be issuable upon such conversion shall be determined on the basis of the total number of shares of Class A Preferred Stock the holder is at the time converting into Common Stock and the aggregate number of shares of Common Stock issuable upon such conversion.

3.3 Mechanics of Conversion.

3.3.1 Notice of Conversion. In order for a holder of Class A Preferred Stock to voluntarily convert shares of Class A Preferred Stock into shares of Common Stock (or other capital stock or securities at the time issuable upon conversion of the Class A Preferred Stock), such holder shall surrender the certificate or certificates for such shares of Class A Preferred Stock (or, if such registered holder alleges that such certificate has been lost, stolen or destroyed, a lost certificate affidavit and agreement reasonably acceptable to the Corporation and bond, if requested by the Corporation, to indemnify the Corporation against any claim that may be made against the Corporation on account of the alleged loss, theft or destruction of such certificate), at the office of the transfer agent for the Class A Preferred Stock (or at the principal office of the Corporation if the Corporation serves as its own transfer agent), together with written notice that such holder elects to convert all or any number of the shares of the Class A Preferred Stock represented by such certificate or certificates and, if applicable, any event on which such conversion is contingent. Such notice shall state such holder's name or the names of the nominees in which such holder wishes the certificate or certificates for shares of Common Stock (or other capital stock or securities at the time issuable upon conversion of the Class A Preferred Stock) to be issued. If required by the Corporation, certificates surrendered for conversion shall be endorsed or accompanied by a written instrument or instruments of transfer, in form satisfactory to the Corporation, duly executed by the registered holder or his, her or its attorney duly authorized in writing. The close of business on the date of receipt by the transfer agent (or by the Corporation if the Corporation serves as its own transfer agent) of such certificates (or lost certificate affidavit and agreement) and notice shall be the time of conversion (the ***"Conversion Time"***), and the shares of Common Stock (or other capital stock or securities at the time issuable upon conversion of the Class A Preferred Stock) issuable upon conversion of the shares represented by such certificate shall be deemed to be outstanding of record as of such date. The Corporation shall, as soon as practicable after the Conversion Time, issue and deliver to such holder of Class A Preferred Stock, or to his, her or its nominees, a certificate or certificates for the number of full shares of Common Stock (or other capital stock or securities at the time issuable upon conversion of the Class A Preferred Stock) issuable upon such conversion in accordance with the provisions hereof, a certificate for the number (if any) of the shares of Class A Preferred Stock represented by the surrendered certificate that were not converted into Common Stock (or other capital stock or securities at the time issuable upon conversion of the Class A Preferred Stock), and cash as provided in Subsection IV.3 .2 in lieu of any fraction of a share of Common Stock (or other capital stock or securities at the time issuable upon conversion of the Class A Preferred Stock) otherwise issuable upon such conversion and payment of any declared but unpaid dividends on the shares of Class A Preferred Stock converted.

3.3.2 Reservation of Shares. The Corporation shall at all times when Class A Preferred Stock shall be outstanding, reserve and keep available out of its authorized but unissued capital stock, for the purpose of effecting the conversion of the Class A Preferred Stock, such number of its duly authorized shares of Common Stock (or other capital stock or securities at the time issuable upon conversion of the Class A Preferred Stock) as shall from time to time be sufficient to effect the conversion of all outstanding Class A Preferred Stock; and if at any time the number of authorized but unissued shares of Common Stock (or other capital stock or securities at the time issuable upon conversion of the Class A Preferred Stock) shall not be sufficient to effect the conversion of all then outstanding shares of the Class A Preferred Stock, the Corporation shall take such corporate action as may be necessary to increase its authorized but unissued shares of Common Stock (or other capital stock or securities at the time issuable upon conversion of the Class A Preferred Stock) to such number of shares as shall be sufficient for such purposes, including, without limitation, engaging in best efforts to obtain the requisite stockholder approval of any necessary amendment to the Second Amended and Restated Certificate of Incorporation.

3.3.3 Effect of Conversion. All shares of Class A Preferred Stock which shall have been surrendered for conversion as herein provided shall no longer be deemed to be outstanding and all rights with respect to such shares shall immediately cease and terminate at the Conversion Time, except only the right of the holders thereof to receive shares of Common Stock (or other capital stock or securities at the time issuable upon conversion of the Class A Preferred Stock) in exchange therefor and to receive payment of any dividends declared but unpaid thereon. Any shares of Class A Preferred Stock so converted shall be retired and cancelled and may not be reissued as shares of such series, and the Corporation may thereafter take such appropriate action (without the need for stockholder action) as may be necessary to reduce the authorized number of shares of Class A Preferred Stock accordingly.

3.3.4 Taxes and Liens. The Corporation shall pay any and all costs incurred by the Corporation to effect the conversion and shall pay any issue and other similar taxes that may be payable in respect of any issuance or delivery of any securities upon conversion of shares of Class A Preferred Stock pursuant to this Subsection IV.3. The Corporation shall not, however, be required to pay any tax which may be payable in respect of any transfer involved in the issuance and delivery of securities in a name other than that in which the shares of Class A Preferred Stock so converted were registered, and no such issuance or delivery shall be made unless and until the person or entity requesting such issuance has paid to the Corporation the amount of any such tax or has established, to the satisfaction of the Corporation, that such tax has been paid. Upon conversion of each share of Class A Preferred Stock, the Corporation shall take all such actions as are necessary in order to ensure that the securities issuable with respect to such conversion shall be validly issued, fully paid and nonassessable, free and clear of all taxes, liens, charges and encumbrances with respect to the issuance thereof (other than restrictions on transfer under applicable federal and state securities law and liens, charges and encumbrances arising through the holder thereof).

3.4 Adjustment for Stock Splits and Combinations. If the Corporation shall at any time or from time to time after the effective date of this Second Amended and Restated Certificate of Incorporation (the ***"Effective Date")*** effect a subdivision of the outstanding Common Stock (or other capital stock or securities at the time issuable upon conversion of the Class A Preferred Stock) (by any stock split, stock dividend, recapitalization or otherwise), the applicable Conversion Ratio of the Class A Preferred Stock in effect immediately before that subdivision shall be proportionately decreased so that the number of shares of Common Stock (or other capital stock or securities at the time issuable upon conversion of the Class A Preferred Stock) issuable on conversion of each share of Class A Preferred Stock, shall be increased in proportion to such increase in the aggregate number of shares of Common Stock (or other capital stock or securities at the time issuable upon conversion of the Class A Preferred Stock) outstanding. If the Corporation shall at any time or from time to time after the Effective Date combine the outstanding shares of Common Stock, the applicable Conversion Ratio in effect immediately before the combination shall be proportionately increased so that the number of shares of Common Stock (or other capital stock or securities at the time issuable upon conversion of the Class A Preferred Stock) issuable on conversion of each share of Class A Preferred Stock, shall be decreased in proportion to such decrease in the aggregate number of shares of Common Stock (or other capital stock or securities at the time issuable upon conversion of the Class A Preferred Stock) outstanding. Any adjustment under this Subsection shall become effective at the close of business on the date the subdivision or combination becomes effective.

3.5 Adjustment for Merger or Reorganization, etc. If there shall occur any reorganization, recapitalization, reclassification, consolidation or merger involving the Corporation in which the Common Stock (but not the Class A Preferred Stock) is converted into or exchanged for securities, cash or other property (other than a transaction covered by Subsection IV.3.4), then, following any such reorganization, recapitalization, reclassification, consolidation or merger, each share of Class A Preferred Stock shall thereafter be convertible in lieu of the Common Stock into which it was convertible prior to such event into the kind and amount of securities, cash or other property which a holder of the number of shares of Common Stock of the Corporation issuable upon conversion of one share of the applicable Class A Preferred Stock immediately prior to such reorganization, recapitalization, reclassification, consolidation or merger would have been entitled to receive pursuant to such transaction; and, in such case, appropriate adjustment (as determined in good faith by the Board of Directors of the Corporation) shall be made in the application of the provisions in Subsection IV.3 with respect to the rights and interests thereafter of the holders of the Class A Preferred Stock to the end that the provisions set forth in Subsection IV.3 (including provisions with respect to changes in and other adjustments of the applicable Conversion Ratio) shall thereafter be applicable, as nearly as reasonably may be, in relation to any securities or other property thereafter deliverable upon the conversion of the Class A Preferred Stock.

3.6 Certificate as to Adjustments. Upon the occurrence of each adjustment or readjustment of the applicable Conversion Ratio pursuant to Subsection IV.3, the Corporation at its expense shall, as promptly as reasonably practicable but in any event not later than 10 days thereafter, compute such adjustment or readjustment in accordance with the terms hereof and furnish to each holder of the applicable series of Class A Preferred Stock a certificate setting forth such adjustment or readjustment (including the kind and amount of securities, cash or other property into which the applicable shares of Class A Preferred Stock are convertible) and showing in detail the facts upon which such adjustment or readjustment is based. The Corporation shall, as promptly as reasonably practicable after the written request at any time of any holder of Class A Preferred Stock (but in any event not later than 10 days thereafter), furnish or cause to be furnished to such holder a certificate setting forth (i) the applicable Conversion Ratio then in effect, and (ii) the number of shares of Common Stock (or other capital stock or securities at the time issuable upon conversion of the Class A Preferred Stock) and the amount, if any, of other securities, cash or property which then would be received upon the conversion of Class A Preferred Stock.

3.7 Notice of Record Date. In the event, (a) the Corporation shall take a record of the holders of its Common Stock (or other capital stock or securities at the time issuable upon conversion of the Class A Preferred Stock) for the purpose of entitling or enabling them to receive any dividend or other distribution, or to receive any right to subscribe for or purchase any shares of capital stock of any class or any other securities, or to receive any other security; or (b) of any capital reorganization of the Corporation, any reclassification of the Common Stock, any voluntary or involuntary liquidation, dissolution or winding up of the Corporation, or any Deemed Liquidation Event (as defined in Subsection IV.3.8), then the Corporation will send or cause to be sent to the holders of the Class A Preferred Stock a notice specifying, as the case may be, (i) the record date for such dividend, distribution or right, and the amount and character of such dividend, distribution or right, or (ii) the effective date on which such reorganization, reclassification, liquidation, dissolution winding up or Deemed Liquidation Event is proposed to take place, and the time, if any is to be fixed, as of which the holders of record of Common Stock (or such other capital stock or securities at the time issuable upon the conversion of the Class A Preferred Stock) shall be entitled to exchange their shares of Common Stock (or such other capital stock or securities) for securities or other property deliverable upon such reorganization, reclassification, liquidation, dissolution, winding up or Deemed Liquidation Event, and the amount per share and character of such exchange applicable to the Class A Preferred Stock and the Common Stock (or such other capital stock or securities at the time issuable upon the conversion of the Class A Preferred Stock). Such notice shall be sent at least 15 days prior to the record date or effective date for the event specified in such notice.

3 . 8 Deemed Liquidation Events. Each of the following events shall be considered a ***"Deemed Liquidation Event"*** unless the holders of at least a majority of the outstanding shares of Class A Preferred Stock elect otherwise by written notice sent to the Corporation at least 5 days prior to the effective date of any such event:

(a) a merger or consolidation in which the Corporation is a constituent party or a subsidiary of the Corporation is a constituent party and the Corporation issues shares of its capital stock pursuant to such merger or consolidation, except any such merger or consolidation involving the Corporation or a subsidiary in which the shares of capital stock of the Corporation outstanding immediately prior to such merger or consolidation continue to represent, or are converted into or exchanged for shares of capital stock that represent, immediately following such merger or consolidation, at least a majority, by voting power, of the capital stock of (1) the surviving or resulting corporation; or (2) if the surviving or resulting corporation is a wholly owned subsidiary of another corporation immediately following such merger or consolidation, the parent corporation of such surviving or resulting corporation; or

(b) the sale, lease, transfer, exclusive license or other disposition, in a single transaction or series of related transactions, by the Corporation or any subsidiary of the Corporation of all or substantially all the assets of the Corporation and its subsidiaries taken as a whole or the sale or disposition (whether by merger, consolidation or otherwise) of one or more subsidiaries of the Corporation if substantially all of the assets of the Corporation and its subsidiaries taken as a whole are held by such subsidiary or subsidiaries, except where such sale, lease, transfer, exclusive license or other disposition is to a wholly owned subsidiary of the Corporation.

4. Waiver. Any of the rights, powers and other terms of the Class A Preferred Stock set forth herein may be waived on behalf of all holders of Class A Preferred Stock by the affirmative written consent or vote of the holders of at least seventy-five percent (75%) of the shares of Class A Preferred Stock then outstanding.

5. Notices. Any notice required or permitted by the provisions of this Article IV to be given to a holder of shares Class A Preferred Stock shall be mailed, postage prepaid, to the post office address last shown on the records of the Corporation, or given by electronic communication in compliance with the provisions of the DGCL, and shall be deemed sent upon such mailing or electronic transmission.

ARTICLE V

The number of directors of the Corporation shall be fixed from time to time as provided in the Bylaws,

ARTICLE VI

Unless and except that the Bylaws of the Corporation shall so require, the election of directors of the Corporation need not be by written ballot.

ARTICLE VII

In furtherance and not in limitation of the powers conferred by the laws of the State of Delaware, the Board of Directors of the Corporation is expressly authorized to make, alter and repeal the Bylaws of the Corporation, subject to the power of the stockholders of the Corporation to alter or repeal any bylaw whether adopted by them or otherwise.

ARTICLE VIII

To the fullest extent permitted by the DGCL as the same exists or as may hereafter be amended, no present or former director of the Corporation shall be personally liable to the Corporation or its stockholders for monetary damages for breach of fiduciary duty as a director. Neither any amendment nor repeal of this Article, nor the adoption of any provision of this Second Amended and Restated Certificate of Incorporation inconsistent with this Article, shall eliminate or reduce the effect of this Article in respect of any matter occurring, or any cause of action, suit or claim that, but for this Article, would accrue or arise, prior to such amendment, repeal or adoption of an inconsistent provision.

ARTICLE IX

The Corporation will indemnify any person who was or is a party or is threatened to be made a party to, or testifies in, any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative in nature, by reason of the fact such person is or was a director, officer or employee or agent of the Corporation, or is or was serving at the request of the Corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, employee benefit plan, trust or other enterprise, against expenses (including attorney's fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with such action, suit or proceeding to the full extent permitted by the DGCL, and the Corporation may adopt Bylaws or enter into agreements with any such person for the purpose of providing for such indemnification.

ARTICLE X

Subject to the provisions of this Second Amended and Restated Certificate of Incorporation, the Corporation reserves the right at any time, and from time to time, to amend, alter, change or repeal any provision contained in this Second Amended and Restated Certificate of Incorporation, and other provisions authorized by the DGCL and the laws of the State of Delaware at the time in force may be added or inserted, in the manner now or hereafter prescribed by law; and all rights, preferences and privileges of whatsoever nature conferred upon stockholders, directors or any other persons whomsoever by and pursuant to this Second Amended and Restated Certificate of Incorporation in its present form or as hereafter amended are granted subject to the rights reserved in this article.

ARTICLE XI

The Corporation is to have perpetual existence.

ARTICLE XII

Meetings of stockholders may be held within or without the State of Delaware, as the Bylaws may provide. The books of this Corporation may be kept (subject to any provision contained in the statutes) outside the State of Delaware at such place or places as may be designated from time to time by the Board of Directors or in the Bylaws of the Corporation.

ARTICLE XIII

The Corporation elects not to be governed by Section 203 of the DGCL. To the fullest extent permitted by section 122(17) of the DGCL, the Corporation, on behalf of itself and its subsidiaries, renounces any interest or expectancy of the Corporation and its subsidiaries in any Excluded Opportunity, or in being offered an opportunity to receive notice of or participate in any Excluded Opportunity, even if the opportunity is one that the Corporation or its subsidiaries might reasonably be deemed to have pursued or had the ability or desire to pursue if granted the opportunity to do so and no such individual, corporation, limited liability company, partnership, firm, joint venture, association, joint-stock company, trust, estate, unincorporated organization, governmental or regulatory body or other entity ***("Person")*** shall be liable to the Corporation or any of its subsidiaries for breach of any fiduciary or other duty, as a director or officer or otherwise, by reason of the fact that such Person pursues or acquires such Excluded Opportunity, directs such Excluded Opportunity to another Person or fails to present such Excluded Opportunity, or information regarding such Excluded Opportunity, to the Corporation or its subsidiaries. An ***"Excluded Opportunity"*** is any matter, transaction or interest that is presented to, or acquired, created or developed by, or which otherwise comes into the possession of, (i) any director of the Corporation who is not an employee of the Corporation or any of its subsidiaries, or (ii) any holder of Class A Preferred Stock or any affiliate, partner, member, director, stockholder, employee, agent or other related person of any such holder, other than someone who is an employee of the Corporation or any of its subsidiaries (collectively, ***"Covered Persons"),*** unless such matter, transaction or interest is presented to, or acquired, created or developed by, or otherwise comes into the possession of, a Covered Person expressly and solely in such Covered Person's capacity as a director of the Corporation. Any Person purchasing or otherwise acquiring any interest in any shares of stock of the Corporation shall be deemed to have notice of and consented to the provisions of this Article XIII. Neither the alteration, amendment or repeal of this Article XIII nor the adoption of any provision of this Second Amended and Restated Certificate of Incorporation inconsistent with this Article XIII shall eliminate or reduce the effect of this Article XIII in respect of any business opportunity first identified or any other matter occurring, or any cause of action, suit or claim that, but for this Article XIII, would accrue or arise, prior to such alteration, amendment, repeal or adoption.

3. That the foregoing amendment and restatement was approved by the holders of the requisite number of shares of this Corporation in accordance with Section 228 of the General Corporation Law.

4. That this Second Amended and Restated Certificate of Incorporation, which restates and integrates and further amends the provisions of this Corporation's Amended and Restated Certificate of Incorporation, has been duly adopted in accordance with Sections 242 and 245 of the General Corporation Law.

* * * *

IN WITNESS WHEREOF, the Corporation has caused this Second Amended and Restated Certificate of Incorporation to be signed by its President and Chief Executive Officer this 12th day of September, 2016.

AVENUE THERAPEUTICS, INC.

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

Exhibit 3.2

BYLAWS
OF
AVENUE THERAPEUTICS, INC.

I. CORPORATE OFFICES

1.1 Registered Office

The registered office of the corporation shall be in the City of Dover County of Kent, State of Delaware. The name of the registered agent of the corporation at such location is Incorporating Services, Ltd.

1.2 Other Offices

The board of directors may at any time establish other offices at any place or places where the corporation is qualified to do business.

II. MEETINGS OF STOCKHOLDERS

2.1 Place of Meetings

Meetings of stockholders shall be held at any place, within or outside the State of Delaware, designated by the board of directors. The board of directors may, in its sole discretion, determine that a meeting shall not be held at any place, but may instead be held solely by means of remote communication as authorized by Section 211 of the General Corporation Law of Delaware.

If authorized by the board of directors in its sole discretion, and subject to such guidelines and procedures as the board of directors may adopt, stockholders and proxyholders not physically present at a meeting of stockholders may, by means of remote communication, participate in a meeting of stockholders, be deemed present in person and vote at a meeting of stockholders whether such meeting is to be held at a designated place or solely by means of remote communication, provided that (i) the corporation shall implement reasonable measures to verify that each person deemed present and permitted to vote at the meeting by means of remote communication is a stockholder or proxyholder, (ii) the corporation shall implement reasonable measures to provide such stockholders and proxyholders a reasonable opportunity to participate in the meeting and to vote on matters submitted to the stockholders, including an opportunity to read or hear the proceedings of the meeting substantially concurrently with such proceedings, and (iii) if any stockholder or proxyholder votes or takes other action at the meeting by means of remote communication, a record of such vote or other action shall be maintained by the corporation.

2.2 Annual Meeting

The annual meeting of stockholders shall be held each year on a date and at a time designated by the board of directors. In the absence of such designation, the annual meeting of stockholders shall be held on the third Monday in April in each year at 1:00 p.m. However, if such day falls on a legal holiday, then the meeting shall be held at the same time and place on the next succeeding full business day. At the meeting, directors shall be elected and any other proper business may be transacted.

2.3 Special Meeting

Special meetings of the stockholders may be called, at any time for any purpose or purposes, by the board of directors or by such person or persons as may be authorized by the certificate of incorporation or these bylaws, or by such person or persons duly designated by the board of directors whose powers and authority, as expressly provided in a resolution of the board of directors, include the power to call such meetings, but such special meetings may not be called by any other person or persons.

2.4 Notice of Stockholders' Meetings

(a) Except to the extent otherwise required by law, all notices of meetings with stockholders shall be in writing and shall be sent or otherwise given in accordance with Section 2.5 of these bylaws not less than ten (10) nor more than sixty (60) days before the date of the meeting to each stockholder entitled to vote at such meeting. The notice shall specify the place, if any, date, and hour of the meeting, the means of remote communication, if any, by which stockholders and proxyholders may be deemed to be present in person and vote at such meeting, and, in the case of a special meeting, the purpose or purposes for which the meeting is called.

(b) Without limiting the manner by which notice otherwise may be given effectively to stockholders, any notice to stockholders given by the corporation shall also be effective if given by a form of electronic transmission consented to by the stockholder to whom the notice is given. Any such consent shall be revocable by the stockholder by written notice to the corporation. Any such consent shall be deemed revoked if (i) the corporation is unable to deliver by electronic transmission two consecutive notices given by the corporation in accordance with such consent, and (ii) such inability becomes known to the secretary or an assistant secretary of the corporation or to the transfer agent, or other person responsible for the giving of notice; provided, however, that the inadvertent failure to recognize such revocation shall not invalidate any meeting or other action.

(c) Without limiting the manner by which notice otherwise may be given effectively to stockholders, any notice to stockholders given by the corporation shall be effective if given by a single written notice to stockholders who share an address if consented to by the stockholders at that address to whom such notice is given. Any such consent shall be revocable by the stockholder by written notice to the corporation. Any stockholder who fails to object in writing to the corporation, within sixty (60) days of having been given written notice by the corporation of its intention to send the single notice permitted under this subsection 2.4(c), shall be deemed to have consented to receiving such single written notice.

(d) Sections 2.4(b) and (c) shall not apply to any notice given to stockholders under Sections 164 (notice of sale of shares of stockholder who failed to pay an installment or call on stock not fully paid), 296 (notice of disputed claims relating to insolvent corporations), 311 (notice of meeting of stockholders to revoke dissolution of corporation), 312 (notice of meeting of stockholders of corporation whose certificate of incorporation has been renewed or revived) and 324 (notice when stock has been attached as required for sale upon execution process) of the General Corporation Law of Delaware.

2.5 Manner of Giving Notice; Affidavit of Notice

(a) Written notice of any meeting of stockholders, if mailed, is given when deposited in the United States mail, postage prepaid, directed to the stockholder at his, her or its address as it appears on the records of the corporation. An affidavit of the secretary or an assistant secretary or of the transfer agent or other agent of the corporation that the notice has been given shall, in the absence of fraud, be prima facie evidence of the facts stated therein.

(b) Notice given pursuant to this Section 2.5(b) shall be deemed given: (i) if by facsimile telecommunication, when directed to a number at which the stockholder has consented to receive notice; (ii) if by electronic mail, when directed to an electronic mail address at which the stockholder has consented to receive notice; (iii) if by a posting on an electronic network together with separate notice to the stockholder of such specific posting, upon the later of such posting and the giving of such separate notice; and (iv) if by any other form of electronic transmission, when directed to the stockholder. An affidavit of the secretary, an assistant secretary or the transfer agent or other agent of the corporation that the notice has been given by a form of electronic transmission shall, in the absence of fraud, be prima facie evidence of the facts stated therein.

2.6 Quorum

The holders of a majority of the stock issued and outstanding and entitled to vote thereat, present in person or represented by proxy, shall constitute a quorum at all meetings of the stockholders for the transaction of business except as otherwise provided by statute or by the certificate of incorporation. If, however, such quorum is not present or represented at any meeting of the stockholders, then the stockholders entitled to vote thereat, present in person or represented by proxy, shall have power to adjourn the meeting from time to time, without notice other than announcement at the meeting, until a quorum is present or represented. At such adjourned meeting at which a quorum is present or represented, any business may be transacted that might have been transacted at the meeting as originally noticed.

2.7 Adjourned Meeting; Notice

When a meeting is adjourned to another time or place, unless these bylaws otherwise require, notice need not be given of the adjourned meeting if the time and place thereof, and the means of remote communication, if any, by which stockholders and proxyholders may be deemed to be present in person and vote at such meeting, are announced at the meeting at which the adjournment is taken. At the adjourned meeting the corporation may transact any business that might have been transacted at the original meeting. If the adjournment is for more than thirty (30) days, or if after the adjournment a new record date is fixed for the adjourned meeting, a notice of the adjourned meeting shall be given to each stockholder of record entitled to vote at the meeting.

2.8 Voting

The stockholders entitled to vote at any meeting of stockholders shall be determined in accordance with the provisions of Section 2.11 of these bylaws, subject to the provisions of Sections 217 and 218 of the General Corporation Law of Delaware (relating to voting rights of fiduciaries, pledgors and joint owners of stock and to voting trusts and other voting agreements).

Except as otherwise provided in the certificate of incorporation, each stockholder shall be entitled to one vote for each share of capital stock held by such stockholder.

2.9 Waiver of Notice

Whenever notice is required to be given under any provision of the General Corporation Law of Delaware or of the certificate of incorporation or these bylaws, a written waiver thereof, signed by the person entitled to notice, or a waiver by electronic transmission by the person entitled to notice, whether before or after the time stated therein, shall be deemed equivalent to notice. Attendance of a person at a meeting shall constitute a waiver of notice of such meeting, except when the person attends a meeting for the express purpose of objecting, at the beginning of the meeting, to the transaction of any business because the meeting is not lawfully called or convened. Neither the business to be transacted at, nor the purpose of, any regular or special meeting of the stockholders need be specified in any written waiver or any waiver by electronic transmission of notice unless so required by the certificate of incorporation or these bylaws.

2.10 Stockholder Action by Written Consent Without a Meeting

Unless otherwise provided in the certificate of incorporation, any action required by the General Corporation Law of Delaware to be taken at any annual or special meeting of stockholders of a corporation, or any action that may be taken at any annual or special meeting of such stockholders, may be taken without a meeting, without prior notice, and without a vote if a consent in writing, setting forth the action so taken, is signed by the holders of outstanding stock having not less than the minimum number of votes that would be necessary to authorize or take such action at a meeting at which all shares entitled to vote thereon were present and voted. A telegram, cablegram or other electronic transmission consenting to an action to be taken and transmitted by a stockholder, proxyholder or other person or persons authorized to act for a stockholder or proxyholder, shall be deemed to be written, signed and dated for the purposes of this Section 2.10, provided that any such telegram, cablegram or other electronic transmission sets forth or is delivered with information from which the corporation can determine (a) that the telegram, cablegram or other electronic transmission was transmitted by the stockholder, proxyholder or other authorized person or persons, and (b) the date on which such stockholder, proxyholder or other authorized person or persons transmitted such telegram, cablegram or electronic transmission. The date on which such telegram, cablegram or electronic transmission is transmitted shall be deemed to be the date on which such consent was signed. No consent given by telegram, cablegram or other electronic transmission shall be deemed to have been delivered until such consent is reproduced in paper form and until such paper form shall have been delivered to the corporation by delivery to its registered office in this State, its principal place of business or an officer or agent of the corporation having custody of the book in which proceedings of meetings of stockholders are recorded. Delivery made to the corporation's registered office shall be made by hand or by certified or registered mail, return receipt requested. Notwithstanding the foregoing limitations on delivery, consents given by telegram, cablegram or other electronic transmission may be otherwise delivered to the principal place of business of the corporation or to an officer or agent of the corporation having custody of the book in which proceedings of meetings of stockholders are recorded, to the extent and in the manner provided by resolution of the board of directors of the corporation. Any copy, facsimile or other reliable reproduction of a consent in writing may be substituted or used in lieu of the original writing for any and all purposes for which the original writing could be used, provided that such copy, facsimile or other reproduction shall be a complete reproduction of the entire original writing.

Prompt notice of the taking of the corporate action without a meeting by written consent shall be given to those stockholders who have not consented in writing. If the action that is consented to is such as would have required the filing of a certificate under any section of the General Corporation Law of Delaware if such action had been voted on by stockholders at a meeting thereof, then the certificate filed under such section shall state, in lieu of any statement required by such section concerning any vote of stockholders, that written notice and written consent have been given as provided in Section 228 of the General Corporation Law of Delaware.

2.11 Record Date for Stockholder Notice; Voting; Giving Consents

In order that the corporation may determine the stockholders entitled to notice of or to vote at any meeting of stockholders or any adjournment thereof, or entitled to express consent to corporate action in writing without a meeting, or entitled to receive payment of any dividend or other distribution or allotment of any rights, or entitled to exercise any rights in respect of any change, conversion or exchange of stock or for the purpose of any other lawful action, the board of directors may fix, in advance, a record date that shall not be more than sixty (60) nor less than ten (10) days before the date of such meeting, nor more than sixty (60) days prior to any other action.

If the board of directors does not so fix a record date:

(a) the record date for determining stockholders entitled to notice of or to vote at a meeting of stockholders shall be at the close of business on the day next preceding the day on which notice is given, or, if notice is waived, at the close of business on the day next preceding the day on which the meeting is held;

(b) the record date for determining stockholders entitled to express consent to corporate action in writing without a meeting, when no prior action by the board of directors is necessary, shall be the day on which the first written consent is expressed; and

(c) the record date for determining stockholders for any other purpose shall be at the close of business on the day on which the board of directors adopts the resolution relating thereto.

A determination of stockholders of record entitled to notice of or to vote at a meeting of stockholders shall apply to any adjournment of the meeting~~;~~provided, however, that the board of directors may fix a new record date for the adjourned meeting.

2.12 Proxies

Each stockholder entitled to vote at a meeting of stockholders or to express consent or dissent to corporate action in writing without a meeting may authorize another person or persons to act for him by a written proxy, signed by the stockholder and filed with the secretary of the corporation, but no such proxy shall be voted or acted upon after three (3) years from its date, unless the proxy provides for a longer period. A proxy shall be deemed signed if the stockholder's name is placed on the proxy (whether by manual signature, typewriting, telegraphic transmission or otherwise) by the stockholder or the stockholder's attorney-in-fact. The revocability of a proxy that states on its face that it is irrevocable shall be governed by the provisions of Section 212(e) of the General Corporation Law of Delaware.

2.13 List of Stockholders Entitled to Vote

The officer who has charge of the stock ledger of a corporation shall prepare and make, at least ten (10) days before every meeting of stockholders, a complete list of the stockholders entitled to vote at the meeting, arranged in alphabetical order, and showing the address of each stockholder and the number of shares registered in the name of each stockholder. The corporation shall not be required to include electronic mail addresses or other electronic contact information on such list. Such list shall be open to the examination of any stockholder for any purpose germane to the meeting for a period of at least ten (10) days prior to the meeting: (a) on a reasonably accessible electronic network, provided that the information required to gain access to such list is provided with the notice of the meeting, or (b) during ordinary business hours, at the principal place of business of the corporation. In the event that the corporation determines to make the list available on an electronic network, the corporation may take reasonable steps to ensure that such information is available only to stockholders of the corporation. If the meeting is to be held at a place, then the list shall be produced and kept at the time and place of the meeting during the whole time thereof, and may be examined by any stockholder who is present. If the meeting is to be held solely by means of remote communication, then the list shall also be open to the examination of any stockholder during the whole time of the meeting on a reasonably accessible electronic network, and the information required to access such list shall be provided with the notice of the meeting.

2.14 Stockholder Proposals

Effective upon the corporation's initial public offering of stock under the Securities Act of 1933, as amended, any stockholder wishing to bring any other business before a meeting of stockholders, including, but not limited to, the nomination of persons for election as directors, must provide notice to the corporation not more than ninety (90) and not less than fifty (50) days before the meeting in writing by registered mail, return receipt requested, of the business to be presented by the stockholders at the stockholders' meeting. Any such notice shall set forth the following as to each matter the stockholder proposes to bring before the meeting: (a) a brief description of the business desired to be brought before the meeting and the reasons for conducting such business at the meeting and, if such business includes a proposal to amend the bylaws of the corporation, the language of the proposed amendment; (b) the name and address, as they appear on the corporation's books, of the stockholder proposing such business; (c) the class and number of shares of the corporation that are beneficially owned by such stockholder; (d) a representation that the stockholder is a holder of record of stock of the corporation entitled to vote at such meeting and intends to appear in person or by proxy at the meeting to propose such business; and (e) any material interest of the stockholder in such business. Notwithstanding the foregoing provisions of this Section 2.14, a stockholder shall also comply with all applicable requirements of all applicable laws, rules and regulations, including, but not limited to, the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder, with respect to the matters set forth in this Section 2.14. In the absence of such notice to the corporation meeting the above requirements, a stockholder shall not be entitled to present any business at any meeting of stockholders.

III. DIRECTORS

3.1 Powers

Subject to the provisions of the General Corporation Law of Delaware and any limitations in the certificate of incorporation or these bylaws relating to action required to be approved by the stockholders or by the outstanding shares, the business and affairs of the corporation shall be managed and all corporate powers shall be exercised by or under the direction of the board of directors.

3.2 Number of Directors

The number of directors constituting the board of directors shall be not more than nine (9) but not less than one (1), and may be fixed or changed, within this minimum and maximum, by the stockholders or the board of directors. The number of directors constituting the initial board of directors shall be fixed at one (1).

No reduction of the authorized number of directors shall have the effect of removing any director before that director's term of office expires.

3.3 Election, Qualification and Term of Office of Directors

Except as provided in Sections 3.4 and 3.18 of these bylaws, directors shall be elected at each annual meeting of stockholders to hold office until the next annual meeting. Directors need not be stockholders unless so required by the certificate of incorporation or these bylaws, wherein other qualifications for directors may be prescribed. Each director, including a director elected to fill a vacancy, shall hold office until his or her successor is elected and qualified or until his or her earlier resignation or removal. Each director shall be a natural person.

Elections of directors need not be by written ballot.

3.4 Resignation and Vacancies

Any director may resign at any time upon notice given in writing or electronic transmission to the corporation. When one or more directors so resigns and the resignation is effective at a future date, a majority of the directors then in office, including those who have so resigned, shall have the power to fill such vacancy or vacancies, the vote thereon to take effect when such resignation or resignations shall become effective, and each director so chosen shall hold office as provided in this Section 3.4 in the filling of other vacancies.

Unless otherwise provided in the certificate of incorporation or these bylaws:

(a) vacancies and newly created directorships resulting from any increase in the authorized number of directors elected by all of the stockholders having the right to vote as a single class may be filled by a majority of the directors then in office, although less than a quorum, or by a sole remaining director; and

(b) whenever the holders of any class or classes of stock or series thereof are entitled to elect one or more directors by the provisions of the certificate of incorporation, vacancies and newly created directorships of such class or classes or series may be filled by a majority of the directors elected by such class or classes or series thereof then in office, or by a sole remaining director so elected.

If at any time, by reason of death or resignation or other cause, the corporation should have no directors in office, then any officer or any stockholder or an executor, administrator, trustee or guardian of a stockholder, or other fiduciary entrusted with like responsibility for the person or estate of a stockholder, may call a special meeting of stockholders in accordance with the provisions of the certificate of incorporation or these bylaws, or may apply to the Court of Chancery for a decree summarily ordering an election as provided in Section 211 of the General Corporation Law of Delaware.

If, at the time of filling any vacancy or any newly created directorship, the directors then in office constitute less than a majority of the whole board (as constituted immediately prior to any such increase), then the Court of Chancery may, upon application of any stockholder or stockholders holding at least ten percent (10%)of the total number of the shares at the time outstanding having the right to vote for such directors, summarily order an election to be held to fill any such vacancies or newly created directorships, or to replace the directors chosen by the directors then in office as aforesaid, which election shall be governed by the provisions of Section 211 of the General Corporation Law of Delaware as far as applicable.

3.5 Place of Meetings; Meetings by Telephone

The board of directors of the corporation may hold meetings, both regular and special, either within or outside the State of Delaware.

Unless otherwise restricted by the certificate of incorporation or these bylaws, members of the board of directors, or any committee designated by the board of directors, may participate in a meeting of the board of directors, or any committee, by means of conference telephone or other communications equipment by means of which all persons participating in the meeting can hear each other, and such participation in a meeting shall constitute presence in person at the meeting.

3.6 First Meetings

The first meeting of each newly elected board of directors shall be held at such time and place as shall be fixed by the vote of the stockholders at the annual meeting and no notice of such meeting shall be necessary to the newly elected directors in order legally to constitute the meeting, provided a quorum shall be present. In the event of the failure of the stockholders to fix the time or place of such first meeting of the newly elected board of directors, or in the event such meeting is not held at the time and place so fixed by the stockholders, the meeting may be held at such time and place as shall be specified in a notice given as hereinafter provided for special meetings of the board of directors, or as shall be specified in a written waiver signed by all of the directors.

3.7 Regular Meetings

Regular meetings of the board of directors may be held without notice at such time and at such place as shall from time to time be determined by the board of directors.

3.8 Special Meetings; Notice

Special meetings of the board of directors for any purpose or purposes may be called at any time by the chairman of the board of directors, the president, any vice president, the secretary or any director.

Notice of the time and place of special meetings shall be delivered either personally or by mail, telex, facsimile, telephone or electronic transmission to each director, addressed to each director at such director's address and/or phone number and/or electronic transmission address as it is shown on the records of the corporation. If the notice is mailed, it shall be deposited in the United States mail at least four (4) days before the time of the holding of the meeting. If the notice is delivered personally or by telex, facsimile, telephone or electronic transmission, it shall be delivered by telephone or transmitted at least forty-eight (48) hours before the time of the holding of the meeting. Any oral notice given personally or by telephone may be communicated either to the director or to a person at the office of the director who the person giving the notice has reason to believe will promptly communicate it to the director. The notice need not specify the purpose or the place of the meeting, if the meeting is to be held at the principal executive office of the corporation. Notice may be delivered by any person entitled to call a special meeting or by an agent of such person.

3.9 Quorum

At all meetings of the board of directors, a majority of the authorized number of directors shall constitute a quorum for the transaction of business and the act of a majority of the directors present at any meeting at which there is a quorum shall be the act of the board of directors, except as otherwise specifically provided by statute or by the certificate of incorporation. If a quorum is not present at any meeting of the board of directors, then the directors present thereat may adjourn the meeting from time to time, without notice other than announcement at the meeting, until a quorum is present.

3.10 Waiver Of Notice

Whenever notice is required to be given under any provision of the General Corporation Law of Delaware or of the certificate of incorporation or these bylaws, a written waiver thereof, signed by the person entitled to notice, or a waiver by electronic transmission by the person entitled to notice, whether before or after the time stated therein, shall be deemed equivalent to notice. Attendance of a person at a meeting shall constitute a waiver of notice of such meeting, except when the person attends a meeting for the express purpose of objecting, at the beginning of the meeting, to the transaction of any business because the meeting is not lawfully called or convened. Neither the business to be transacted at, nor the purpose of, any regular or special meeting of the directors, or meeting of a committee of directors, need be specified in any written waiver of notice unless so required by the certificate of incorporation or these bylaws.

3.11 Adjourned Meeting; Notice

If a quorum is not present at any meeting of the board of directors, then the directors present thereat may adjourn the meeting from time to time, without notice other than announcement at the meeting, until a quorum is present.

3.12 Board Action by Written Consent Without a Meeting

Unless otherwise restricted by the certificate of incorporation or these bylaws, any action required or permitted to be taken at any meeting of the board of directors, or of any committee thereof, may be taken without a meeting if all members of the board of directors or committee, as the case may be, consent thereto in writing or by electronic transmission and the writing or writings or electronic transmission or transmissions are filed with the minutes of proceedings of the board of directors or committee. Such filing shall be in paper form if the minutes are maintained in paper form and shall be in electronic form if the minutes are maintained in electronic form.

3.13 Fees and Compensation of Directors

Unless otherwise restricted by the certificate of incorporation or these bylaws, the board of directors shall have the authority to fix the compensation of directors.

3.14 Approval of Loans to Officers

Subject to compliance with applicable law, including without limitation any federal or state securities laws, the corporation may lend money to, or guarantee any obligation of, or otherwise assist any officer or other employee of the corporation or of its subsidiary, including any officer or employee who is a director of the corporation or its subsidiary, whenever, in the judgment of the directors, such loan, guaranty or assistance may reasonably be expected to benefit the corporation. The loan, guaranty or other assistance may be with or without interest and may be unsecured, or secured in such manner as the board of directors shall approve, including, without limitation, a pledge of shares of stock of the corporation. Nothing contained in this Section 3.14 shall be deemed to deny, limit or restrict the powers of guaranty or warranty of the corporation at common law or under any statute.

3.15 Removal of Directors

Unless otherwise restricted by statute, by the certificate of incorporation or by these bylaws, any director or the entire board of directors may be removed, with or without cause, by the holders of a majority of the shares then entitled to vote at an election of directors; provided, that, whenever the holders of any class or classes of stock, or series thereof, are entitled to elect one or more directors by the provisions of the certificate of incorporation, removal of any directors elected by such class or classes of stock, or series thereof, shall be by the holders of a majority of the shares of such class or classes of stock, or series of stock, then entitled to vote at an election of directors.

No reduction of the authorized number of directors shall have the effect of removing any director prior to the expiration of such director's term of office.

3.16 Chairman of the Board of Directors

The corporation may also have, at the discretion of the board of directors, a chairman of the board of directors. The chairman of the board of directors shall, if such a person is elected, preside at the meetings of the board of directors and exercise and perform such other powers and duties as may from time to time be assigned to him or her by the board of directors, or as may be prescribed by these bylaws.

IV. COMMITTEES

4.1 Committees of Directors

The board of directors may, by resolution passed by a majority of the whole board of directors, designate one or more committees, with each committee to consist of one or more of the directors of the corporation. The board of directors may designate one or more directors as alternate members of any committee, who may replace any absent or disqualified member at any meeting of the committee. In the absence or disqualification of a member of a committee, the member or members thereof present at any meeting and not disqualified from voting, whether or not he or they constitute a quorum, may unanimously appoint another member of the board of directors to act at the meeting in the place of any such absent or disqualified member. Any such committee, to the extent provided in the resolution of the board of directors or in the bylaws of the corporation, shall have and may exercise all the powers and authority of the board of directors in the management of the business and affairs of the corporation, and may authorize the seal of the corporation to be affixed to all papers that may require it; but no such committee shall have the power or authority to (i) approve or adopt, or recommend to the stockholders, any action or matter expressly required by the General Corporation Law of Delaware to be submitted to stockholders for approval, or (ii) adopt, amend or repeal any bylaws of the corporation.

4.2 Committee Minutes

Each committee shall keep regular minutes of its meetings and report the same to the board of directors when required.

4.3 Meetings and Action of Committees

Meetings and actions of committees shall be governed by, and be held and taken in accordance with, the provisions of Article III of these bylaws, Section 3.5 (place of meetings and meetings by telephone), Section 3.7 (regular meetings), Section 3.8 (special meetings and notice), Section 3.9 (quorum), Section 3.10 (waiver of notice), Section 3.11 (adjourned meeting and notice), and Section 3.12 (board action by written consent without a meeting), with such changes in the context of those bylaws as are necessary to substitute the committee and its members for the board of directors and its members; provided, however, that the time of regular meetings of committees may also be called by resolution of the board of directors and that notice of special meetings of committees shall also be given to all alternate members, who shall have the right to attend all meetings of the committee. The board of directors may adopt rules for the government of any committee not inconsistent with the provisions of these bylaws.

V. OFFICERS

5.1 Officers

The officers of the corporation shall be a chief executive officer, a president, one or more vice presidents, a secretary and a treasurer. The corporation may also have, at the discretion of the board of directors, a chairman of the board, one or more assistant vice presidents, assistant secretaries, assistant treasurers and any such other officers as may be appointed in accordance with the provisions of Section 5.3 of these bylaws. Any number of offices may be held by the same person.

5.2 Election of Officers

The officers of the corporation, except such officers as may be appointed in accordance with the provisions of Sections 5.3 of these bylaws, shall be chosen by the board of directors, subject to the rights, if any, of an officer under any contract of employment.

5.3 Subordinate Officers

The board of directors may appoint, or empower the president to appoint, such other officers and agents as the business of the corporation may require, each of whom shall hold office for such period, have such authority and perform such duties as are provided in these bylaws or as the board of directors may from time to time determine.

5.4 Removal and Resignation of Officers

Subject to the rights, if any, of an officer under any contract of employment, any officer may be removed, either with or without cause, by an affirmative vote of the majority of the board of directors at any regular or special meeting of the board of directors or by any officer upon whom such power of removal may be conferred by the board of directors.

Any officer may resign at any time by giving written notice to the corporation. Any resignation shall take effect at the date of the receipt of that notice or at any later time specified in that notice; and, unless otherwise specified in that notice, the acceptance of the resignation shall not be necessary to make it effective. Any resignation is without prejudice to the rights, if any, of the corporation under any contract to which the officer is a party.

5.5 Vacancies in Offices

Any vacancy occurring in any office of the corporation shall be filled by the board of directors.

5.6 Chairman of the Board

The chairman of the board, if such an officer be elected, shall, if present, preside at meetings of the board of directors and exercise and perform such other powers and duties as may from time to time be assigned to him by the board of directors or as may be prescribed by these bylaws. If there is no chief executive officer, then the chairman of the board shall also be the chief executive officer of the corporation and shall have the powers and duties prescribed in Section 5.7 of these bylaws. The chairman of the board shall be chosen by the board of directors.

5.7 Chief Executive Officer

Subject to such supervisory powers, if any, as may be given by the board of directors to the chairman of the board, the chief executive officer of the corporation shall, subject to the control of the board of directors, have general supervision, direction and control of the business and the officers of the corporation. The chief executive officer shall preside at all meetings of the stockholders and, in the absence or nonexistence of a chairman of the board, at all meetings of the board of directors at which he or she is present. The chief executive officer shall have the general powers and duties of management usually vested in the office of chief executive officer of a corporation and shall have such other powers and duties as may be prescribed by the board of directors or these bylaws.

5.8 President

Subject to such supervisory powers, if any, as may be given by the board of directors to the chairman of the board or the chief executive officer, if there be such officers, the president shall, subject to the control of the board of directors, have general supervision, direction and control of the business and the officers of the corporation. In the absence or nonexistence of the chief executive officer, he or she shall preside at all meetings of the stockholders and, in the absence or nonexistence of a chairman of the board and chief executive officer, at all meetings of the board of directors at which he or she is present. He or she shall have the general powers and duties of management usually vested in the office of president of a corporation and shall have such other powers and duties as may be prescribed by the board of directors or these bylaws. The board of directors may provide in their discretion that the offices of president and chief executive officer may be held by the same person.

5.9 Vice Presidents

In the absence or disability of the chief executive officer and president, the vice presidents, if any, in order of their rank as fixed by the board of directors or, if not ranked, a vice president designated by the board of directors, shall perform all the duties of the president and when so acting shall have all the powers of, and be subject to all the restrictions upon, the president. The vice presidents shall have such other powers and perform such other duties as from time to time may be prescribed for them by the board of directors, these bylaws, the president or the chairman of the board.

5.10 Secretary

The secretary or an agent of the corporation shall keep or cause to be kept, at the principal executive office of the corporation or such other place as the board of directors may direct, a book of minutes of all meetings and actions of directors, committees of directors and stockholders. The minutes shall show the time and place of each meeting, whether regular or special (and, if special, how authorized and the notice given), the names of those present at directors' meetings or committee meetings, the number of shares present or represented at stockholders' meetings and the proceedings thereof.

The secretary shall keep, or cause to be kept, at the principal executive office of the corporation or at the office of the corporation's transfer agent or registrar, as determined by resolution of the board of directors, a share register, or a duplicate share register, showing the names of all stockholders and their addresses, the number and classes of shares held by each, the number and date of certificates evidencing such shares, and the number and date of cancellation of every certificate surrendered for cancellation.

The secretary shall give, or cause to be given, notice of all meetings of the stockholders and of the board of directors required to be given by law or by these bylaws. The secretary shall keep the seal of the corporation, if one be adopted, in safe custody and shall have such other powers and perform such other duties as may be prescribed by the board of directors or by these bylaws.

5.11 Treasurer

The treasurer shall keep and maintain, or cause to be kept and maintained, adequate and correct books and records of accounts of the properties and business transactions of the corporation, including accounts of its assets, liabilities, receipts, disbursements, gains, losses, capital, retained earnings and shares. The books of account shall at all reasonable times be open to inspection by any director.

The treasurer shall deposit all money and other valuables in the name and to the credit of the corporation with such depositaries as may be designated by the board of directors. The treasurer shall disburse the funds of the corporation as may be ordered by the board of directors, shall render to the president and directors, whenever they request it, an account of all of his or her transactions as treasurer and of the financial condition of the corporation, and shall have such other powers and perform such other duties as may be prescribed by the board of directors or these bylaws.

5.12 Assistant Secretary

The assistant secretary, or, if there is more than one, the assistant secretaries in the order determined by the stockholders or board of directors (or if there be no such determination, then in the order of their election) shall, in the absence of the secretary or in the event of his or her inability or refusal to act, perform the duties and exercise the powers of the secretary and shall perform such other duties and have such other powers as the board of directors or the stockholders may from time to time prescribe.

5.13 Representation of Shares of Other Corporations

The chairman of the board, the chief executive officer, the president, any vice president, the treasurer, the secretary or assistant secretary of this corporation, or any other person authorized by the board of directors or the chief executive officer, president or a vice president, is authorized to vote, represent, and exercise on behalf of this corporation all rights incident to any and all shares of any other corporation or corporations standing in the name of this corporation. The authority granted herein may be exercised either by such person directly or by any other person authorized to do so by proxy or power of attorney duly executed by such person having the authority.

5.14 Authority and Duties of Officers

In addition to the foregoing authority and duties, all officers of the corporation shall respectively have such authority and perform such duties in the management of the business of the corporation as may be designated from time to time by the board of directors or the stockholders.

VI. INDEMNITY

6.1 Indemnification of Directors and Officers

The corporation shall, to the maximum extent and in the manner permitted by the General Corporation Law of Delaware, indemnify each of its directors and Officers against expenses (including attorneys' fees), judgments, fines, settlements, and other amounts actually and reasonably incurred in connection with any proceeding, arising by reason of the fact that such person is or was an agent of the corporation. For purposes of this Section 6.1, a director or Officer of the corporation includes any person (a) who is or was a director or Officer of the corporation, (b) who is or was serving at the request of the corporation as a director, Officer manager, member, partner, trustee, or other agent of another corporation, limited liability company, partnership, joint venture, trust or other enterprise, or (c) who was a director or Officer of a corporation that was a predecessor corporation of the corporation or of another enterprise at the request of such predecessor corporation. Such indemnification shall be a contract right and shall include the right to receive payment of any expenses incurred by the indemnitee in connection with any proceeding in advance of its final disposition, consistent with the provisions of applicable law as then in effect. The right of indemnification provided in this Section 6.1 shall not be exclusive of any other rights to which those seeking indemnification may otherwise be entitled, and the provisions of this Section 6.1 shall inure to the benefit of the heirs and legal representatives of any person entitled to indemnity under this Section 6.1 and shall be applicable to proceedings commenced or continuing after the adoption of this Section 6.1, whether arising from acts or omissions occurring before or after such adoption. In furtherance, but not in limitation of the foregoing provisions, the following procedures, presumptions and remedies shall apply with respect to advancement of expenses and the right to indemnification under this Section 6.1.

(a) Advancement of Expenses. All reasonable expenses incurred by or on behalf of the indemnitee in connection with any proceeding shall be advanced to the indemnitee by the corporation within twenty (20) days after the receipt by the corporation of a statement or statements from the indemnitee requesting such advance or advances from time to time, whether prior to or after final disposition of such proceeding, unless, prior to the expiration of such twenty-day period, the board of directors shall unanimously (except for the vote, if applicable, of the indemnitee) determine that the indemnitee has no reasonable likelihood of being entitled to indemnification pursuant to this Section 6.1. Such statement or statements shall reasonably evidence the expenses incurred by the indemnitee and, if required by law at the time of such advance, shall include or be accompanied by an undertaking by or on behalf of the indemnitee to repay the amounts advanced if it should ultimately be determined that the indemnitee is not entitled to be indemnified against such expenses pursuant to this Section 6.1.

(b) Procedure for Determination of Entitlement to Indemnification.

(i) To obtain indemnification under this Section 6.1, an indemnitee shall submit to the secretary of the corporation a written request, including such documentation and information as is reasonably available to the indemnitee and reasonably necessary to determine whether and to what extent the indemnitee is entitled to indemnification (the "Supporting Documentation"). The determination of the indemnitee's entitlement to indemnification shall be made not later than sixty (60) days after receipt by the corporation of the written request for indemnification together with the Supporting Documentation. The secretary of the corporation shall, promptly upon receipt of such a request for indemnification, advise the board of directors in writing that the indemnitee has requested indemnification, whereupon the corporation shall provide such indemnification, including without limitation advancement of expenses, so long as the indemnitee is legally entitled thereto in accordance with applicable law.

(ii) The indemnitee's entitlement to indemnification under this Section 6.1 shall be determined in one of the following ways: (A) by a majority vote of the Disinterested Directors (as hereinafter defined), even though less than a quorum of the board of directors; (B) by a committee of such Disinterested Directors, even though less than a quorum of the board of directors; (C) by a written opinion of Independent Counsel (as hereinafter defined) if (x) a Change of Control (as hereinafter defined) shall have occurred and the indemnitee so requests or (y) a quorum of the board of directors consisting of Disinterested Directors is not obtainable or, even if obtainable, a majority of such Disinterested Directors so directs; (D) by the stockholders of the corporation (but only if a majority of the Disinterested Directors, if they constitute a quorum of the board of directors, presents the issue of entitlement to indemnification to the stockholders for their determination); or (E) as provided in paragraph (c) below.

(iii) In the event the determination of entitlement to indemnification is to be made by Independent Counsel pursuant to paragraph (b)(ii) above, a majority of the Disinterested Directors shall select the Independent Counsel, but only an Independent Counsel to which the indemnitee does not reasonably object; provided, however, that if a Change of Control shall have occurred, the indemnitee shall select such Independent Counsel, but only an Independent Counsel to which the board of directors does not reasonably object.

(iv) The only basis upon which a finding that indemnification may not be made is that such indemnification is prohibited by law.

(c) Presumptions and Effect of Certain Proceedings. Except as otherwise expressly provided in this Section 6.1, if a Change of Control shall have occurred, the indemnitee shall be presumed to be entitled to indemnification under this Section 6.1 upon submission of a request for Indemnification together with the Supporting Documentation in accordance with paragraph (b)(i), and thereafter the corporation shall have the burden of proof to overcome that presumption in reaching a contrary determination. In any event, if the person or persons empowered under paragraph (b)(ii) above to determine entitlement to indemnification shall not have been appointed or shall not have made a determination within sixty (60) days after receipt by the corporation of the request therefor together with the Supporting Documentation, the indemnitee shall be deemed to be entitled to indemnification and the indemnitee shall be entitled to such indemnification unless (A) the indemnitee misrepresented or failed to disclose a material fact in making the request for indemnification or in the Supporting Documentation or (B) such indemnification is prohibited by law. The termination of any proceeding described in this Section 6.1, or of any claim, issue or matter therein, by judgment, order, settlement or conviction, or upon a plea of *nolo contendere* or its equivalent, shall not, of itself, adversely affect the right of the indemnitee to indemnification or create a presumption that the indemnitee did not act in good faith and in a manner that the indemnitee reasonably believed to be in or not opposed to the best interests of the corporation or, with respect to any criminal proceeding, that the indemnitee had reasonable cause to believe that the indemnitee's conduct was unlawful.

(d) Remedies of Indemnitee.

(i) In the event that a determination is made pursuant to paragraph (b)(ii) that the indemnitee is not entitled to indemnification under this Section 6.1: (A) the indemnitee shall be entitled to seek an adjudication of his or her entitlement to such indemnification either, at the indemnitee's sole option, in (x) an appropriate court of the State of Delaware or any other court of competent jurisdiction, or (y) an arbitration to be conducted by a single arbitrator pursuant to the rules of the American Arbitration Association; (B) any such judicial proceeding or arbitration shall be *de novo* and the indemnitee shall not be prejudiced by reason of such adverse determination; and (C) in any such judicial proceeding or arbitration the corporation shall have the burden of proving that the indemnitee is not entitled to indemnification under this Section 6.1.

(ii) If a determination shall have been made or is deemed to have been made, pursuant to paragraph (b)(ii) or (iii), that the indemnitee is entitled to indemnification, the corporation shall be obligated to pay the amounts constituting such indemnification within five (5) days after such determination has been made or is deemed to have been made and shall be conclusively bound by such determination unless (A) the indemnitee misrepresented or failed to disclose a material fact in making the request for indemnification or in the Supporting Documentation, or (B) such indemnification is prohibited by law. In the event that: (X) advancement of expenses is not timely made pursuant to paragraph (a); or (Y) payment of indemnification is not made within five (5) days after a determination of entitlement to indemnification has been made or deemed to have been made pursuant to paragraph (b)(ii) or (iii), the indemnitee shall be entitled to seek judicial enforcement of the corporation's obligation to pay to the indemnitee such advancement of expenses or indemnification. Notwithstanding the foregoing, the corporation may bring an action, in an appropriate court in the State of Delaware or any other court of competent jurisdiction, contesting the right of the indemnitee to receive indemnification hereunder due to the occurrence of an event described in subclause (A) or (B) of this clause (ii) (a “Disqualifying Event”); provided, however, that in any such action the corporation shall have the burden of proving the occurrence of such Disqualifying Event.

(iii) The corporation shall be precluded from asserting in any judicial proceedings or arbitration commenced pursuant to this paragraph (d) that the procedures and presumptions of this Section 6.1 are not valid, binding and enforceable and shall stipulate in any such court or before any such arbitrator that the corporation is bound by all the provisions of this Section 6.1.

(iv) In the event that the indemnitee, pursuant to this paragraph (d), seeks a judicial adjudication of or an award in arbitration to enforce his or her rights under, or to recover damages for breach of, this Section 6.1, the indemnitee shall be entitled to recover from the corporation, and shall be indemnified by the corporation against, any expenses actually and reasonably incurred by the indemnitee if the indemnitee prevails in such judicial adjudication or arbitration. If it shall be determined in such judicial adjudication or arbitration that the indemnitee is entitled to receive part but not all of the indemnification or advancement of expenses sought, the expenses incurred by the indemnitee in connection with such judicial adjudication shall be prorated accordingly.

(e) Definitions. For purposes of this Section 6.1:

(i) "Change in Control" means a change in control of the corporation of a nature that would be required to be reported in response to Item 6(e) of Schedule 14A of Regulation 14A promulgated under the Securities Exchange Act of 1934, as amended (the "Act"), whether or not the corporation is then subject to such reporting requirement; provided that, without limitation, such a change in control shall be deemed to have occurred if (i) any "person" (as such term is used in Sections 13(d) and 14(d) of the Act) is or becomes the "beneficial owner" (as defined in Rule l3d-3 under the Act), directly or indirectly, of securities of the corporation representing twenty-five percent (25%) or more of the combined voting power of the corporation's then outstanding securities without the prior approval of at least a majority of the members of the board of directors in office immediately prior to such acquisition; (ii) the corporation is a party to a merger, consolidation, sale of assets or other reorganization, or a proxy contest, as a consequence of which members of the board of directors in office immediately prior to such transaction or event constitute less than a majority of the board of directors thereafter; or (iii) during any period of two (2) consecutive years, individuals who at the beginning of such period constituted the board of directors (including for this purpose any new director whose election or nomination for election by the corporation's stockholders was approved by a vote of at least a majority of the directors then still in office who were directors at the beginning of such period) cease for any reason to constitute at least a majority of the board of directors;

(ii) "Disinterested Director" means a director of the corporation who is not a party to the proceeding in respect of which indemnification is sought by the indemnitee; and

(iii) "Independent Counsel" means a law firm or a member of a law firm that neither presently is, nor in the past five (5) years has been, retained to represent: (A) the corporation or the indemnitee in any matter material to either such party or (B) any other party to the proceeding giving rise to a claim for indemnification under this Section 6.1. Notwithstanding the foregoing, the term "Independent Counsel" shall not include any person who, under the applicable standards of professional conduct then prevailing under such persons, relevant jurisdiction of practice, would have a conflict of interest in representing either the corporation or the indemnitee in an action to determine the indemnitee's rights under this Section 6.1.

(f) Invalidity; Severability; Interpretation. If any provision or provisions of this Section 6.1 shall be held to be invalid, illegal or unenforceable for any reason whatsoever: (i) the validity, legality and enforceability of the remaining provisions of this Section 6.1 (including, without limitation, all portions of any paragraph of this Section 6.1 containing any such provision held to be invalid, illegal or unenforceable, that are not themselves invalid, illegal or unenforceable) shall not in any way be affected or impaired thereby; and (ii) to the fullest extent possible, the provisions of this Section 6.1 (including, without limitation, all portions of any paragraph of this Section 6.1 containing any such provision held to be invalid, illegal or unenforceable, that are not themselves invalid; illegal or unenforceable) shall be construed so as to give effect to the intent manifested by the provision held invalid, illegal or unenforceable. Reference herein to laws, regulations or agencies shall be deemed to include all amendments thereof, substitutions therefor and successors thereto.

6.2 Indemnification of Others

The corporation shall have the power, to the extent and in the manner permitted by the General Corporation Law of Delaware, to indemnify each of its officers, employees and agents (other than directors) against expenses (including attorneys' fees), judgments, fines, settlements, and other amounts actually and reasonably incurred in connection with any proceeding, arising by reason of the fact that such person is or was an agent of the corporation. For purposes of this Section 6.2, an officer, employee or agent of the corporation (other than a director) includes any person (a) who is or was an employee or agent of the corporation, (b) who is or was serving at the request of the corporation as a director, officer, manager, member, partner, trustee, employee or other agent of another corporation, limited liability company, partnership, joint venture, trust or other enterprise, or (c) who was an employee or agent of a corporation that was a predecessor corporation of the corporation or of another enterprise at the request of such predecessor corporation.

6.3 Insurance

The corporation may purchase and maintain insurance on behalf of any person who is or was a director, officer, manager, member, partner, trustee, employee or other agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, limited liability company, partnership, joint venture, trust or other enterprise against any liability asserted against him and incurred by him in any such capacity, or arising out of his or her status as such, whether or not the corporation would have the power to indemnify him against such liability under the provisions of the General Corporation Law of Delaware.

VII. RECORDS AND REPORTS

7.1 Maintenance and Inspection of Records

The corporation shall, either at its principal executive office or at such place or places as designated by the board of directors, keep a record of its stockholders listing their names and addresses and the number and class of shares held by each stockholder, a copy of these bylaws as amended to date, accounting books and other records.

Any stockholder of record, in person or by attorney or other agent, shall, upon written demand under oath stating the purpose thereof, have the right during the usual hours for business to inspect for any proper purpose the corporation's stock ledger, a list of its stockholders and its other books and records and to make copies or extracts therefrom. A proper purpose shall mean a purpose reasonably related to such person's interest as a stockholder. In every instance where an attorney or other agent is the person who seeks the right to inspection, the demand under oath shall be accompanied by a power of attorney or such other writing that authorizes the attorney or other agent to so act on behalf of the stockholder. The demand under oath shall be directed to the corporation at its registered office in Delaware or at its principal place of business.

Any records maintained by a corporation in the regular course of its business, including its stock ledger, books of account and minute books, may be kept on, or by means of, or be in the form of, any information storage device or method, provided that the records so kept can be converted into clearly legible paper form within a reasonable time. Any corporation shall so convert any records so kept upon the request of any person entitled to inspect such records pursuant to any provision of the certificate of incorporation, these bylaws or the General Corporation Law of Delaware. When records are kept in such manner, a clearly legible paper from or by means of the information storage device or method shall be admissible in evidence, and accepted for all other purposes, to the same extent as an original paper record of the same information would have been, provided the paper form accurately portrays the record.

7.2 Inspection by Directors

Any director shall have the right to examine the corporation's stock ledger, a list of its stockholders and its other books and records for a purpose reasonably related to his or her position as a director. The Court of Chancery is hereby vested with the exclusive jurisdiction to determine whether a director is entitled to the inspection sought. The court may summarily order the corporation to permit the director to inspect any and all books and records, the stock ledger and the stock list and to make copies or extracts therefrom. The burden of proof shall be upon the corporation to establish that the inspection such director seeks is for an improper purpose. The court may, in its discretion, prescribe any limitations or conditions with reference to the inspection, or award such other and further relief as the court may deem just and proper.

7.3 Annual Statement to Stockholders

The board of directors shall present at each annual meeting, and at any special meeting of the stockholders when called for by vote of the stockholders, a full and clear statement of the business and condition of the corporation.

VIII. GENERAL MATTERS

8.1 Checks

From time to time, the board of directors shall determine by resolution which person or persons may sign or endorse all checks, drafts, other orders for payment of money, notes or other evidences of indebtedness that are issued in the name of or payable to the corporation, and only the persons so authorized shall sign or endorse those instruments.

8.2 Execution of Corporate Contracts and Instruments

The board of directors, except as otherwise provided in these bylaws, may authorize any officer or officers, or agent or agents, to enter into any contract or execute any instrument in the name of and on behalf of the corporation; such authority may be general or confined to specific instances. Unless so authorized or ratified by the board of directors or within the agency power of an officer, no officer, agent or employee shall have any power or authority to bind the corporation by any contract or engagement or to pledge its credit or to render it liable for any purpose or for any amount.

8.3 Stock Certificates; Partly Paid Shares

The shares of the corporation shall be represented by certificates, provided that the board of directors of the corporation may provide by resolution or resolutions that some or all of any or all classes or series of its stock shall be uncertificated shares. Any such resolution shall not apply to shares represented by a certificate until such certificate is surrendered to the corporation. Notwithstanding the adoption of such a resolution by the board of directors, every holder of stock represented by certificates and upon request every holder of uncertificated shares shall be entitled to have a certificate signed by, or in the name of the corporation by the chairman or vice-chairman of the board of directors, or the president or vice president, and by the treasurer or an assistant treasurer, or the secretary or an assistant secretary of such corporation representing the number of shares registered in certificate form. Any or all of the signatures on the certificate may be a facsimile. In case any officer, transfer agent or registrar who has signed or whose facsimile signature has been placed upon a certificate has ceased to be such officer, transfer agent or registrar before such certificate is issued, it may be issued by the corporation with the same effect as if he were such officer, transfer agent or registrar at the date of issue. The corporation shall not have power to issue a certificate in bearer form.

The corporation may issue the whole or any part of its shares as partly paid and subject to call for the remainder of the consideration to be paid therefor. Upon the face or back of each stock certificate issued to represent any such partly paid shares, and upon the books and records of the corporation in the case of uncertificated partly paid shares, the total amount of the consideration to be paid therefor and the amount paid thereon shall be stated. Upon the declaration of any dividend on fully paid shares, the corporation shall declare a dividend upon partly paid shares of the same class, but only upon the basis of the percentage of the consideration actually paid thereon.

8.4 Special Designation on Certificates

If the corporation is authorized to issue more than one class of stock or more than one series of any class, then the powers, the designations, the preferences, and the relative, participating, optional or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights shall be set forth in full or summarized on the face or back of the certificate that the corporation shall issue to represent such class or series of stock; provided, however, that, except as otherwise provided in Section 202 of the General Corporation Law of Delaware, in lieu of the foregoing requirements there may be set forth on the face or back of the certificate that the corporation shall issue to represent such class or series of stock a statement that the corporation will furnish without charge to each stockholder who so requests the powers, the designations, the preferences, and the relative, participating, optional or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights.

8.5 Lost Certificates

Except as provided in this Section 8.5, no new certificates for shares shall be issued to replace a previously issued certificate unless the latter is surrendered to the corporation and cancelled at the same time. The corporation may issue a new certificate of stock or uncertificated shares in the place of any certificate theretofore issued by it, alleged to have been lost, stolen or destroyed, and the corporation may require the owner of the lost, stolen or destroyed certificate, or his or her legal representative, to give the corporation a bond sufficient to indemnify it against any claim that may be made against it on account of the alleged loss, theft or destruction of any such certificate or the issuance of such new certificate or uncertificated shares.

8.6 Construction; Definitions

Unless the context requires otherwise, the general provisions, rules of construction, and definitions in the Delaware General Corporation Law shall govern the construction of these bylaws. Without limiting the generality of this provision, the singular number includes the plural, the plural number includes the singular, and the term “person” includes both a corporation and a natural person.

8.7 Dividends

The directors of the corporation, subject to any rights or restrictions contained in the certificate of incorporation, may declare and pay dividends upon the shares of its capital stock pursuant to the General Corporation Law of Delaware. Dividends may be paid in cash, in property or in shares of the corporation's capital stock.

The directors of the corporation may set apart out of any of the funds of the corporation available for dividends a reserve or reserves for any proper purpose and may abolish any such reserve. Such purposes shall include but not be limited to equalizing dividends, repairing or maintaining any property of the corporation and meeting contingencies.

8.8 Fiscal Year

The fiscal year of the corporation shall be fixed by resolution of the board of directors and may be changed by the board of directors.

8.9 Seal

The corporation may adopt a corporate seal which may be altered as desired, and may use the same by causing it, or a facsimile thereof, to be impressed or affixed or in any other manner reproduced.

8.10 Transfer of Stock

Upon surrender to the corporation or the transfer agent of the corporation of a certificate for shares duly endorsed or accompanied by proper evidence of succession, assignation or authority to transfer, it shall be the duty of the corporation to issue a new certificate to the person entitled thereto, cancel the old certificate and record the transaction in its books.

8.11 Stock Transfer Agreements and Restrictions

The corporation shall have power to enter into and perform any agreement with any number of stockholders of any one or more classes of stock of the corporation to restrict the transfer of shares of stock of the corporation of any one or more classes owned by such stockholders in any manner not prohibited by the General Corporation Law of Delaware.

8.12 Electronic Transmission

For purposes of these bylaws, “electronic transmission” means any form of communication, not directly involving the physical transmission of paper, that creates a record that may be retained, retrieved and reviewed by a recipient thereof, and that may be directly reproduced in paper form by such a recipient through an automated process.

IX. AMENDMENTS

The original or other bylaws of the corporation may be adopted, amended or repealed by the stockholders entitled to vote; provided, however, that the corporation may, in its certificate of incorporation, confer the power to adopt, amend or repeal bylaws upon the directors. The fact that such power has been so conferred upon the directors shall not divest the stockholders of the power, nor limit their power to adopt, amend or repeal bylaws.

X. DISSOLUTION

If it should be deemed advisable in the judgment of the board of directors of the corporation that the corporation should be dissolved, the board, after the adoption of a resolution to that effect by a majority of the whole board at any meeting called for that purpose, shall cause notice to be mailed to each stockholder entitled to vote thereon of the adoption of the resolution and of a meeting of stockholders to take action upon the resolution.

At the meeting a vote shall be taken for and against the proposed dissolution. If a majority of the outstanding stock of the corporation entitled to vote thereon votes for the proposed dissolution, then a certificate stating, among other things, that the dissolution has been authorized in accordance with the provisions of Section 275 of the General Corporation Law of Delaware and setting forth the names and residences of the directors and officers shall be executed, acknowledged, and filed and shall become effective in accordance with Section 103 of the General Corporation Law of Delaware. Upon such certificate's becoming effective in accordance with Section 103 of the General Corporation Law of Delaware, the corporation shall be dissolved.

Whenever all the stockholders entitled to vote on a dissolution consent in writing, either in person or by duly authorized attorney, to a dissolution, no meeting of directors or stockholders shall be necessary. The consent shall be filed and shall become effective in accordance with Section 103 of the General Corporation Law of Delaware. Upon such consent's becoming effective in accordance with Section 103 of the General Corporation Law of Delaware, the corporation shall be dissolved. If the consent is signed by an attorney, then the original power of attorney or a photocopy thereof shall be attached to and filed with the consent. The consent filed with the Secretary of State shall have attached to it the affidavit of the secretary or some other officer of the corporation stating that the consent has been signed by or on behalf of all the stockholders entitled to vote on a dissolution; in addition, there shall be attached to the consent a certification by the secretary or some other officer of the corporation setting forth the names and residences of the directors and officers of the corporation.

XI. CUSTODIAN

11.1 Appointment of a Custodian in Certain Cases

The Court of Chancery, upon application of any stockholder, may appoint one or more persons to be custodians and, if the corporation is insolvent, to be receivers, of and for the corporation when:

(a) at any meeting held for the election of directors the stockholders are so divided that they have failed to elect successors to directors whose terms have expired or would have expired upon qualification of their successors;

(b) the business of the corporation is suffering or is threatened with irreparable injury because the directors are so divided respecting the management of the affairs of the corporation that the required vote for action by the board of directors cannot be obtained and the stockholders are unable to terminate this division; or

(c) the corporation has abandoned its business and has failed within a reasonable time to take steps to dissolve, liquidate or distribute its assets.

11.2 Duties of Custodian

The custodian shall have all the powers and title of a receiver appointed under Section 291 of the General Corporation Law of Delaware, but the authority of the custodian shall be to continue the business of the corporation and not to liquidate its affairs and distribute its assets, except when the Court of Chancery otherwise orders and except in cases arising under Sections 226(a)(3) or 352(a)(2) of the General Corporation Law of Delaware.

CERTIFICATE OF ADOPTION OF BYLAWS
OF
AVENUE THERAPEUTICS, INC.

The undersigned hereby certifies that he is a duly elected, qualified and acting officer of AVENUE THERAPEUTICS, INC., and that the foregoing bylaws, comprising 26 pages, were adopted as the bylaws of the corporation effective February 9, 2015, by the board of directors of the corporation pursuant to action of the board of directors by unanimous written consent, and were recorded in the minutes thereof.

IN WITNESS WHEREOF, the undersigned has hereunto set his or her hand and affixed the corporate seal this February 9, 2015.

/s/ Robyn Hunter
Robyn Hunter, Secretary

See Reverse Side for Restrictive Legends

Exhibit 4.1

THE SECURITIES REPRESENTED BY THIS CERTIFICATE HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED, OR APPLICABLE STATE SECURITIES LAWS. THESE SECURITIES HAVE BEEN ACQUIRED FOR INVESTMENT AND NOT WITH A VIEW TO DISTRIBUTION OR RESALE, AND MAY NOT BE SOLD, MORTGAGED, PLEDGED, HYPOTHECATED OR OTHERWISE TRANSFERRED WITHOUT AN EFFECTIVE REGISTRATION STATEMENT FOR SUCH SECURITIES UNDER THE SECURITIES ACT OF 1933, AS AMENDED, AND ANY APPLICABLE STATE SECURITIES LAWS, OR THE AVAILABILITY OF AN EXEMPTION FROM THE REGISTRATION PROVISIONS OF THE SECURITIES ACT OF 1933, AS AMENDED, AND APPLICABLE STATE SECURITIES LAWS.

THIS CERTIFICATE AND THE SHARES REPRESENTED HEREBY ARE ISSUED AND SHALL BE HELD SUBJECT TO ALL THE PROVISIONS OF THE CERTIFICATE OF INCORPORATION AND THE BYLAWS OF THE CORPORATION AND ANY AMENDMENTS THERETO, TO ALL OF WHICH THE HOLDER OF THIS CERTIFICATE, BY ACCEPTANCE HEREOF, ASSENTS. A STATEMENT OF THE RIGHTS, PREFERENCES, PRIVILEGES AND RESTRICTIONS GRANTED TO OR IMPOSED UPON THE SHARES OF THE CORPORATION AND UPON THE HOLDERS THEREOF MAY BE OBTAINED BY ANY STOCKHOLDER UPON REQUEST AND WITHOUT CHARGE AT THE PRINCIPAL OFFICE OF THE CORPORATION. THE BYLAWS OF THE CORPORATION CONTAIN RESTRICTIONS ON THE TRANSFER OF SHARES OF THE CORPORATION.

For Value Received, ____ *hereby sell, assign and transfer unto* _____ _____ *Shares represented by the within Certificate, and do hereby irrevocably constitute and appoint* _____ _____ *Attorney to transfer the said Shares on the books of the within named Corporation with full power of substitution in the premises.*

Dated _____ *A.D. 20*____

In presence of

_____ _____

NOTICE: THE SIGNATURE OF THIS ASSIGNMENT MUST CORRESPOND WITH THE NAME AS WRITTEN UPON THE FACE OF THE CERTIFICATE, IN EVERY PARTICULAR, WITHOUT ALTERATION OR ENLARGEMENT OR ANY CHANGE WHATEVER.

Exhibit 4.2

THE SECURITIES REPRESENTED HEREBY HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "ACT"), OR ANY STATE SECURITIES LAWS, AND MAY NOT BE SOLD, TRANSFERRED, ASSIGNED OR HYPOTHECATED UNLESS THERE IS AN EFFECTIVE REGISTRATION STATEMENT UNDER SUCH ACT AND ANY APPLICABLE STATE SECURITIES LAWS COVERING SUCH SECURITIES OR THE SALE IS MADE IN ACCORDANCE WITH AN EXEMPTION UNDER THE ACT AND ANY APPLICABLE STATE SECURITIES LAWS, AND THE COMPANY RECEIVES AN OPINION OF COUNSEL FOR THE HOLDER OF THESE SECURITIES REASONABLY SATISFACTORY TO THE COMPANY STATING THAT SUCH SALE, TRANSFER, ASSIGNMENT OR HYPOTHECATION IS EXEMPT FROM THE REGISTRATION AND PROSPECTUS DELIVERY REQUIREMENTS OF SUCH ACT AND ANY APPLICABLE STATE SECURITIES LAWS.

Avenue Therapeutics, Inc.

COMMON STOCK WARRANT

This Warrant is issued as of this ____ day of _____ (the "***Issue Date***") by [Avenue Therapeutics, Inc.], a Delaware corporation (the "***Company***"), to _____, or permitted assigns (the "***Holder***").

1. Issuance of Warrant; Number and Type of Securities Subject to Warrant; Exercise Price. The Company hereby grants to the Holder the right to purchase _____ shares of the Company's Common Stock (the "***Common Stock***"). The exercise price of the warrant will be $_____.

2. Term. This Warrant shall only be exercisable in accordance with the terms of Section 6 hereof, and shall expire on the date that is ten (10) years after the Issue Date.

3. Adjustments and Notices. This Warrant shall be subject to adjustment from time to time in accordance with the following provisions.

(a) Stock Splits, Subdivisions or Combinations. If at any time on or after the date hereof the Company shall split, subdivide or otherwise change its outstanding shares of any securities receivable upon exercise of this Warrant into a greater number of securities, the Warrant Price in effect immediately prior to such subdivision shall thereby be proportionately reduced and the number of Warrant Shares shall thereby be proportionately increased; and, conversely, if at any time on or after the date hereof the outstanding number of shares of any securities receivable upon exercise of this Warrant shall be combined into a smaller number of securities, the Warrant Price in effect immediately prior to such combination shall thereby be proportionately increased and the number of Warrant Shares shall thereby be proportionately decreased, all subject to further adjustment as provided in this Section 3.

(b) Reclassification. If the Company, by reclassification of securities, reorganization of the Company (or any other entity the securities of which are at the time receivable upon the exercise of this Warrant) or otherwise (including by merger or consolidation), shall change any of the securities as to which purchase rights under this Warrant exist into the same or a different number of securities of any other class or classes, this Warrant shall thereafter represent the right to acquire such number and kind of securities as would have been issuable as the result of such change with respect to the securities that were subject to the purchase rights under this Warrant immediately prior to such reclassification or other change and the Warrant Price therefor shall be appropriately adjusted, all subject to further adjustment as provided in this Section 3.

(c) No Impairment. The Company shall not, by amendment of its Certificate of Incorporation or Bylaws, each as amended to date, or through a reorganization, transfer of assets, consolidation, merger, dissolution, issue, or sale of securities or any other voluntary action, avoid or seek to avoid the observance or performance of any of the terms to be observed or performed under this Warrant by the Company, but shall at all times in good faith assist in carrying out the provisions of this Warrant and in taking all such action as may be necessary or appropriate to protect the Holder's rights under this Warrant against impairment.

(d) Fractional Shares. No fractional Warrant Shares shall be issuable upon exercise or conversion of the Warrant and the number of Warrant Shares to be issued shall be rounded to the nearest whole Warrant Share. If a fractional Warrant Share arises upon any exercise or conversion of the Warrant, the Company shall eliminate such fractional Warrant Share by paying the Holder an amount computed by multiplying the fractional interest by the fair market value of a full Warrant Share.

4. No Voting or Dividend Rights. Nothing contained in this Warrant shall be construed as conferring upon the holder hereof the right to vote or to consent to receive notice as a stockholder of the Company on any other matters or any rights whatsoever as a stockholder of the Company. No dividends or interest shall be payable or accrued in respect of this Warrant or the interest represented hereby or the shares purchasable hereunder until, and only to the extent that, this Warrant shall have been exercised.

5. Shares to be Fully Paid; Reservation of Shares. The Company covenants and agrees that all Warrant Shares will, upon issuance and payment of the applicable Warrant Price, be duly authorized, validly issued, fully paid and nonassessable, and free of all preemptive rights, liens and encumbrances, except for restrictions on transfer provided for herein. The Company shall at all times reserve and keep available out of its authorized and unissued Common Stock, solely for the purpose of providing for the exercise of the rights to purchase all Warrant Shares granted pursuant to this Warrant, such number of shares of Common Stock as shall, from time to time, be sufficient therefor.

6. Exercise of Warrant. Subject to Section 4, this Warrant may be exercised in whole or in part, at any time, by the surrender of this Warrant, together with the Notice of Exercise and Investment Representation Statement in substantially the forms attached hereto as Attachment 1 and Attachment 2, respectively (subject to appropriate revision if this Warrant is adjusted pursuant to Section 3 hereof), duly completed and executed at the principal office of the Company, and accompanied by payment in full of the applicable aggregate Warrant Price in cash or by check with respect to the Warrant Shares being purchased. Prior to exercise of the Warrant, the Holder shall notify the Company of its desire to exercise the Warrant. This Warrant shall be deemed to have been exercised immediately prior to the close of business on the date of its surrender for exercise as provided above, and the person or entity entitled to receive the Warrant Shares issuable upon such exercise shall be treated for all purposes as holder of such shares of record as of the close of business on such date.

7. Notice of Proposed Transfer. Prior to any proposed transfer of this Warrant or the Warrant Shares received on the exercise of this Warrant (together, the "***Securities***"), unless there is in effect a registration statement under the Securities Act of 1933, as amended (the "***Act***") covering the proposed transfer, the Holder thereof shall give written notice to the Company of such Holder's intention to effect such transfer. Each such notice shall describe the manner and circumstances of the proposed transfer in sufficient detail, and shall, if the Company so requests, be accompanied (except in transactions in compliance with Rule 144) by either (i) an unqualified written opinion of legal counsel who shall be reasonably satisfactory to the Company addressed to the Company and reasonably satisfactory in form and substance to the Company's counsel, to the effect that the proposed transfer of the Securities may be effected without registration under the Act, or (ii) a "no action" letter from the Securities and Exchange Commission (the "***Commission***") to the effect that the transfer of such Securities without registration will not result in a recommendation by the staff of the Commission that action be taken with respect thereto, whereupon the Holder of the Securities shall be entitled to transfer the Securities in accordance with the terms of the notice delivered by the Holder to the Company; provided, however, no such registration statement or opinion of counsel shall be necessary for a transfer by a Holder to any affiliate of such Holder. Each certificate evidencing the Securities transferred as above provided shall bear the appropriate restrictive legend set forth above, except that such certificate shall not bear such restrictive legend if in the opinion of counsel for the Company such legend is not required in order to establish compliance with any provisions of the Act.

8. Certificate of Adjustment. Whenever the Warrant Price or number or type of Warrant Shares issuable upon exercise of this Warrant is adjusted, as herein provided, the Company shall promptly deliver to the record holder of this Warrant a certificate of the Secretary of the Company setting forth the nature of such adjustment and a brief statement of the facts requiring such adjustment.

9. Replacement of Warrants. Upon receipt by the Company of evidence reasonably satisfactory to the Company of the loss, theft, destruction or mutilation of the Warrant, and in the case of any such loss, theft or destruction of the Warrant, on delivery of an indemnity agreement or security reasonably satisfactory in form and amount to the Company, and reimbursement to the Company of all reasonable expenses incidental thereto, and upon surrender and cancellation of the Warrant if mutilated, the Company will execute and deliver, in lieu thereof, a new Warrant of like tenor.

10. Amendment, Waiver, etc. Except as expressly provided herein, neither this Warrant nor any term hereof may be amended, waived, discharged or terminated other than by a written instrument signed by the party against whom enforcement of any such amendment, waiver, discharge or termination is sought; provided, however, that any provisions hereof may be amended, waived, discharged or terminated upon the written consent of the Company and a Requisite Majority. For purposes hereof, "***Requisite Majority***" shall mean Holders of at least a majority of the Warrant Shares then issuable upon exercise of then outstanding warrants of like tenor to this Warrant issued by the Company (the "***Offering Warrants***"); provided, however, that no such amendment or waiver may disproportionately and adversely affect the Holder relative to the holders of all other Offering Warrants without the Holder's consent. Any amendment effected in accordance with this Section shall be binding upon all holders of the Offering Warrants, each future holder of the Offering Warrants, and the Company. By acceptance hereof, the Holder acknowledges that in the event the required consent is obtained, any term of this Warrant may be amended or waived with or without the consent of the Holder.

11. Successors and Assigns. This Warrant and the rights evidenced hereby shall inure to the benefit of and be binding upon the successors of the Company and the successors and assigns of the Holder. The provisions of this Warrant are intended to be for the benefit of all Holders from time to time of this Warrant, and shall be enforceable by any such Holder.

12. Severability. In case any one or more of the provisions of this Warrant shall be invalid or unenforceable in any respect, the validity and enforceability of the remaining terms and provisions of this Warrant shall not in any way be affected or impaired thereby and the parties will attempt in good faith to agree upon a valid and enforceable provision which shall be a commercially reasonable substitute therefor, and upon so agreeing, shall incorporate such substitute provision in this Warrant.

13. Miscellaneous. This Warrant shall be governed by the laws of the State of New York as such laws are applied to contracts to be entered into and performed entirely in New York. The headings in this Warrant are for purposes of convenience and reference only, and shall not be deemed to constitute a part hereof.

ISSUED this ____ day of _____.

[Avenue Therapeutics, Inc.]

By: _____

Lucy Lu, MD
Interim President and CEO

Attachment 1

NOTICE OF EXERCISE

TO: Avenue Therapeutics, Inc.

1. The undersigned hereby elects to purchase _____ shares of _____ of Avenue Therapeutics, Inc. (the "Warrant Shares") pursuant to the terms of the attached Warrant, and tenders herewith payment of the purchase price in full, together with all applicable transfer taxes, if any.

2. Please issue a certificate or certificates representing said number of Warrant Shares in the name of the undersigned or in such other name as is specified below:

_____
(Name)

_____
(Address)

_____
_____
(Date)

(Name of Warrant Holder)

By: _____

Title: _____

Attachment 2
INVESTMENT REPRESENTATION STATEMENT

Shares of _____ of
Avenue Therapeutics, Inc.

In connection with the purchase of the shares of _____ of Avenue Therapeutics, Inc., the undersigned hereby represents to Avenue Therapeutics, Inc. (the "Company") as follows:

(A) The undersigned is an accredited investor (as defined in Rule 501(a) of Regulation D promulgated under the Securities Act of 1933, as amended (the "Act")). The undersigned acknowledges that an investment in the Company is highly speculative and represents that it is able to fend for itself in the transactions contemplated by this Statement, has such knowledge and experience in financial and business matters as to be capable of evaluating the merits and risks of its investments, and has the ability to bear the economic risks (including the risk of a total loss) of its investment. The undersigned represents that it has had the opportunity to ask questions of the Company concerning the Company's business and assets and to obtain any additional information which it considered necessary to verify the accuracy of or to amplify the Company's disclosures, and has had all questions which have been asked by it satisfactorily answered by the Company.

(B) The undersigned understands that no liquid public market now exists for the securities being issued by the Company and that the Company has made no assurances that a public market will ever exist for the Company's securities being obtained hereby.

(C) The undersigned understands that the securities issued upon exercise of the Warrant (the "Securities"), and any securities issued in respect thereof or exchange therefor, may bear the following legend:

"THE SECURITIES REPRESENTED BY THIS CERTIFICATE HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "ACT") OR ANY STATE SECURITIES LAWS, AND MAY NOT BE SOLD, TRANSFERRED, ASSIGNED OR HYPOTHECATED UNLESS THERE IS AN EFFECTIVE REGISTRATION STATEMENT UNDER SUCH ACT AND ANY APPLICABLE STATE SECURITIES LAWS COVERING SUCH SECURITIES OR THE SALE IS MADE IN ACCORDANCE WITH AN EXEMPTION UNDER THE ACT AND ANY APPLICABLE STATE SECURITIES LAWS, AND THE COMPANY RECEIVES AN OPINION OF COUNSEL FOR THE HOLDER OF THESE SECURITIES REASONABLY SATISFACTORY TO THE COMPANY STATING THAT SUCH SALE, TRANSFER, ASSIGNMENT OR HYPOTHECATION IS EXEMPT FROM THE REGISTRATION AND PROSPECTUS DELIVERY REQUIREMENTS OF SUCH ACT AND ANY APPLICABLE STATE SECURITIES LAWS."

(D) By executing this Statement, the undersigned further represents that it does not have any contract, undertaking, agreement or arrangement with any person to sell, transfer or grant participation to such person or to any third person, with respect to any Securities issuable upon exercise of the Warrant.

(E) The undersigned understands that the Securities issuable upon exercise of the Warrant at the time of issuance and exercise may not be registered under the Act, and applicable state securities laws, on the ground that the issuance of such securities is exempt pursuant to Section 4(2) of the Act and state law exemptions relating to offers and sales not by means of a public offering, and that the Company's reliance on such exemptions is predicated on the undersigned's representations set forth herein.

(F) The undersigned agrees that in no event will it make a disposition of any Securities acquired upon the exercise of the Warrant unless and until (i) it shall have notified the Company of the proposed disposition and shall have furnished the Company with a statement of the circumstances surrounding the proposed disposition, and (ii) if reasonably required by the Company it shall have furnished the Company with an opinion of counsel reasonably satisfactory to the Company and Company's counsel to the effect that (A) appropriate action necessary for compliance with the Act and any applicable state securities laws has been taken or an exemption from the registration requirements of the Act and such laws is available, and (B) the proposed transfer will not violate any of said laws.

(G) The undersigned acknowledges that the Securities issuable upon exercise of the Warrant must be held indefinitely unless subsequently registered under the Act or an exemption from such registration is available. The undersigned is aware of the provisions of Rule 144 promulgated under the Act which permit limited resale of shares purchased in a private placement subject to the satisfaction of certain conditions, including, among other things, the existence of a public market for the shares, the availability of certain current public information about the Company, the resale occurring not less than one year after a party has purchased and paid for the security to be sold, the sale being through a "broker's transaction" or in transactions directly with a "market makers" (as provided by Rule 144(f)) and the number of shares being sold during any three-month period not exceeding specified limitations.

[Signature on Next Page]

Dated: _____

_____
(Print Name of Holder)

By: _____
(signature)

Name: _____
(print name of person signing)

Title: _____

CONFIDENTIAL TREATMENT REQUESTED. Confidential portions of this document have been redacted and have been separately filed with the Commission.

Exhibit No. 10.1

ASSET TRANSFER AND LICENSE AGREEMENT

This Asset Transfer and License Agreement (the "Agreement"), is entered into as of February 17, 2015 (the "Effective Date"), by and between Revogenex Ireland Limited, an Irish limited company ("Revogenex"), and Coronado Biosciences, Inc., a Delaware corporation ("Coronado"). Coronado and Revogenex are both referred to herein as "Parties" or each individually, as a "Party."

WITNESSETH:

WHEREAS, Coronado has substantial knowledge and expertise relating to the Development, Commercialization, marketing and distribution of private label, prescription pharmaceutical products;

WHEREAS, Revogenex owns certain Intellectual Property Rights related to Intravenous Tramadol HC1 ("Product") and is seeking approval from the FDA for the marketing and sale of products that incorporates or is comprised of Tramadol, and has substantial knowledge and expertise relating to the development, formulation, and manufacturing of pharmaceutical products;

WHEREAS, on the Effective Date Coronado will, subject to the terms and conditions set forth herein, acquire the exclusive rights to develop, market and sell the Product in the Territory; and

WHEREAS, Revogenex will transfer the IND, and license the Product Intellectual Property, to Coronado, all as set forth in greater detail in this Agreement, and Coronado shall use Commercially Reasonable Efforts to complete the Development of the Product and submit the NDA for the Product to the FDA for approval, and thereafter commercialize, market and sell the Product in the Territory.

NOW, THEREFORE, in consideration of the mutual covenants contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, and intending to be legally bound, the Parties hereby agree as follows:

ARTICLE 1 - DEFINITIONS

1.1 "AAA" shall have the meaning set forth in Section 17.9.

1.2 "Action" shall have the meaning set forth in Section 9.6(b).

1.3 "Acquired Assets" shall have the meaning set forth in Section 3.1.

1.4 "Affiliate" shall mean any Person which, directly or indirectly, owns, is owned by, or is under common ownership with a Party to this Agreement or any Person actually controlled by, controlling, or under common control with a Party to this Agreement. For purposes of this definition, "ownership" or "control" shall mean (i) ownership of at least 50% of the voting equity securities of a Person, or (ii) the power to direct or cause the direction of the management and polices of such Person. An entity that is an investment company (including for the avoidance of doubt, Coronado Biosciences Inc.), whether or not registered under the Investment Company Act of 1940, as amended, shall not be deemed an Affiliate of Coronado.

1.5 "Agreement" has the meaning set forth in the Preamble.

1.6 "Applicable Law" shall mean any applicable provision of any federal, state or foreign statute, rule or regulation.

1.7 "Approval Date" shall mean the date upon which the FDA grants Regulatory Approval of the Product.

1.8 "Assignment and Assumption Agreement" shall have the meaning set forth in Section 4.1(c).

1.9 "Assumed Contracts" shall have the meaning set forth in Section 3.1(a).

1.10 "Bill of Sale" shall have the meaning set forth in Section 4.2(c).

1.11 "cGMP" shall mean current Good Manufacturing Practices, as set forth in 21 C.F.R. §§ 210 and 211 or any successor provision thereto, for methods to be used in, and the facilities or controls to be used for, the manufacture, processing, packing, or handling of a Product to assure that it is safe, and has the identity and strength and meets the quality and purity characteristics.

1.12 "Claims" means any and all liens (other than liens for taxes which are not yet due and payable), mortgages, pledges, security interests, options, restrictions, charges, prior assignments, agreements, claims, and encumbrances of any kind whatsoever.

1.13 "Closing" has the meaning set forth in Section 4.1.

1.14 "Closing Date" has the meaning set forth in Section 4.1.

1.15 "Commercially Reasonable Efforts" shall mean with respect to a particular Product, the carrying out of obligations or tasks in a manner consistent with the exercise of prudent scientific business judgment and the efforts that a Party devotes to research, development or marketing of a pharmaceutical product or products of similar market potential, profit potential or strategic value resulting from its own research efforts or for its own benefit, taking into account commercial viability, technical, regulatory and intellectual property factors, including, without limitation, the patent and other intellectual property position of third parties with respect to such Product, target product profiles, product labeling, past performance, costs, economic return, the regulatory environment and competitive market conditions in the therapeutic or market niche, all based on conditions then prevailing, and subject to and in consideration of, in each case, the resources available to such Party and within such Party's organization for such efforts.

1.16 "Commence" or "Commencement" means, when used to describe a Phase 2 Trial, a Phase 3 Trial, or any other human clinical trial of a Product, the first dosing of the first patient for such trial.

1.17 "Commercial Launch" shall mean the first commercial sale of a Product by or on behalf of Coronado or its Affiliates or a licensee to an independent third party for human therapeutic or prophylactic use after receipt of Regulatory Approval for such Product. A sale for clinical trial, research, development, test marketing, sampling, promotional, compassionate use, or resale purposes will not be considered a first commercial sale.

1.18 "Commercialization/Commercialize" shall mean the activities carried out by or for Coronado and/or its Affiliates after Regulatory Approval of a particular Product involving the manufacture, marketing, sale and distribution of such Product.

1.19 "Confidential Information" shall have the meaning set forth in Section 13.1.

1.20 "Controlling Party" shall have the meaning set forth in Section 9.7.

1.21 "Coronado" shall mean Coronado Biosciences, Inc. or its successor or permitted assign.

1.22 "Coronado Marks" shall have the meaning set forth in Section 9.8.

1.23 "Cover" means that the use, manufacture, sale, offer for sale, development, commercialization or importation of the subject matter in question by an unlicensed entity would infringe a Valid Claim of a Patent.

1.24 "Cure Right" shall have the meaning set forth in Section 16.2.

1.25 "Develop or Development" shall mean, with respect to a particular Product, engaging in preclinical, clinical and other pharmaceutical product development activities, including, in particular, scientific, technical data, work, development and manufacturing operations directed towards Regulatory Approval of a Product in the Territory such as the preparation and filing of an NDA with the FDA.

1.26 "Development Program" shall mean the program of work undertaken by Coronado to develop Products promptly and in sufficient time to meet regulatory reporting, delivery requirements, and timely NDA filing requirements pre-submission of the FDA application as needed and post-submission as required, including formulation, method development, method validation, stability batch testing and clinical trials, any work related to the Acquired Assets including Product evaluation batches and process validation and manufacturing required for NDA approval by FDA and Commercialization. Such work shall be undertaken by Coronado at its sole cost and expense.

1.27 "European Union" means the member states of the European Union as of the Effective Date.

1.28 "Effective Date" shall have the meaning set forth in the Preamble.

1.29 "Effective Time" shall have the meaning set forth in Section 4.1.

1.30 "Excluded Assets" shall have the meaning set forth in Section 3.2.

1.31 "Existing IND" shall have the meaning set forth in Section 3.1(b).

1.32 "Expenses" shall have the meaning set forth in Section 14.1.

1.33 "Evaluation Data" shall mean any data, information, or results related to the Product derived internally by Revogenex or received from Third Parties prior to the Closing. Such Evaluation Data shall include, without limitation, any such data, information, or results received from Third Parties that Revogenex does not own but to which Revogenex has a license or other right to use or otherwise exploit.

1.34 "FDA" shall mean the United States Food and Drug Administration, and any successor federal agency thereto.

1.35 "FDA Transfer of Ownership Letter" means the letter submitted by each of the Parties and the application form submitted by Revogenex to the FDA notifying the agency of the change in ownership of any Governmental Filings with the FDA.

1.36 "Field" means all therapeutic, preventive, palliative and diagnostic uses and applications for humans and animals.

1.37 "Force Majeure Event" shall have the meaning set forth in Section 17.9.

1.38 "Generic Product" shall mean an intravenous Tramadol HC1 product that has an FDA approved ANDA with a therapeutic equivalence AA, AP or AB rating to the Product listed in the FDA Orange Book.

1.39 "Governmental Authority" means any court, agency, department or other instrumentality of any foreign, federal, state, county, city or other political subdivision.

1.40 "Government Filings" shall have the meaning set forth in Section 3.1(b).

1.41 "Improvement" means any improvements, enhancements, or modifications of any Products or other technology Covered by or described in any Patents or License Agreement.

1.42 "Improvement Option" shall have the meaning set forth in Section 9.3.

1.43 "Improvement Period" shall have the meaning set forth in Section 9.3.

1.44 "Indemnitee" shall have the meaning set forth in Section 14.1.

1.45 "Indemnitor" shall have the meaning set forth in Section 14.1.

1.46 "Intellectual Property" shall mean all (i) patents, patent applications, patent disclosures, inventions and Improvements (whether patentable or not), (ii) trademarks, service marks, trade dress, trade names, logos, corporate names, internet domain names, and registrations and applications for the registration thereof together with all of the goodwill associated therewith, (iii) copyrights and copyrightable works (including computer programs and mask works) and registrations and applications thereof, (iv) Trade Secrets, know-how and other Proprietary Information, (v) waivable or assignable rights of publicity, waivable or assignable moral rights and (vi) unregistered and registered design rights and any applications for registration thereof; (vii) database rights and other data; and (viii) all other forms of intellectual property.

1.47 "Intellectual Property Rights" shall mean any and all rights, title and interest of any nature whatsoever in and to any Intellectual Property.

1.48 "IND" shall mean an Investigational New Drug Application filed with the FDA or the equivalent application or filing filed with any equivalent agency or government authority outside of the United States (including with any supra-national agency such as the European Union) necessary to Commence human clinical trials in such jurisdiction, and including all regulations at 21 C.F.R. § 312 et. esq., and equivalent foreign regulations, together with all subsequent submissions, supplements and amendments thereto, and any materials, documents and information referred to or relied upon thereby seeking Regulatory Approval for a Product, as well as any annual or other periodic reports as required to maintain such Regulatory Approval.

1.49 "Information" means information, results and data of any type whatsoever, including without limitation, databases, inventions, practices, methods, techniques, specifications, formulations, formulae, knowledge, know-how, skill, experience, test data including pharmacological, biological, chemical, biochemical, toxicological and clinical test data, analytical and quality control data, stability data, studies and procedures, and patent and other legal information or descriptions.

1.50 "Know-How" means any non-public, proprietary Information and other data, instructions, processes, methods, formulae, techniques, compositions, materials, expert opinions and information, including without limitation, biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, clinical, safety, manufacturing and quality control data, and other knowledge, information, skills and materials pertaining to the Patents or necessary in the manufacture, sale or use of the Products. Know-How does not include any rights under Patents.

1.51 "Licensee" means a Third Party granted a license under the Patents by Coronado.

1.52 "License Agreement" means a license agreement or other contract or arrangement pursuant to which Revogenex licenses or has rights to any Patents or Know-How relating to the discovery, research, Development, manufacture, or Commercialization of Tramadol or any Product.

1.53 "Licensed Improvements" shall have the meaning set forth in Section 9.1.

1.54 "Losses" shall have the meaning set forth in Section 14.1.

1.55 "Manufacturer" shall have the meaning set forth in Section 8.2.

1.56 "Net Sales" means the sum of (i) any trademark license fees or other similar fees payable to Coronado or its affiliates in respect of the Coronado Marks used in conjunction with the Product and (ii) gross amounts invoiced or billed (or, if not invoiced or billed, received) by Coronado or any Affiliate thereof during the applicable fiscal year with respect to the sale or other disposition for commercial purposes of Products, in each case as determined in accordance with GAAP, IFRS, or other internationally-recognized accounting standards then applied by Coronado or its Affiliates at the time of determination of Net Sales, consistently applied, minus, to the extent documented and attributable to the sale or other disposition for commercial purposes of Products, (i) returns, rebates, chargebacks, allowances for damaged or missing goods and any discounts allowed, (ii) special outbound packing, transportation, freight, handling, postage charges or other charges such as insurance relating thereto, (iii) sales, excise, value added, turnover, use and other like taxes or customs duties paid or any other governmental charges imposed upon the sale of Products or, and (iv) wholesaler and distributor fees; provided, further, that, for the avoidance of doubt, no sales shall be Net Sales hereunder if the products or services generating such sales are not made, used or sold, directly or indirectly, in a jurisdiction in which at least one Valid Claim of a Patent Covers such products.

1.57 "NDA" shall mean a New Drug Application as defined in *21 C.F.R. Part 314.50* et seq. in the United States (as may be amended, supplemented or replaced from time to time) to commence commercial sale and marketing of a drug for human use in the United States, including but not limited to any amendments, supplements, or supporting correspondence with respect thereto.

1.58 "Paragraph IV Certification" means a certification pursuant to the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417), as amended, which shall include but not be limited to any such certification pursuant to 21 U.S.C. §355(b)(2)(A)(iv) or 21 U.S.C. §355(j)(2)(A)(vii)(IV), or any reasonably similar or equivalent certification or notice in the United States or any jurisdiction outside the United States, included in (or made with respect to or in connection with) a regulatory filing concerning a Product and challenging the validity, infringement, or enforceability of any Patent.

1.59 "Party" or "Parties" shall have the meaning set forth in the Preamble.

1.60 "Patent(s)" means all rights under (i) the patents and patent applications listed on Schedule B, (ii) all other Patents directly or indirectly controlled by Revogenex or any Affiliate thereof as of the Effective Date under any License Agreement, or coming under the direct or indirect control of Revogenex or any Affiliate thereof following the Effective Date, Covering any subject matter claimed in, or described or disclosed by, the Patents referenced in clause (i), (iii) any Patents claiming Licensed Improvements, (iv) all Patents directly or indirectly controlled by Revogenex or any Affiliate thereof claiming priority to any of the Patents referenced in clause (i), (ii), or (iii) above; (v) all divisionals, continuations, continuations-in-part, conversion, extensions, improvements, term restorations, registrations, re-instatements, amendments, reissuances, corrections, substitutions, re-examinations, registrations, revalidations, supplementary protection certificates, renewals, corrections, additions, and foreign counterparts of any Patents described in clause (i), (ii), (iii), or (iv) above, (vi) all patents issuing from any of the Patents mentioned in clause (i), (ii), (iii), (iv), or (v) above, and (vii) any foreign and domestic counterparts of any such Patents.

1.61 "Person" shall mean any individual, partnership, association, corporation, limited liability company, trust or other legal person or entity.

1.62 "Phase 1 Trial" means a human clinical trial of a Product, the principal purpose of which is a preliminary determination of safety in patients or healthy individuals, or the metabolism and pharmacokinetic properties and clinical pharmacology of such Product, and generally consistent with 21 C.F.R. § 312.21(a).

1.63 "Phase 2 Trial" means a clinical trial of a Product on patients, including possibly pharmacokinetic studies, the principal purpose of which is to make a preliminary determination that such Product is safe for its intended use and to obtain sufficient information about such Product's efficacy to permit the design of further clinical trials, and generally consistent with 21 C.F.R. § 312.21(b).

1.64 "Phase 3 Trial" means a clinical trial that provides for a pivotal human clinical trial of a Product, which trial is designed to: (a) establish that a Product is safe and efficacious for its intended use, (b) define warnings, precautions and adverse reactions that are associated with the Product in the dosage range to be prescribed, (c) support Regulatory Approval of such Product, and (d) be generally consistent with 21 C.F.R. § 312.21(c).

1.65 "Pre-Launch Marketing Activities" shall have the meaning set forth in Section 8.3.

1.66 "Product" shall mean Intravenous Tramadol HC1.

1.67 "Product Intellectual Property" means the Patents, Know-How, Improvements, Evaluation Data, and other Intellectual Property and Intellectual Property Rights related to Tramadol or any other Product.

1.68 "Product Related Materials" shall have the meaning set forth in Section 17.12.

1.69 "Proprietary Information" shall mean any data or information, including, without limitation, Trade Secrets, without regard to form, that is of value to a Party and is not generally known to competitors of such Party. To the extent consistent with the foregoing, Proprietary Information includes, but is not limited to, any information about a Party's executives and employees, marketing techniques, price lists, pricing policies, business methods, and contracts and contractual relations with a Party's customers and suppliers. Proprietary Information also includes any information described in this definition that a Party obtains from another party and which such Party treats as proprietary or designates as Proprietary Information, whether or not owned or developed by such Party.

1.70 "Regulatory Approval" means any and all approvals (including supplements, amendments, pre- and post-approvals, pricing and reimbursement approvals), licenses, registrations, clearances, or authorizations of any national, supra-national (e.g., the European Commission or the Council of the European Union), regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity, that are necessary for the manufacture, distribution, use or, in Coronado's reasonable judgment, sale of a Product for use in the Field in any particular jurisdiction.

1.71 "Regulatory Authority" means any Governmental Authority with responsibility for granting any licenses or approvals necessary for the marketing and sale of pharmaceutical products in a particular jurisdiction, including, without limitation, the FDA, and where applicable any ethics committee or any equivalent review board.

1.72 "Regulatory Documentation" shall mean all submissions to Regulatory Authorities, including, without limitation, clinical studies, tests, and biostudies, regulatory applications, as well as all correspondence with Regulatory Authorities, registration and licenses, regulatory drug lists, advertising and promotion documents, adverse event files, complaint files, manufacturing records and inspection reports, in each case related to or used in connection with the Product.

1.73 "Required Consents" means those consents to assignment of certain of the Assumed Contracts, as listed on Schedule 4.2(b).

1.74 "Revogenex" shall mean Revogenex Ireland Limited or its successor or permitted assign.

1.75 "Royalty" shall have the meaning set forth in Section 12.2(a).

1.76 "Royalty Term" shall have the meaning set forth in Section 12.2(b).

1.77 "Technology Transfer" shall have the meaning set forth in Section 8.2.

1.78 "Term" shall have the meaning set forth in Section 16.1.

1.79 "Territory" means worldwide.

1.80 "Third Party" means any entity other than (a) Revogenex, (b) Coronado or (c) an Affiliate of either of them.

1.81 "Third Party Action" means any claim or action made by a Third Party against a Party that claims that a Licensed Product, or its use, development, manufacture or sale infringes such Third Party's intellectual property rights.

1.82 "Third Party Claim" shall have the meaning set forth in Section 14.2.

1.83 "Trade Secret" shall mean any information of a Party, without regard to form, including but not limited to, technical or non-technical data, a formula, a pattern, a compilation, a program, a device, a method, a technique, a drawing, a process, financial data, financial plans, product plans, software programs (including the object and source code thereto) or a list of actual or potential customers or suppliers, which is not commonly known by or available to the public, and which information (i) derives economic value, actual or potential, from not being generally known to and not being readily ascertainable by proper means by other Persons who can obtain economic value from its disclosure or use and (ii) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy. Trade Secrets also include any information described in this definition that a Party obtains from another Person and which such Party treats as proprietary or designates as a trade secret, whether or not owned or developed by such Party.

1.84 "Tramadol" shall have the meaning set forth in the Preamble.

1.85 "Transaction" shall have the meaning set forth in Section 3.1.

1.86 "Valid Claim" means a claim of any pending patent application or any issued, unexpired United States or granted foreign patent within the Patents that has not been dedicated to the public, disclaimed, abandoned or held invalid or unenforceable by a court or other body of competent jurisdiction from which no further appeal can be taken, and that has not been explicitly disclaimed, or admitted by Revogenex in writing to be invalid or unenforceable or of a scope not covering Products through reissue, disclaimer or otherwise.

1.87 "Working Committee" shall have the meaning set forth in Section 11.1.

ARTICLE 2 - DEVELOPMENT PROGRAM

2.1 Development Program. Coronado shall use its Commercially Reasonable Efforts to carry out all of the Product Development with the overall objective of obtaining all Regulatory Approvals necessary for the Commercialization of Product(s); including, but not limited to, all clinical development, the filing with the FDA of an NDA for a Product and seeking to obtain the FDA's Regulatory Approval to market such Product in accordance with its terms and in compliance with all Applicable Laws. Without limiting the foregoing, Coronado and/or its Affiliates shall perform all Development activities in compliance with all cGMP, good laboratory practices, standard industry practices and Applicable Laws.

2.2 Records and Reports. Revogenex shall maintain complete and accurate records in a scientific and detailed manner, reflecting its activities under the Development Program and the results obtained therefrom and Revogenex shall make such records available to Coronado at reasonable times upon prior written notice from Coronado.

2.3 Cost and Responsibility. Coronado shall bear the cost and risk of completing the Development of the Product. Revogenex shall have no liability for any clinical development or Regulatory Approval related to the Development of the Product.

ARTICLE 3 - OWNERSHIP AND TRANSFER OF ASSETS

3.1 Transfer of Acquired Assets. On the terms and subject to the conditions hereinafter set forth, Revogenex hereby assigns, transfers and conveys to Coronado, effective as of the Closing, the Acquired Assets (as defined below) in exchange for the assumption by Coronado of the Assumed Liabilities (collectively, the "Transaction"). For purposes of this Agreement, "Acquired Assets" shall mean Revogenex's right, title and interest in and to the following properties, assets and rights, subject to any limitations, restrictions, or conditions imposed under the Assumed Contracts, the Assumed Liabilities or this Agreement:

(a) Contracts. All of Coronado's rights (including the right to receive any payment due by the other party thereto after the Effective Date) under the Contracts listed on Schedule 3.1(a) (the "Assumed Contracts").

(b) Governmental Filings. All of Revogenex's rights, title and interest to the governmental filings and authorizations listed on Schedule 3.1(b) and all other government filings and authorizations primarily relating to the Acquired Assets, including, without limitation, (i) any NDAs, Biologic License Applications, INDs and any other filings or submissions required by Regulatory Authorities relating to the Development and Commercialization of any Products, and (ii) that certain IND filed with the FDA relating to Products (the "Existing IND") and the Regulatory Documentation owned by Revogenex and used in connection with the IND on Products (collectively the "Governmental Filings").

(c) Claims. All Claims (including, without limitation, claims related to past breach or other violations of the Assumed Contracts by Persons other than Revogenex) and causes of action of Revogenex against other Persons relating to the Acquired Assets (regardless of whether or not such Claims and causes of action have been asserted by Revogenex), and all rights of indemnity, warranty rights, rights of transfer, rights to refunds, rights of reimbursement and other rights of recovery possessed by Coronado relating to the Acquired Assets (regardless of whether such rights are currently exercisable), including without limitation all those items set forth on Schedule 3.1(c).

3.2 Excluded Assets. Notwithstanding anything in this Agreement to the contrary, all assets of Revogenex not specifically identified as an Acquired Asset, including but not limited to all rights of Revogenex or its Affiliates under this Agreement (collectively the "Excluded Assets"), are not part of the Transaction and shall remain the property of Revogenex after the Closing.

3.3 Assumed and Excluded Liabilities.

(a) Assumed Liabilities. Upon the terms and subject to the conditions of this Agreement, Coronado hereby assumes, and from and after the Effective Time Coronado shall pay, perform, discharge and otherwise fully satisfy when due, any and all liabilities, obligations and commitments arising out of or related to the liabilities set forth below (collectively the "Assumed Liabilities"):

(i) all liabilities arising from events occurring on or after the Effective Time, other than the Excluded Liabilities, arising out of the ownership or use of the Acquired Assets;

(ii) all liabilities arising from events occurring on or after the Effective Time for Taxes arising out of or relating to, directly or indirectly, the Acquired Assets, or the ownership, sale or lease of any of the Acquired Assets (other than any Taxes based on Revogenex's net income); and

(iii) all liabilities arising from events occurring on or after the Effective Time that relate to, directly or indirectly, the Assumed Contracts.

(b) Excluded Liabilities. Except as specifically set forth in Section 3.3(a), Coronado shall not assume any liabilities of Revogenex (the "Excluded Liabilities"). The Excluded Liabilities shall be retained and paid, performed and discharged when due by Revogenex.

ARTICLE 4 - CLOSING; CONDITIONS TO CLOSING

4.1 Closing. The closing of the Transaction (the "Closing") will take place at the offices of Coronado's counsel, Wyrick Robbins Yates & Ponton, LLP at 4101 Lake Boone Trail Suite 300, Raleigh, North Carolina at a mutually agreeable time on the date first listed above (or such other time or date as Coronado and Revogenex mutually agree). The time of consummation of the transactions contemplated by this Agreement ("Effective Time") is deemed to be at 10:00 a.m. North Carolina time on the date on which the Closing occurs (the "Closing Date").

4.2 Conditions of the Parties to the Closing. Each party's obligation to consummate the Closing is subject to satisfaction of the following conditions:

(a) Receipt of the assignment of the Acquired Assets and the assumption of the Assumed Liabilities by Coronado; and

(b) All consents and approvals of Third Parties that are required to be obtained by Revogenex as of the Closing for the transfer and assignment of the Acquired Assets and the assumption of the Assumed Liabilities have been obtained (or have been waived by a Third Party), including but not limited to, the procurement of all Governmental Filings and all Required Consents as further described on Schedule 4.2(b); provided that the filing of all FDA Transfer of Ownership Letters shall not be required at Closing but shall be filed within sixty (60) days of Closing; and

(c) In addition to any other documents to be delivered under other provisions of this Agreement, at the Closing Revogenex shall deliver to Coronado:

(i) a bill of sale for all of the Acquired Assets that are tangible personal property substantially in the form attached hereto as Exhibit B (the "Bill of Sale") executed by Revogenex;

(ii) an assignment of all Acquired Assets that are intangible personal property substantially in the form attached hereto as Exhibit C, which assignment shall also contain Coronado's undertaking and assumption of the Assumed Liabilities (the "Assignment and Assumption Agreement") executed by Revogenex;

(iii) such other deeds, bill of sale, assignments, certificates of title, documents and other instruments of transfer and conveyance as may be reasonably requested by Coronado, each in the form and substance satisfactory to Coronado and its counsel and executed by Revogenex.

(d) Coronado's payment of $2,000,000.00 to Revogenex pursuant to Section 12.1(a) below.

ARTICLE 5 - REPRESENTATIONS AND WARRANTIES OF REVOGENEX

Except as set forth in the Disclosure Schedule attached hereto, Revogenex hereby represents and warrants to Coronado as of immediately prior to the Closing as follows:

5.1 Authority, Ownership and Delivery of Acquired Assets. Such Party has all requisite legal and corporate power and authority to enter into this Agreement and to perform the services contemplated hereunder. All corporate actions on the part of it, the boards of directors or managers, or similar governing body of it and the equity holders of it necessary for (i) the authorization, execution, delivery and performance by it of this Agreement, and (ii) the consummation of the transactions contemplated hereby have been duly taken. On the date hereof Revogenex has the full right, power, and authority to assign, transfer, and deliver the Acquired Assets and will convey to Coronado good title to the Acquired Assets, free and clear of any and all Claims.

5.2 Organization and Good Standing. Such Party is duly organized, validly existing and in good standing under the laws of the jurisdiction of incorporation or organization. Such Party has the requisite legal and corporate power and authority to conduct its business as presently being conducted and as proposed to be conducted by it and is duly qualified to do business in those jurisdictions where its ownership of property or the conduct of its business requires.

5.3 Binding Obligation. This Agreement is a legally valid and binding obligation of it, enforceable against it in accordance with its terms (except in all cases as such enforceability may be limited by applicable bankruptcy, insolvency, reorganization, moratorium, or similar laws affecting the enforcement of creditors' rights generally and except that the availability of the equitable remedy of specific performance or injunctive relief is subject to the discretion of the court before which any proceeding may be brought).

5.4 No Conflicts. None of the execution and delivery of this Agreement, the consummation of the transactions provided for herein or contemplated hereby, or the fulfillment by it of the terms hereof or thereof, will (with or without notice or passage of time or both) (i) conflict with or result in a breach of any provision of the certificate or articles of incorporation or formation, by-laws, statutes, operating agreement or other governing documents of it, (ii) result in a default, constitute a default under, give rise to any right of termination, cancellation or acceleration, or require any consent or approval (other than approvals that have heretofore been obtained or are expressly contemplated herein) of any governmental authority or under any of the terms, conditions or provisions of any material note, bond, mortgage, indenture, loan, arrangement, license, agreement, lease or other instrument or obligation to which it is a Party or by which its assets may be bound, or (iii) violate any law or regulation applicable to it or any of its assets.

5.5 Legal Proceedings. There is no action, suit, proceeding or investigation pending or, to its actual knowledge, currently threatened, against it or any other Person that questions the validity of this Agreement or the right of it to enter into this Agreement, or to consummate the transactions contemplated hereby, nor does it have actual knowledge that there is any basis for the foregoing. To its actual knowledge, it is not a Party or subject to the provisions of any order, writ, injunction, judgment or decree of any governmental authority, which would adversely affect its rights or obligations hereunder or the transactions contemplated hereby.

5.6 Consents and Approvals. All material consents, approvals, qualifications, orders or authorizations of, filings with, or notices to any governmental authority or any other Person required in connection with its execution, delivery or performance of (i) this Agreement, and (ii) the consummation of any other transaction contemplated on the part of it hereby have been obtained, made or given.

5.7 No Violation of Law; Permits. Such Party is not in violation of any law or regulation (nor is it aware of any violation of any law or regulation by any other Person), which violation could reasonably be expected to adversely affect its performance of its obligations hereunder or the ability of the other Party to realize the intended benefits to such other Party under this Agreement.

5.8 Form 483. During the 2 year period ending on the date of this Agreement, it has not received any FDA Form 483 or other governmental authority notice of inspectional observations, "warning letters," "untitled letters" or similar correspondence or written notice from the FDA or other Governmental Authority asserting material noncompliance with any applicable legal requirements. There are currently no outstanding FDA Form 483s with respect to it.

5.9 Ownership. The Acquired Assets are wholly-owned by Revogenex, free and clear of all mortgages, pledges, charges, liens, equities, security interests, shop rights, or other encumbrances or similar agreements, or any other obligation. No Third Party or Affiliate of Revogenex has any rights or ownership interest in any Acquired Assets.

5.10 Other Assets. Other than the License Agreements, neither Revogenex nor its Affiliates are a party to any license agreement or other contract or arrangement pursuant to which it licenses or has rights to any Intellectual Property relating to the discovery, research, Development, manufacture, or Commercialization of Tramadol or any Product.

5.11 Regulatory Filings. All Regulatory Filings and Regulatory Approvals included in the Acquired Assets and related to the Product Intellectual Property are and have been filed, updated, and maintained in accordance with Applicable Laws and pharmaceutical industry standards, and neither Revogenex nor any Affiliate thereof has received nor been the subject of, nor is aware of any information for which one would reasonably expect Revogenex or any Affiliate thereof to receive or be the subject of, any correspondence or other action on the part of any Regulatory Authority which would reasonably be expected to have a material adverse effect on any study with respect to the Product, or on the research, development, manufacture or commercialization of the Product.

5.12 Materials. All tangible embodiments of the Products have been manufactured, handled, shipped, and stored in accordance with Applicable Laws and GMP.

5.13 Intellectual Property. Revogenex represents and warrants that:

(a) it is the sole and exclusive legal and beneficial owner of the entire right, title, and interest in and to the Product Intellectual Property;

(b) it has, and throughout the Term, will retain the unconditional and irrevocable right, power and authority to grant the licenses granted hereunder;

(c) neither its grant of the license, nor its performance of any of its obligations, under this Agreement does or will at any time during the Term, require the provision of any payment or other consideration to any third party.

(d) it has not granted and will not grant any licenses or other contingent or non-contingent right, title or interest under or relating to the Product Intellectual Property, or is or will be under any obligation, that does or will conflict with or otherwise affect this Agreement, including any of Revogenex's representations, warranties or obligations or Coronado's rights or licenses hereunder;

(e) there neither are nor at any time during the Term will be any encumbrances, liens or security interests involving any Product Intellectual Property;

(f) no prior art or other information exists that would adversely affect the validity, enforceability, term or scope of any Product Intellectual Property;

(g) there is no settled, pending or to its knowledge threatened litigation or re-examination, post-grant or*inter partes* review, interference, derivation, opposition, claim of invalidity or other claim or proceeding (including in the form of any offer to obtain a license):

(i) alleging the invalidity, misuse, unregistrability, unenforceability or noninfringement of any Product Intellectual Property; or

(ii) challenging Revogenex's ownership of, or right to practice or license, any Product Intellectual Property, or alleging any adverse right, title or interest with respect thereto; or

(iii) alleging that the practice of any Product Intellectual Property or the making, using, offering to sell, sale or importation of any Product Intellectual Property in the Field in the Territory does or would infringe, misappropriate or otherwise violate any patent, trade secret or other intellectual property of any third party.

(h) it has no knowledge after reasonable investigation of any factual, legal or other reasonable basis for any litigation, claim or proceeding described in Section 5.13(g);

(i) it has not brought or threatened any claim against any third party alleging infringement of any Product Intellectual Property, nor, to its knowledge, is any third party infringing or, to its knowledge, preparing or threatening to infringe any patent, or practicing any claim of any patent application, included as a Patent; and

(j) the Product Intellectual Property does not infringe the Intellectual Property Rights of any Third Party.

5.14 Insolvency. Revogenex is not now insolvent, and will not be rendered insolvent by any of the transactions contemplated by this Agreement.

ARTICLE 6 - REPRESENTATIONS AND WARRANTIES OF CORONADO

Except as set forth in the Disclosure Schedule attached hereto, Revogenex hereby represents and warrants to Coronado as of immediately prior to the Closing as follows:

6.1 Authority. Such Party has all requisite legal and corporate power and authority to enter into this Agreement and to perform the services contemplated hereunder. All corporate actions on the part of it, the boards of directors or managers, or similar governing body of it and the equity holders of it necessary for (i) the authorization, execution, delivery and performance by it of this Agreement, and (ii) the consummation of the transactions contemplated hereby have been duly taken.

6.2 Organization and Good Standing. Such Party is duly organized, validly existing and in good standing under the laws of the jurisdiction of incorporation or organization. Such Party has the requisite legal and corporate power and authority to conduct its business as presently being conducted and as proposed to be conducted by it and is duly qualified to do business in those jurisdictions where its ownership of property or the conduct of its business requires.

6.3 Binding Obligation. This Agreement is a legally valid and binding obligation of it, enforceable against it in accordance with its terms (except in all cases as such enforceability may be limited by applicable bankruptcy, insolvency, reorganization, moratorium, or similar laws affecting the enforcement of creditors' rights generally and except that the availability of the equitable remedy of specific performance or injunctive relief is subject to the discretion of the court before which any proceeding may be brought).

6.4 No Conflicts. None of the execution and delivery of this Agreement, the consummation of the transactions provided for herein or contemplated hereby, or the fulfillment by it of the terms hereof or thereof, will (with or without notice or passage of time or both) (i) conflict with or result in a breach of any provision of the certificate or articles of incorporation or formation, by-laws, statutes, operating agreement or other governing documents of it, (ii) result in a default, constitute a default under, give rise to any right of termination, cancellation or acceleration, or require any consent or approval (other than approvals that have heretofore been obtained or are expressly contemplated herein) of any governmental authority or under any of the terms, conditions or provisions of any material note, bond, mortgage, indenture, loan, arrangement, license, agreement, lease or other instrument or obligation to which it is a Party or by which its assets may be bound, or (iii) violate any law or regulation applicable to it or any of its assets.

6.5 Legal Proceedings. There is no action, suit, proceeding or investigation pending or, to its actual knowledge, currently threatened, against it or any other Person that questions the validity of this Agreement or the right of it to enter into this Agreement, or to consummate the transactions contemplated hereby, nor does it have actual knowledge that there is any basis for the foregoing. To its actual knowledge, it is not a Party or subject to the provisions of any order, writ, injunction, judgment or decree of any governmental authority, which would adversely affect its rights or obligations hereunder or the transactions contemplated hereby.

6.6 Consents and Approvals. All material consents, approvals, qualifications, orders or authorizations of, filings with, or notices to any governmental authority or any other Person required in connection with its execution, delivery or performance of (i) this Agreement, and (ii) the consummation of any other transaction contemplated on the part of it hereby have been obtained, made or given.

6.7 No Violation of Law; Permits. Such Party is not in violation of any law or regulation (nor is it aware of any violation of any law or regulation by any other Person), which violation could reasonably be expected to adversely affect its performance of its obligations hereunder or the ability of the other Party to realize the intended benefits to such other Party under this Agreement.

6.8 Form 483. During the 2 year period ending on the date of this Agreement, it has not received any FDA Form 483 or other governmental authority notice of inspectional observations, "warning letters," "untitled letters" or similar correspondence or written notice from the FDA or other governmental entity asserting material noncompliance with any applicable legal requirements. There are currently no outstanding FDA Form 483s with respect to it.

ARTICLE 7 - ADDITIONAL COVENANTS

7.1 Governmental Filings.

(a) Submissions to Governmental Entities. Revogenex and Coronado each agree to prepare and file within sixty (60) days whatever filings, requests or applications are required or deemed advisable to be filed with any Governmental Authority in connection with the transactions contemplated by this Agreement, including any FDA Transfer of Ownership Letters and to cooperate with one another as reasonably necessary to accomplish the foregoing.

(b) Further Assurances. Revogenex and Coronado shall: (i) diligently take, or fully cooperate in the taking of, all necessary and proper steps to make such filings as required or deemed advisable pursuant to Section 7.1(a); (ii) take, or cause to be taken, all actions, and to do or cause to be done, and to assist and cooperate with the other Party in doing all things reasonably necessary, proper, and/or advisable under applicable law or otherwise (A) to consummate and make effective the transactions contemplated by this Agreement and (B) obtain from any Governmental Authority any non-actions, clearances, waivers, consents, approvals, authorizations, permits or orders required to be obtained in connection with the execution and performance of this Agreement or the transactions contemplated by this Agreement. Within sixty (60) days after the Closing Date, Revogenex shall deliver to Coronado all tangible and electronic data related to the Governmental Filings.

(c) Assumption of Regulatory Compliance Responsibilities. Except as otherwise provided in this Agreement, from and after the Effective Time, Coronado shall assume all regulatory responsibilities in connection with the Acquired Assets and the Governmental Filings related thereto.

(d) Responsibility of Revogenex. Revogenex shall have no obligation whatsoever in connection with any regulatory filings, requests or applications related to the Acquired Assets, except as otherwise provided herein and except for actions of Revogenex reasonably required by a Governmental Authority in connection therewith.

(e) Governmental Authority Fees. From and after the Effective Time, Coronado shall have all responsibility for any and all Governmental Authority fee obligations for holders or owners of the Governmental Filings that relate to periods on or after the Effective Time, and Revogenex shall retain responsibility for such fee obligations which relate to periods prior to the Effective Time. Each Party shall promptly reimburse the other to the extent a Party pays amounts that are the responsibility of the other Party hereunder.

(f) Dealings With Governmental Entities. From and after the Effective Time, Coronado shall have the sole authority and responsibility to respond to any Governmental Authorities, all at Coronado's sole cost and expense.

7 . 2 Ownership After Transfer. After the transfer of the IND in accordance with Article 3 and approval of the first NDA related to a Product, Coronado shall maintain the IND and subsequent NDA with the applicable Regulatory Authority. The IND, NDA and all other Regulatory Documentation shall reflect Coronado (or its designated Affiliate) as the owner of the Product and all Regulatory Approvals issued pursuant thereto shall thereafter be in the name of and owned by Coronado (or its designated Affiliate). The amendment of the IND, NDA and any Regulatory Documentation in accordance herewith to reflect Coronado (or its designated Affiliate) as the owner of the Product or any transfer to such an Affiliate shall be conditioned upon the written undertaking by that Affiliate to accept all of the terms and conditions of this Agreement applicable to the IND or NDA. After the transfer of the IND in accordance with Article 3, Coronado shall be the sole and exclusive owner of all right, title and interest in and to the IND and NDA for the Product and shall retain the exclusive control of such IND and NDA, including all amendments, supplements and all other communications with the FDA. After the transfer of the IND in accordance with Article 3, Coronado shall comply with all requests of the Regulatory Authorities and shall be responsible for all regulatory costs and related legal expenses. After the transfer of the IND in accordance with Article 3, Revogenex, shall have no liability for any regulatory costs or related legal expenses. Coronado shall maintain a complete copy of the IND and NDA filed with the FDA and all Regulatory Documentation or any proposed amendment to the IND and NDA, and Coronado shall make such IND, NDA, proposed amendments and Regulatory Documentation available to Revogenex at reasonable times upon prior written notice from Revogenex.

ARTICLE 8 - TRANSITION; COMMERCIALIZATION; MANUFACTURE

8 . 1 Commercialization. Coronado, at its sole cost and expense, shall be responsible for the Commercialization of the Product, and shall utilize Commercially Reasonable Efforts in manufacturing, having manufactured, promoting, marketing, selling and otherwise Commercializing the Product. Coronado shall be responsible for and retain control of all decisions regarding Commercialization of the Product. In furtherance of its obligations to Commercialize the Product under this Section 8.1, Coronado shall:

(a) book sales of the Product;

(b) have responsibility for all pricing, managed care, marketing, sales and distribution strategies;

(c) field an adequately sized sales force that reflects Commercially Reasonable Efforts to address the market for Products;

(d) utilize its existing field resources and add incremental resources at its sole discretion to derive revenue from the Product; and

(e) have responsibility for all regulatory items dealing with the Commercialization of the Product after Regulatory Approval by the FDA and transfer of the NDA and Regulatory Documentation pursuant to Article 3;

(f) use commercially reasonable efforts to provide a comprehensive marketing plan to Revogenex six months prior to the Commercial Launch related to the first commercial sale of a Product.

8.2 Manufacturing and Technology Transfer. Coronado shall have the right to assume, at its sole discretion, the existing manufacturing agreement with Polpharma Laboratories (the existing contract "Manufacturer"). Coronado can contract another third party manufacturer (also the "Manufacturer") sufficiently far enough in advance of the anticipated Approval Date to manufacture all Product evaluation batches and complete all process validation of the Product. Following execution of a manufacturing and supply agreement with a Manufacturer, Revogenex shall provide Coronado and Manufacturer with all reasonable cooperation and assistance requested by Coronado (or its designated Affiliate) or Manufacturer in connection with transitioning the manufacture and supply of the Product to Manufacturer. Such cooperation shall include making reasonably available to Coronado personnel with appropriate technical and other expertise, as reasonably requested by Coronado, and providing any available information and documentation reasonably requested by Coronado, including all data, manufacturing technology, methods, information, documentation, materials and assistance reasonably necessary for the effective transfer. Coronado shall reimburse Revogenex for all reasonable out-of-pocket expenses (i.e. reasonable travel, meal and accommodation expenses) incurred by such personnel in connection with such a request of Coronado. Upon a successful technology transfer of the Product's manufacturing process from Revogenex as contemplated by this Section 8.2 and as determined by Coronado in its reasonable discretion ("Technology Transfer"), at Coronado's sole cost and expense, Coronado will cause Manufacturer to manufacture and supply the Product.

8.3 Pre-Launch Marketing Activities. After the Effective Time and prior to the Approval Date, Coronado shall undertake the following pre-launch marketing activities with respect to the Product in furtherance of its obligations to Commercialize the Product (the "Pre-Launch Marketing Activities"):

(a) Determine what is needed to facilitate an attractive reimbursement position within their plans and initiate applicable activities so as to be in a position to take the product to market after commercialization;

(b) Determine what is needed to facilitate an attractive reimbursement position within the Medicare and Medicaid programs and initiate applicable activities so as to be in a position to take the product to market for commercialization;

(c) Regularly connect with national and regional experts to develop advocacy behind the Product;

8.4 Post-Effective Time Cooperation.

(a) Except as otherwise provided in this Agreement, Revogenex and Coronado shall cooperate with each other, and shall cause their officers, employees, agents, auditors, Affiliates and representatives to cooperate with each other, for a period of two (2) years after the Closing to ensure the orderly transition of the Acquired Assets from Revogenex to Coronado and to minimize any disruption to the Development and Commercialization of the Products; provided, however, that for the first one hundred and twenty (120) days after Closing, such cooperation by Revogenex will be at Revogenex's expense, and thereafter will be at Coronado's expense. After the Effective Time, upon reasonable written notice, Coronado shall furnish or cause to be furnished to Revogenex and its employees, counsel, auditors and representatives access, during normal businesses hours, to such information and assistance relating to the Product as is reasonably requested for financial reporting and accounting matters.

(b) After the Effective Time, upon reasonable written notice, Revogenex and Coronado shall furnish or cause to be furnished to each other, as promptly as practicable, such information and assistance (to the extent within the control of such Party) relating to the Acquired Assets (including access to books and records) as is reasonably requested for the filing of all tax returns, and making of any election related to Taxes, the preparation for any audit by any Taxing authority, and the prosecution or defense of any claim, suit or proceeding related to any tax return. Revogenex and Coronado shall cooperate with each other in the conduct of any audit or other proceeding relating to Taxes involving the Acquired Assets.

ARTICLE 9 - INTELLECTUAL PROPERTY

9 . 1 Retained Rights. As between Revogenex and Coronado, Revogenex shall retain all right, title and interest in and to the Product Intellectual Property and Coronado shall assume control of the patent prosecution and maintenance for the Patents at Coronado's sole cost but in form and content reasonably acceptable to Revogenex. Coronado shall use Commercially Reasonable Efforts to maintain all Patents in active and good standing. Except as expressly set forth herein, no rights are granted to the other Party under this Agreement.

9.2 License.

(a) Subject to the terms and conditions of this Agreement, Revogenex grants to Coronado, as of the date of execution of this Agreement and Coronado accepts, a personal, perpetual, exclusive and nontransferable (except as otherwise permitted in this Agreement) right and license under the Product Intellectual Property, to make, have made, use, offer to sell, sell and import Products in the Field in the Territory for the sole purpose of completing the Pre-Launch Marketing Activities prior to the transfer of the NDA pursuant to Article 3 and thereafter a transferable license for the sole purpose of Commercialization of the Product in the Territory in accordance with this Agreement. Coronado acknowledges and agrees that Revogenex is the exclusive owner of, and retains all right, title and interest in and to the Product Intellectual Property, and that Coronado shall have no rights therein other than those expressly granted under this Agreement, and that the rights granted to Coronado herein are subject to the terms and conditions hereof. Coronado further acknowledges and agrees that the rights hereby granted are personal to Coronado and, except as otherwise expressly permitted in this Agreement, or except with respect to an assignment to an Affiliate who has agreed to be bound by the terms if this Agreement, cannot be further assigned or sublicensed, by operation of law or otherwise, by Coronado without Revogenex's prior written consent, such consent not to be unreasonably withheld.

(b) All rights and licenses granted under this Section 9.2 shall terminate immediately upon termination of this Agreement for any reason, whereupon Coronado shall immediately cease all use of the Product Intellectual Property and shall return to Revogenex all originals and copies in its possession or under its control of materials and physical items documenting or embodying such.

9.3 Exclusive Option to Improvements. Revogenex shall provide prompt written notice to Coronado of each Improvement. Revogenex hereby grants to Coronado an exclusive option to acquire an exclusive, worldwide license to each Improvement (and related patent rights) (such option the "Improvement Option"). Coronado shall have a period of six (6) months from the receipt of written disclosure of each Improvement from Revogenex within which to exercise such option in writing with respect to each Improvement (the "Improvement Option Period"). If Licensee exercises such option with respect to a particular Improvement (a "Licensed Improvement"), then from that day forward all such Patents covering such Licensed Improvement will be deemed Patents hereunder. During the Improvement Option Period for a particular Improvement, Revogenex shall not offer a commercial license to any other party with respect to such Improvement (or related patent rights). If Coronado does not exercise the Improvement Option for a particular Improvement during the applicable Improvement Option Period, Revogenex shall thereafter be free to license its rights in such Improvement to any Third Party.

9.4 Retained Rights. As between Revogenex and Coronado, Revogenex shall retain all right, title and interest in and to the Improvements and Coronado shall assume control of the patent prosecution and maintenance for the Intellectual Property Rights claiming the Licensed Improvement at Coronado's sole cost. Coronado shall use Commercially Reasonable Efforts to maintain all Patents claiming Licensed Improvements in active and good standing. Except as expressly set forth herein, no rights are granted to the other Party under this Agreement.

9.5 Bankruptcy. All licenses granted under this Agreement are deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code, licenses of right to "intellectual property" as defined in Section 101 of such Code. The Parties agree that Coronado and its Affiliates may fully exercise all of its and their rights and elections under the U.S. Bankruptcy Code and any foreign equivalent thereto in any country having jurisdiction over a Party, any Affiliate thereof, or any of its or their assets. The Parties further agree that, in the event Coronado or any Affiliate(s) thereof elect to retain its rights as a licensee under such Code, Coronado and/or such Affiliate(s), as applicable, shall be entitled to complete access to any technology or intellectual property licensed to them hereunder and all embodiments of such technology and intellectual property. Such embodiments of the technology and intellectual property shall be delivered to Coronado and its Affiliates not later than:

(a) the commencement of bankruptcy proceedings against Revogenex, upon written request, unless Revogenex elects to perform its obligations under this Agreement, or

(b) if not delivered above under this Section 9.5 upon the rejection of this Agreement by or on behalf of Revogenex, upon Coronado's written request.

9.6 Protection of Intellectual Property; Infringement and Enforcement Rights

(a) Should Coronado or any employee of Coronado make, discover, develop or assist in the development of any Improvements during the Term, Coronado shall forthwith disclose or cause the Improvement to be disclosed to Revogenex and such Improvement shall be deemed to be a part of the "Product Intellectual Property" and shall be subject to the terms of this Agreement. Revogenex shall own all right, title and interest in any Improvement, and any patent arising therefrom will be filed in the name of Revogenex, subject to the license granted to Coronado pursuant to this Agreement. If so requested by Revogenex, Coronado shall (i) reasonably assist in the filing of any patent applications domestic and/or foreign, in Revogenex's name, which are necessary to protect the Product Intellectual Property and/or Improvements to the Product Intellectual Property, (ii) make available or supply to Revogenex such information or data as is necessary or convenient for the proper understanding or use of such Improvement, and (iii) provide technical assistance and sign all necessary legal papers for Revogenex's protection of the Product Intellectual Property and/or Improvements including the filing of patent applications at Coronado's expense.

(b) Enforcement of Intellectual Property.

(i) If either Party becomes aware of (i) any actual, potential, or alleged infringement of any of the rights to Product Intellectual Property granted to Coronado under this Agreement with respect to Products or a Paragraph W Certification (each of subclauses (i) and (ii), an "Action") and, such Party shall give to the other Party prompt and reasonably detailed written notice of such actual, potential, or alleged infringement. Notwithstanding the foregoing, each Party shall notify the other Party within two (2) business days of its receipt of, or receipt of notice of, any Paragraph W Certification. With respect to any Action, Coronado shall have the first and primary right, but not the obligation, to, at its expense, initiate, prosecute, and control any action or legal proceedings, and/or enter into a settlement, including any declaratory judgment action, with respect thereto; provided, however, if in the reasonable opinion of counsel to Revogenex, Revogenex has available to it one or more defenses or counterclaims which are inconsistent with one or more defenses or counterclaims which may be alleged by Coronado, as a result of which representation would be advisable, Revogenex shall have the right, subject to the terms of this Section 9.6(b), to participate in such Action at its own cost and expense. In any such litigation brought by Coronado, Coronado shall have the right to use and sue in Revogenex's name and join Revogenex as a party to such litigation, and Revogenex shall cooperate reasonably with respect thereto, as requested by Coronado. If, within one hundred eighty (180) calendar days of the notice in this Section 9.6(b)(i) (or, in the case of a Paragraph W Certification, thirty-five (35) calendar days from the date of Coronado's receipt of the Paragraph W Certification or notice thereof from Revogenex), Coronado shall, (i) have been unsuccessful in persuading the actual, potential, or alleged infringer to desist, (ii) shall not have brought and shall not be diligently prosecuting an infringement or other action with respect to such actual, potential, or alleged infringement or Paragraph W Certification, or (iii) has not entered into settlement discussions with respect to such actual, potential, or alleged infringement or Paragraph W Certification, or if Coronado notifies Revogenex that it has decided not to undertake any of the foregoing against any such alleged, potential, or actual infringer or Third Party making such Paragraph W Certification, then Revogenex shall have the right, at its expense, to bring suit to enforce such Product Intellectual Property against such actual, alleged, or potential infringer, or take action with respect to such Paragraph W Certification, at its own expense, unless Coronado has provided Revogenex with a reasonable strategic rationale for not taking action to terminate such actual, potential, or alleged infringement or with respect to such Paragraph W Certification. Notwithstanding the foregoing, Revogenex shall not, and shall not permit any Affiliate thereof or Third Party to, proceed against an alleged infringer of the Product Intellectual Property in the Territory (1) unless (A) significant damages are reasonably expected to be recovered from the infringer in such proceeding or (B) Revogenex believes, in its reasonable discretion, that such infringement would materially and adversely affect its interest in the Product or the Product Intellectual Property and (2) without first consulting with Coronado regarding the strategy for such proceeding and considering in good faith Coronado's comments regarding such proceeding.

(ii) Each Party involved in an Action under Section 9.6(i) shall pay its own costs and expenses incurred in connection with such Action.

(iii) No Party shall settle or otherwise compromise (or resolve by consent to the entry of judgment upon) any Action by admitting that any Product Intellectual Property is to any extent invalid or unenforceable without the other Party's prior written consent, and, in the case of Revogenex, Revogenex may not settle or otherwise compromise (or resolve by consent to the entry of judgment upon) an Action in a way that adversely affects or would be reasonably expected to adversely affect any of Coronado's rights or benefits hereunder with respect to any Product Intellectual Property or Product, without Coronado's prior written consent.

(iv) Each Party (if it is not the Party enforcing or defending the Revogenex Intellectual Property) shall provide reasonable assistance to the other Party, including providing access to relevant documents and other evidence and making its employees and consultants available, subject to the other Party's reimbursement of any reasonable out-of-pocket expenses incurred on an on-going basis by the non-enforcing or non-defending Party in providing such assistance.

(v) Any amounts recovered by the Party initiating an Action pursuant to this Section 6.5, whether by settlement or judgment, shall be allocated in the following order: (i) to reimburse the Party initiating such Action for any costs incurred; (ii) to reimburse the Party not initiating such Action for its costs incurred in such Action, if it joins (as opposed to taking over) such Action; and (iii) the remaining amount of such recovery shall (A) if Coronado initiated the Action, the remainder shall be allocated to Coronado and the portion thereof attributable to "lost sales" shall be deemed to be Net Sales for the Calendar Quarter in which the amount is actually received by Coronado and Coronado shall pay to Revogenex a royalty on such portion based on the royalty rates set forth in Article 12, and the portion thereof not attributable to "lost sales" shall be allocated to Coronado and (B) if Revogenex initiated the Action, the remainder shall be allocated to Coronado and the portion thereof attributable to "lost sales" shall be deemed to be Net Sales for the Calendar Quarter in which the amount is actually received by Coronado and Coronado shall pay to Revogenex a royalty on such portion based on the royalty rates set forth in Article 12, and the portion thereof not attributable to "lost sales" shall be allocated to 50% to Revogenex and 50% to Coronado.

9.7 Third Party Actions.

(a) If either Revogenex or Coronado becomes aware of any Third Party Action, such Party shall promptly notify the other of all details regarding such claim or action that is reasonably available to such Party.

(b) Coronado shall have the right, at its sole expense, but not the obligation, to defend a Third Party Action described in Section 9.7(a) and (subject to Section 9.7(f)) to compromise or settle such Third Party Action. If Coronado declines or fails to assert its intention to defend such Third Party Action within 40 days of receipt/sending of notice under Section 9.7(a), then Revogenex shall have the right, at its sole expense, to defend such Third Party Action and (subject to Section 9.7(a)) to compromise or settle such Third Party Action. The Party defending such Third Party Action shall have the sole and exclusive right to select counsel for such Third Party Action.

(c) The Party defending a Third Party Action pursuant to Section 9.7(b) shall be the "Controlling Party". The Controlling Party shall consult with the non-Controlling Party, pursuant to an appropriate joint defense or common interest agreement, on all material aspects of the defense. The non-Controlling Party shall have a reasonable opportunity for meaningful participation in decision-making and formulation of defense strategy. The Parties shall reasonably cooperate with each other in all such actions or proceedings. The non-Controlling Party will be entitled to join the Third Party Action and be represented by independent counsel of its own choice at its own expense.

(d) In the event that a judgment in a Third Party Action is entered against either Party and an appeal is available, the Controlling Party shall have the first right, but not the obligation, to file such appeal. In the event the Controlling Party does not desire to file such an appeal, it will promptly, in a reasonable time period (i.e., with sufficient time for the non-Controlling Party to take whatever action may be necessary) before the date on which such right to appeal will lapse or otherwise diminish, permit the non-Controlling Party to pursue such appeal at such non-Controlling Party's own cost and expense. If applicable Law requires the other Party's involvement in an appeal, the other Party shall be a nominal party in the appeal and shall provide reasonable cooperation to such Party at such Party's expense.

(e) Subject to the respective indemnity obligations of the Parties set forth in this Agreement, the Controlling Party shall pay all costs and expenses associated with such Third Party Action other than the expenses of the other Party if the other Party elects to join such Third Party Action (as provided in the last sentence of Section 9.7(c)).

(f) Neither Revogenex or Coronado shall settle or otherwise compromise (or resolve by consent to the entry of judgment upon) any Third Party Action by admitting that any Patent is to any extent invalid or unenforceable or that any Licensed Product, or its use, Development, importation, manufacture or sale infringes such Third Party's intellectual property rights, in each case without the other Party's prior written consent, and, in the case of Revogenex, Revogenex may not settle or otherwise compromise (or resolve by consent to the entry of judgment upon) a Third Party Action in a way that adversely affects or would be reasonably expected to adversely affect Coronado's rights and benefits hereunder with respect to any Product Intellectual Property or any Product, without Coronado's prior written consent, which shall not be unreasonably withheld, conditioned or delayed.

9.8 Copyrights and Trademarks. Revogenex represents, warrants and acknowledges that Coronado will distribute, market and sell the Product under its own proprietary trademarks, trade name, service marks and copyrights ("Coronado Marks"), and that Revogenex will have no rights, title or interest in or to the Coronado Marks.

ARTICLE 10 - ADVERSE REACTIONS AND RECALLS

10.1 Notice of Adverse Reactions. Each Party shall provide prompt notice to the other Party of any information it receives concerning serious side effects, injury, toxicity, or sensitivity reaction associated with the Product, whether or not determined to be attributable to the Product. Further, each Party shall notify the other Party in writing within 3 business days of the time such Party first becomes aware of a circumstance that might necessitate expedited notification of relevant Regulatory Authorities or significant change in the labeling of the Product.

10.2 Recalls. To the extent permitted or required by law, any decision to recall, withdraw or cease distribution of any Product as a result of a violation of an applicable Regulatory Approval or any Applicable Laws, or because the Product presents a possible safety risk shall be made by Coronado. Any such recall or market withdrawal shall be controlled by Coronado. Coronado shall bear the cost of any recall or market withdrawal of any Product and such costs shall not be charged to Revogenex. For the purposes of this Section 10.2, expenses of recall shall include, without limitation, the expense of notification and destruction or return of the recalled Product and the refund to consumers of amounts paid for the recalled Product.

ARTICLE 11 - COMMITTEE

11.1 Working Committee. The parties will establish a working committee (the "Working Committee") to coordinate the Development and Commercialization activities relating to the Product, to monitor the progress of the Development of the Product, to strategize plans and objectives related to the Commercialization of the Product and to facilitate communication among the parties. The Working Committee shall consist of a chief representative appointed by each of Revogenex and Coronado together with such additional development, regulatory and business personnel of Revogenex and Coronado as may be necessary to accomplish the Development and Commercialization of the Product. It is the intent of this Agreement that during the period prior to and following the Regulatory Approval of the NDA, the role of Revogenex in the Working Committee shall be one of an advisor to the decision makers of Coronado.

ARTICLE 12 - CONSIDERATION

12.1 Milestone Payments. Each of the following payments shall be mutually exclusive of one another and shall be payable in accordance with its terms as, if and when earned. For the avoidance of doubt, each such milestone payment is payable only once under this Agreement, with respect to the initial accomplishment thereof, regardless of the number of Products (or indications therefor) or the number of times such milestone may be achieved.

(a) Coronado will pay to Revogenex a one-time fee of $2,000,000.00 USD on the Closing Date.

(b) Within 120 calendar days of the Effective Date, Coronado will pay to Revogenex $1,000,000.00 USD, provided, that, Revogenex has fully transferred to Coronado all of the Acquired Assets, including the Existing IND, by such date.

(c) Within 45 days of submission of the NDA to the FDA, Coronado will pay a one-time payment of $* USD to Revogenex.

(d) Within 45 days of Approval of the Product by the FDA pursuant to Article 1 Coronado will pay to Revogenex $* USD.

12.2 Royalty Payments.

(a) Royalty Rates. Following the Commercial Launch of a Product by Coronado, Coronado will pay to Revogenex a royalty payment (the "Royalty") equal to:

(i) *% of annual Net Sales of Products for annual Net Sales of $* or less, and

(ii) *% of annual Net Sales of Products for annual Net Sales in excess of $*, both payable in accordance with Section 12.2.

(b) Royalty Term. Royalties shall be payable on a country-by-country and Product-by-Product basis for sales occurring, as applicable, with respect to a particular Product in a particular country until the date on which such Product is no longer covered by a Valid Claim of a Product Patent in such country (the "Royalty Term").

12.3 Payment and Sales Reports. Within 90 days after the end of each calendar quarter following the Commercial Launch of the Product by Coronado for which Revogenex is entitled to Royalty payments pursuant to Section 12.1, Coronado shall pay the amount owed on Net Sales generated during such calendar quarter. All payments due under Section 12.1 shall be accompanied by a report that sets forth for the preceding Calendar Quarter the following information:

(a) on a country by country basis, the aggregate Net Sales during such period;

(b) on a country by country basis, the amount of Product sold;

(c) a summary of itemized deductions, as described in the definition of Net Sales, used in calculating aggregate Net Sales; and

(d) the total amount due to Revogenex under Section 12.1 for such calendar quarter and the calculation thereof.

*Confidential material redacted and filed separately with the Commission.

12.4 Audit Rights. During each calendar quarter in which Royalties are due under Agreement and for a minimum of 18 months following the calendar quarter to which such records pertain, Coronado shall maintain, and shall require its Affiliates to maintain, books and records, consistent with sound business and accounting practices and in such form and in such detail as to enable the Revogenex, through an independent certified public accountant, to verify compliance with Applicable Law and the terms of this Agreement and any related agreement, including the amounts payable and other costs and financial information associated with Coronado's duties under this Agreement. Upon the prior written request of Revogenex made at least 45 days in advance, but not more than once in each calendar year, the Coronado shall permit an independent certified public accounting firm selected by the Revogenex to have access, during normal business hours, to such of its records as may be reasonably necessary to verify the accuracy of payments, reports and the like made to Revogenex with respect to any calendar year ending not more than three (3) years prior to Revogenex's request. Coronado shall provide reasonable cooperation with such accounting firm and shall not charge Revogenex for such cooperation. The accounting firm shall be bound by obligations of confidentiality and may disclose Revogenex only whether the records are correct or not and the specific details concerning any discrepancies; otherwise the accounting firm shall be prohibited from disclosing any information obtained or generated in connection with such review to any other Person. All audit materials and reports shall be held in confidence and not used for any purpose except for enforcing this Agreement. Prompt adjustment shall be made for any errors disclosed by such examination. If said audit reveals underpayments or other material record-keeping errors in excess of 5% of the amount actually due hereunder with respect to the calendar year in question, Coronado will pay all costs associated with such audit or will reimburse Revogenex for all costs associated with such audit within 30 days of receipt of notice setting forth such costs. Any underpayment shall be paid to Revogenex within 30 days of the report that identifies such overpayment or underpayment.

12.5 Currency; Payment Method; and Timing. All payments made under this Agreement shall be in U.S. dollars (USD) and shall be paid by wire transfer in same day funds. With respect to Net Sales invoiced in a currency other than United States dollars, such Net Sales will be converted into the United States dollar equivalent using the average conversion rate existing in the United States (as reported in The Wall Street Journal, New York edition) during the applicable calendar quarter.

12.6 Legally Required Taxes. Coronado shall be entitled to deduct any applicable withholding or other taxes, levies or charges that are required under Applicable Law to be withheld from any amounts payable to Revogenex hereunder; provided, such amounts are reflected on the payment and sales reports delivered pursuant to Section 12.2.

ARTICLE 13 - CONFIDENTIALITY

1 3 . 1 Confidential Information. As used herein, "Confidential Information" of Revogenex or Coronado shall mean all Proprietary Information or confidential information disclosed or furnished, whether in writing or orally, or obtained by a Party hereunder prior to or during the Term of this Agreement (a) that the receiving Party knows, or should reasonably know are or contain Trade Secrets or other Proprietary Information of the disclosing Party, (b) that bears a legend indicating that such information is confidential, or (c) without limiting subsection (a) above, if such information is disclosed orally, that is reduced to writing within 30 days of such disclosure and marked as confidential.

13.2 Non-Disclosure. During the Term of this Agreement, and for a period of 7 years thereafter with respect to the other Party's Confidential Information and indefinitely with regard Confidential Information that constitutes Trade Secrets, except as expressly authorized by the other Party in writing, each of Revogenex and Coronado agrees as follows:

(a) to use such Confidential Information exclusively for the purpose of exercising its rights and fulfilling its obligations under this Agreement or as may otherwise be agreed by the Parties in writing;

(b) to use the same degree of care to maintain such Confidential Information in confidence as it applies to confidential information of its own of the same type, but in no event less than a reasonable standard of care;

(c) to restrict disclosure of such Confidential Information to those of its Affiliates, employees, agents, directors, officers, financial advisors and consultants (and the employees of any thereof) who have a need to know such information and who are bound by obligations of confidentiality at least as stringent as those set forth herein, and refrain from disclosing such Confidential Information to anyone other than such Affiliates, employees, agents and consultants (and the employees of any thereof) on a need-to-know basis;

(d) to cause its Affiliates and each of its and its Affiliates' employees, Affiliates, employees, agents, directors, officers, financial advisors and consultants (and the employees of any thereof) who are to be given access to such Confidential Information to agree to be bound by the provisions of this Article 9 or by other provisions at least as protective as those set forth in this Article 9.

13.3 Exclusions. The confidentiality obligations set forth above in this Article 9 shall not be applicable to the following:

(a) information which was already in the public domain prior to its disclosure hereunder;

(b) information which became available to the public after the date of disclosure hereunder through no fault of the receiving Party;

(c) information which the receiving Party can demonstrate it already possessed without any confidentiality obligation therefore at the time of receipt thereof from the disclosing Party or is independently developed by the receiving Party without use of the Confidential Information;

(d) information which the receiving Party has obtained from a third Party which has no confidentiality obligation and duly possesses it; and

(e) information required to be disclosed by law or regulation or by order of a court or other governmental body after consultation with the Party who owns the Confidential Information and, if requested by such Party, cooperating with the Party who owns the Confidential Information to seek confidential treatment where available and only to the extent required thereby.

13.4 Destruction of Confidential Information. The receiving Party shall, upon the disclosing Party's written request, promptly return to the disclosing Party all copies of Confidential Information received from the disclosing Party, and shall return or destroy, and confirm the destruction of, all summaries, abstracts, extracts or other documents that contain any Confidential Information of the disclosing Party; provided, however, that the receiving Party may retain copies of Confidential Information (including summaries, abstracts, extracts or other documents that contain any Confidential Information) received from the disclosing Party if the retention of the same is necessary for regulatory purposes or is otherwise required by law or regulation.

13.5 Ownership. All Confidential Information disclosed hereunder shall remain the property of the disclosing Party unless it has been transferred pursuant to the terms of this Agreement.

13.6 Publicity; Disclosures. In the event either of the Parties desire to make an announcement of this Agreement, such announcement shall not be made unless reasonably satisfactory to both Parties. Except for such jointly agreed upon announcement, neither Party shall issue any press release or other publicity materials, or make any public presentation with respect to the terms or conditions of this Agreement without the prior written consent of the other Party (such consent to be given in the sole discretion of such Party). If this Agreement is terminated or expires, neither Party shall disclose to any third party the reason for such termination without the express written consent of the other Party, and the Parties shall agree upon statements for public disclosure, such agreement not to be unreasonably withheld or delayed.

13.7 Remedies. It is understood and agreed by both Revogenex and Coronado that misuse or disclosure of Confidential Information of the other Party could irreparably harm the business of the disclosing Party or that Party's Affiliates, and that as such, the aggrieved Party shall have the right to seek injunctive relief to protect its rights in connection therewith.

13.8 Trade Secrets. Nothing in this Agreement will be construed as limiting the availability or effect of any Applicable Laws purporting to protect Trade Secrets.

ARTICLE 14 - INDEMNIFICATION

14.1 Indemnity. Each Party (an "Indemnitor") hereby agrees to indemnify and hold harmless the other Party and its respective Affiliates, and each of their respective officers, directors, managers, employees, agents, members, partners and stockholders (collectively, an "Indemnitee"), to the fullest extent lawful, from and against any and all losses, claims, damages, expenses or liabilities incurred or payable (collectively, "Losses"), including reasonable attorneys' fees and expenses incurred in connection with the investigation of any pending or threatened claims or preparation for any pending or threatened litigation or other proceedings (collectively, "Expenses") in connection with (a) any claims by the other Party for a breach of such Indemnitor's representations or warranties set forth in this Agreement or covenants made pursuant to this Agreement or (b) any Third Party Claims arising out of or relating to: (i) the Indemnitor's breach of any representation or warranty set forth in this Agreement; (ii) where Coronado is the Indemnitor, any infringement of any rights of any other Person by the marketing, Commercialization or sale of the Product provided that such infringement does not relate to the formulation of the Product or the Product Intellectual Property licensed to Coronado or Intellectual Property Rights or Acquired Assets sold to Coronado hereunder; or (iii) where Revogenex is the Indemnitor, any infringement of any rights of any other Person by the manufacturing, marketing and distribution of the Product developed by Revogenex hereunder, including the formulation of the Product.

14.2 Defense of Third Party Claims. Any Indemnitee making a claim for indemnification under this Article 10 shall notify the Indemnitor of the claim in writing promptly after receiving written notice of any action, lawsuit, proceeding, investigation or other claim against it (if by a third party) (each, a "Third Party Claim"), describing the claim, the amount thereof (if known and quantifiable) and the basis thereof; provided, however, that the failure to so notify an Indemnitor shall not affect the obligations of the Indemnitor hereunder unless the Indemnitor is actually prejudiced by such failure. Any Indemnitor shall be entitled to participate in the defense of such Third Party Claim giving rise to an Indemnitee's claim for indemnification at such Indemnitor's expense, and at its option (subject to the limitations set forth below) shall be entitled to assume the defense thereof by appointing a reputable counsel reasonably acceptable to the Indemnitee to be the lead counsel in connection with such defense; provided, however, that prior to the Indemnitor assuming control of such defense it shall first verify to the Indemnitee in writing that such Indemnitor shall be fully responsible (with no reservation of any rights) for all Losses and Expenses relating to such claim for indemnification and that it shall provide full indemnification to the Indemnitee with respect to such Third Party Claim giving rise to such claim for indemnification hereunder; and provided, further, that:

(a) the Indemnitee shall be entitled to participate in the defense of such claim and to employ counsel of its choice for such purpose, provided, that the fees and expenses of such separate counsel shall be borne by the Indemnitee (other than any fees and expenses of such separate counsel that are incurred prior to the date the Indemnitor effectively assumes control of such defense which, notwithstanding the foregoing, shall be borne by the Indemnitor);

(b) the Indemnitor shall not be entitled to assume control of such defense and shall pay the reasonable fees and expenses of counsel retained by the Indemnitee if (i) the claim for indemnification relates to or arises in connection with any criminal proceeding, action, indictment, allegation or investigation of or concerning the Indemnitee but not the Indemnitor; (ii) the Indemnitee reasonably believes that an adverse determination with respect to the Third Party Claim giving rise to such claim for indemnification would be detrimental to or injure the Indemnitee's reputation or future business prospects; (iii) the claim seeks an injunction or equitable relief against the Indemnitee; (iv) a conflict of interest exists between the Indemnitor and the Indemnitee; or (v) the Indemnitor failed or is failing to vigorously prosecute or defend such claim; and

(c) if the Indemnitor is controlling the defense of any such claim, the Indemnitor shall obtain the prior written consent of the Indemnitee before entering into any settlement or ceasing to defend such claim if, pursuant to or as a result of such settlement or cessation, injunctive or other equitable relief will be imposed against the Indemnitee or any Intellectual Property Rights of the Indemnitee shall be rendered invalid or unenforceable, or if such settlement does not expressly and unconditionally release the Indemnitee from all liabilities and obligations with respect to such claim, without prejudice, or if any payment is required by the Indemnitee which is not entitled to indemnification from the Indemnitor.

14.3 LIMITED LIABILITY. EXCEPT WITH RESPECT TO FRAUD, OR ANY BREACH OF THE CONFIDENTIALITY OBLIGATIONS SET FORTH IN ARTICLE 10, NO PARTY TO THIS AGREEMENT SHALL BE LIABLE WITH RESPECT TO ANY SUBJECT MATTER OF THIS AGREEMENT UNDER ANY CONTRACT, NEGLIGENCE, STRICT LIABILITY OR OTHER LEGAL OR EQUITABLE THEORY FOR (A) ANY INCIDENTAL OR CONSEQUENTIAL DAMAGES OR LOST PROFITS OR (B) THE COST OF PROCUREMENT OF SUBSTITUTE GOODS, TECHNOLOGY OR SERVICES. IN ADDITION, REVOGENEX'S LIABILITY TO CORONADO WITH RESPECT TO ANY SUBJECT MATTER OF THIS AGREEMENT UNDER ANY CONTRACT, NEGLIGENCE, STRICT LIABILITY OR OTHER LEGAL OR EQUITABLE THEORY SHALL NOT EXCEED AMOUNTS RECEIVED BY REVOGENEX PURSUANT TO THE TERMS OF THIS AGREEMENT. THIS SECTION 14.3 DOES NOT LIMIT OR RESTRICT THE OBLIGATIONS OF A PARTY WITH RESPECT TO INDEMNIFICATION AGAINST THIRD PARTY CLAIMS.

ARTICLE 15 - INSURANCE

15.1 Insurance. In order to provide for the protection of the Parties against any claims, suits, liabilities, losses or damages arising in connection with this Agreement, each of the Parties shall obtain and maintain in full force and effect during the Royalty Term of this Agreement, and for a period of 2 years thereafter, at its own expense, the following insurance from an insurance carrier with an AM Best rating of A or higher:

(a) Product liability insurance (including without limitation bodily injury and property damage coverage) (i) at limits not less than $* per occurrence/ $* aggregate prior to the Commercial Launch of the Product by Coronado and (ii) at limits not less than $* occurrence per $* aggregate following the Commercial Launch of the Product by Coronado; and

(b) Commercial General liability insurance (including without limitation bodily injury and property damage coverage), at limits not less than $* per occurrence/ $* aggregate.

15.2 Additional Insured. Each Party's commercial general liability, products liability, and clinical trials liability insurance policy (if any) shall name the other Party and its Affiliates as an additional insured and provide that the other Party shall receive at least 30 days' notice of any cancellation, modification or expiration of such policy. Each Party shall provide a fully paid certificate of insurance naming the other Party as an additional named insured promptly after the Effective Date. Each Party shall provide the other with prompt written notice of any actual or threatened cancellation, modification or expiration of such policy of which it becomes aware. If a Party terminates its commercial general liability, products liability or clinical trials insurance policies during the term of this Agreement, or any of the referenced policies are claims-made, that Party shall obtain and maintain the maximum available extended discovery period (i.e., "tail coverage") insurance, but not less than 3 years for non-topical products.

*Confidential material redacted and filed separately with the Commission.

ARTICLE 16 - TERM AND TERMINATION

16.1 Term. This Agreement shall commence as of the Effective Date and, unless terminated earlier in accordance with Section 16.2, shall remain in force on a Product-by-Product and country-by-country basis until the expiration of the last Valid Claim to expire of the Patents covering such Product in such country (the "Term").

16.2 Termination. This Agreement shall terminate upon the occurrence of any of the following events or conditions which termination shall automatically occur where termination by a specified Party is not indicated and shall occur by action of the specified Party where so indicated:

(a) The expiration of the Term;

(b) The material breach by either Party of any provision of this Agreement which is not cured within 60 days from the date of written notice delivered to the defaulting Party, unless such breach, not involving the payment of money, is of a nature that cannot be cured within such 60 day period and the breaching Party initiates the cure of such breach and proceeds diligently to remedy same, but in no event may such period exceed 90 days, provided, however, that only the aggrieved Party can terminate this Agreement pursuant to this Section 16.2(b);

(c) The mutual written agreement of the Parties to this Agreement;

(d) By either Party hereto, effective immediately upon receipt of written notice, if (i) the other Party hereto applies for or consents to the appointment of a custodian, receiver, trustee, or liquidator of all or a substantial part of its assets, or makes a general assignment for the benefit of creditors, or (ii) the other Party hereto files, or submits, a petition or answer seeking an arrangement with its creditors under any bankruptcy or insolvency law or proceeding, or (iii) any order, judgment or decree is entered against the other Party hereto, without the application, consent or approval of such Party appointing a custodian, receiver, trustee or liquidator or a substantial part of its assets or approving a petition seeking reorganization of such party and such order, judgment, or decree shall continue unstayed and in effect for any period of 60 days, or (iv) the other Party hereto fails to remove an involuntary petition in bankruptcy filed against it within 45 days of the filing thereof, or (v) any order for relief is entered against the other Party hereto under the United States Bankruptcy Code; or

(e) By Revogenex if the NDA has not been filed within 36 months of the Effective Date and Coronado is in breach of Section 2.1 for failure to use Commercially Reasonable Efforts to carry out all of the Product Development.

(f) 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; provided, however, this termination right arising at the end of such 15 month period shall be tolled if Coronado is using Commercially Reasonable Efforts in its negotiations with the FDA for Approval; provided further, if Coronado receives a "not approvable" notice, Coronado shall have a 15 month period to correct any issues and re-file the NDA for Approval.

(g) By Coronado given its reasonable determination prior to NDA Approval pursuant to Article 3 that the Development of the Product pursuant to this Agreement is not economically viable.

(h) By either Revogenex or Coronado (provided Coronado is using or has used Commercially Reasonable Efforts to commercialize the Product), at each Party's respective option, if, after the third anniversary of the date of Commercial Launch, Coronado fails to achieve annual Net Sales with respect to the Product of at least $* in any given calendar year; provided, however, Coronado shall have a right (the "Cure Right"), in order to avoid termination by Revogenex pursuant to this subsection, to pay Revogenex, within 45 days after the end of the calendar year in which Net Sales were less than $*, an amount equal to the difference in the Royalties actually paid to Revogenex for such calendar year and the amount of Royalties that would be payable on $* of Net Sales; provided, however, Coronado shall not exercise the Cure Right more than once without Revogenex's express written consent; provided further, that this provision shall not be effective if at the time Coronado fails to achieve annual Net Sales of $* for any given calendar year, during such calendar year a Generic Product was marketed and sold in the Territory.

16.3 Accrued Obligations. Except as otherwise expressly provided for in this Agreement, termination or expiration of this Agreement shall not relieve the Parties of any obligation accruing prior thereto and shall be without prejudice to any other rights or remedies that may be available to a Party under this Agreement, at law, in equity or otherwise.

16.4 Return of IND/NDA Upon Termination. Upon Termination of the Agreement as set forth in Section 16.2, Coronado shall assign to Revogenex (i) the IND/NDA and all Regulatory Documentation, (ii) all Coronado Marks, (iii) any manufacturing and supply agreements between Coronado and the Manufacturer or any other third party for manufacture of the Product, to the extent assignable and (iv) all other agreements or documents related to the IND/NDA, Coronado marks or manufacture of the Product, to the extent assignable. Coronado shall use commercially reasonable efforts to assign all agreements or documents referenced in subsections (iii) and (iv) above.

*Confidential material redacted and filed separately with the Commission;

ARTICLE 17 - MISCELLANEOUS

17.1 Notices. All notices, requests, demands, claims, and other communications hereunder will be in writing in English. Any notice, request, demand, claim, or other communication hereunder shall be deemed duly given (i) when delivered personally to the recipient, (ii) 1 business day after being sent to the recipient by reputable overnight courier service (charges prepaid), (iii) 1 business day after being sent to the recipient by facsimile transmission or electronic mail with confirmation of receipt, or (iv) 4 business days after being mailed to the recipient by certified or registered mail, return receipt requested and postage prepaid, and addressed to the intended recipient as set forth below:

If to Revogenex:	Revogenex Ireland Limited c/o Trinity House Charleston Road Dublin 6, Ireland Attention: Jeffrey H. Ping. Email: j.ping@revogenex.com
With copies to:	Sutherland Asbill & Brennan LLP 999 Peachtree Suite NE, Suite 2300 Atlanta, Georgia 30309 Attention: Michael J. Voynich Email: michael.voynich@sutherland.com
If to Coronado:	Coronado Biosciences, Inc. 3 Columbus Circle New York, New York 10023 Attention: Lucy Lu Email: llu@coronadobio.com
With copy to:	Alston & Bird LLP 90 Park Ave. New York, NY 10016 Attention: Mark F. McElreath Email: mark.mcelreath@alston.com

Any Party may change the address to which notices, requests, demands, claims, and other communications hereunder are to be delivered by giving the other Party notice in the manner herein set forth.

17.2 Governing Law. This Agreement shall be governed by and construed in accordance with the domestic laws of the State of New York without giving effect to any choice or conflict of law provision or rule (whether of the State of New York or any other jurisdiction) that would cause the application of the laws of any jurisdiction. The Parties expressly exclude any application of the United Nations Convention on Contracts for the International Sale of Goods.

17.3 Amendment. The terms and conditions of this Agreement take precedence over any terms and conditions in any form of purchase order or other business form used by the Parties. No amendment of this Agreement shall be effective unless expressly set forth in a writing referring specifically to the provision to be amended and executed by each of the Parties. This Agreement constitutes the entire agreement of the Parties with respect to the subject matter hereof.

17.4 Waiver. No waiver by any Party of any default, misrepresentation, or breach of warranty or covenant hereunder, whether intentional or not, shall be valid unless the same shall be in writing and signed by the Party making such waiver nor shall such waiver be deemed to extend to any prior or subsequent default, misrepresentation, or breach of warranty or covenant hereunder or affect in any way any rights arising by virtue of any prior or subsequent default, misrepresentation, or breach of warranty or covenant. Notwithstanding the foregoing, a Party shall be deemd to have waived any default, misrepresentation or breach of a warranty or covenant hereunder arising prior to the date hereof if Effective Time if such Party has actual knowledge of such, default, misrepresentation or breach prior to the Effective Time.

17.5 Severability. Any term or provision of this Agreement that is invalid or unenforceable in any situation in any jurisdiction shall not affect the validity or enforceability of the remaining terms and provisions hereof or the validity or enforceability of the offending term or provision in any other situation or in any other jurisdiction; and insofar as commercially reasonable, the Parties in good faith shall endeavor to implement the remaining terms of this Agreement.

17.6 Expenses. Other than as set forth herein, each Party will bear its own costs and expenses (including legal fees and expenses) incurred in connection with this Agreement and the transactions contemplated hereby.

17.7 Construction. The Parties have participated jointly in the negotiation and drafting of this Agreement. In the event an ambiguity or question of intent or interpretation arises, this Agreement shall be construed as if drafted jointly by the Parties and no rule of strict construction, presumption or burden of proof shall arise favoring or disfavoring any Party by virtue of the authorship of any of the provisions of this Agreement. As used herein, the word “including” shall be deemed to mean “including without limitation” and the word “will” has the same meaning as the word “shall” and means an imperative.

17.8 Force Majeure. Neither Party shall be liable for any failure or delay in the performance of its obligations under this Agreement to the extent such failure or delay both: (i) is caused by any of the following: acts of war, terrorism, civil riots or rebellions; quarantines, embargoes and other similar unusual governmental action; extraordinary elements of nature or acts of God or other event or condition outside the reasonable control of the Party subject to such failure or delay; and (ii) could not have been prevented by the non-performing Party’s reasonable precautions or commercially accepted processes, or could not reasonably be circumvented by the non-performing Party through the use of substitute services, disaster recovery plans, alternate sources, work-around plans or other means. An event meeting both of the criteria set forth in (i) and (ii) is referred to herein as a “Force Majeure Event.” The Parties expressly acknowledge that Force Majeure Events do not include the regulatory acts of governmental agencies in the ordinary course or labor strikes by the workforce of the Party subject to the failure or delay. Upon the occurrence of a Force Majeure Event, the non-performing Party shall be excused from any further performance or observance of the affected obligation(s) for as long as such circumstances prevail, so long as such Party continues to attempt to recommence performance or observance to the greatest extent possible without delay.

17.9 Alternative Dispute Resolution. In the event of any dispute relating to this Agreement, the Parties shall refer such dispute to the Chief Executive Officer of Revogenex and the Chief Executive Officer of Coronado, who, as soon as is practicable, and in any event within 30 days, with the optional assistance of a mediator as provided below, shall attempt in good faith to resolve the dispute. The Parties shall select a mediator who shall serve as an impartial facilitator of such discussion. If the Parties are unable to agree upon a mediator, a mediator shall be designated by the American Arbitration Association ("AAA"). The mediator shall be treated as a settlement discussion and therefore matters discussed will be privileged and confidential. The mediator may not testify for either Party in any later proceeding relating to the dispute, and no recording or transcript shall be made of the mediation proceedings. Each Party shall bear its own costs in the mediation and the fees and costs thereof shall be shared equally.

17.10 Submission to Jurisdiction. Each of the Parties irrevocably submits to the jurisdiction of any state or federal court sitting in New York in any action or proceeding arising out of or relating to this Agreement and agrees that all claims in respect of the action or proceeding may be heard and determined in any such court. Each Party also agrees not to bring any action or proceeding arising out of or relating to this Agreement in any other court (except as may be necessary to protect its proprietary rights or obtain injunctive relief or specific performance). Each of the Parties waives any defense of inconvenient forum, lack of jurisdiction or improper venue to the maintenance of any action or proceeding so brought and waives any bond, surety, or other security that might be required of any other Party with respect thereto. Any Party may make service on the other Party by sending or delivering a copy of the process to the Party to be served at the address and in the manner provided for the giving of notices in Section 17.1 above. Nothing in this Section 17.12, however, shall affect the right of any Party to serve legal process in any other manner permitted by law or in equity. Each Party agrees that a final judgment in any action or proceeding so brought shall be conclusive and may be enforced by suit on the judgment or in any other manner provided by law or in equity.

17.11 THE PARTIES HEREBY WAIVE ANY RIGHT TO TRIAL BY JURY IN ANY ACTION OR PROCEEDING ARISING OUT OF OR RELATING TO THIS AGREEMENT OR ANY TRANSACTION CONTEMPLATED HEREBY, WHETHER NOW EXISTING OR HEREAFTER ARISING, AND WHETHER SOUNDING IN CONTRACT, TORT OR OTHERWISE. THE PARTIES AGREE THAT ANY OF THEM MAY FILE A COPY OF THIS SECTION WITH ANY COURT AS WRITTEN EVIDENCE OF THE KNOWING, VOLUNTARY AND BARGAINED-FOR AGREEMENT AMONG THE PARTIES IRREVOCABLY TO WAIVE TRIAL BY JURY AND THAT ANY ACTION OR PROCEEDING WHATSOEVER BETWEEN THEM RELATING TO THIS AGREEMENT OR ANY TRANSACTION CONTEMPLATED HEREBY SHALL INSTEAD BE TRIED IN A COURT OF COMPETENT JURISDICTION BY A JUDGE SITTING WITHOUT A JURY.

17.12 Assignment; Binding Effect. The terms and provisions hereof shall inure to the benefit of, and be binding upon Revogenex, Coronado and their respective successors and permitted assigns. Except as set forth below, neither Party may assign, sublicense or transfer any of its rights or obligations under this Agreement, by operation of law or otherwise, without the prior written consent of the other, except that assignments, sublicenses and transfers to an Affiliate of a Party may be made without written consent of the other Party; provided, such Affiliate agrees to be bound by the terms of this Agreement; provided, further, that this Agreement shall not be assigned, sublicensed or transferred to an entity that does not own the Acquired Assets, the IND/NDA and all Regulatory Documentation, the Coronado Marks and the other documents described in Section 16.4 (collectively, the "Product Related Materials") and Coronado will not transfer the Product Related Materials to any entity unless this Agreement is assigned in accordance with this Agreement in conjunction with such transfer. Notwithstanding anything herein to the contrary, Revogenex shall, without consent of the other Party hereto, have the right to assign its rights in and to any payments hereunder and collaterally assign its rights in and to this Agreement and the Product Intellectual Property. Any attempt to assign this Agreement in violation of the provisions set forth herein shall be deemed a default by the assigning Party under this Agreement and null and void. Notwithstanding the forgoing, this Agreement shall be assignable by the other Party to any Person who acquires all or substantially all of the assets of such other Party or otherwise acquires the other Party, directly or indirectly (whether by purchase of stock, merger, consolidation or otherwise), including the Product Related Materials. Any permitted assignee of either Party will, as a condition to such assignment, assume all obligations of its assignor arising under this Agreement following such assignment. This Agreement shall inure to the benefit of and be binding upon the successors and permitted assigns and permitted transferees of the Parties hereto.

17.13 No Third Party Beneficiaries. Except as may be set forth elsewhere in this Agreement, neither Coronado nor Revogenex intend that any third Party is to benefit from the terms of this Agreement other than an Affiliate, successor or permitted assign.

17.14 Section Headings. The titles or headings of all sections in this Agreement are for convenient reference only, are not part of this Agreement, and do not limit or otherwise affect its terms.

17.15 Independent Contractors. Each of Coronado and Revogenex are independent contractors, and nothing in this Agreement shall be construed as to create a partnership, agency, or employer-employee relationship between Coronado and Revogenex. The rights, obligations and liabilities of the Parties shall be several and not joint or collective.

17.16 Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

17.17 Further Assurances. Each Party hereto agrees to execute such further documents or agreements and take such further actions as may be reasonably necessary or desirable to effect the purpose of this Agreement and carry out its provisions.

17.18 Survival. Notwithstanding any termination, expiration or cancellation of this Agreement, the terms and conditions set forth in Articles 1, 3, 4, 5, 6, 7, 10, 13, 14, and 17, and Sections 8.4, 9.2, 9.5, 12.4, 12.6, 16.2, 16.3, and 16.4 shall continue in full force and effect.

[The remainder of this page is intentionally blank. Signatures appear on the following page.]

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their duly authorized representatives as of the Effective Date.

REVOGENEX IRELAND LIMITED

By: /s/
Title:
Date:

CORONADO BIOSCIENCES, INC.

By: /s/
Title:
Date:

Schedule A
Patents

1. U.S. Serial No. *, filed *, a continuation of *; Inventors: *; Issued *.

2. *; Inventors: *; Issued *.

*Confidential material redacted and filed separately with the Commission.

EXHIBIT B

BILL OF SALE

THIS BILL OF SALE (this "Instrument") is made, executed and delivered by and between Coronado Biosciences, Inc., a Delaware corporation ("Coronado"), and Revogenex Ireland Limited, an Irish limited company ("Revogenex"), dated as of February 17, 2015 (the "Closing Date"). Capitalized terms not defined herein have the meanings set forth in the Agreement (as defined below).

WITNESSETH

WHEREAS, Revogenex and Coronado have entered into an Asset Transfer and License Agreement, dated as of February 17, 2015 (the "Agreement"), pursuant to which Coronado will acquire certain of Revogenex's assets and assume certain of Revogenex's liabilities;

WHEREAS, the execution and delivery of this Instrument by Revogenex and Coronado is required to consummate the transactions contemplated by the Agreement;

NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, and pursuant to the Agreement, Revogenex and Coronado hereby agree as follows (capitalized terms used and not defined herein are used herein as defined in the Agreement):

1. Bill of Sale. As of the Closing Date, Revogenex does hereby sell, convey, assign and transfer unto Coronado forever all right, title and interest, legal and equitable, of Revogenex in and to all of the Acquired Assets.

2. Miscellaneous Provisions.

(a) Further Assurances. On and after the Closing Date, Revogenex shall give such further assurances to Coronado and shall execute, acknowledge and deliver all such acknowledgements, endorsements, assignments and other instruments and take such further action as may be reasonably necessary and appropriate to vest in Coronado all of Revogenex's right, title, and interest in and to the Acquired Assets.

(b) Successors in Interest. This Instrument is binding upon the parties and their successors and assigns and inures to the benefit of the parties and their permitted successors and assigns.

(c) Agreement. This Bill of Sale is made and accepted subject to the terms and provisions of the Agreement.

(d) Controlling Law. This Instrument shall be governed by, construed and enforced in accordance with the laws of the State of New York.

(e) Counterparts. This Instrument may be executed in counterparts, each of which shall be deemed to be an original, but all of which together shall constitute one and the same instrument.

[Signatures are on the following page]

DULY EXECUTED and delivered by the parties to this Instrument as of the date and time first written above.

Revogenex:

REVOGENEX IRELAND LIMITED

By: _____
Name: _____
Title: _____

Coronado:

CORONADO BIOSCIENCES, INC.

By: _____
Name: _____
Title: _____

* * * * *

EXHIBIT C

ASSIGNMENT AND ASSUMPTION AGREEMENT

THIS ASSIGNMENT AND ASSUMPTION AGREEMENT (this "Instrument") is made by and between Coronado Biosciences, Inc., a Delaware corporation ("Asignee"), and Revogenex Ireland Limited, an Irish limited company ("Assignor"), dated as of February 17, 2015 (the "Closing Date"). Capitalized terms not defined herein have the meanings set forth in the Agreement (as defined below).

WITNESSETH

WHEREAS, Assignor and Assignee are parties to that certain Asset Transfer and License Agreement, dated as of February 17, 2015 (the "Agreement"), pursuant to which Assignor has agreed to sell and assign to Assignee the Acquired Assets together with the Assumed Liabilities;

WHEREAS, in connection with the Agreement, Assignor wishes to assign, and Assignee wishes to assume, the Acquired Assets together with the Assumed Liabilities; and

NOW, THEREFORE, in consideration of the foregoing and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereby agree as follows:

1 . Assignment and Assumption. Assignor hereby assigns, conveys, transfers and delivers to Assignee, and Assignee hereby accepts and assumes, in full, all of the Acquired Assets. Assignor hereby assigns, conveys, transfers and delivers to Assignee, and Assignee hereby accepts and assumes, in full, the Assumed Liabilities. For the avoidance of doubt, Assignor does not assign, convey, transfer or deliver to Assignee, and Assignee does not accept or assume, any Excluded Assets or any Excluded Liabilities.

2 . Further Assurances. On and after the Closing Date, Assignor shall give such further assurances to Assignee and Assignee shall give such further assurances to Assignor, and Assignor and Assignee shall execute, acknowledge and deliver all such acknowledgements, endorsements, assignments and other instruments and take such further action as may be reasonably necessary and appropriate to cause the transactions contemplated in this Instrument to be carried out promptly in accordance with the terms of this Instrument and the Agreement.

3. Miscellaneous Provisions.

(a) Successors in Interest. This Instrument is binding upon the parties and their successors and assigns and inures to the benefit of the parties and their permitted successors and assigns.

(b) Agreement. This Agreement is made and accepted subject to the terms and provisions of the Agreement.

(c) Governing Law. This Agreement shall be interpreted, construed, and enforced in all respects in accordance with the laws of the State of New York.

(d) Counterparts. This Agreement may be executed in one or more counterparts, each of which is deemed an original, but all of which together constitute one and the same instrument.

[Signatures are on the following page]

Schedule 3.1(a)
Assumed Contracts

1. Polpharma Product Manufacturing Agreement, dated October 12, 2010 by and among Revogenex Ireland Limited and Z.F. Polpharma S.A. .

Schedule 3.1(b)
Government Filings

1. IND #: *, Sponsor: Revogenex, Inc.; Product Name: * (Tramadol Hydrochloride Solution); Date of Submission: *.

*Confidential material redacted and filed separately with the Commission.

Schedule 3.1(c)
Claims

1. None

Schedule 4.2(b)
Required Consents

1. Consent of Polpharnia, to be obtained within 120 days after the Effective Date.

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their duly authorized representatives as of the Effective Date.

REVOGENEX IRELAND LIMITED

By: _____
Title:
Date:

CORONADO BIOSCIENCES, INC.

By: _____
Title:
Date:

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their duly authorized representatives as of the Effective Date.

REVOGENEX IRELAND LIMITED

By: _____
Title:
Date:

CORONADO BIOSCIENCES, INC.

By: _____
Title:
Date:

Exhibit 10.2

AMENDED AND RESTATED FOUNDERS AGREEMENT

THIS AMENDED AND RESTATED FOUNDERS AGREEMENT (this "***Agreement***") is made as of September 13, 2016 (the "***Effective Date***") by and between Fortress Biotech, Inc., a Delaware corporation (the "***Founder***"), and Avenue Therapeutics, Inc., a Delaware corporation (the "***Company***").

WHEREAS, Founder formed Company on February 9, 2015, for the purpose of acquiring, licensing, developing and commercializing specialty pharmaceutical products (the "***Business***") and Founder and the Company previously entered into a Founders Agreement effective as of February 17, 2015 (the "***Existing Founders Agreement***"); and

WHEREAS, Founder has identified or has acquired certain assets (the "***Assets***") that will allow Company to carry out the Business and Founder is willing to assign and contribute its interest in the Assets to Company under the terms and conditions of this Agreement;

NOW, THEREFORE, in consideration of the mutual representations, warranties, covenants and agreements contained in this Agreement, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties agree as follows:

1. Assignment of Assets and Payment.

1.1 Assignment of Founders Rights in Assets. Founder negotiated the right to acquire or license the Assets and agreed to assign all of its right, title and interest in the Assets, including without limitation, the Founder contributing, assigning, transferring and delivering to Company on February 17, 2015 the Assets set forth on Schedule A, free and clear of all liens.

1.2 In exchange for the consideration contained in Section 1.1:

(a) Founder shall receive 250,000 shares of Class A Preferred Stock of the Company and 8,471,250 shares of Common Stock of the Company;

(b) Company shall assume in the future all of Founder's liabilities, obligations, rights, title and interest in that certain indebtedness described on Schedule A (the "***Indebtedness***");

(c) [Reserved].

(d) Founder shall receive an equity fee payable in shares of Common Stock equal to two and one-half percent (2.5%) of the gross amount of any equity or debt financing, payable within five (5) business days of the closing of any equity or debt financing for the Company or any of its respective subsidiaries that occurs after the date hereof and ending on the date when Founder no longer has majority voting control in Company's voting equity. In calculating the number of shares payable hereunder, in the case of an equity financing, the number of shares issuable will be based on the share price of the equity in such round; and (ii) in the case of a debt financing, the number of shares issuable will be based on the closing price of the common shares of the company on the day prior to the closing of the debt financing or if not publicly-traded, the price of the common shares in the last equity financing.

(e) In the event of a Change in Control, Founder shall receive a one-time change in control fee equal to five times the product of (i) Net Sales (defined below) for the twelve (12) months immediately preceding the Change in Control and (ii) 4.5%.

For purposes of this Agreement, "***Change of Control***" shall mean the occurrence of any of the following events:

(i) during any consecutive 12-month period, individuals who, at the beginning of such period, constitute the board of directors of the Company (the "***Incumbent Directors***") cease for any reason to constitute at least a majority of such Board, provided that any person becoming a director after the beginning of such 12-month period and whose election or nomination for election was approved by a vote of at least a majority of the Incumbent Directors then on the Board shall be an Incumbent Director; provided, however, that no individual initially elected or nominated as a director of the Company as a result of an actual or threatened election contest with respect to the election or removal of directors ("***Election Contest***") or other actual or threatened solicitation of proxies or consents by or on behalf of any "person" (as such term is defined in Section 3(a)(9) of the Securities Exchange Act of 1934 (the "***1934 Act***") and as used in Section 13(d)(3) and 14(d)(2) of the 1934 Act) other than the Board ("***Proxy Contest***"), including by reason of any agreement intended to avoid or settle any Election Contest or Proxy Contest, shall be deemed an Incumbent Director;

(ii) any person becomes a "beneficial owner" (as defined in Rule 13d-3 under the 1934 Act), directly or indirectly, of either (A) 35% or more of the then-outstanding shares of common stock of the Company ("***Company Common Stock***") or (B) securities of the Company representing 35% or more of the combined voting power of the Company's then-outstanding securities eligible to vote for the election of directors (the "***Company Voting Securities***"); provided, however, that for purposes of this subsection (ii), the following acquisitions of Company Common Stock or Company Voting Securities shall not constitute a Change of Control: (i) an acquisition directly from the Company, (ii) an acquisition by the Company or any corporation, limited liability company, partnership or other entity of which a majority of the outstanding voting stock or voting power is beneficially owned directly or indirectly by the Company (a "***Subsidiary***"), (iii) an acquisition by any employee benefit plan (or related trust) sponsored or maintained by the Company or any Subsidiary, or (iv) an acquisition pursuant to a Non-Qualifying Transaction (as defined in subsection (iii) below);

(iii) the consummation of a reorganization, merger, consolidation, statutory share exchange or similar form of corporate transaction involving the Company or a subsidiary (a "***Reorganization***"), or the sale or other disposition of all or substantially all of the Company's assets (a "***Sale***") or the acquisition of assets or stock of another corporation or other entity (an "***Acquisition***"), unless immediately following such Reorganization, Sale or Acquisition: (A) all or substantially all of the individuals and entities who were the beneficial owners, respectively, of the outstanding Company Common Stock and outstanding Company Voting Securities immediately prior to such Reorganization, Sale or Acquisition beneficially own, directly or indirectly, more than 35% of, respectively, the then outstanding shares of common stock and the combined voting power of the then outstanding voting securities entitled to vote generally in the election of directors, as the case may be, of the entity resulting from such Reorganization, Sale or Acquisition (including, without limitation, an entity which as a result of such transaction owns the Company or all or substantially all of the Company's assets or stock either directly or through one or more subsidiaries, the "***Surviving Entity***") in substantially the same proportions as their ownership, immediately prior to such Reorganization, Sale or Acquisition, of the outstanding Company Common Stock and the outstanding Company Voting Securities, as the case may be, and (B) no person (other than (x) the Company or any Subsidiary, (y) the Surviving Entity or its ultimate parent entity, or (z) any employee benefit plan (or related trust) sponsored or maintained by any of the foregoing) is the beneficial owner, directly or indirectly, of 35% or more of the total common stock or 35% or more of the total voting power of the outstanding voting securities eligible to elect directors of the Surviving Entity, and (C) at least a majority of the members of the board of directors of the Surviving Entity were Incumbent Directors at the time of the Board's approval of the execution of the initial agreement providing for such Reorganization, Sale or Acquisition (any Reorganization, Sale or Acquisition which satisfies all of the criteria specified in (A), (B) and (C) above shall be deemed to be a "***Non-Qualifying Transaction***"); or

(iv) approval by the stockholders of the Company of a complete liquidation or dissolution of the Company.

(f) Founder shall receive a cash fee equal to four percent (4.5%) of annual Net Sales, payable on an annual basis, within 90 days of the end of each calendar year. For purposes of this Agreement, "***Net Sales***" shall mean the gross amount invoiced or otherwise charged by Company, its Affiliates and Licensees ("***Selling Party***") to third parties in arm's length transactions for sales of any Product during a calendar year, less:

(i) Normal and customary trade, quantity, cash and discounts and credits allowed and taken;

(ii) Discounts, refunds, rebates, chargebacks, retroactive price adjustments, and any other allowances given and taken which effectively reduce the net selling price (other than such which have already diminished the gross amount invoiced such as those outlined in Section 1.2(f)(i) above), including, without limitation, Medicaid rebates, institutional rebates or volume discounts;

(iii) Product returns and allowances granted to such third party;

(iv) Administrative fees paid to group purchasing organizations (e.g., Medicare) and government-mandated rebates;

(v) Shipping, handling, freight, postage, insurance and transportation charges, but all only to the extent included as a separate line item in the gross amount invoiced;

(vi) Any tax, tariff or duties imposed on the production, sale, delivery or use of the Product, including, without limitation, sales, use, excise or value added taxes and customs and duties, but all only to the extent included as a separate line item (e.g., "taxes") in the gross amount invoiced; and

(vii) Bad debt actually written off during the accounting period, as reported by the Selling Party in accordance with GAAP, applied on a consistent basis (provided, that any bad debt write-off so taken which is later reversed shall be added back to Net Sales in the accounting period in which the reversal occurs.)

Products are considered "sold" when billed out or invoiced or, in the event such Products are not billed out or invoiced, when the consideration for sale of the Products is received. If a sale, transfer or other disposition with respect to Products involves consideration other than cash or is not at arm's length, then the Net Sales from such sale, transfer or other disposition shall be calculated from the average selling price for such Product during the calendar quarter in the country where such sale, transfer or disposition took place. Notwithstanding the foregoing, Net Sales shall not include, and shall be deemed zero with respect to, (i) Products used by Company, its Affiliates, or Licensees for their internal use, (ii) the distribution of promotional samples of Products provided free of charge, (iii) Products provided for clinical trials or research, development, or evaluation purposes, or (iv) sales of Products among Company and its Licensees and their respective Affiliates for resale.

"***Product***" means any product, (i) owned by Company or (ii) exclusively licensed to Company.

"***License***" means granting a third party or Affiliate a right to make, have made, use, offer for sale, sell or import a Product.

"***Licensee***" means a person or entity granted a License.

1.3 Reports; Audits.

(a) Within ninety (90) days following the last day of each calendar year, Company shall provide to Founder a written statement (i) stating (as applicable) the aggregate Net Sales, by country, of each Product sold during the relevant calendar year by Company, its Affiliates and Licensees, and (ii) detailing the calculation of amounts due pursuant to Section 1.2(f) for such calendar year.

(b) Company shall keep or cause to be kept such records as are reasonably required to determine the amounts due under this Agreement; such records must be kept for a minimum of three (3) years following the calendar year to which such records pertain. At the request (and expense) of Founder, Company shall permit Founder to engage an independent certified public accounting firm reasonably acceptable to Company, at reasonable times not more than once a year and upon reasonable notice, to examine only those records as may be necessary to determine, with respect to any calendar year ending not more than three (3) years prior to Founder's request, the correctness or completeness of any payment made under this Agreement. Founder shall promptly provide a copy of the results of any such audit or examination to Company. Founder shall bear the full cost of the performance of any such audit or examination, unless such audit or examination discloses an underpayment exceeding ten percent (10%) of the amount actually due hereunder with respect to any particular calendar year, in which case Company shall bear the reasonable, documented cost of the performance of such audit or examination. Company shall promptly pay to Founder the amount of any underpayment of royalties revealed by such an examination and review. Any overpayment by Company revealed by an examination and review shall be refunded to Company within thirty (30) calendar days of its request.

2. Representations and Warranties of the Parties. Each of the parties hereto hereby represents and warrants to the other as follows:

2.1 Each party may execute, deliver, and perform this Agreement without the necessity of obtaining any consent, approval, authorization, registration, filing, or waiver or giving any notice, other than those already obtained;

2.2 This Agreement has been duly authorized by all necessary actions of the party and constitutes the legal, valid, and binding obligation of such party; and

2.3 Each party has the full right, power, and authority to enter into this Agreement and to consummate the transactions contemplated hereby.

3. Notices. All notices hereunder must be in writing and will be deemed to have been duly given upon receipt of hand delivery, upon electronic transmission with confirmation of receipt, or upon receipt of registered mail, return receipt requested, addressed to the address set forth for each party, respectively, on the signature page of this Agreement or to such other address as may be designated by written notice.

4. **Entire Agreement.** This Agreement constitutes the entire agreement of the parties with respect to the transactions contemplated herein. All prior agreements among the parties concerning the subject matter hereof, whether written or oral, are merged herein and shall be of no force or effect. This Agreement cannot be altered, modified, or discharged orally but only by an agreement in writing.

5. **Benefit.** This Agreement shall be binding upon and shall inure to the benefit of the parties, their legal representatives, and assigns.

6. **Severability.** If any provision contained in this Agreement is or becomes invalid, illegal, or unenforceable in any respect, the validity, legality, and enforceability of the remaining provisions contained herein will not in any way be affected or impaired thereby.

7. **Further Assurances.** The parties hereby agree to execute and deliver such further instruments and do such further acts as may be required to carry out the intent and purposes of this Agreement.

8. **Counterparts.** This Agreement may be executed separately by each party in multiple originals, and each original of this Agreement separately executed by one party, when assembled with one or more copies of this Agreement separately executed by the other parties, shall be and constitute a fully executed original of this Agreement.

9. **Survival.** All representations and warranties made herein by the parties will survive the execution of this Agreement.

10. **Governing Law.** This Agreement shall be governed by and construed in accordance with the substantive laws of the state of New York, without giving effect to any choice of law or conflict of law provision or rule that would cause the application of the laws of any jurisdiction other than the state of New York.

11. **Term.** This Agreement shall be in effect for a period equal to fifteen (15) years from the Effective Date (the "***Initial Term***"). Upon expiration of the Initial Term, this Agreement shall be automatically renewed for successive periods of one (1) year (together with the Initial Term, the "***Term***"), unless terminated by Founder by a letter sent by recorded delivery to the Company at least six (6) months prior to the end of the contractual period in force. In the event of Change in Control, as defined by this Agreement, termination is governed in accordance with that provision and subject to the one-time change in control fee.

12. **Amendment and Restatement.** The terms and provisions of the Existing Founders Agreement are hereby amended and restated in their entirety by the terms and provisions of this Amended and Restated Founders Agreement and shall supersede all provisions of the Existing Founders Agreement as of the date hereof. From and after the date hereof, all references made to the Existing Founders Agreement in any document shall, without more, be deemed to refer to this Amended and Restated Founders Agreement.

IN WITNESS WHEREOF, this Agreement has been duly executed by the parties effective for all purposes as of the date first written above.

FORTRESS BIOTECH, INC.

By: /s/ Lindsay A. Rosenwald, MD
Name: Lindsay A. Rosenwald, MD
Title: President and Chief Executive Officer

Address for Notice:

2 Gansevoort Street, 9th Floor
New York, NY 10014
Attn: Lindsay A. Rosenwald, MD
lr@fortressbiotech.com

AVENUE THERAPEUTICS, INC.

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

Address for Notice:

2 Gansevoort Street, 9th Floor
New York, NY 10014
Attn: Lucy Lu, MD
llu@fortressbiotech.com

SCHEDULE A

As used herein, ***"Assets"*** shall mean the following assets, properties, rights and claims of Founder used or held for use in the Business, or relating to or arising from the conduct of the Business:

1. License Agreement, dated as of February 17, 2015, by and between Fortress Biotech, Inc. and Revogenex Ireland Ltd.

SCHEDULE B

Indebtedness

1. Promissory Note, with an issuance date of February, 17, 2015, issued by Avenue Therapeutics, Inc. to the order of NSC Biotech Venture Fund I, LLC in the original principal amount of $3,000,000.00.

Exhibit 10.3

AVENUE THERAPEUTICS, INC.

Promissory Note

Issuance Date: February 17, 2015 Original Principal Amount: U.S. $3,000,000
Execution Date: October 31, 2015

FOR VALUE RECEIVED, Avenue Therapeutics, Inc., a Delaware corporation (the "**Company**"), hereby promises to pay to the order of NSC Biotech Venture Fund I, LLC or its registered assigns ("**Holder**") the amount set out above as the Original Principal Amount (the "**Principal**") on the Maturity Date (as defined below), and to pay Interest ("**Interest**") on any outstanding Principal (as defined below) at the applicable Interest Rate (as defined below) from the date set out above as the Issuance Date (the "**Issuance Date**") until the same becomes due and payable. This Promissory Note (including all Promissory Notes issued in exchange, transfer or replacement hereof, this "**Note**") is issued is partial satisfaction of the Promissory Note under which Fortress Biotech, Inc. (f/k/a Coronado Biosciences, Inc.) owed Holder (the "**Original Note**"). Accordingly, although later issued, the Issuance Date is the date of the Original Note. The issuance of this Note is in effect a novation of the Original Note by the Company, and Fortress Biotech, Inc. (f/k/a Coronado Biosciences, Inc.) is no longer primarily liable for the Principal, although a guarantee may still be in effect.

1. PAYMENTS OF PRINCIPAL. During the first 24 months after the Issuance Date, no Principal will be payable. Commencing on the 25th month (or the 31st month if the Maturity Date Extension occurs pursuant to Section 2(c)), the outstanding Principal will be paid in 12 equal monthly installments on the Interest Dates (as defined in Section 2(a) below. The last day of the 36th month after the Issuance Date (or the 42nd month if the Maturity Date Extension occurs) will be the "**Maturity Date**". On the Maturity Date, the Company shall pay to the Holder an amount in cash representing all outstanding Principal, accrued and unpaid Interest and accrued and unpaid Late Charges on such Principal and Interest. Other than as specifically permitted by this Note, the Company may not prepay any portion of the outstanding Principal, accrued and unpaid Interest or accrued and unpaid Late Charges on Principal and Interest, if any.

2. INTEREST; INTEREST RATE.

(a) Interest on this Note shall commence accruing on the Issuance Date and shall be computed on the basis of a 365-day year, and shall be payable (i) for the first 24 months following the Issuance Date (or the first 30 months following the Issuance Date, if the Maturity Date Extension occurs pursuant to Section 2(c) below), in arrears for each Quarter on January 1, April 1, July 1 and October 1 of each year, and (ii) for the 25th through 36th months following the Issuance Date (or the 31st through 42nd months following the Issuance Date, if the Maturity Date Extension (as defined in Section 2(c)) occurs), in arrears for each calendar month on the first day of the following calendar month (each date that interest is payable is an "**Interest Date**"), with the first Interest Date being April 1, 2015, and shall compound on each Interest Date. Interest shall be payable on each Interest Date, to the record Holder of this Note on the applicable Interest Date, in cash (the "**Interest**").

(b) Prior to the payment of Interest on an Interest Date, Interest on this Note shall accrue at the rate of eight percent (8%) per annum (the "**Interest Rate**"). From and after the occurrence and during the continuance of any Event of Default (as defined in Section 4(a) below), the Interest Rate shall automatically be increased to twelve percent (12%). In the event that such Event of Default is subsequently cured, the adjustment referred to in the preceding sentence shall cease to be effective as of the calendar day immediately following the date of such cure; provided that the Interest as calculated and unpaid at such increased rate during the continuance of such Event of Default shall continue to apply to the extent relating to the days after the occurrence of such Event of Default through and including the date of such cure of such Event of Default.

(c) The Company may, in its sole discretion, upon notice to Holder, extend the Maturity Date by 6 months, if Company gives Holder notice of such extension during the first 24 months following the Issuance Date (such extension being the "**Maturity Date Extension**").

3. RESERVED.

4. RIGHTS UPON EVENT OF DEFAULT.

(a) Event of Default. Each of the following events shall constitute an "**Event of Default**":

(i) the Company's failure to pay to the Holder any amount of Principal, Interest, Late Charges or other amounts when and as due under this Note or any other agreement, document, certificate or other instrument delivered in connection with the transactions contemplated hereby, except, in the case of a failure to pay Interest and Late Charges when and as due, only if such failure remains uncured for a period of at least five (5) days;

(ii) bankruptcy, insolvency, reorganization or liquidation proceedings or other proceedings for the relief of debtors shall be instituted against the Company and, shall not be dismissed within thirty (30) days of their initiation; or

(iii) the commencement by the Company of a voluntary case or proceeding under any applicable federal, state or foreign bankruptcy, insolvency, reorganization or other similar law, or the consent by it to the filing of such petition or to the appointment of or taking possession by a custodian, receiver, liquidator, assignee, trustee, sequestrator or other similar official of the Company or of any substantial part of its property, or the making by it of an assignment for the benefit of creditors, or the execution of a composition of debts, or the occurrence of any other similar federal, state or foreign proceeding, or the admission by it in writing of its inability to pay its debts generally as they become due.

5. VOTING RIGHTS. The Holder shall have no voting rights as the holder of this Note, except as required by law (including, without limitation, the Delaware General Corporation Law) and as expressly provided in this Note.

6. RESERVED.

7. AMENDING THE TERMS OF THIS NOTE. Excluding a Maturity Date Extension, the prior written consent of the Holder shall be required for any change or amendment to this Note.

8. TRANSFER. This Note may be offered, sold, assigned or transferred by the Holder without the consent of the Company.

9. REISSUANCE OF THIS NOTE.

(a) Transfer. If this Note is to be transferred, the Holder shall surrender this Note to the Company, whereupon the Company will forthwith issue and deliver upon the order of the Holder a new Note (in accordance with Section 9(c)), registered as the Holder may request, representing the outstanding Principal being transferred by the Holder and, if less than the entire outstanding Principal is being transferred, a new Note (in accordance with Section 9(c)) to the Holder representing the outstanding Principal not being transferred.

(b) Lost, Stolen or Mutilated Note. Upon receipt by the Company of evidence reasonably satisfactory to the Company of the loss, theft, destruction or mutilation of this Note (as to which a written certification and the indemnification contemplated below shall suffice as such evidence), and, in the case of loss, theft or destruction, of any indemnification undertaking by the Holder to the Company in customary and reasonable form and, in the case of mutilation, upon surrender and cancellation of this Note, the Company shall execute and deliver to the Holder a new Note (in accordance with Section 9(c)) representing the outstanding Principal.

(c) Issuance of New Notes. Whenever the Company is required to issue a new Note pursuant to the terms of this Note, such new Note (i) shall be of like tenor with this Note, (ii) shall represent, as indicated on the face of such new Note, the Principal remaining outstanding (or in the case of a new Note being issued pursuant to Section 9(a), the Principal designated by the Holder which, when added to the principal represented by the other new Notes issued in connection with such issuance, does not exceed the Principal remaining outstanding under this Note immediately prior to such issuance of new Notes), (iii) shall have an issuance date, as indicated on the face of such new Note, which is the same as the Issuance Date of this Note, (iv) shall have the same rights and conditions as this Note, and (v) shall represent accrued and unpaid Interest and Late Charges on the Principal and Interest of this Note, from the Issuance Date.

10. REMEDIES, CHARACTERIZATIONS, OTHER OBLIGATIONS, BREACHES AND INJUNCTIVE RELIEF. The remedies provided in this Note shall be cumulative and in addition to all other remedies available under this Note and Note Purchase Agreement at law or in equity (including a decree of specific performance and/or other injunctive relief), and nothing herein shall limit the Holder's right to pursue actual and consequential damages for any failure by the Company to comply with the terms of this Note. The Company covenants to the Holder that there shall be no characterization concerning this instrument other than as expressly provided herein. Amounts set forth or provided for herein with respect to payments, shall be the amounts to be received by the Holder and shall not, except as expressly provided herein, be subject to any other obligation of the Company (or the performance thereof). The Company acknowledges that a breach by it of its obligations hereunder may cause irreparable harm to the Holder and that the remedy at law for any such breach may be inadequate. The Company therefore agrees that, in the event of any such breach or threatened breach, the Holder shall be entitled, in addition to all other available remedies, to seek an injunction restraining any such breach or any such threatened breach, without the necessity of showing economic loss and without any bond or other security being required. The Company shall provide all information and documentation to the Holder that is requested by the Holder to enable the Holder to confirm the Company's compliance with the terms and conditions of this Note.

11. PAYMENT OF COLLECTION, ENFORCEMENT AND OTHER COSTS. If (a) this Note is placed in the hands of an attorney for collection or enforcement or is collected or enforced through any legal proceeding or the Holder otherwise takes action to collect amounts due under this Note or to enforce the provisions of this Note or (b) there occurs any bankruptcy, reorganization, receivership of the Company or other proceedings affecting Company creditors' rights and involving a claim under this Note, then the Company shall pay the reasonable costs incurred by the Holder for such collection, enforcement or action or in connection with such bankruptcy, reorganization, receivership or other proceeding, including, without limitation, attorneys' fees and disbursements. The Company expressly acknowledges and agrees that no amounts due under this Note shall be affected, or limited, by the fact that the purchase price paid for this Note was less than the original Principal amount hereof.

12. CONSTRUCTION; HEADINGS. This Note shall be deemed to be jointly drafted by the Company and the Holder and shall not be construed against any Person as the drafter hereof. The headings of this Note are for convenience of reference and shall not form part of, or affect the interpretation of, this Note. Terms used in this Note but defined in the Note Purchase Agreement shall have the meanings ascribed to such terms on the Closing Date in such Note Purchase Agreement unless otherwise consented to in writing by the Holder.

13. FAILURE OR INDULGENCE NOT WAIVER. No failure or delay on the part of the Holder in the exercise of any power, right or privilege hereunder shall operate as a waiver thereof, nor shall any single or partial exercise of any such power, right or privilege preclude other or further exercise thereof or of any other right, power or privilege. No waiver shall be effective unless it is in writing and signed by an authorized representative of the waiving party.

14. NOTICES; CURRENCY; PAYMENTS.

(a) Notices. Whenever notice is required to be given under this Note, unless otherwise provided herein, such notice shall be given in accordance with Section 6.1 of the Note Purchase Agreement. The Company shall provide the Holder with prompt written notice of all actions taken pursuant to this Note, including in reasonable detail a description of such action and the reason therefore.

(b) Currency. All dollar amounts referred to in this Note are in United States Dollars ("**U.S. Dollars**"), and all amounts owing under this Note shall be paid in U.S. Dollars.

(c) Payments. Whenever any payment of cash is to be made by the Company to any Person pursuant to this Note, unless otherwise expressly set forth herein, such payment shall be made in lawful money of the United States of America by a check drawn on the account of the Company and sent to such Person at such address as previously provided to the Company in writing (which address, in the case of each of the Buyers, shall initially be as set forth on the Note Purchase Agreement), provided that the Holder may elect to receive a payment of cash via wire transfer of immediately available funds by providing the Company with prior written notice setting out such request and the Holder's wire transfer instructions. Whenever any amount expressed to be due by the terms of this Note is due on any day which is not a Business Day, the same shall instead be due on the next succeeding day which is a Business Day. Any amount of Principal or Interest which is not paid when due shall result in a late charge being incurred and payable by the Company in an amount equal to interest on such amount at the rate of twelve (12%) per annum from the date such amount was due until the same is paid in full ("**Late Charge**").

15. CANCELLATION. After all Principal, accrued Interest, Late Charges and other amounts at any time owed on this Note have been paid in full, this Note shall automatically be deemed canceled, shall be surrendered to the Company for cancellation and shall not be reissued.

16. WAIVER OF NOTICE. To the extent permitted by law, the Company hereby irrevocably waives demand, notice, presentment, protest and all other demands and notices in connection with the delivery, acceptance, performance, default or enforcement of this Note and the Note Purchase Agreement.

17. GOVERNING LAW. This Note shall be construed and enforced in accordance with, and all questions concerning the construction, validity, interpretation and performance of this Note shall be governed by, the internal laws of the State of New York, without giving effect to any choice of law or conflict of law provision or rule (whether of the State of New York or any other jurisdictions) that would cause the application of the laws of any jurisdictions other than the State of New York. The Company hereby irrevocably submits to the exclusive jurisdiction of the state and federal courts sitting in The City of New York, Borough of Manhattan, for the adjudication of any dispute hereunder or in connection herewith or with any transaction contemplated hereby or discussed herein, and hereby irrevocably waives, and agrees not to assert in any suit, action or proceeding, any claim that it is not personally subject to the jurisdiction of any such court, that such suit, action or proceeding is brought in an inconvenient forum or that the venue of such suit, action or proceeding is improper. Nothing contained herein shall be deemed to limit in any way any right to serve process in any manner permitted by law. In the event that any provision of this Note is invalid or unenforceable under any applicable statute or rule of law, then such provision shall be deemed inoperative to the extent that it may conflict therewith and shall be deemed modified to conform with such statute or rule of law. Any such provision which may prove invalid or unenforceable under any law shall not affect the validity or enforceability of any other provision of this Note. Nothing contained herein shall be deemed or operate to preclude the Holder from bringing suit or taking other legal action against the Company in any other jurisdiction to collect on the Company's obligations to the Holder, to realize on any collateral or any other security for such obligations, or to enforce a judgment or other court ruling in favor of the Holder. **THE COMPANY HEREBY IRREVOCABLY WAIVES ANY RIGHT IT MAY HAVE TO, AND AGREES NOT TO REQUEST, A JURY TRIAL FOR THE ADJUDICATION OF ANY DISPUTE HEREUNDER OR IN CONNECTION WITH OR ARISING OUT OF THIS NOTE OR ANY TRANSACTION CONTEMPLATED HEREBY.**

18. MAXIMUM PAYMENTS. Nothing contained herein shall be deemed to establish or require the payment of a rate of interest or other charges in excess of the maximum permitted by applicable law. In the event that the rate of interest required to be paid or other charges hereunder exceed the maximum permitted by such law, any payments in excess of such maximum shall be credited against amounts owed by the Company to the Holder and thus refunded to the Company.

19. CERTAIN DEFINITIONS. For purposes of this Note, the following terms shall have the following meanings:

(a) "**Business Day**" means any day other than Saturday, Sunday or other day on which commercial banks in The City of New York are authorized or required by law to remain closed.

(b) "**Closing Date**" shall have the meaning set forth in the Note Purchase Agreement, which date is the date the Company initially issued Notes pursuant to the terms of the Note Purchase Agreement.

(c) "**Person**" means an individual, a limited liability company, a partnership, a joint venture, a corporation, a trust, an unincorporated organization, any other entity or a government or any department or agency thereof.

(d) "**Quarter**" means each of: (i) the period beginning on and including January 1 and ending on and including March 31; (ii) the period beginning on and including April 1 and ending on and including June 30; (iii) the period beginning on and including July 1 and ending on and including September 30; and (iv) the period beginning on and including October 1 and ending on and including December 31.

(e) "**Note Purchase Agreement**" means those certain securities purchase agreements by and among the Company and the initial Holders pursuant to which the Company issued the Notes, as may be amended from time to time.

(f) "**Subsidiary**" means, as of any date of determination, any Person which the Company, directly or indirectly) controls.

IN WITNESS WHEREOF, the Company has caused this Note to be duly executed as of the Issuance Date set out above.

AVENUE THERAPEUTICS, INC.

By: /s/ Lucy Lu
Lucy Lu, M.D., President and CEO

Exhibit 10.4

Avenue Therapeutics, Inc.

FUTURE ADVANCE PROMISSORY NOTE

FOR AMOUNTS ADVANCED AS SHOWN
ON EXHIBIT A ATTACHED HERETO

1 . Principal and Interest. Avenue Therapeutics, Inc. (the "***Company***"), for value received, pursuant to this Future Advance Promissory Note (the "***Note***") hereby promises to pay to the order of Fortress Biotech, Inc. ("***Fortress***"), in lawful money of the United States of America, the principal amount as may be advanced from time to time by Fortress as shown on Exhibit A attached hereto, with interest from the date of each advance at 8% per annum on the unpaid balance until paid. Interest shall be accrued and, following a Financing (as defined below), payable quarterly on the day following each calendar quarter. Following a Financing, such principal and accrued interest shall be due and payable on demand. All unpaid principal and interest on this Note may be prepaid at any time without penalty. For purposes of this Note, a "***Financing***" shall mean an equity, debt or royalty financing or series of related equity, debt or royalty financings by the Company resulting in the Company receiving cash proceeds from unaffiliated third parties.

2. Advances. Advances under this Note shall be subject to the following terms and conditions:

(a) draws may be made upon request by the Company with at least three (3) days advance notice to Fortress;

(b) in its sole and absolute discretion, Fortress may refuse to make any advance hereunder;

(c) all advances, at the time made, shall be noted on Exhibit A of this Note and shall be signed by an authorized officer of the Company; and

(d) no advances will be made if the outstanding principal and accrued interest hereunder exceeds Two Million Five Hundred Thousand Dollars ($2,500,000) at the time a request is made by the Company.

3. Attorneys' Fees. If the indebtedness represented by this Note or any part thereof is collected in bankruptcy, receivership or other judicial proceedings or if this Note is placed in the hands of attorneys for collection after default, the Company agrees to pay, in addition to the principal and interest payable hereunder, reasonable attorneys' fees and costs incurred by Fortress.

4. Notices. Any notice, other communication or payment required or permitted hereunder shall be in writing and shall be deemed to have been given upon receipt by the other party.

5. Acceleration. This Note shall become immediately due and payable if (i) the Company commences any proceeding in bankruptcy or for dissolution, liquidation, winding-up, composition or other relief under state or federal bankruptcy laws; or (ii) such proceedings are commenced against the Company, or a receiver or trustee is appointed for the Company or a substantial part of its property; or (iii) there is any material breach of any material covenant, warranty, representation or other term or condition of this Note at any time that is not cured within the time periods permitted therein, or if no cure period therein, within five (5) days after the date on which such breach occurs.

6. No Dilution or Impairment. The Company will not, by amendment of its charter documents or through any reorganization, transfer of assets, consolidation, merger, dissolution, issue or sale of securities or any other voluntary action, avoid or seek to avoid the observance or performance of any of the terms of this Note, but will at all times in good faith assist in the carrying out of all such terms and in the taking of all such action as may be necessary or appropriate in order to protect the rights of the holder of this Note.

7. Waivers. Company hereby waives presentment, demand for performance, notice of nonperformance, protest, notice of protest and notice of dishonor. No delay on the part of Fortress in exercising any right hereunder shall operate as a waiver of such right or any other right. This Note is being delivered in and shall be construed in accordance with the laws of the State of Delaware, without regard to the conflicts of laws provisions thereof.

8. Governing Law. This Note is being delivered in and shall be construed in accordance with the laws of the State of New York, without regard to the conflicts of laws provisions thereof.

ISSUED as of December 16, 2015, effective March 15, 2015.

Avenue Therapeutics, Inc.

By: /s/ Lucy Lu
Lucy Lu, MD
Interim President and CEO

EXHIBIT A

SCHEDULE OF ADVANCES

Date of Advance	Amount Advanced	Signature
March 15, 2015	$972,904.30	/s/ Lucy Lu

Exhibit 10.5

MANAGEMENT SERVICES AGREEMENT

THIS MANAGEMENT SERVICES AGREEMENT (this "Agreement") is effective as of February 17, 2015, by and between Avenue Therapeutics, Inc. a Delaware corporation (the "Company"), and Fortress Biotech, Inc., a Delaware corporation (the "Manager" and individually a "Party" or collectively the "Parties").

WHEREAS, on the terms and subject to the conditions contained in this Agreement, the Company desires to obtain certain management, advisory and consulting services from the Manager, and the Manager has agreed to perform such management, advisory and consulting services;

WHEREAS, the Parties are also entering into as of the date hereof the Founders Agreement for the transfer of the Assets (as defined in the Founders Agreement), and the execution of this Agreement is a condition to the willingness of the Manager to transfer the Assets.

WHEREAS, this Agreement has been approved by the Company's Board of Directors.

NOW, THEREFORE, in consideration of the mutual covenants contained herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereto agree as follows:

1. Management, Advisory and Consulting Services.

1.1 Board of Directors Supervision. The activities of the Manager to be performed under this Agreement shall be subject to the supervision of the Board of Directors ("Board") and subject to reasonable policies not inconsistent with the terms of this Agreement adopted by the Board and in effect from time-to-time. Where not required by applicable law or regulation, the Manager shall not require the prior approval of the Board to perform its duties under this Agreement. Notwithstanding the foregoing, the Manager shall not have the authority to bind the Company, and nothing contained herein shall be construed to create an agency relationship between the Company and the Manager.

1 . 2 Services. Subject to any limitations imposed by applicable law or regulation, the Manager shall render or cause to be rendered management, advisory and consulting services to the Company, which services may include advice and assistance concerning any and all aspects of the operations, clinical trials, financial planning and strategic transactions and financings of the Company and conducting relations on behalf of the Company with accountants, attorneys, financial advisors and other professionals (collectively, the "Services"). The Manager shall provide and devote to the performance of this Agreement such employees, Affiliates and agents of the Manager as the Manager shall deem appropriate to the furnishing of the Services hereunder. Additionally, at the request of Manager, the Company will utilize clinical research services, medical education, communication and marketing services and investor relations/public relation services of companies or individuals designated by Manager, including Affiliates, employees or consultants of Manager, provided those services are offered at market prices. "Affiliate" means a person or entity that controls, is controlled by or is under common control with a party, but only for so long as such control exists. For the purposes of this Section 1.1, the word "control" (including, with correlative meaning, the terms "controlled by" or "under common control with") means the actual power, either directly or indirectly through one or more intermediaries, to direct the management and policies of such person or entity, whether by the ownership of at least 50% of the voting stock of such entity, or by contract or otherwise.

1.3 Non-exclusivity, Freedom to Pursue Opportunities and Limitation on Liability.

1.3.1 Non Exclusivity. The Manager shall devote such time and efforts to the performance of Services contemplated hereby as the Manager deems reasonably necessary or appropriate; provided, however, that no minimum number of hours is required to be devoted by the Manager on a weekly, monthly, annual or other basis. The Company acknowledges that the Manager's Services are not exclusive to the Company and that the Manager will render similar Services to other persons and entities.

1.3.2 Freedom to Pursue Opportunities. In recognition that the Manager and its Affiliates currently have, and will in the future have or will consider acquiring, investments in numerous companies with respect to which the Manager or its Affiliates may serve as an advisor, a director or in some other capacity, and in recognition that the Manager and its Affiliates have a myriad of duties to various investors, and in anticipation that the Company and the Manager (or one or more Affiliates or clients of the Manager) may engage in the same or similar activities or lines of business and have an interest in the same areas of corporate opportunities, and in recognition of the benefits to be derived by the Company hereunder and in recognition of the difficulties that may confront any manager who desires and endeavors fully to satisfy such manager's duties in determining the full scope of such duties in any particular situation, the provisions of this Section 1.3.2 are set forth to regulate, define and guide the conduct of certain affairs of the Company as they may involve the Manager.

Except as the Manager may otherwise agree in writing after the date hereof:

(i) the Manager will have the right: (A) to directly or indirectly engage in any business including, without limitation, any business activities or lines of business that are the same as or similar to those pursued by, or competitive with, any of the Company's, (B) to directly or indirectly do business with any client or customer of the Company, (C) to take any other action that the Manager believes in good faith is necessary to or appropriate to fulfill its obligations as described in the first sentence of this Section 1.3.2, and (D) not to present potential transactions, matters or business opportunities to the Company, and to pursue, directly or indirectly, any such opportunity for itself, and to direct any such opportunity to another person.

(ii) the Manager and its officers, directors, employees, partners, members, other clients, Affiliates and other associated entities will have no duty (contractual or otherwise) to communicate or present any corporate opportunities to the Company or to refrain from any action specified in Section 1.3.2(i), and the Company on its own behalf and on behalf of its Affiliates, hereby renounces and waives any right to require the Manager or any of its Affiliates to act in a manner inconsistent with the provisions of this Section 1.3.2.

(iii) Neither the Manager nor any officer, director, employee, partner, member, stockholder, Affiliate or associated entity thereof will be liable to the Company for breach of any duty (contractual or otherwise) by reason of any activities or omissions of the types referred to in this Section 1.3.2 or of any such person's participation therein.

1.3.3 Limitation of Liability. In no event will the Manager or any of its Affiliates be liable to the Company for any indirect, special, incidental or consequential damages, including, without limitation, lost profits or savings, whether or not such damages are foreseeable, or for any third party claims (whether based in contract, tort or otherwise), relating to the Services to be provided by the Manager hereunder. The Manager's liability shall be limited to direct damages not to exceed the total fees paid to Manager for the Services provided to the Company through the date of any claim.

2. Term. The Manager shall provide the Services set forth in Section 1 above from the date hereof until the earlier of (a) termination of this Agreement by mutual agreement of the Manager and the Company and (b) the 5th anniversary of this Agreement; provided that this Agreement shall be automatically extended for additional five year periods unless the Manager or the Company provides written notice of its desire not to automatically extend the term of this Agreement to the other Parties hereto at least ninety (90) days prior to such date (such period, the "Term").

No termination of this Agreement, whether pursuant to this Section 2 or otherwise, will affect the Company's duty to pay any Management Fee (as defined herein in Section 3) accrued, or to reimburse any cost or expense incurred pursuant to Section 4 hereof, prior to the effective date of such termination. Upon termination of this Agreement, the Manager's right to receive any further Management Fee or reimbursement for costs and expenses that have not accrued or been incurred to the date of termination shall cease and terminate. Additionally, the obligations of the Company under Section 4 (Expenses), Section 7 (Indemnification), the provisions of Section 1.3.2 above (whether in respect of or relating to Services rendered prior to termination of this Agreement or in respect of or relating to any Services provided after termination of this Agreement) and the provisions of Section 14 (Governing Law) will also survive any termination of this Agreement to the maximum extent permitted under applicable law.

3. Compensation.

3.1 In consideration of the management, consulting and financial services to be rendered, the Company will pay to the Manager an annual base management and consulting fee in cash in the aggregate amount 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, 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. For purposes of this Agreement, "Net Assets" shall mean the difference between total assets on the one hand and current liabilities and non-capitalized long-term liabilities on the other hand.

The fees due to Manager pursuant to this Section 3.1 shall be referred to as the "Management Fee." Notwithstanding the foregoing, the first Annual Consulting Fee payment shall be made on the first business day of the calendar quarter immediately following the completion of the first equity financing for the Company that is in excess of $10,000,000 in gross proceeds. The first payment shall include all amounts in arrears from the date hereof through such payment as well as the amounts in advance for such first quarterly payment.

3.2 Any payment pursuant to this Section 3 shall be made in cash by wire transfer(s) of immediately available funds to or among one or more accounts as designated from time-to-time by the Manager to the Company in writing.

4. Expenses. Actual and direct out-of-pocket expenses reasonably incurred by the Manager and its personnel in performing the Services shall be reimbursed to the Manager by the Company upon the delivery to the Company of an invoice, receipt or such other supporting data as the Company reasonably shall require. The Company shall reimburse the Manager by wire transfer of immediately available funds for any amount paid by the Manager, which shall be in addition to any other amount payable to the Manager under this Agreement.

5. Reserved.

6. Decisions and Authority of the Manager.

6.1 No Liability. The Company reserves the right to make all decisions with regard to any matter upon which the Manager has rendered advice and consultation, and there shall be no liability of the Manager for any such advice accepted by the Company pursuant to the provisions of this Agreement. The Manager will not be liable for any mistakes of fact, errors of judgment or losses sustained by the Company or for any acts or omissions of any kind (including acts or omissions of the Manager), except to the extent caused by intentional misconduct of the Manager as finally determined by a court of competent jurisdiction.

6.2 Independent Contractor. The Manager shall act solely as an independent contractor and shall have complete charge of its respective personnel engaged in the performance of the Services under this Agreement. Neither the Manager nor its officers, directors, employees or agents will be considered employees or agents of the Company or any of its respective subsidiaries as a result of this Agreement. As an independent contractor, the Manager shall have authority only to act as an advisor to the Company and shall have no authority to enter into any agreement or to make any representation, commitment or warranty binding upon the Company or to obtain or incur any right, obligation or liability on behalf of the Company. Nothing contained in this Agreement shall result in the Manager or any of its partners or members or any of their Affiliates, investment managers, investment advisors or partners being a partner of or joint venturer with the Company.

7. Indemnification.

7.1 Indemnification. The Company shall (i) indemnify the Manager and its respective Affiliates, directors, officers, employees and agents (collectively, the "Indemnified Party"), to the fullest extent permitted by law, from and against any and all actions, causes of action, suits, claims, liabilities, losses, damages and costs and expenses in connection therewith, including without limitation reasonable attorneys' fees and expenses ("Indemnified Liabilities") to which the Indemnified Party may become subject, directly or indirectly caused by, related to or arising out of the Services or any other advice or Services contemplated by this Agreement or the engagement of the Manager pursuant to, and the performance by such Manager of the Services contemplated by, this Agreement, and (ii) promptly reimburse the Indemnified Party for Indemnified Liabilities as incurred, in connection with the investigation of, preparation for or defense of any pending or threatened claim or any action or proceeding arising therefrom, whether or not such Indemnified Party is a party and whether or not such claim, action or proceeding is initiated or brought by or on behalf of the Company or Manager and whether or not resulting in any liability. If and to the extent that the foregoing undertaking may be unenforceable for any reason, the Company hereby agrees to make the maximum contribution to the payment and satisfaction of each of the Indemnified Liabilities that is permissible under applicable law.

7.2 Limited Liability. The Company shall not be liable under the indemnification contained in Section 7.1 hereof with respect to the Indemnified Party to the extent that such Indemnified Liabilities are found in a final non-appealable judgment by a court of competent jurisdiction to have resulted directly from the Indemnified Party's willful misconduct or gross negligence. The Company further agrees that no Indemnified Party shall have any liability (whether direct or indirect, in contract, tort or otherwise) to the Company, holders of its securities or its creditors related to or arising out of the engagement of the Manager pursuant to, or the performance by the Manager of the Services contemplated by, this Agreement.

8. Notices. All notices, demands, or other communications to be given or delivered under or by reason of the provisions of this Agreement shall be in writing and shall be deemed to have been given or made when (i) delivered personally to the recipient, (ii) telecopied to the recipient (with a hard copy sent to the recipient by reputable overnight courier service (charges prepaid)) if telecopied before 5:00 p.m. Eastern Standard Time on a business day, and otherwise on the next business day, (iii) one (1) business day after being sent to the recipient by reputable overnight courier service (charges prepaid) or (iv) received via electronic mail by the recipient if received via electronic mail before 5:00 p.m. Eastern Standard Time on a business day, and otherwise on the next business day after such receipt. Such notices, demands and other communications shall be sent to the address for such recipient indicated below or to such other address or to the attention of such other person as the recipient party has specified by prior written notice to the sending party.

Notices to the Manager

3 Columbus Circle, 15th Floor
New York, NY 10023
Attn: Michael S. Weiss
mw@fortressbiotech.com

Notices to the Company:

3 Columbus Circle, 15th Floor
New York, NY 10023
Attn: Lindsay A. Rosenwald, MD
lr@fortressbiotech.com

9. Severability. If any term, provision, covenant or restriction of this Agreement is held by a court of competent jurisdiction to be invalid, illegal, void or unenforceable, the remainder of the terms, provisions, covenants and restrictions set forth herein shall remain in full force and effect and shall in no way be affected, impaired or invalidated, and the Parties hereto shall use their best efforts to find and employ an alternative means to achieve the same or substantially the same result as that contemplated by such term, provision, covenant or restriction. It is hereby stipulated and declared to be the intention of the Parties that they would have executed the remaining terms, provisions, covenants and restrictions without including any such terms, provisions, covenants and restrictions which may be hereafter declared invalid, illegal, void or unenforceable.

10. Entire Agreement. This Agreement contains the entire understanding of the Parties with respect to the subject matter hereof and supersedes any prior communication or agreement with respect thereto.

11. Counterparts. This Agreement may be executed in multiple counterparts, and any Party may execute any such counterpart, each of which when executed and delivered will thereby be deemed to be an original and all of which counterparts taken together will constitute one and the same instrument. The delivery of this Agreement may be effected by means of an exchange of facsimile or portable document format (.pdf) signatures.

12. Amendments and Waiver. No amendment or waiver of any term, provision or condition of this Agreement will be effective, unless in writing and executed by both the Company and the Manager. No waiver on any one occasion will extend to, effect or be construed as a waiver of any right or remedy on any future occasion. No course of dealing of any person nor any delay or omission in exercising any right or remedy will constitute an amendment of this Agreement or a waiver of any right or remedy of any Party hereto.

13. Successors and Assigns. All covenants and agreements contained in this Agreement by or on behalf of any of the Parties hereto will bind and inure to the benefit of the respective successors and assigns of the Parties hereto whether so expressed or not. Neither the Company nor the Manager may assign its rights or delegate its obligations hereunder without the prior written consent of the other Party, which consent shall not be unreasonably withheld; provided, that the Manager may assign this Agreement to any of its Affiliates.

14. Governing Law. This Agreement shall be governed by and construed in accordance with the substantive laws of the state of New York, without giving effect to any choice of law or conflict of law provision or rule that would cause the application of the laws of any jurisdiction other than the state of New York.

15. Waiver of Jury Trial. To the extent not prohibited by applicable law which cannot be waived, each of the Parties hereto hereby waives, and covenants that it will not assert (whether as plaintiff, defendant or otherwise), any right to trial by jury in any forum in respect of any issue, claim, demand, cause of action, action, suit or proceeding arising out of or based upon this Agreement or the subject matter hereof, in each case whether now existing or hereafter arising and whether in contract or tort or otherwise. Any of the Parties hereto may file an original counterpart or a copy of this Agreement with any court as written evidence of the consent of each of the Parties hereto to the waiver of its right to trial by jury.

16. No Strict Construction. The Parties hereto have participated jointly in the negotiation and drafting of this Agreement. In the event an ambiguity or question of intent or interpretation arises, this Agreement will be construed as if drafted jointly by the Parties hereto, and no presumption or burden of proof will arise favoring or disfavoring any Party by virtue of the authorship of any of the provisions of this Agreement.

17. Headings; Interpretation. The headings in this Agreement are for convenience and reference only and shall not limit or otherwise affect the meaning hereof. The use of the word "including" in this Agreement will be by way of example rather than by limitation.

* * * * * *

IN WITNESS WHEREOF, the Parties hereto have executed this Management Services Agreement as of the date first written above.

AVENUE THERAPEUTICS, INC.

By: /s/ Lucy Lu
Name: Lucy Lu
Title: Interim Chief Executive Officer

FORTRESS BIOTECH, INC.

By: /s/ Lindsay A. Rosenwald
Name: Lindsay A. Rosenwald
Title: Chief Executive Officer

Exhibit 10.6

EXECUTIVE EMPLOYMENT AGREEMENT

This **Executive Employment Agreement** (this "***Agreement***") is made and entered into as of June 10, 2015 by and between**Avenue Therapeutics, Inc.** (the "***Company***") and **Lucy Lu, M.D.** ("***Executive***"). The Company and Executive are hereinafter collectively referred to as the "***Parties***", and individually referred to as a "***Party***".

Recitals

WHEREAS the Company desires to employ Executive and Executive desires to accept such employment, on the terms and conditions set forth in this Agreement; and

WHEREAS, in her position, Executive will have access to confidential information concerning the Company's business, its customers and employees; and

WHEREAS, the Company wishes to protect itself from unauthorized use of this information and to protect its investment in its employees, customer relationships and confidential information.

NOW, THEREFORE, in consideration of the foregoing, the mutual agreements contained herein, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

Agreement

1. Employment.

1.1 Title. Effective as of the Effective Date, Executive is employed by the Company in the position of President and CEO, subject to the terms and conditions set forth in this Agreement.

1.2 Term. The term of this Agreement shall begin on the date on which the Company becomes a public company (the "***Effective Date***"), and shall continue until it is terminated pursuant to Section 4 herein (the "***Term***").

1.3 Duties. Executive shall do and perform all services, acts or things necessary or advisable to conduct the business of the Company and that are normally associated with the position of President and CEO. In her capacity as President and CEO, Executive shall report to the Company's Executive Chairman, or in the absence of an Executive Chairman, the Company's Board of Directors (the "***Board***").

1.4 Policies and Practices. Executive will abide by the policies and practices established by the Company and/or the Board (or any designated committee thereof), of which she is made aware. In the event that the terms of this Agreement differ from or are in conflict with the Company's policies or practices or the Company's Employee Handbook, this Agreement shall control.

2. Loyalty; Noncompetition; Nonsolicitation.

2.1 Loyalty. During Executive's employment by the Company, Executive shall devote Executive's full business energies, interest, abilities and productive time to the proper and efficient performance of Executive's duties under this Agreement. Notwithstanding the foregoing, except as otherwise agreed to in writing, Executive shall have the right to perform such incidental services as are necessary in connection with (a) her private passive investments, (b) her charitable or community activities, (c) her participation in trade or professional organizations, and (d) her service on the board of directors (or comparable body) of one third-party corporate entity that is not a Competitive Entity (as defined in Section 2.4), so long as these activities do not interfere with Executive's duties hereunder and, with respect to (d), Executive obtains prior Company consent, which consent will not be unreasonably withheld.

2.2 Agreements Protecting Confidential and Proprietary Information. In connection with and as a material condition of the Company's decision to offer Executive employment, Executive understands, acknowledges and agrees to promptly execute and be bound by certain restrictive covenants during and after her employment with the Company, as contained in the Company's Proprietary Information and Inventions Agreement (" ***PIIA***"). A copy of the PIIA is attached to this Agreement as Exhibit A.

2.3 Agreement not to Participate in Company's Competitors. During the Term, Executive agrees not to acquire, assume or participate in, directly or indirectly, any position, investment or interest known by Executive to be adverse or antagonistic to the Company, its business, or prospects, financial or otherwise, or in any company, person, or entity that is, directly or indirectly, in competition with the business of the Company or any of its Affiliates (as defined below). Ownership by Executive, in professionally managed funds over which the Executive does not have control or discretion in investment decisions, or as a passive investment, of less than two percent (2%) of the outstanding shares of capital stock of any corporation with one or more classes of its capital stock listed on a national securities exchange or publicly traded on a national securities exchange or in the over-the-counter market shall not constitute a breach of this Section 2.3. For purposes of this Agreement, "***Affiliate***" means, with respect to any specific entity, any other entity that, directly or indirectly, through one or more intermediaries, controls, is controlled by or is under common control with such specified entity.

2.4 Covenant not to Compete. During the Term and for a period of twelve (12) months thereafter (the "***Restricted Period***"), Executive shall not, within the United States, engage in competition with the Company and/or any of its Affiliates, either directly or indirectly, in any manner or capacity, as adviser, principal, agent, affiliate, promoter, partner, officer, director, employee, stockholder, owner, co-owner, consultant, or member of any association or otherwise, in any phase of the business of developing, manufacturing and marketing of products or services that are in the same field of use and which materially compete with the products or services of the Company (a "***Competitive Entity***"), except with the prior written consent of the Board.

2.5 Nonsolicitation. During the Restricted Period, Executive shall not: (i) solicit or induce, or attempt to solicit or induce, any employee of the Company or its Affiliates to leave the employ of the Company or such Affiliate; or (ii) solicit or attempt to solicit the business of any client or customer of the Company or its Affiliates with respect to products, services, or investments similar to those provided or supplied by the Company or its Affiliates.

2.6 Acknowledgements. Executive acknowledges and agrees that her services to the Company pursuant to this Agreement are unique and extraordinary and that in the course of performing such services Executive shall have access to and knowledge of significant confidential, proprietary, and trade secret information belonging to the Company. Executive agrees that the covenant not to compete and the nonsolicitation obligations imposed by this Section 2 are reasonable in duration, geographic area, and scope and are necessary to protect the Company's legitimate business interests in its goodwill, its confidential, proprietary, and trade secret information, and its investment in the unique and extraordinary services to be provided by Executive pursuant to this Agreement. If, at the time of enforcement of this Section 2, a court holds that the covenant not to compete and/or the nonsolicitation obligations described herein are unreasonable or unenforceable under the circumstances then existing, then the Parties agree that the maximum duration, scope, and/or geographic area legally permissible under such circumstances will be substituted for the duration, scope and/or area stated herein.

3. Compensation of Executive.

3.1 Base Salary. The Company shall pay Executive a base salary at the annualized rate of Three Hundred Ninety-Five Thousand Dollars ($395,000.00) (the "***Base Salary***"), less all applicable taxes, deductions and withholdings, to be paid in equal installments in accord with the Company's normal payroll practices. The Base Salary shall be prorated for any partial year of employment on the basis of a 365-day fiscal year and may be changed in the discretion of the Board. The Base Salary may only be decreased in connection with a Company-wide decrease in executive compensation; provided, however that Executive shall not be subject to any greater percentage reduction than any other Company executive.

3.2 Annual Bonus. At the sole discretion of the Board or the compensation committee of the Board (the "***Compensation Committee***"), following each calendar year of the Company while employed hereunder, Executive will be eligible to receive an additional cash bonus of up to fifty percent (50%) of the Base Salary (the "***Annual Bonus***"). The amount of the Annual Bonus to be paid shall be based on Executive's attainment of certain financial, clinical development, and/or business milestones (the "***Goals and Objectives***") to be established annually no later than January 31 of each year by agreement between Executive and the Executive Chairman. Executive is required to prepare an initial proposal of Goals and Objections for each calendar year. If no Goals and Objections are established by January 31 of a given year as a result of (i) Executive's failure to propose Goals and Objections in a timely manner, or (ii) the Executive's and Executive Chairman's inability to agree on Goals and Objectives (provided that Executive Chairman is reasonable) the Executive will not be entitled to an Annual Bonus for that year. For calendar year 2015 only, the Goals and Objectives will be as set forth on Exhibit C hereto, and requirement that Goals and Objectives be established by January 31 will not apply. The determination of whether Executive has met the Goals and Objectives, and if so, the bonus amount (if any) that will be paid, shall be determined by the Board or the Compensation Committee in its sole discretion. Except as described in Sections 4.5.2 or 4.5.4 below, Executive must remain employed by the Company through and including the last day of the applicable calendar year in order to be eligible to earn or receive any Annual Bonus for that year. The Annual Bonus for any given calendar year will be paid in cash as a single lump-sum payment no later than two (2) months following the conclusion of the calendar year.

3.3 Equity. Executive has previously been granted 1,000,000 shares of the Company's common stock pursuant to a Restricted Stock Issuance Agreement between the Company and Executive dated June 10, 2015.

3.4 Expense Reimbursements. The Company will reimburse Executive for all reasonable business expenses incurred by Executive in connection with the performance of her duties hereunder, subject to the Company's reimbursement policies in effect from time to time.

3.5 Benefits. Executive shall, in accordance with Company policy and the applicable plan documents, be eligible to participate in benefits under any benefit plan or arrangement that may be in effect from time to time and made available to the Company's senior management employees.

3.6 Holidays and Vacation. Executive shall be eligible to accrue up to four (4) weeks of paid vacation per year and will receive paid Company holidays in accordance with Company policy. Unless otherwise required by law, accrued but unused vacation time is not carried forward from one year to the next, and is not paid out upon termination of employment for any reason. All available time off must be used in accord with the Company's policies and procedures. To the extent Executive would be entitled to a greater number of vacation days or personal days under any other Company policy, such other policy shall govern.

3.7 Withholdings. The Company may withhold from any amounts payable under this Agreement such federal, state and local taxes required to be withheld pursuant to any applicable law or other amount properly requested by Executive.

4. Termination.

4.1 Termination by the Company. Executive's employment with the Company is at will and may be terminated by the Company at any time and for any reason, or for no reason, including, but not limited to, under the following conditions:

4.1.1 Termination by the Company for Cause. The Company may terminate Executive's employment under this Agreement for "Cause" (as defined below) by delivery of written notice to Executive in accordance with the procedures set forth in Section 4.6.2 below. Any notice of termination given pursuant to this Section 4.1.1 shall effect termination as of the date of the notice or as of such other date as specified in the notice, subject to Section 4.6.2.

4.1.2 Termination by the Company without Cause. The Company may terminate Executive's employment under this Agreement without Cause at any time and for any reason or for no reason. Such termination shall be effective on the date Executive is so informed or as otherwise specified by the Company.

4.2 Termination by Resignation of Executive. Executive's employment with the Company is at will and may be terminated by Executive at any time and for any reason or for no reason, including via a resignation for Good Reason in accordance with the procedures set forth in Section 4.6.3 below.

4.3 Termination for Death or Complete Disability. Executive's employment with the Company shall terminate effective upon the date of Executive's death or Complete Disability (as defined below).

4.4 Termination by Mutual Agreement of the Parties. Executive's employment with the Company may be terminated at any time upon a mutual agreement in writing of the Parties. Any such termination of employment shall have the consequences specified in such agreement.

4.5 Compensation Upon Termination.

4.5.1 Generally. When this Agreement is terminated for any reason, Executive, or her estate, as the case may be, will be entitled to receive the compensation and benefits earned through the effective date of termination, including, but not limited to, as applicable, any Base Salary earned by Executive, expense reimbursement amounts owed to Executive, all unpaid amounts of the Annual Bonus for the prior year, if any, Executive earned prior to the termination date by meeting the conditions set forth in Section 3.2, less standard deductions and withholdings.

4.5.2 Death or Complete Disability. If Executive's employment under this Agreement is terminated by her death or Complete Disability, then, in addition to the amounts described in Section 4.5.1, and conditioned upon Executive (or her estate or heirs as applicable) executing and not revoking a release of claims in the form attached as Exhibit B (the "***Release***") within the time periods specified therein, the Company will provide the following separation benefits: (i) the Company will continue Executive's Base Salary (at the rate in effect as of the termination) for a period of ninety (90) days beginning on the sixtieth (60^{th}) day following the termination of Executive's employment with the Company, (ii) Executive shall be entitled to a pro-rata share of the Annual Bonus, to be paid when and if such Annual Bonus would have been paid under this Agreement, and (iii) immediate partial accelerated vesting of all unvested equity awards with respect to the same number of shares that would have vested if Executive had continued in employment for one year after the termination date. The Base Salary payments will be subject to standard payroll deductions and withholdings and will be made on the Company's regular payroll cycle, provided, however, that any payments otherwise scheduled to be made prior to the effective date of the Release shall accrue and be paid in the first payroll period that follows such effective date.

4.5.3 Termination For Cause or Resignation without Good Reason. If Executive's employment is terminated by the Company for Cause, or Executive resigns her employment hereunder without Good Reason, the Company shall pay Executive the amounts described in Section 4.5.1. The Company shall thereafter have no further obligations to Executive under this Agreement, except as otherwise provided by law.

4.5.4 Termination Without Cause or Resignation For Good Reason Not In Connection with a Change of Control. If Executive's employment under this Agreement is terminated by the Company without Cause or Executive resigns for Good Reason, at any time other than at the time of, or within six (6) months following a Change of Control, then, in addition to the amounts described in Section 4.5.1, and conditioned upon Executive executing and not revoking the Release within the time periods specified therein, the Company will provide the following separation benefits: (i) the Company will continue Executive's Base Salary (at the rate in effect as of the termination) for a period of twelve (12) months, beginning on the sixtieth (60^{th}) day following the termination of Executive's employment with the Company, (ii) if Executive timely elects continued health insurance coverage under COBRA, the Company shall pay the entire premium necessary to continue such coverage for Executive and Executive's eligible dependents until the conclusion of the time when Executive is receiving continuation of Base Salary payments or until Executive becomes eligible for group health insurance coverage under another employer's plan, whichever occurs first, provided however that the Company has the right to terminate such payment of COBRA premiums on behalf of Executive and instead pay Executive a lump sum amount equal to the COBRA premium times the number of months remaining in the specified period if the Company determines in its discretion that continued payment of the COBRA premiums is or may be discriminatory under Section 105(h) of the Internal Revenue Code; (iii) Executive shall be entitled to a pro-rata share of the Annual Bonus for the year in which the termination occurred, to be paid when and if such Annual Bonus would have been paid under this Agreement; and (iv) immediate partial accelerated vesting of all unvested equity awards with respect to the same number of shares that would have vested if Executive had continued in employment for one year after the termination date. The Base Salary payments will be subject to standard payroll deductions and withholdings and will be made on the Company's regular payroll cycle, provided, however, that any payments otherwise scheduled to be made prior to the effective date of the Release shall accrue and be paid in the first payroll period that follows such effective date.

4.5.5 Termination Without Cause or Resignation For Good Reason In Connection with a Change of Control. If the Company terminates Executive's employment without Cause, or if Executive resigns for Good Reason, upon the occurrence of, or within the six (6) months following, the effective date of a Change of Control, then, in addition to the amounts described in Section 4.5.1, and conditioned upon Executive executing and not revoking the Release within the time periods specified therein, the Company will provide the following separation benefits: (i) the Company will continue Executive's Base Salary (at the rate in effect as of the termination) for a period of twelve (12) months, beginning on the sixtieth (60^{th}) day following the termination of Executive's employment with the Company, (ii) if Executive timely elects continued health insurance coverage under COBRA, the Company shall pay the entire premium necessary to continue such coverage for Executive and Executive's eligible dependents until the conclusion of the time when Executive is receiving continuation of Base Salary payments or until Executive becomes eligible for group health insurance coverage under another employer's plan, whichever occurs first, provided however that the Company has the right to terminate such payment of COBRA premiums on behalf of Executive and instead pay Executive a lump sum amount equal to the COBRA premium times the number of months remaining in the specified period if the Company determines in its discretion that continued payment of the COBRA premiums is or may be discriminatory under Section 105(h) of the Internal Revenue Code; (iii) Executive shall be entitled to a pro-rata share of the Annual Bonus for the year in which the termination occurred, to be paid when and if such Annual Bonus would have been paid under this Agreement; and (iv) immediate accelerated vesting of all unvested equity awards such that, on the effective date of the Release, the Executive shall be vested in one hundred percent (100%) of all such equity awards. The Base Salary payments will be subject to standard payroll deductions and withholdings and will be made on the Company's regular payroll cycle, provided, however, that any payments otherwise scheduled to be made prior to the effective date of the Release shall accrue and be paid in the first payroll period that follows such effective date.

4.6 Definitions. For purposes of this Agreement, the following terms shall have the following meanings:

4.6.1 Complete Disability. As used herein, "***Complete Disability***" means the inability of Executive, due to the condition of her physical, mental or emotional health, effectively to perform the essential functions of her job with or without reasonable accommodation for a continuous period of more than 90 days or for 90 days in any period of 180 consecutive days, as determined by the Board in consultation with an independent physician retained for such purpose. For purposes of making a determination as to whether a Complete Disability exists, at the Board's request Executive agrees to make herself available and to cooperate in a reasonable examination by the independent physician retained by the Board and to authorize the disclosure and release to the Board of all medical records related to such examination.

4.6.2 Cause. As used herein, "***Cause***" means: (i) Executive's fraud, embezzlement or misappropriation with respect to the Company, (ii) Executive's material breach of this Agreement, (iii) Executive's material breach of the PIIA, (iv) Executive's breach of fiduciary duties to the Company, (v) Executive's willful failure or refusal to perform her material duties under this Agreement or failure to follow any specific lawful instructions of the Board, (vi) Executive's conviction or plea of nolo contendere in respect of a felony or of a misdemeanor involving moral turpitude, or (vii) Executive's willful or negligent misconduct that has a material adverse effect on the property, business, or reputation of the Company. Prior to terminating Executive's employment for Cause pursuant to clauses (ii), (iii), (iv), (v) or (vii), Executive shall have thirty (30) days after Executive's receipt of written notice thereof from the Company to cure any such failure, action or breach.

4.6.3 Good Reason. For purposes of this Agreement, "***Good Reason***" means the occurrence of any of the following events without Executive's consent: (i) a material reduction of Executive's Base Salary (except in connection with a Company-wide decrease in executive compensation, as provided in Section 3.1 of this Agreement) (ii) a material diminution of Executive's authority, duties, or responsibilities, (iii) the Company's material breach of this Agreement, or (iv) a change in Executive's office location to a location that is greater than thirty (30) miles from New York City. In order for Executive to resign for Good Reason, Executive must provide written notice to the Company of the existence of the Good Reason condition within thirty (30) days of the date on which Executive discovers, or reasonably should have discovered, the existence of such Good Reason condition. Upon receipt of such notice, the Company will have thirty (30) days during which it may remedy the Good Reason condition and not be required to provide for the benefits described in Section 4.5.4 as a result of such proposed resignation. If the Good Reason condition is not remedied within such thirty (30) day period, Executive may resign based on the Good Reason condition specified in the notice effective immediately upon the expiration of the thirty (30) day cure period.

4.6.4 Change of Control. For purposes of this Agreement, "***Change of Control***" shall mean the occurrence, in a single transaction or in a series of related transactions, of any one or more of the following events (excluding in any case transactions in which the Company or its successors issues securities to investors primarily for capital raising purposes):

(i) the acquisition by a third party of securities of the Company representing more than fifty percent (50%) of the combined voting power of the Company's then outstanding securities other than by virtue of a merger, consolidation or similar transaction;

(ii) a merger, consolidation or similar transaction following which the stockholders of the Company immediately prior thereto do not own at least fifty percent (50%) of the combined outstanding voting power of the surviving entity (or that entity's parent) in such merger, consolidation or similar transaction;

(iii) the dissolution or liquidation of the Company; or

(iv) the sale, lease, exclusive license or other disposition of all or substantially all of the assets of the Company.

4.7 Survival of Certain Sections. Sections 2, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 17, and 18 of this Agreement will survive the termination of this Agreement.

4.8 Parachute Payment. If any payment or benefit the Executive would receive pursuant to this Agreement, either alone or together with other payments and benefits provided to her by the Company (the "***Total Payments***") would (i) constitute a "parachute payment" within the meaning of Section 280G of the Internal Revenue Code of 1986, as amended (the "***Code***"), and (ii) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the "***Excise Tax***"), then the Total Payments shall be reduced if and to the extent that a reduction in the Total Payments would result in Executive retaining a larger amount than if Executive received all of the Total Payments, in each case measured on an after-tax basis (taking into account federal, state, and local income taxes, and, if applicable, the Excise Tax). The determination of any reduction in the Total Payments will be made at the Company's expense by the Company's independent public accountants or a law or consulting firm selected by the Company, applying reasonable, good faith interpretations regarding the applicability of Section 280G and Section 4999, along with any other applicable portions of the Code or other tax laws. If a reduction in the Total Payment is necessary, such reduction shall occur in the following order: (i) reduction of cash payments; (ii) cancellation of accelerated vesting of equity awards other than stock options; (iii) cancellation of accelerated vesting of stock options; and (iv) reduction of other benefits paid to Executive. Within any such category of payments and benefits (that is, (i), (ii), (iii) or (iv)), a reduction shall occur first with respect to amounts that are not "deferred compensation" within the meaning of Section 409A (as defined in Section 4.9 below) and then with respect to amounts that are. In the event that acceleration of compensation from Executive's equity awards is to be reduced, such acceleration of vesting shall be canceled, subject to the immediately preceding sentence, in the reverse order of the date of grant.

4.9 Section 409A Compliance. The Parties intend that all provisions of this Agreement and the payments made pursuant thereto will comply with, or be exempt from, the application of Section 409A of the Code and the regulations and other guidance thereunder and any state law of similar effect (collectively "***Section 409A***"), and all provisions of this Agreement will be construed, to the maximum extent possible, in a manner consistent with the requirements for avoiding taxes or penalties under Section 409A. Notwithstanding anything to the contrary set forth herein, any payments and benefits provided under this Section 4 that constitute "deferred compensation" within the meaning of Section 409A will not commence in connection with Executive's termination of employment unless and until Executive has also incurred a "separation from service" (as such term is defined in Treasury Regulation Section 1.409A-1(h), unless the Company reasonably determines that such amounts may be provided to Executive without causing Executive to incur the additional 20% tax under Section 409A. The parties intend that each installment of the separation benefits payments provided for in this Agreement is a separate "payment" for purposes of Treasury Regulation Section 1.409A-2(b)(2)(i). For the avoidance of doubt, the parties intend that payments of the Separation Benefits set forth in this Agreement satisfy, to the greatest extent possible, the exemptions from the application of Section 409A provided under Treasury Regulation Sections 1.409A-1(b)(4), 1.409A-1(b)(5) and 1.409A-1(b)(9). Executive and the Company agree to use their best efforts to amend the terms of this Agreement from time to time as may be necessary to avoid the imposition of penalties or additional taxes under Section 409A of the Internal Revenue Code; provided, however, any such amendment will provide Executive substantially equivalent economic payments and benefits as set forth herein and will not in the aggregate, materially increase the cost to, or liability of, the Company hereunder. However, if the Company determines that the Separation Benefits constitute "deferred compensation" under Section 409A and Executive is, on the termination of service, a "specified employee" of the Company or any successor entity thereto, as such term is defined in Section 409A, then, solely to the extent necessary to avoid the incurrence of the adverse personal tax consequences under Section 409A, the timing of the Separation Benefits payments will be delayed until the earlier to occur of: (i) the date that is six months and one day after Executive's separation from service, or (ii) the date of Executive's death (such applicable date, the "***Specified Employee Initial Payment Date***"), and the Company (or the successor entity thereto, as applicable) will (A) pay to Executive a lump sum amount equal to the sum of the Separation Benefits payments that Executive would otherwise have received through the Specified Employee Initial Payment Date if the commencement of the payment of the Separation Benefits had not been so delayed pursuant to this Section and (B) commence paying the balance of the separation benefits in accordance with the applicable payment schedules set forth in this Agreement.

5. Assignment and Binding Effect.

This Agreement shall be binding upon and inure to the benefit of Executive and Executive's heirs, executors, personal representatives, assigns, administrators and legal representatives. Because of the unique and personal nature of Executive's duties under this Agreement, neither this Agreement nor any rights or obligations under this Agreement shall be assignable by Executive. This Agreement shall be binding upon and inure to the benefit of the Company and its successors, assigns and legal representatives. Any such successor of the Company will be deemed substituted for the Company under the terms of this Agreement for all purposes. For this purpose, "successor" means any person, firm, corporation or other business entity which at any time, whether by purchase, merger or otherwise, directly or indirectly acquires all or substantially all of the assets or business of the Company.

6. Notices.

All notices or demands of any kind required or permitted to be given by the Company or Executive under this Agreement shall be given in writing and shall be personally delivered (and receipted for) or faxed during normal business hours or mailed by certified mail, return receipt requested, postage prepaid, addressed as follows:

If to the Company:

Avenue Therapeutics
3 Columbus Circle
New York, New York 10019
Attn: Chairman of the Board

If to Executive:

Lucy Lu, MD
455 Main Street, #4F
New York, NY 10044

Any such written notice shall be deemed given on the earlier of the date on which such notice is personally delivered or three (3) days after its deposit in the United States mail as specified above. Either Party may change its address for notices by giving notice to the other Party in the manner specified in this Section.

7. Choice of Law.

This Agreement shall be construed and interpreted in accordance with the internal laws of the State of New York without regard to its conflict of laws principles.

8. Integration.

This Agreement, including all documents referenced herein, contains the complete, final and exclusive agreement of the Parties relating to the terms and conditions of Executive's employment and the termination of Executive's employment, and supersedes all prior and contemporaneous oral and written employment agreements or arrangements between the Parties.

9. Amendment.

This Agreement cannot be amended or modified except by a written agreement signed by Executive and the Company.

10. Waiver.

No term, covenant or condition of this Agreement or any breach thereof shall be deemed waived, except with the written consent of the Party against whom the wavier is claimed, and any waiver or any such term, covenant, condition or breach shall not be deemed to be a waiver of any preceding or succeeding breach of the same or any other term, covenant, condition or breach.

11. Severability.

The finding by a court of competent jurisdiction of the unenforceability, invalidity or illegality of any provision of this Agreement shall not render any other provision of this Agreement unenforceable, invalid or illegal. Such court shall have the authority to modify or replace the invalid or unenforceable term or provision with a valid and enforceable term or provision, which most accurately represents the Parties' intention with respect to the invalid or unenforceable term, or provision.

12. Interpretation; Construction.

The headings set forth in this Agreement are for convenience of reference only and shall not be used in interpreting this Agreement. This Agreement has been drafted by legal counsel representing the Company, but Executive has been encouraged to consult with, and has consulted with, Executive's own independent counsel and tax advisors with respect to the terms of this Agreement. The Parties acknowledge that each Party and its counsel has reviewed and revised, or had an opportunity to review and revise, this Agreement, and any rule of construction to the effect that any ambiguities are to be resolved against the drafting party shall not be employed in the interpretation of this Agreement.

13. Attorneys Fees.

Except as otherwise prohibited by law, in the event a Party brings an action to enforce the terms of this Agreement, in addition to any other remedies, the prevailing party will be entitled to recovery of its reasonable attorneys' fees and costs incurred by it arising out of such breach or the defense thereof.

14. Representations and Warranties.

14.1 Obligations to Prior Employers. Executive represents and warrants to the Company that Executive is not obligated or restricted under any agreement (including any non-competition or confidentiality agreement), judgment, decree, order or other restraint of any kind that could impair Executive's ability to perform the duties and obligations required of Executive hereunder. Executive further represents and warrants to the Company that she has not violated any confidentiality agreement or other similar obligation that she has to any former employer and that she has not disclosed any confidential or trade secret information belonging to any former employer to the Company or its agents. Executive agrees that she will not use confidential information and/or trade secrets belonging to any former employer in her employment with the Company or otherwise as a resource for building the business of the Company and will structure her and the Company's work environment and practices in such a way to ensure that any such information will not be used or disclosed during the course of her relationship with the Company.

14.2 Litigation Support. Both during and after Executive's employment with the Company, if the Company is evaluating, pursuing, contesting or defending any proceeding, charge, complaint, claim, demand, notice, action, suit, litigation, hearing, audit, investigation, arbitration or mediation, in each case whether initiated by or against the Company (collectively, a "***Proceeding***"), other than a Proceeding initiated by or against Executive, Executive will reasonably cooperate with the Company and its counsel in the evaluation, pursuit, contest or defense of the Proceeding and provide such testimony and access to books and records as may be necessary in connection therewith. Any such cooperation shall be done at times mutually convenient for Executive and the Company, and the Company will ensure that any such cooperation does not interfere with any duties or obligations that Executive may have to a third party, including any future employer. The Company will reimburse Executive for Executive's out-of-pocket expenses related to such cooperation.

14.3 Future Employment. In the event of Executive's separation from the Company, regardless of the reason or cause of that separation, Executive agrees that for a period of twelve (12) months from the date her employment terminates, she will provide the Company with no fewer than three (3) business days' notice of her intent to accept employment with or for an organization other than Company for the express purpose of allowing the Company to determine if such proposed employment interferes with any of Executive's surviving obligations under this Agreement. The notice of intent to accept employment will identify the new employer, list Executive's anticipated title and describe her anticipated duties.

15. Indemnification.

The Company shall defend and indemnify Executive in her capacity as President and Chief Executive Officer of the Company to the fullest extent permitted under the Delaware General Corporate Law (the "***DGCL***"). The Company shall also maintain a policy for indemnifying its officers and directors, including but not limited to the Executive, for all actions permitted under the DGCL taken in good faith pursuit of their duties for the Company, including but not limited to maintaining an appropriate level of Directors and Officers Liability coverage and maintaining the inclusion of such provisions in the Company's by-laws or certificate of incorporation, as applicable and customary.

16. Counterparts.

This Agreement may be executed in two counterparts, each of which shall be deemed an original, all of which together shall contribute one and the same instrument. Signatures to this Agreement transmitted by fax, by email in "portable document format" (".pdf") or by any other electronic means intended to preserve the original graphic and pictorial appearance of this Agreement shall have the same effect as physical delivery of the paper document bearing original signature.

17. Jurisdiction; Venue.

The Parties agree that any litigation arising out of or related to this Agreement or Executive's employment by the Company shall be brought exclusively in any state or federal court in New York, New York. Each Party (i) consents to the personal jurisdiction of said courts, (ii) waives any venue or inconvenient forum defense to any proceeding maintained in such courts, and (iii) except as otherwise provided in this Agreement, agrees not to bring any proceeding arising out of or relating to this Agreement or Executive's employment by the Company in any other court.

18. Advertising Waiver.

Executive agrees to permit the Company, and persons or other organizations authorized by the Company, to use, publish and distribute advertising or sales promotional literature concerning the products and/or services of the Company, or the machinery and equipment used in the provision thereof, in which Executive's name and/or pictures of Executive taken in the course of Executive's provision of services to the Company appear. Executive hereby waives and releases any claim or right Executive may otherwise have arising out of such use, publication or distribution.

[**Remainder of Page Intentionally Left Blank. Signature Page Immediately Follows**]

In Witness Whereof, the Parties have executed this Agreement as of the date first above written.

Avenue Therapeutics, Inc.

/s/ Lindsay A. Rosenwald — 6/11/2015

Name: Lindsay A. Rosenwald — **Date**

Position: Executive Chairman

Executive:

/s/ Lucy Lu, MD — 6/10/2015

Lucy Lu, M.D. — **Date**

EXHIBIT A

Form of Proprietary Information and Inventions Agreement

EXHIBIT B

RELEASE OF CLAIMS

THIS RELEASE OF CLAIMS (this "**Release**") is made by Lucy Lu, M.D. ("**Executive**") as of the date it is signed by Executive, as indicated on the signature page hereof.

Executive acknowledges that she previously executed an Executive Employment Agreement (the "**Agreement**") that included, among other items, a promise of severance pay and other benefits by Avenue Therapeutics, Inc. (the "**Company**") in certain situations, contingent upon Executive's execution of a release of claims. Pursuant to the terms of the Agreement and Company's promise to provide severance pay and other benefits, Executive executes this Release.

Executive, on her own behalf and on behalf of her heirs, personal representatives, successors and assigns, hereby release and forever discharge the Company and each of its Affiliates and each and every one of their respective present and former shareholders, directors, officers, members, employees, agents, insurers, predecessors, successors and assigns (the "**Released Parties**"), of and from any and all claims, demands, actions, causes of action, damages, costs and expenses which Executive now has or may have by reason of anything occurring, done or omitted to be done as of or prior to date she signs this Release including, but not limited to, (i) any and all claims related to Executive's employment with Company and the termination of same; (ii) any and all claims for additional compensation or benefits other than the compensation and benefits set forth in the Agreement, including but not limited to wages, commissions, deferred compensation, bonuses, or other benefits of any kind; (iii) any and all claims relating to employment practices or policies of Company or its Affiliates; (iv) any common law claims, including but not limited to wrongful discharge, breach of contract, negligent or intentional infliction of emotional distress, or negligent supervision or retention; and (v) any and all claims arising under any state or federal legislation, including, but not limited to, claims under the Employee Retirement Income Security Act, the Family Medical Leave Act, Title VII of the Civil Rights Act of 1964, as amended, the Civil Rights Act of 1991, the Age Discrimination in Employment Act, the Americans with Disabilities Act, as amended, the Older Workers Benefit Protection Act, the New York Human Rights Law, N.Y. Exec. Law § 290 et seq., the New York City Human Rights Law, N.Y.C. Admin. Code § 8-101 et seq., N.Y. Civ. Rights Law § 40-c et seq. (New York anti-discrimination law), N.Y. Lab. Law § 190 (New York wage payment law), N.Y. Lab. Law § 740 (New York whistleblower protection law), and any other federal, state or local law or regulation prohibiting employment discrimination or otherwise governing the employment relationship between Executive and Company (the "**Released Claims**"), except that notwithstanding anything contained in this Release, Executive understands that she is not releasing (i) any claim for indemnification or advancement by the Company, whether pursuant to law, the Company's bylaws, or under any directors and officers insurance policy maintained by the Company; or (ii) any claims which cannot by law be released.

Executive further covenants and agrees that she will not sue any of the Released Parties on any ground arising out of or related to any of the Released Claims. Executive acknowledges and agrees that this covenant does not preclude her from filing a charge or complaint with any government agency, to the extent permitted by law, but expressly releases, waives, and disclaims any right to compensation or other benefit that may otherwise inure to her as a result of any such charge or complaint involving the Company.

In making this Release, Executive further represents and acknowledges that:

(a) She is voluntarily entering into and signing this Release;

(b) The claims waived, released and discharged in the above Release include any and all claims Executive has or may have arising out of or related to her employment with the Company and the termination of that employment, including any and all claims under the Age Discrimination in Employment Act;

(c) Those claims waived, released and discharged in this Release do not include, and Executive is not waiving, releasing or discharging, any claims that may arise after the date she signs this Release;

(d) The payments and benefits conditioned upon Executive's execution of this Release constitute consideration that Executive was not entitled to receive before the effective date of this Release absent the execution of this Release;

(e) Executive was given twenty-one (21) days within which to consider this Release;

(f) The Company has advised Executive of her right to consult with an attorney regarding this Release before executing the Release and encouraged her to exercise that right;

(g) Executive may revoke this Release at any time within seven (7) days after the date she signs this Release, and this document will not become effective or enforceable until the eighth (8th) day after the date she signs this Release (on which day this Release will automatically become effective and enforceable unless previously revoked within that seven (7) day period); and

(h) EXECUTIVE HAS CAREFULLY READ THIS DOCUMENT, AND FULLY UNDERSTANDS EACH AND EVERY TERM.

I hereby execute this Release on the 10th day of June, 2015.

/s/ Lucy Lu, MD
Lucy Lu, M.D.

EXHIBIT C

2015 Goals and Objectives

[To be added]

Exhibit 10.7

AVENUE THERAPEUTICS, INC.
2015 INCENTIVE PLAN

ARTICLE 1
PURPOSE

1 . 1 . GENERAL. The purpose of the Avenue Therapeutics, Inc. 2015 Incentive Plan (the "Plan") is to promote the success, and enhance the value, of Avenue Therapeutics, Inc. (the "Company"), by linking the personal interests of employees, officers, directors and consultants of the Company or any Affiliate (as defined below) to those of Company stockholders and by providing such persons with an incentive for outstanding performance. The Plan is further intended to provide flexibility to the Company in its ability to motivate, attract, and retain the services of employees, officers, directors and consultants upon whose judgment, interest, and special effort the successful conduct of the Company's operation is largely dependent. Accordingly, the Plan permits the grant of incentive awards from time to time to selected employees, officers, directors and consultants of the Company and its Affiliates.

ARTICLE 2
DEFINITIONS

2.1. DEFINITIONS. When a word or phrase appears in this Plan with the initial letter capitalized, and the word or phrase does not commence a sentence, the word or phrase shall generally be given the meaning ascribed to it in this Section or in Section 1.1 unless a clearly different meaning is required by the context. The following words and phrases shall have the following meanings:

(a) "Affiliate" means (i) any Subsidiary or Parent, or (ii) an entity that directly or through one or more intermediaries controls, is controlled by or is under common control with, the Company, as determined by the Committee.

(b) "Award" means an award of Options, Stock Appreciation Rights, Restricted Stock, Restricted Stock Units, Deferred Stock Units, Performance Awards, Other Stock-Based Awards, or any other right or interest relating to Stock or cash, granted to a Participant under the Plan.

(c) "Award Certificate" means a written document, in such form as the Committee prescribes from time to time, setting forth the terms and conditions of an Award. Award Certificates may be in the form of individual award agreements or certificates or a program document describing the terms and provisions of an Award or series of Awards under the Plan. The Committee may provide for the use of electronic, internet or other non-paper Award Certificates, and the use of electronic, internet or other non-paper means for the acceptance thereof and actions thereunder by a Participant.

(d) "Beneficial Owner" shall have the meaning given such term in Rule 13d-3 of the General Rules and Regulations under the 1934 Act.

(e) "Board" means the Board of Directors of the Company.

(f) "Cause" as a reason for a Participant's termination of employment shall have the meaning assigned such term in the employment, consulting, severance or similar agreement, if any, between such Participant and the Company or an Affiliate; provided, however, that if there is no such employment, consulting, severance or similar agreement in which such term is defined, and unless otherwise defined in the applicable Award Certificate, "Cause" shall mean any of the following acts by the Participant, as determined by the Committee: (i) the commission of any act by the Participant constituting financial dishonesty against the Company or any of its Affiliates (which act would be chargeable as a crime under applicable law); (ii) the Participant's engaging in any other act of dishonesty, fraud, intentional misrepresentation, moral turpitude, illegality or harassment which would: (A) materially adversely affect the business or the reputation of the Company or any of its Affiliates with their respective then-current or prospective customers, suppliers, lenders and/or other third parties with whom such entity does or might do business; or (B) expose the Company or any of its Affiliates to a risk of civil or criminal legal damages, liabilities or penalties; (iii) the willful and repeated failure by the Participant to follow the lawful directives of the Board or the Participant's supervisor; (iv) any material misconduct, material violation of the Company's written policies, or willful and deliberate non-performance of duty by the Participant in connection with the business affairs of the Company or any of its Affiliates; or (v) the Participant's material breach of any employment, severance, non-competition, non-solicitation, confidential information, or restrictive covenant agreement, or similar agreement, with the Company or an Affiliate. The determination of the Committee as to the existence of "Cause" shall be conclusive on the Participant and the Company.

(g) "Change in Control" means and includes the occurrence of any one of the following events but shall specifically exclude a Public Offering:

(i) during any consecutive 12-month period, individuals who, at the beginning of such period, constitute the Board (the "Incumbent Directors") cease for any reason to constitute at least a majority of such Board, provided that any person becoming a director after the beginning of such 12-month period and whose election or nomination for election was approved by a vote of at least a majority of the Incumbent Directors then on the Board shall be an Incumbent Director; provided, however, that no individual initially elected or nominated as a director of the Company as a result of an actual or threatened election contest with respect to the election or removal of directors ("Election Contest") or other actual or threatened solicitation of proxies or consents by or on behalf of any Person other than the Board ("Proxy Contest"), including by reason of any agreement intended to avoid or settle any Election Contest or Proxy Contest, shall be deemed an Incumbent Director; or

(ii) any Person, other than a Principal Stockholder, becomes a Beneficial Owner, directly or indirectly, of either (A) 50% or more of the then-outstanding shares of common stock of the Company ("Company Common Stock") or (B) securities of the Company representing 50% or more of the combined voting power of the Company's then outstanding securities eligible to vote for the election of directors (the "Company Voting Securities"); provided, however, that for purposes of this subsection (ii), the following acquisitions of Company Common Stock or Company Voting Securities shall not constitute a Change in Control: (w) an acquisition directly or indirectly from the Company, (x) an acquisition by the Company or a Subsidiary, (y) an acquisition by any employee benefit plan (or related trust) sponsored or maintained by the Company or any Subsidiary, or (z) an acquisition pursuant to a Non-Qualifying Transaction (as defined in subsection (iii) below); or

(iii) the consummation of a reorganization, merger, consolidation, statutory share exchange or similar form of corporate transaction involving the Company or a Subsidiary (a "Reorganization"), or the sale or other disposition of all or substantially all of the Company's assets (a "Sale") or the acquisition of assets or stock of another corporation or other entity (an "Acquisition"), unless immediately following such Reorganization, Sale or Acquisition: (A) all or substantially all of the individuals and entities who were the Beneficial Owners, respectively, of the outstanding Company Common Stock and outstanding Company Voting Securities immediately prior to such Reorganization, Sale or Acquisition beneficially own, directly or indirectly, more than 50% of, respectively, the then outstanding shares of common stock and the combined voting power of the then outstanding voting securities entitled to vote generally in the election of directors, as the case may be, of the entity resulting from such Reorganization, Sale or Acquisition (including, without limitation, an entity which as a result of such transaction owns the Company or all or substantially all of the Company's assets or stock either directly or through one or more subsidiaries, the "Surviving Entity") in substantially the same proportions as their ownership, immediately prior to such Reorganization, Sale or Acquisition, of the outstanding Company Common Stock and the outstanding Company Voting Securities, as the case may be, and (B) no person (other than (x) the Company or any Subsidiary, (y) the Surviving Entity or its ultimate parent entity, or (z) any employee benefit plan (or related trust) sponsored or maintained by any of the foregoing) is the Beneficial Owner, directly or indirectly, of 50% or more of the total common stock or 50% or more of the total voting power of the outstanding voting securities eligible to elect directors of the Surviving Entity, and (C) at least a majority of the members of the board of directors of the Surviving Entity were Incumbent Directors at the time of the Board's approval of the execution of the initial agreement providing for such Reorganization, Sale or Acquisition (any Reorganization, Sale or Acquisition which satisfies all of the criteria specified in (A), (B) and (C) above shall be deemed to be a "Non-Qualifying Transaction").

(h) "Code" means the Internal Revenue Code of 1986, as amended from time to time. For purposes of this Plan, references to sections of the Code shall be deemed to include references to any applicable regulations thereunder and any successor or similar provision.

(i) "Committee" means the committee of the Board described in Article 4.

(j) "Company" means Avenue Therapeutics, Inc., a Delaware corporation, or any successor corporation.

(k) "Continuous Service" means the absence of any interruption or termination of service as an employee, officer, consultant or director of the Company or any Affiliate, as applicable; provided, however, that for purposes of an Incentive Stock Option "Continuous Service" means the absence of any interruption or termination of service as an employee of the Company or any Parent or Subsidiary, as applicable, pursuant to applicable tax regulations. Continuous Service shall not be considered interrupted in the following cases: (i) a Participant transfers employment between the Company and an Affiliate or between Affiliates, (ii) in the discretion of the Committee as specified at or prior to such occurrence, in the case of a spin-off, sale or disposition of the Participant's employer from the Company or any Affiliate, (iii) a Participant transfers from being an employee of the Company or an Affiliate to being a director of the Company or of an Affiliate, or vice versa, (iv) in the discretion of the Committee as specified at or prior to such occurrence, a Participant transfers from being an employee of the Company or an Affiliate to being a consultant to the Company or of an Affiliate, or vice versa, or (v) any leave of absence authorized in writing by the Company prior to its commencement; provided, however, that for purposes of Incentive Stock Options, no such leave may exceed 90 days, unless reemployment upon expiration of such leave is guaranteed by statute or contract. If reemployment upon expiration of a leave of absence approved by the Company is not so guaranteed, on the 91st day of such leave any Incentive Stock Option held by the Participant shall cease to be treated as an Incentive Stock Option and shall be treated for tax purposes as a Nonstatutory Stock Option. Whether military, government or other service or other leave of absence shall constitute a termination of Continuous Service shall be determined in each case by the Committee at its discretion, and any determination by the Committee shall be final and conclusive; provided, however, that for purposes of any Award that is subject to Code Section 409A, the determination of a leave of absence must comply with the requirements of a "bona fide leave of absence" as provided in Treas. Reg. Section 1.409A-1(h).

(l) "Deferred Stock Unit" means a right granted to a Participant under Article 9 to receive Shares (or the equivalent value in cash or other property if the Committee so provides) at a future time as determined by the Committee, or as determined by the Participant within guidelines established by the Committee in the case of voluntary deferral elections.

(m) "Disability" of a Participant means that the Participant is unable to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment which can be expected to result in death or can be expected to last for a continuous period of not less than 12 months. If the determination of Disability relates to an Incentive Stock Option, Disability means Permanent and Total Disability as defined in Section 22(e)(3) of the Code. In the event of a dispute, the determination of whether a Participant is Disabled will be made by the Committee and may be supported by the advice of a physician competent in the area to which such Disability relates.

(n) "Dividend Equivalent" means a right granted with respect to an Award pursuant to Article 11.

(o) "Effective Date" has the meaning assigned such term in Section 3.1.

(p) "Eligible Participant" means an employee, officer, consultant or director of the Company or any Affiliate.

(q) "Exchange" means any national securities exchange on which the Stock may from time to time be listed or traded.

(r) "Fair Market Value," on any date, means (i) if the Stock is listed on an Exchange, the closing sales price on such Exchange on such date or, in the absence of reported sales on such date, the closing sales price on the immediately preceding date on which sales were reported, or (ii) if the Stock is not listed on an Exchange, the mean between the bid and offered prices as quoted by the applicable interdealer quotation system for such date, provided that if the Stock is not quoted on an interdealer quotation system or it is determined that the fair market value is not properly reflected by such quotations, Fair Market Value will be determined by such other method as the Committee determines in good faith to be reasonable and in compliance with Code Section 409A.

(s) "Full-Value Award" means an Award other than in the form of an Option or SAR, and which is settled by the issuance of Stock (or at the discretion of the Committee, settled in cash valued by reference to Stock value).

(t) "Good Reason" (or a similar term denoting constructive termination) has the meaning, if any, assigned such term in the employment, consulting, severance or similar agreement, if any, between a Participant and the Company or an Affiliate; provided, however, that if there is no such employment, consulting, severance or similar agreement in which such term is defined, "Good Reason" shall have the meaning, if any, given such term in the applicable Award Certificate. If not defined in either such document, the term "Good Reason" as used herein shall not apply to a particular Award.

(u) "Grant Date" of an Award means the first date on which all necessary corporate action has been taken to approve the grant of the Award as provided in the Plan, or such later date as is determined and specified as part of that authorization process. Notice of the grant shall be provided to the grantee within a reasonable time after the Grant Date.

(v) "Incentive Stock Option" means an Option that is intended to be an incentive stock option and meets the requirements of Section 422 of the Code or any successor provision thereto.

(w) "Independent Directors" means those members of the Board who qualify at any given time as an "independent" director under the applicable rules of each Exchange on which the Shares are listed, and as a "non-employee" director under Rule 16b-3 of the 1934 Act.

(x) "Non-Employee Director" means a director of the Company who is not a common law employee of the Company or an Affiliate.

(y) "Nonstatutory Stock Option" means an Option that is not an Incentive Stock Option.

(z) "Option" means a right granted to a Participant under Article 7 of the Plan to purchase Stock at a specified price during specified time periods. An Option may be either an Incentive Stock Option or a Nonstatutory Stock Option.

(aa) "Other Stock-Based Award" means a right, granted to a Participant under Article 12, that relates to or is valued by reference to Stock or other Awards relating to Stock.

(bb) "Parent" means a corporation, limited liability company, partnership or other entity which owns or beneficially owns a majority of the outstanding voting stock or voting power of the Company. Notwithstanding the above, with respect to an Incentive Stock Option, Parent shall have the meaning set forth in Section 424(e) of the Code.

(cc) "Participant" means an Eligible Participant who has been granted an Award under the Plan; provided that in the case of the death of a Participant, the term "Participant" refers to a beneficiary designated pursuant to Section 13.4 or the legal guardian or other legal representative acting in a fiduciary capacity on behalf of the Participant under applicable state law and court supervision.

(dd) "Performance Award" means any award granted under the Plan pursuant to Article 10.

(ee) "Person" means any individual, entity or group, within the meaning of Section 3(a)(9) of the 1934 Act and as used in Section 13(d)(3) or 14(d)(2) of the 1934 Act.

(ff) "Plan" means the Avenue Therapeutics, Inc. 2015 Incentive Plan, as amended from time to time.

(gg) "Principal Stockholder" means Fortress Biotech, Inc., or any entity that is directly or indirectly affiliated with the Principal Stockholder.

(hh) "Public Offering" means a public offering of any class or series of the Company's equity securities pursuant to a registration statement filed by the Company under the 1933 Act or registration of the Company's equity securities pursuant to Section 12(b) or 12(g) of the 1934 Act.

(ii) "Restricted Stock" means Stock granted to a Participant under Article 9 that is subject to certain restrictions and to risk of forfeiture.

(jj) "Restricted Stock Unit" means the right granted to a Participant under Article 9 to receive shares of Stock (or the equivalent value in cash or other property if the Committee so provides) in the future, which right is subject to certain restrictions and to risk of forfeiture.

(kk) "Shares" means shares of the Company's Stock. If there has been an adjustment or substitution with respect to the Shares (whether or not pursuant to Article 14), the term "Shares" shall also include any shares of stock or other securities that are substituted for Shares or into which Shares are adjusted.

(ll) "Specified Employee" has the meaning given such term in Code Section 409A and the final regulations thereunder.

(mm) "Stock" means the $0.001 par value common stock of the Company and such other securities of the Company as may be substituted for Stock pursuant to Article 14.

(nn) "Stock Appreciation Right" or "SAR" means a right granted to a Participant under Article 8 to receive a payment equal to the difference between the Fair Market Value of a Share as of the date of exercise of the SAR over the base price of the SAR, all as determined pursuant to Article 8.

(oo) "Subsidiary" means any corporation, limited liability company, partnership or other entity of which a majority of the outstanding voting stock or voting power is beneficially owned directly or indirectly by the Company. Notwithstanding the above, with respect to an Incentive Stock Option, Subsidiary shall have the meaning set forth in Section 424(f) of the Code.

(pp) "1933 Act" means the Securities Act of 1933, as amended from time to time.

(qq) "1934 Act" means the Securities Exchange Act of 1934, as amended from time to time.

ARTICLE 3
EFFECTIVE TERM OF PLAN

3.1. EFFECTIVE DATE. Subject to the approval of the Plan by the Company's stockholders within 12 months after the Plan's adoption by the Board, the Plan will become effective on the date that it is adopted by the Board (the "Effective Date").

3.2. TERMINATION OF PLAN. Unless earlier terminated as provided herein, the Plan shall continue in effect until the tenth anniversary of the Effective Date or, if the stockholders approve an amendment to the Plan that increases the number of Shares subject to the Plan, the tenth anniversary of the date of such approval. The termination of the Plan on such date shall not affect the validity of any Award outstanding on the date of termination, which shall continue to be governed by the applicable terms and conditions of the Plan.

ARTICLE 4
ADMINISTRATION

4.1. COMMITTEE. The Plan shall be administered by a Committee appointed by the Board (which Committee shall consist of at least two directors) or, at the discretion of the Board from time to time, the Plan may be administered by the Board. It is intended that at least two of the directors appointed to serve on the Committee shall be Independent Directors and that any members of the Committee who do not so qualify shall abstain from participating in any decision to make or administer Awards that are made to Eligible Participants who at the time of consideration for such Award are persons subject to the short-swing profit rules of Section 16 of the 1934 Act. However, the mere fact that a Committee member shall fail to qualify as an Independent Director or shall fail to abstain from such action shall not invalidate any Award made by the Committee which Award is otherwise validly made under the Plan. The members of the Committee shall be appointed by, and may be changed at any time and from time to time in the discretion of, the Board. Unless and until changed by the Board, the Compensation Committee of the Board is designated as the Committee to administer the Plan. The Board may reserve to itself any or all of the authority and responsibility of the Committee under the Plan or may act as administrator of the Plan for any and all purposes. To the extent the Board has reserved any authority and responsibility or during any time that the Board is acting as administrator of the Plan, it shall have all the powers and protections of the Committee hereunder, and any reference herein to the Committee (other than in this Section 4.1) shall include the Board. To the extent any action of the Board under the Plan conflicts with actions taken by the Committee, the actions of the Board shall control.

4.2. ACTION AND INTERPRETATIONS BY THE COMMITTEE. For purposes of administering the Plan, the Committee may from time to time adopt rules, regulations, guidelines and procedures for carrying out the provisions and purposes of the Plan and make such other determinations, not inconsistent with the Plan, as the Committee may deem appropriate. The Committee may correct any defect, supply any omission or reconcile any inconsistency in the Plan or in any Award in the manner and to the extent it deems necessary to carry out the intent of the Plan. The Committee's interpretation of the Plan, any Awards granted under the Plan, any Award Certificate and all decisions and determinations by the Committee with respect to the Plan are final, binding, and conclusive on all parties and shall be given the maximum deference permitted by applicable law. Each member of the Committee is entitled to, in good faith, rely or act upon any report or other information furnished to that member by any officer or other employee of the Company or any Affiliate, the Company's or an Affiliate's independent certified public accountants, Company counsel or any executive compensation consultant or other professional retained by the Company to assist in the administration of the Plan. No member of the Committee will be liable for any good faith determination, act or omission in connection with the Plan or any Award.

4.3. AUTHORITY OF COMMITTEE. Except as provided in Section 4.1 hereof, the Committee has the exclusive power, authority and discretion to:

(a) grant Awards;

(b) designate Participants;

(c) determine the type or types of Awards to be granted to each Participant;

(d) determine the number of Awards to be granted and the number of Shares or dollar amount to which an Award will relate;

(e) determine the terms and conditions of any Award granted under the Plan;

(f) prescribe the form of each Award Certificate, which need not be identical for each Participant;

(g) decide all other matters that must be determined in connection with an Award;

(h) establish, adopt or revise any rules, regulations, guidelines or procedures as it may deem necessary or advisable to administer the Plan;

(i) make all other decisions and determinations that may be required under the Plan or as the Committee deems necessary or advisable to administer the Plan;

(j) amend the Plan or any Award Certificate as provided herein; and

(k) adopt such modifications, procedures, and subplans as may be necessary or desirable to comply with provisions of the laws of the United States or any non-U.S. jurisdictions in which the Company or any Affiliate may operate, in order to assure the viability of the benefits of Awards granted to participants located in the United States or such other jurisdictions and to further the objectives of the Plan.

Notwithstanding any of the foregoing, grants of Awards to Non-Employee Directors hereunder shall (i) be subject to the applicable award limits set forth in Section 5.1 hereof, and (ii) 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 that is approved and administered by the Board. The Committee may not make other discretionary grants hereunder to Non-Employee Directors.

4.4. DELEGATION. The Committee may, by resolution, expressly delegate to a special committee, consisting of one or more directors who may but need not be officers of the Company, the authority, within specified parameters as to the number and terms of Awards, to (i) designate officers and/or employees of the Company or any of its Affiliates to be recipients of Awards under the Plan, and (ii) to determine the number of such Awards to be received by any such Participants; provided, however, that such delegation of duties and responsibilities to an officer of the Company may not be made with respect to the grant of Awards to eligible participants who are subject to Section 16(a) of the 1934 Act at the Grant Date. The acts of such delegates shall be treated hereunder as acts of the Committee and such delegates shall report regularly to the Committee regarding the delegated duties and responsibilities and any Awards so granted.

4.5. INDEMNIFICATION. Each person who is or shall have been a member of the Committee, or of the Board, or an officer of the Company to whom authority was delegated in accordance with this Article 4 shall be indemnified and held harmless by the Company against and from any loss, cost, liability, or expense that may be imposed upon or reasonably incurred by him or her in connection with or resulting from any claim, action, suit, or proceeding to which he or she may be a party or in which he or she may be involved by reason of any action taken or failure to act under the Plan and against and from any and all amounts paid by him or her in settlement thereof, with the Company's approval, or paid by him or her in satisfaction of any judgment in any such action, suit, or proceeding against him or her, provided he or she shall give the Company an opportunity, at its own expense, to handle and defend the same before he or she undertakes to handle and defend it on his or her own behalf, unless such loss, cost, liability, or expense is a result of his or her own willful misconduct or except as expressly provided by statute. The foregoing right of indemnification shall not be exclusive of any other rights of indemnification to which such persons may be entitled under the Company's charter or bylaws, as amended from time to time, as a matter of law, or otherwise, or any power that the Company may have to indemnify them or hold them harmless.

ARTICLE 5
SHARES SUBJECT TO THE PLAN

5.1. NUMBER OF SHARES. Subject to adjustment as provided in Sections 5.2 and Section 14.1, the aggregate number of Shares reserved and available for issuance pursuant to Awards granted under the Plan shall be 2,000,000. The maximum number of Shares that may be issued upon exercise of Incentive Stock Options granted under the Plan shall be 2,000,000. The maximum aggregate number of Shares associated with any Award granted under the Plan in any calendar year to any one Non-Employee Director shall be 100,000 Shares.

5.2. SHARE COUNTING. Shares covered by an Award shall be subtracted from the Plan share reserve as of the Grant Date, but shall be added back to the Plan share reserve in accordance with this Section 5.2.

(a) To the extent that an Award is canceled, terminates, expires, is forfeited or lapses for any reason, any unissued or forfeited Shares originally subject to the Award will be added back to the Plan share reserve and again be available for issuance pursuant to Awards granted under the Plan.

(b) Shares subject to Awards settled in cash will be added back to the Plan share reserve and again be available for issuance pursuant to Awards granted under the Plan.

(c) Shares withheld or repurchased from an Award or delivered by a Participant to satisfy minimum tax withholding requirements will be added back to the Plan share reserve and again be available for issuance pursuant to Awards granted under the Plan.

(d) If the exercise price of an Option is satisfied in whole or in part by delivering Shares to the Company (by either actual delivery or attestation), the number of Shares so tendered (by delivery or attestation) shall be added to the Plan share reserve and will be available for issuance pursuant to Awards granted under the Plan.

(e) To the extent that the full number of Shares subject to an Option or SAR is not issued upon exercise of the Option or SAR for any reason, including by reason of net-settlement of the Award, the unissued Shares originally subject to the Award will be added back to the Plan share reserve and again be available for issuance pursuant to other Awards granted under the Plan.

(f) To the extent that the full number of Shares subject to an Award other than an Option or SAR is not issued for any reason, including by reason of failure to achieve maximum performance goals, the unissued Shares originally subject to the Award will be added back to the Plan share reserve and again be available for issuance pursuant to Awards granted under the Plan.

(g) Substitute Awards granted pursuant to Section 13.9 of the Plan shall not count against the Shares otherwise available for issuance under the Plan under Section 5.1.

(h) Subject to applicable Exchange requirements, shares available under a stockholder-approved plan of a company acquired by the Company (as appropriately adjusted to Shares to reflect the transaction) may be issued under the Plan pursuant to Awards granted to individuals who were not employees of the Company or its Affiliates immediately before such transaction and will not count against the maximum share limitation specified in Section 5.1.

5.3. STOCK DISTRIBUTED. Any Stock distributed pursuant to an Award may consist, in whole or in part, of authorized and unissued Stock, treasury Stock or Stock purchased on the open market.

ARTICLE 6
ELIGIBILITY

6.1. GENERAL. Awards may be granted only to Eligible Participants. Incentive Stock Options may be granted only to Eligible Participants who are employees of the Company or a Parent or Subsidiary as defined in Section 424(e) and (f) of the Code. Eligible Participants who are service providers to an Affiliate may be granted Options or SARs under this Plan only if the Affiliate qualifies as an "eligible issuer of service recipient stock" within the meaning of Treas. Reg. Section 1.409A-1(b)(5)(iii)(E) of the final regulations under Code Section 409A.

ARTICLE 7
STOCK OPTIONS

7.1. GENERAL. The Committee is authorized to grant Options to Participants on the following terms and conditions:

(a) EXERCISE PRICE. The exercise price per Share under an Option shall be determined by the Committee, provided that the exercise price for any Option (other than an Option issued as a substitute Award pursuant to Section 13.9) shall not be less than the Fair Market Value as of the Grant Date.

(b) PROHIBITION ON REPRICING. Except as otherwise provided in Article 14, without the prior approval of stockholders of the Company: (i) the exercise price of an Option may not be reduced, directly or indirectly, (ii) an Option may not be cancelled in exchange for cash, other Awards, or Options or SARs with an exercise or base price that is less than the exercise price of the original Option, or otherwise, and (iii) the Company may not repurchase an Option for value (in cash or otherwise) from a Participant if the current Fair Market Value of the Shares underlying the Option is lower than the exercise price per share of the Option

(c) TIME AND CONDITIONS OF EXERCISE. The Committee shall determine the time or times at which an Option may be exercised in whole or in part, subject to Section 7.1(e). The Committee shall also determine the performance or other conditions, if any, that must be satisfied before all or part of an Option may be exercised or vested.

(d) PAYMENT. The Committee shall determine the methods by which the exercise price of an Option may be paid, the form of payment, and the methods by which Shares shall be delivered or deemed to be delivered to Participants. As determined by the Committee at or after the Grant Date, payment of the exercise price of an Option may be made, in whole or in part, in the form of (i) cash or cash equivalents, (ii) delivery (by either actual delivery or attestation) of previously-acquired Shares based on the Fair Market Value of the Shares on the date the Option is exercised, (iii) withholding of Shares from the Option based on the Fair Market Value of the Shares on the date the Option is exercised, (iv) broker-assisted market sales, or (iv) any other "cashless exercise" arrangement.

(e) EXERCISE TERM. Except for Nonstatutory Options granted to Participants outside the United States, no Option granted under the Plan shall be exercisable for more than ten years from the Grant Date.

(f) NO DEFERRAL FEATURE. No Option shall provide for any feature for the deferral of compensation other than the deferral of recognition of income until the exercise or disposition of the Option.

(g) NO DIVIDEND EQUIVALENTS. No Option shall provide for Dividend Equivalents.

7.2. INCENTIVE STOCK OPTIONS. The terms of any Incentive Stock Options granted under the Plan must comply with the requirements of Section 422 of the Code. Without limiting the foregoing, any Incentive Stock Option granted to a Participant who at the Grant Date owns more than 10% of the voting power of all classes of shares of the Company must have an exercise price per Share of not less than 110% of the Fair Market Value per Share on the Grant Date and an Option term of not more than five years. If all of the requirements of Section 422 of the Code (including the above) are not met, the Option shall automatically become a Nonstatutory Stock Option.

ARTICLE 8
STOCK APPRECIATION RIGHTS

8.1. GRANT OF STOCK APPRECIATION RIGHTS. The Committee is authorized to grant Stock Appreciation Rights to Participants on the following terms and conditions:

(a) RIGHT TO PAYMENT. Upon the exercise of a SAR, the Participant has the right to receive, for each Share with respect to which the SAR is being exercised, the excess, if any, of (i) the Fair Market Value of one Share on the date of exercise; over (ii) the base price of the SAR as determined by the Committee and set forth in the Award Certificate, which shall not be less than the Fair Market Value of one Share on the Grant Date.

(b) PROHIBITION ON REPRICING. Except as otherwise provided in Article 14, without the prior approval of stockholders of the Company: (i) the base price of a SAR may not be reduced, directly or indirectly, (ii) a SAR may not be cancelled in exchange for cash, other Awards, or Options or SARs with an exercise or base price that is less than the base price of the original SAR, or otherwise, and (iii) the Company may not repurchase a SAR for value (in cash or otherwise) from a Participant if the current Fair Market Value of the Shares underlying the SAR is lower than the base price per share of the SAR.

(c) TIME AND CONDITIONS OF EXERCISE. The Committee shall determine the time or times at which a SAR may be exercised in whole or in part. Except for SARs granted to Participants outside the United States, no SAR shall be exercisable for more than ten years from the Grant Date.

(d) NO DEFERRAL FEATURE. No SAR shall provide for any feature for the deferral of compensation other than the deferral of recognition of income until the exercise or disposition of the SAR.

(e) NO DIVIDEND EQUIVALENTS. No SAR shall provide for Dividend Equivalents.

(f) OTHER TERMS. All SARs shall be evidenced by an Award Certificate. Subject to the limitations of this Article 8, the terms, methods of exercise, methods of settlement, form of consideration payable in settlement (e.g., cash, Shares or other property), and any other terms and conditions of the SAR shall be determined by the Committee at the time of the grant and shall be reflected in the Award Certificate.

ARTICLE 9
RESTRICTED STOCK, RESTRICTED STOCK UNITS
AND DEFERRED STOCK UNITS

9.1. GRANT OF RESTRICTED STOCK, RESTRICTED STOCK UNITS AND DEFERRED STOCK UNITS. The Committee is authorized to make Awards of Restricted Stock, Restricted Stock Units or Deferred Stock Units to Participants in such amounts and subject to such terms and conditions as may be selected by the Committee. An Award of Restricted Stock, Restricted Stock Units or Deferred Stock Units shall be evidenced by an Award Certificate setting forth the terms, conditions, and restrictions applicable to the Award.

9.2. ISSUANCE AND RESTRICTIONS. Restricted Stock, Restricted Stock Units or Deferred Stock Units shall be subject to such restrictions on transferability and other restrictions as the Committee may impose (including, for example, limitations on the right to vote Restricted Stock or the right to receive dividends on the Restricted Stock). These restrictions may lapse separately or in combination at such times, under such circumstances, in such installments, upon the satisfaction of performance goals or otherwise, as the Committee determines at the time of the grant of the Award or thereafter. Except as otherwise provided in an Award Certificate or any special Plan document governing an Award, a Participant shall have all of the rights of a stockholder with respect to Restricted Stock, but none of the rights of a stockholder with respect to Restricted Stock Units or Deferred Stock Units until such time as Shares of Stock are paid in settlement of such Awards. Unless otherwise provided in the applicable Award Certificate, Restricted Stock will be entitled to full dividend rights, and any dividends paid thereon will be paid or distributed to the holder no later than the end of the calendar year in which the dividends are paid to stockholders or, if later, the 15th day of the third month following the date the dividends are paid to stockholders.

9.3. FORFEITURE. Subject to the terms of the Award Certificate and except as otherwise determined by the Committee at the time of the grant of the Award or thereafter, upon termination of Continuous Service during the applicable restriction period or upon failure to satisfy a performance goal during the applicable restriction period, Restricted Stock or Restricted Stock Units that are at that time subject to restrictions shall be forfeited.

9.4. DELIVERY OF RESTRICTED STOCK . Shares of Restricted Stock shall be delivered to the Participant at the Grant Date either by book-entry registration or by delivering to the Participant, or a custodian or escrow agent (including, without limitation, the Company or one or more of its employees) designated by the Committee, a stock certificate or certificates registered in the name of the Participant. If physical certificates representing shares of Restricted Stock are registered in the name of the Participant, such certificates must bear an appropriate legend referring to the terms, conditions, and restrictions applicable to such Restricted Stock.

ARTICLE 10
PERFORMANCE AWARDS

10.1. GRANT OF PERFORMANCE AWARDS. The Committee is authorized to grant any Award under this Plan, including cash-based Awards, with performance-based vesting criteria, on such terms and conditions as may be selected by the Committee. Any such Awards with performance-based vesting criteria are referred to herein as Performance Awards. The Committee shall have the complete discretion to determine the number of Performance Awards granted to each Participant and to designate the provisions of such Performance Awards as provided in Section 4.3. All Performance Awards shall be evidenced by an Award Certificate or a written program established by the Committee, pursuant to which Performance Awards are awarded under the Plan under uniform terms, conditions and restrictions set forth in such written program.

10.2. PERFORMANCE GOALS. The Committee may establish performance goals for Performance Awards which may be based on any criteria selected by the Committee. Such performance goals may be described in terms of Company-wide objectives or in terms of objectives that relate to the performance of the Participant, an Affiliate or a division, region, department or function within the Company or an Affiliate. If the Committee determines that a change in the business, operations, corporate structure or capital structure of the Company or the manner in which the Company or an Affiliate conducts its business, or other events or circumstances render performance goals to be unsuitable, the Committee may modify such performance goals in whole or in part, as the Committee deems appropriate. If a Participant is promoted, demoted or transferred to a different business unit or function during a performance period, the Committee may determine that the performance goals or performance period are no longer appropriate and may (i) adjust, change or eliminate the performance goals or the applicable performance period as it deems appropriate to make such goals and period comparable to the initial goals and period, or (ii) make a cash payment to the participant in an amount determined by the Committee.

ARTICLE 11
DIVIDEND EQUIVALENTS

11.1. GRANT OF DIVIDEND EQUIVALENTS. The Committee is authorized to grant Dividend Equivalents with respect to Full-Value Awards granted hereunder, subject to such terms and conditions as may be selected by the Committee. Dividend Equivalents shall entitle the Participant to receive payments equal to ordinary cash dividends or distributions with respect to all or a portion of the number of Shares subject to a Full-Value Award, as determined by the Committee. The Committee may provide that Dividend Equivalents will be paid or distributed when accrued or be deemed to have been reinvested in additional Shares or otherwise reinvested. Unless otherwise provided by the Committee or in the Award Certificate, Dividend Equivalents will be paid or distributed to the Participant no later than the end of the calendar year in which the dividends are paid to stockholders or, if later, the 15th day of the third month following the date the dividends are paid to stockholders.

ARTICLE 12
STOCK OR OTHER STOCK-BASED AWARDS

12.1. GRANT OF STOCK OR OTHER STOCK-BASED AWARDS. The Committee is authorized, subject to limitations under applicable law, to grant to Participants such other Awards that are payable in, valued in whole or in part by reference to, or otherwise based on or related to Shares, as deemed by the Committee to be consistent with the purposes of the Plan, including without limitation Shares awarded purely as a "bonus" and not subject to any restrictions or conditions, convertible or exchangeable debt securities, other rights convertible or exchangeable into Shares, and Awards valued by reference to book value per Share or the value of securities of or the performance of specified Parents or Subsidiaries. The Committee shall determine the terms and conditions of such Awards.

ARTICLE 13
PROVISIONS APPLICABLE TO AWARDS

13.1. AWARD CERTIFICATES. Each Award shall be evidenced by an Award Certificate. Each Award Certificate shall include such provisions, not inconsistent with the Plan, as may be specified by the Committee.

13.2. FORM OF PAYMENT FOR AWARDS . At the discretion of the Committee, payment of Awards may be made in cash, Stock, a combination of cash and Stock, or any other form of property as the Committee shall determine. In addition, payment of Awards may include such terms, conditions, restrictions and/or limitations, if any, as the Committee deems appropriate, including, in the case of Awards paid in the form of Stock, restrictions on transfer and forfeiture provisions. Further, payment of Awards may be made in the form of a lump sum, or in installments, as determined by the Committee.

13.3. LIMITS ON TRANSFER. No right or interest of a Participant in any unexercised or restricted Award may be pledged, encumbered, or hypothecated to or in favor of any party other than the Company or an Affiliate, or shall be subject to any lien, obligation, or liability of such Participant to any other party other than the Company or an Affiliate. No unexercised or restricted Award shall 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 ("Immediate Family Members"), 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 Committee may (but need not) permit other transfers (other than transfers for value) where the Committee concludes that such transferability (i) does not result in accelerated taxation, (ii) does not cause any Option intended to be an Incentive Stock Option to fail to be described in Code Section 422(b), and (iii) is otherwise appropriate and desirable, taking into account any factors deemed relevant, including without limitation, state or federal tax or securities laws applicable to transferable Awards.

13.4. BENEFICIARIES. Notwithstanding Section 13.3, a Participant may, in the manner determined by the 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. A beneficiary, legal guardian, legal representative, or other person claiming any rights under the Plan is subject to all terms and conditions of the Plan and any Award Certificate applicable to the Participant, except to the extent the Plan and Award Certificate otherwise provide, and to any additional restrictions deemed necessary or appropriate by the Committee. If no beneficiary has been designated or survives the Participant, any payment due to the Participant shall be made to the Participant's estate. Subject to the foregoing, a beneficiary designation may be changed or revoked by a Participant, in the manner provided by the Company, at any time provided the change or revocation is filed with the Committee.

13.5. STOCK TRADING RESTRICTIONS. All Stock issuable under the Plan is subject to any stop-transfer orders and other restrictions as the Committee deems necessary or advisable to comply with federal or state securities laws, rules and regulations and the rules of any Exchange or automated quotation system on which the Stock is listed, quoted, or traded. The Committee may place legends on any Stock certificate or issue instructions to the transfer agent to reference restrictions applicable to the Stock.

13.6. EFFECT OF A CHANGE IN CONTROL. Upon the occurrence of a Change in Control: (i) outstanding Options, SARs, and other Awards in the nature of rights that may be exercised shall become fully exercisable, (ii) time-based vesting restrictions on outstanding Awards shall lapse, and (iii) the target payout opportunities attainable under outstanding performance-based Awards shall be deemed to have been fully earned as of the effective date of the Change in Control based upon an assumed achievement of all relevant performance goals at the "target" level, and there shall be a prorata payout to Participants within sixty (60) days following the Change in Control (unless a later date is required by Section 16.3 hereof), based upon the length of time within the performance period that has elapsed prior to the Change in Control. Any Awards shall thereafter continue or lapse in accordance with the other provisions of the Plan and the Award Certificate. To the extent that this provision causes Incentive Stock Options to exceed the dollar limitation set forth in Code Section 422(d), the excess Options shall be deemed to be Nonstatutory Stock Options.

13.7. ACCELERATION FOR ANY OTHER REASON. Regardless of whether an event has occurred as described in Section 13.6 above, the Committee may in its sole discretion at any time determine that all or a portion of a Participant's Options, SARs, and other Awards in the nature of rights that may be exercised shall become fully or partially exercisable, that all or a part of the time-based vesting restrictions on all or a portion of the outstanding Awards shall lapse, and/or that any performance-based criteria with respect to any Awards shall be deemed to be wholly or partially satisfied, in each case, as of such date as the Committee may, in its sole discretion, declare. The Committee may discriminate among Participants and among Awards granted to a Participant in exercising its discretion pursuant to this Section 13.7. Notwithstanding anything in the Plan, including this Section 13.7, the Committee may not accelerate the payment of any Award if such acceleration would violate Section 409A(a)(3) of the Code.

13.8. FORFEITURE EVENTS. Awards under the Plan shall be subject to any compensation recoupment policy that the Company may adopt from time to time that is applicable by its terms to the Participant. In addition, the Committee may specify in an Award Certificate that the Participant's rights, payments and benefits with respect to an Award shall be subject to reduction, cancellation, forfeiture or recoupment upon the occurrence of certain specified events, in addition to any otherwise applicable vesting or performance conditions of an Award. Such events may include, but shall not be limited to, (i) termination of employment for cause, (ii) violation of material Company or Affiliate policies, (iii) breach of noncompetition, confidentiality or other restrictive covenants that may apply to the Participant, (iv) other conduct by the Participant that is detrimental to the business or reputation of the Company or any Affiliate, or (v) a later determination that the vesting of, or amount realized from, a Performance Award was based on materially inaccurate financial statements or any other materially inaccurate performance metric criteria, whether or not the Participant caused or contributed to such material inaccuracy.

13.9. SUBSTITUTE AWARDS. The Committee may grant Awards under the Plan in substitution for stock and stock-based awards held by employees of another entity who become employees of the Company or an Affiliate as a result of a merger or consolidation of the former employing entity with the Company or an Affiliate or the acquisition by the Company or an Affiliate of property or stock of the former employing corporation. The Committee may direct that the substitute awards be granted on such terms and conditions as the Committee considers appropriate in the circumstances.

ARTICLE 14
CHANGES IN CAPITAL STRUCTURE

14.1. MANDATORY ADJUSTMENTS. In the event of a nonreciprocal transaction between the Company and its stockholders that causes the per-share value of the Stock to change (including, without limitation, any stock dividend, stock split, spin-off, rights offering, or large nonrecurring cash dividend), the Committee shall make such adjustments to the Plan and Awards as it deems necessary, in its sole discretion, to prevent dilution or enlargement of rights immediately resulting from such transaction. Action by the Committee may include: (i) adjustment of the number and kind of shares that may be delivered under the Plan; (ii) adjustment of the number and kind of shares subject to outstanding Awards; (iii) adjustment of the exercise price of outstanding Awards or the measure to be used to determine the amount of the benefit payable on an Award; and (iv) any other adjustments that the Committee determines to be equitable. Notwithstanding the foregoing, the Committee shall not make any adjustments to outstanding Options or SARs that would constitute a modification or substitution of the stock right under Treas. Reg. Section 1.409A-1(b)(5)(v) that would be treated as the grant of a new stock right or change in the form of payment for purposes of Code Section 409A. Without limiting the foregoing, in the event of a subdivision of the outstanding Stock (stock-split), a declaration of a dividend payable in Shares, or a combination or consolidation of the outstanding Stock into a lesser number of Shares, the authorization limits under Section 5.1 shall automatically be adjusted proportionately, and the Shares then subject to each Award shall automatically, without the necessity for any additional action by the Committee, be adjusted proportionately without any change in the aggregate purchase price therefor.

14.2 DISCRETIONARY ADJUSTMENTS. Upon the occurrence or in anticipation of any corporate event or transaction involving the Company (including, without limitation, any merger, reorganization, recapitalization, combination or exchange of shares, or any transaction described in Section 14.1), the Committee may, in its sole discretion, provide (i) that Awards will be settled in cash rather than Stock, (ii) that Awards will become immediately vested and non-forfeitable and exercisable (in whole or in part) and will expire after a designated period of time to the extent not then exercised, (iii) that Awards will be assumed by another party to a transaction or otherwise be equitably converted or substituted in connection with such transaction, (iv) that outstanding Awards may be settled by payment in cash or cash equivalents equal to the excess of the fair market value of the underlying Stock, as of a specified date associated with the transaction (or the per-shares transaction price), over the exercise or base price of the Award, (v) that performance targets and performance periods for Performance Awards will be modified, or (vi) any combination of the foregoing. The Committee's determination need not be uniform and may be different for different Participants whether or not such Participants are similarly situated.

14.3 GENERAL. Any discretionary adjustments made pursuant to this Article 14 shall be subject to the provisions of Section 15.2. To the extent that any adjustments made pursuant to this Article 14 cause Incentive Stock Options to cease to qualify as Incentive Stock Options, such Options shall be deemed to be Nonstatutory Stock Options.

ARTICLE 15
AMENDMENT, MODIFICATION AND TERMINATION

15.1. AMENDMENT, MODIFICATION AND TERMINATION. The Board or the Committee may, at any time and from time to time, amend, modify or terminate the Plan without stockholder approval; provided, however, that if an amendment to the Plan would, in the reasonable opinion of the Board or the Committee, constitute a material change requiring stockholder approval under applicable laws, policies or regulations or the applicable listing or other requirements of an Exchange, then such amendment shall be subject to stockholder approval; and provided, further, that the Board or Committee may condition any other amendment or modification on the approval of stockholders of the Company for any reason, including by reason of such approval being necessary or deemed advisable (i) to comply with the listing or other requirements of an Exchange, or (ii) to satisfy any other tax, securities or other applicable laws, policies or regulations. Except for any mandatory adjustments to the Plan and Awards contemplated by Section 14.1, without the prior approval of the stockholders of the Company, the Plan may not be amended to permit: (i) the exercise price or base price of an Option or SAR to be reduced, directly or indirectly, (ii) an Option or SAR to be cancelled in exchange for cash, other Awards, or Options or SARs with an exercise or base price that is less than the exercise price or base price of the original Option or SAR, or otherwise, or (iii) the Company to repurchase an Option or SAR for value (in cash or otherwise) from a Participant if the current Fair Market Value of the Shares underlying the Option or SAR is lower than the exercise price or base price per share of the Option or SAR.

15.2. AWARDS PREVIOUSLY GRANTED. At any time and from time to time, the Committee may amend, modify or terminate any outstanding Award without approval of the Participant; provided, however:

(a) Subject to the terms of the applicable Award Certificate, such amendment, modification or termination shall not, without the Participant's consent, reduce or diminish the value of such Award determined as if the Award had been exercised, vested, cashed in or otherwise settled on the date of such amendment or termination (with the per-share value of an Option or SAR for this purpose being calculated as the excess, if any, of the Fair Market Value as of the date of such amendment or termination over the exercise or base price of such Award);

(b) The original term of an Option or SAR may not be extended without the prior approval of the stockholders of the Company;

(c) Except as otherwise provided in Article 14, without the prior approval of the stockholders of the Company: (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 or base price that is less than the exercise price or base price of the original Option or SAR, or otherwise, and (iii) the Company 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 underlying the Option or SAR is lower than the exercise price or base price per share of the Option or SAR; and

(d) No termination, amendment, or modification of the Plan shall adversely affect any Award previously granted under the Plan, without the written consent of the Participant affected thereby. An outstanding Award shall not be deemed to be "adversely affected" by a Plan amendment if such amendment would not reduce or diminish the value of such Award determined as if the Award had been exercised, vested, cashed in or otherwise settled on the date of such amendment (with the per-share value of an Option or SAR for this purpose being calculated as the excess, if any, of the Fair Market Value as of the date of such amendment over the exercise or base price of such Award).

15.3. COMPLIANCE AMENDMENTS. Notwithstanding anything in the Plan or in any Award Certificate to the contrary, the Board may amend the Plan or an Award Certificate, to take effect retroactively or otherwise, as deemed necessary or advisable for the purpose of conforming the Plan or Award Certificate to any present or future law relating to plans of this or similar nature (including, but not limited to, Section 409A of the Code), and to the administrative regulations and rulings promulgated thereunder. By accepting an Award under this Plan, a Participant agrees to any amendment made pursuant to this Section 15.3 to any Award granted under the Plan without further consideration or action.

ARTICLE 16
GENERAL PROVISIONS

16.1. RIGHTS OF PARTICIPANTS.

(a) No Participant or any Eligible Participant shall have any claim to be granted any Award under the Plan. Neither the Company, its Affiliates nor the Committee is obligated to treat Participants or Eligible Participants uniformly, and determinations made under the Plan may be made by the Committee selectively among Eligible Participants who receive, or are eligible to receive, Awards (whether or not such Eligible Participants are similarly situated).

(b) Nothing in the Plan, any Award Certificate or any other document or statement made with respect to the Plan, shall interfere with or limit in any way the right of the Company or any Affiliate to terminate any Participant's employment or status as an officer, or any Participant's service as a director, at any time, nor confer upon any Participant any right to continue as an employee, officer, or director of the Company or any Affiliate, whether for the duration of a Participant's Award or otherwise.

(c) Neither an Award nor any benefits arising under this Plan shall constitute an employment contract with the Company or any Affiliate and, accordingly, subject to Article 15, this Plan and the benefits hereunder may be terminated at any time in the sole and exclusive discretion of the Committee without giving rise to any liability on the part of the Company or any of its Affiliates.

(d) No Award gives a Participant any of the rights of a stockholder of the Company unless and until Shares are in fact issued to such person in connection with such Award.

16.2. WITHHOLDING. The Company or any Affiliate shall have the authority and the right to deduct or withhold, or require a Participant to remit to the Company or such Affiliate, an amount sufficient to satisfy federal, state, and local taxes (including the Participant's FICA obligation) required by law to be withheld with respect to any exercise, lapse of restriction or other taxable event arising as a result of the Plan. The obligations of the Company under the Plan will be conditioned on such payment or arrangements and the Company or such Affiliate will, to the extent permitted by law, have the right to deduct any such taxes from any payment of any kind otherwise due to the Participant. Unless otherwise determined by the Committee at the time the Award is granted or thereafter, any such withholding requirement may be satisfied, in whole or in part, by withholding from the Award Shares having a Fair Market Value on the date of withholding equal to the minimum amount (and not any greater amount) required to be withheld for tax purposes, all in accordance with such procedures as the Committee establishes. All such elections shall be subject to any restrictions or limitations that the Committee, in its sole discretion, deems appropriate.

16.3. SPECIAL PROVISIONS RELATED TO SECTION 409A OF THE CODE

(a) It is intended that the payments and benefits provided under the Plan and any Award shall either be exempt from the application of, or comply with, the requirements of Section 409A of the Code. The Plan and all Award Certificates shall be construed in a manner that effects such intent. Nevertheless, the tax treatment of the benefits provided under the Plan or any Award is not warranted or guaranteed. Neither the Company, its Affiliates nor their respective directors, officers, employees or advisers (other than in his or her capacity as a Participant) shall be held liable for any taxes, interest, penalties or other monetary amounts owed by any Participant or other taxpayer as a result of the Plan or any Award.

(b) Notwithstanding anything in the Plan or in any Award Certificate to the contrary, to the extent that any amount or benefit that would constitute non-exempt "deferred compensation" for purposes of Section 409A of the Code ("Non-Exempt Deferred Compensation") would otherwise be payable or distributable, or a different form of payment (e.g., lump sum or installment) of such Non-Exempt Deferred Compensation would be effected, under the Plan or any Award Certificate by reason of the occurrence of a Change in Control, or the Participant's Disability or separation from service, such Non-Exempt Deferred Compensation will not be payable or distributable to the Participant, and/or such different form of payment will not be effected, by reason of such circumstance unless the circumstances giving rise to such Change in Control, Disability or separation from service meet any description or definition of "change in control event", "disability" or "separation from service", as the case may be, in Section 409A of the Code and applicable regulations (without giving effect to any elective provisions that may be available under such definition). This provision does not affect the dollar amount or prohibit the *vesting* of any Award upon a Change in Control, Disability or separation from service, however defined. If this provision prevents the payment or distribution of any amount or benefit, or the application of a different form of payment of any amount or benefit, such payment or distribution shall be made at the time and in the form that would have applied absent the non-409A-conforming event.

(c) If any one or more Awards granted under the Plan to a Participant could qualify for any separation pay exemption described in Treas. Reg. Section 1.409A-1(b)(9), but such Awards in the aggregate exceed the dollar limit permitted for the separation pay exemptions, the Company shall determine which Awards or portions thereof will be subject to such exemptions.

(d) Notwithstanding anything in the Plan or in any Award Certificate to the contrary, if any amount or benefit that would constitute Non-Exempt Deferred Compensation would otherwise be payable or distributable under this Plan or any Award Certificate by reason of a Participant's separation from service during a period in which the Participant is a Specified Employee, then, subject to any permissible acceleration of payment by the Committee under Treas. Reg. Section 1.409A-3(j)(4)(ii) (domestic relations order), (j)(4)(iii) (conflicts of interest), or (j)(4)(vi) (payment of employment taxes): (i) the amount of such Non-Exempt Deferred Compensation that would otherwise be payable during the six-month period immediately following the Participant's separation from service will be accumulated through and paid or provided on the first day of the seventh month following the Participant's separation from service (or, if the Participant dies during such period, within 30 days after the Participant's death) (in either case, the "Required Delay Period"); and (ii) the normal payment or distribution schedule for any remaining payments or distributions will resume at the end of the Required Delay Period.

(e) If, pursuant to an Award, a Participant is entitled to a series of installment payments, such Participant's right to the series of installment payments shall be treated as a right to a series of separate payments and not to a single payment. For purposes of the preceding sentence, the term "series of installment payments" has the meaning provided in Treas. Reg. Section 1.409A-2(b)(2)(iii) (or any successor thereto).

(f) Whenever an Award conditions a payment or benefit on the Participant's execution and non-revocation of a release of claims, such release must be executed and all revocation periods shall have expired within 60 days after the date of termination of the Participant's employment; failing which such payment or benefit shall be forfeited. If such payment or benefit is exempt from Section 409A of the Code, the Company may elect to make or commence payment at any time during such 60-day period. If such payment or benefit constitutes Non-Exempt Deferred Compensation, then, subject to subsection (d) above, (i) if such 60-day period begins and ends in a single calendar year, the Company may make or commence payment at any time during such period at its discretion, and (ii) if such 60-day period begins in one calendar year and ends in the next calendar year, the payment shall be made or commence during the second such calendar year (or any later date specified for such payment under the applicable Award), even if such signing and non-revocation of the release occur during the first such calendar year included within such 60-day period. In other words, a Participant is not permitted to influence the calendar year of payment based on the timing of signing the release.

(g) The Company shall have the sole authority to make any accelerated distribution permissible under Treas. Reg. Section 1.409A-3(j)(4) to Participants of deferred amounts, provided that such distribution(s) meets the requirements of Treas. Reg. Section 1.409A-3(j)(4).

16.4. UNFUNDED STATUS OF AWARDS. The Plan is intended to be an "unfunded" plan for incentive and deferred compensation. With respect to any payments not yet made to a Participant pursuant to an Award, nothing contained in the Plan or any Award Certificate shall give the Participant any rights that are greater than those of a general creditor of the Company or any Affiliate. In its sole discretion, the Committee may authorize the creation of grantor trusts or other arrangements to meet the obligations created under the Plan to deliver Shares or payments in lieu of Shares or with respect to Awards. This Plan is not intended to be subject to ERISA.

16.5. RELATIONSHIP TO OTHER BENEFITS. No payment under the Plan shall be taken into account in determining any benefits under any pension, retirement, savings, profit sharing, group insurance, welfare or benefit plan of the Company or any Affiliate unless provided otherwise in such other plan. Nothing contained in the Plan will prevent the Company from adopting other or additional compensation arrangements, subject to stockholder approval if such approval is required; and such arrangements may be either generally applicable or applicable only in specific cases.

16.6. EXPENSES. The expenses of administering the Plan shall be borne by the Company and its Affiliates.

16.7. TITLES AND HEADINGS. The titles and headings of the Sections in the Plan are for convenience of reference only, and in the event of any conflict, the text of the Plan, rather than such titles or headings, shall control.

16.8. GENDER AND NUMBER. Except where otherwise indicated by the context, any masculine term used herein also shall include the feminine; the plural shall include the singular and the singular shall include the plural.

16.9. FRACTIONAL SHARES. No fractional Shares shall be issued and the Committee shall determine, in its discretion, whether cash shall be given in lieu of fractional Shares or whether such fractional Shares shall be eliminated by rounding up or down.

16.10. GOVERNMENT AND OTHER REGULATIONS.

(a) Notwithstanding any other provision of the Plan, no Participant who acquires Shares pursuant to the Plan may, during any period of time that such Participant is an affiliate of the Company (within the meaning of the rules and regulations of the Securities and Exchange Commission under the 1933 Act), sell such Shares, unless such offer and sale is made (i) pursuant to an effective registration statement under the 1933 Act, which is current and includes the Shares to be sold, or (ii) pursuant to an appropriate exemption from the registration requirement of the 1933 Act, such as that set forth in Rule 144 promulgated under the 1933 Act.

(b) Notwithstanding any other provision of the Plan, if at any time the Committee shall determine that the registration, listing or qualification of the Shares covered by an Award upon any Exchange or under any foreign, federal, state or local law or practice, or the consent or approval of any governmental regulatory body, is necessary or desirable as a condition of, or in connection with, the granting of such Award or the purchase or receipt of Shares thereunder, no Shares may be purchased, delivered or received pursuant to such Award unless and until such registration, listing, qualification, consent or approval shall have been effected or obtained free of any condition not acceptable to the Committee. Any Participant receiving or purchasing Shares pursuant to an Award shall make such representations and agreements and furnish such information as the Committee may request to assure compliance with the foregoing or any other applicable legal requirements. The Company shall not be required to issue or deliver any certificate or certificates for Shares under the Plan prior to the Committee's determination that all related requirements have been fulfilled. The Company shall in no event be obligated to register any securities pursuant to the 1933 Act or applicable state or foreign law or to take any other action in order to cause the issuance and delivery of such certificates to comply with any such law, regulation or requirement.

16.11. GOVERNING LAW. To the extent not governed by federal law, the Plan and all Award Certificates shall be construed in accordance with and governed by the laws of the State of Delaware.

16.12. SEVERABILITY. In the event that any provision of this Plan is found to be invalid or otherwise unenforceable under any applicable law, such invalidity or unenforceability will not be construed as rendering any other provisions contained herein as invalid or unenforceable, and all such other provisions will be given full force and effect to the same extent as though the invalid or unenforceable provision was not contained herein.

16.13. NO LIMITATIONS ON RIGHTS OF COMPANY. The grant of any Award shall not in any way affect the right or power of the Company to make adjustments, reclassification or changes in its capital or business structure or to merge, consolidate, dissolve, liquidate, sell or transfer all or any part of its business or assets. The Plan shall not restrict the authority of the Company, for proper corporate purposes, to draft or assume awards, other than under the Plan, to or with respect to any person. If the Committee so directs, the Company may issue or transfer Shares to an Affiliate, for such lawful consideration as the Committee may specify, upon the condition or understanding that the Affiliate will transfer such Shares to a Participant in accordance with the terms of an Award granted to such Participant and specified by the Committee pursuant to the provisions of the Plan.

The foregoing is hereby acknowledged as being the Avenue Therapeutics, Inc. 2015 Incentive Plan as adopted by the Board and the Stockholders to be effective as of December 10, 2015.

AVENUE THERAPEUTICS, INC.

By: Lucy Lu, MD

Its: Interim CEO

Exhibit 10.8

CONSULTING AGREEMENT

THIS CONSULTING AGREEMENT (this "Agreement"), effective as of this 22 day of July, 2015 ("**Effective Date**") is by and between Scott A. Reines, MD, PhD having an address set forth below (hereinafter referred to as "**Consultant**") and Avenue Therapeutics, Inc. and its affiliates, having offices at 3 Columbus Circle, 1511' Floor, New York, NY 10019 ("**Avenue**").

WITNESSETH:

WHEREAS, Avenue and its affiliates specialize in the development of pharmaceutical products;

WHEREAS, Consultant will provide Avenue, for consideration described herein, with general consulting services relating to statistical, clinical and other strategic issues;

NOW, THEREFORE, in consideration of the mutual covenants and agreements hereinafter set forth, the parties hereto agree as follows:

Section 1. Term of Agreement. This Agreement shall be in effect for a period of one (1) year from the date hereof. The term of this Agreement may be extended for consecutive periods of one (1) year each upon mutual written agreement of both Consultant and Avenue.

Section 2. Services. Commencing on the Effective Date, Avenue hereby retains Consultant, and Consultant hereby agrees to serve, as a consultant to Avenue to provide services with respect to Avenue's business as may be mutually agreed upon by the Parties including, without limitation, meeting or telephone consultation with Avenue management and consultants, providing advice and support for the Avenue's clinical product development activities as requested by the Avenue. Consultant agrees to exercise the highest degree of professionalism and to utilize Consultant's expertise and creative talents to the fullest in performing these services. Avenue shall own all rights, title and interest in any Work Product, which will be deemed Avenue Confidential Information as defined in Section 5 herein.

Section 3. Compensation.

(a) Avenue will pay Consultant $400.00 per hour (the "Fee") for any amount of time Consultant spends performing his or her duties pursuant to the terms hereof. Invoices will set forth the actual number of hours worked, activities undertaken, and itemization of all other reimbursable costs incurred.

(b) Invoices submitted to Avenue by the Consultant for services rendered will be based upon the amount of time the Consultant actually expends performing his or her duties pursuant to the terms hereof and shall be payable within thirty (30) days of receipt of the invoice and resolution of any issues concerning the invoice.

(c) Avenue represents and warrants that any obligation to compensate Consultant under this Section 3 that arise prior to termination of this Agreement shall survive the termination of this Agreement.

(d) Avenue's checks shall be made payable to: Scott A. Reines, MD, PhD

Section 4. Expenses**.** Avenue will reimburse Consultant for all reasonable and necessary expenses, including domestic and foreign travel, incurred by him or her in connection with his or her consulting hereunder; provided, however, those expenses are pre-approved in writing by Avenue.

Section 5. Confidential Information.

(a) Consultant recognizes and acknowledges that in the course of his or her duties he or she is likely to receive confidential or proprietary information owned by Avenue, its affiliates or third parties with whom Avenue or any such affiliates has an obligation of confidentiality. Accordingly, during and after the term of this agreement, Consultant agrees to keep confidential and not disclose or make accessible to any other person or use for any other purpose other than in connection with the fulfillment of his or her duties under this Agreement, any Confidential and Proprietary Information (as defined below) owned by, or received by or on behalf of, Avenue or any of its affiliates. "Confidential and Proprietary Information" shall include, but shall not be limited to, confidential or proprietary scientific or technical information, data, formulas and related concepts, business plans (both current and under development), client lists, promotion and marketing programs, trade secrets, or any other confidential or proprietary business information relating to development programs, costs, revenues, marketing, investments, sales activities, promotions, credit and financial data, manufacturing processes, financing methods, plans or the business and affairs of Avenue or of any affiliate or client of Avenue. Consultant expressly acknowledges the proprietary status of the Confidential and Proprietary Information and that the Confidential and Proprietary Information constitutes a trade secret and/or protectable business interest of Avenue. Consultant agrees: (i) not to use any such Confidential and Proprietary Information for himself or herself or others; and (ii) not to take any Avenue material or reproductions (including but not limited to writings, correspondence, notes, drafts, records, invoices, technical and business policies, computer programs or disks) thereof from any of Avenue's offices at any time during his or her engagement with Avenue, except as required in the execution of Consultant's duties to Avenue. Consultant agrees to return immediately all Avenue material and reproductions (including but not limited, to writings, correspondence, notes, drafts, records, invoices, technical and business policies, computer programs or disks) thereof in his or her possession to Avenue upon request and in any event immediately upon termination of this Agreement.

(b) Except with prior written authorization by Avenue, Consultant agrees not to disclose or publish any Confidential and Proprietary Information, or any confidential, scientific, technical or business information of any other party to whom Avenue or any of its affiliates owes an obligation of confidence, at any time during or after his or her engagement with Avenue.

(c) Confidential Information shall not include any information that:

(i) can be established, by written records, as already in Consultant's possession or control prior to the date of;

(ii) was or becomes generally available to the public other than as a result of a disclosure by Consultant by reason of any default with respect to a confidentiality obligation under this Agreement or otherwise between the parties;

(iii) becomes available to Consultant from a source other than Avenue, its agents, consultants or representatives, provided that such source is not prohibited from disclosing such information by any confidentiality agreement or other contractual, legal or fiduciary obligation of nondisclosure; or

(iv) is required to be disclosed by Consultant pursuant to an order of law provided, however, that such Confidential Information shall not be disclosed prior to written intent of such disclosure being given to Avenue along with the asserted grounds for disclosure.

Section 6. Insider Trading. Consultant recognizes that in the course of his or her duties hereunder, Consultant may receive from Avenue or others information that may be considered "material, nonpublic information" concerning a public company that is subject to the reporting requirements of the Securities and Exchange Act of 1934, as amended. Consultant agrees NOT to:

(a) Buy or sell any security, option, bond or warrant while in possession of relevant material, nonpublic information received from Avenue or others in connection herewith;

(b) Provide Avenue with information with respect to any public company that may be considered material, nonpublic information; or

(c) Provide any person with material, nonpublic information, received from Avenue, including any relative, associate, or other individual who intends to, or may, (a) trade securities with respect to the company which is the subject of such information, or (b) otherwise directly or indirectly benefit from such information.

Section 7. Representations and Warranties of Consultant.

(a) Neither the execution or delivery of this Agreement nor the performance by Consultant of his or her duties and other obligations hereunder violate or will violate any statute, law, determination or award, or conflict with or constitute a default or breach of any covenant or obligation under (whether immediately, upon the giving of notice or lapse of time or both) any prior employment agreement, contract, or other instrument to which Consultant is a party or by which he or she is bound.

(b) Consultant has the full right, power and legal capacity to enter and deliver this Agreement and to perform his or her duties and other obligations hereunder. This Agreement constitutes the legal, valid and binding obligation of Consultant enforceable against him or her in accordance with its terms. No approvals or consents of any persons or entities are required for Consultant to execute and deliver this Agreement or perform his or her duties and other obligations hereunder.

Section 8. Consultant not an Employee. Avenue and Consultant hereby acknowledge and agree that Consultant shall perform the services hereunder as an independent contractor and not as an employee or agent of Avenue or any Avenue affiliate. Consultant will be solely responsible for all taxes, withholding and other similar statutory obligations. Consultant is not to represent that he or she is an employee of Avenue or any Avenue affiliate under any circumstance. In addition, nothing in this Agreement shall be construed as establishing any joint venture, partnership or other business relationship between the parties hereto or representing any commitment by either party to enter into any other agreement by implication or otherwise except as specifically stated herein. Consultant shall have no authority, express or implied, to bind Avenue or any Avenue affiliate to any agreement, contract, or other commitment. Consultant further understands and agrees that this Agreement is entered into by Avenue on a non-exclusive basis and that Avenue and its affiliates remain free to deal with others and retain other consultants, agents, employees, brokers, finders, etc. in the same or similar capacity as Consultant has been retained at any time at their own option.

Section 9. Termination.

(a) Notwithstanding the foregoing, this Agreement may be terminated by Consultant or Avenue upon three (3) days written notice. Immediately upon receipt of such notice from Avenue, Consultant shall institute such termination procedures as may be specified in the notice and shall use his best efforts to minimize the cost to Avenue resulting from such termination. In the event of such termination, Avenue shall pay to Consultant reasonable charges for the work performed and expenses incurred up to the notice of termination.

(b) Termination of this Agreement shall not relieve either party of any obligation to the other in respect of any other provisions of this Agreement which by their nature are intended to survive termination shall also survive.

(c) Upon termination, Consultant will provide Avenue with a report detailing the work product and results of the work performed under the Agreement, and if requested to do so by Avenue, shall return all confidential information and materials provided by Avenue, other than such confidential information which Consultant has a legal or regulatory obligation to retain.

(d) Any Confidential Disclosure Agreements (CDAs) signed between Avenue and Consultant shall remain in effect beyond the termination of this Agreement.

Section 10. Miscellaneous.

(a) Severability of Provisions. If any provision of this Agreement shall be declared by a court of competent jurisdiction to be invalid, illegal or incapable of being enforced in whole or in part, the remaining conditions and provisions or portions thereof shall nevertheless remain in full force and effect and enforceable to the extent they are valid, legal and enforceable, and no provision shall be deemed dependent upon any other covenant or provision unless so expressed herein.

(b) Entire Agreement; Modification. This Agreement is the entire agreement of the parties relating to the subject matter hereof and the parties hereto have made no agreements, representations or warranties relating to the subject matter of this Agreement that are not set forth herein. No amendment or modification of this Agreement shall be valid unless made in writing and signed by each of the parties hereto.

(c) Binding Effect. The rights, benefits, duties and obligations under this Agreement shall inure to, and be binding upon, Avenue, its successors and assigns, and upon Consultant and his or her legal representatives. This Agreement constitutes a personal service agreement, and the performance of Consultant's obligations hereunder may not be transferred or assigned by Consultant and any such purported transfer or assignment shall be null and void ab initio.

(d) Third Party Beneficiaries. This Agreement is for the benefit of the parties hereto and their permitted successors and assigns, and is not intended to confer upon any other person or entity, any rights or remedies hereunder.

(e) Non-Waiver. The failure of either party to insist upon the strict performance of any of the terms, conditions and provisions of this Agreement shall not be construed as a waiver or relinquishment of future compliance therewith, and said terms, conditions and provisions shall remain in full force and effect. No waiver of any term or condition of this Agreement on the part of either party shall be effective for any purpose whatsoever unless such waiver is in writing and signed by such party.

(f) Governing Law. This Agreement shall be governed by, and construed and interpreted in accordance with, the laws of the State of New York without regard to such State's principles of conflict of laws.

(g) Headings. The headings of the Sections are inserted for convenience of reference only and shall not affect any interpretation of this Agreement.

(h) Gender and Number. As used in this Agreement, the masculine, feminine or neuter gender, and the singular or plural, shall be deemed to include the others whenever and wherever the context so requires. Additionally, unless the context requires otherwise, "or" is not exclusive.

(i) Notices. Any notice given pursuant to this Agreement will be written and sent to:

AVENUE THERAPEUTICS, INC:
Attention: Robyn Hunter
3 Columbus Circle
15th Floor
New York, NY 10019

CONSULTANT:
Attention: Scott A. Reines, MD, PhD
Independent Consultant
11 W Bridlewood Drive
New Hope, PA 18938

IN WITNESS WHEREOF, the parties hereto have executed this Agreement by proper person thereunto duly authorized.

AVENUE THERAPEUTICS, INC.

By: /s/ Lucy Lu
Name:
Title: President
Date:

CONSULTANT

By: /s/ Scott A. Reines
Name:
Title: Independent Consultant
Date:

Exhibit 10.9

FIRST AMENDMENT TO CONSULTING AGREEMENT

THIS FIRST AMENDMENT TO CONSULTING AGREEMENT (this "**Amendment**") is made and entered into this 25th day of January, 2016 by and between Scott A. Reines, MD, PhD ("**Consultant**") Avenue Therapeutics, Inc. and its affiliates, having offices at 3 Columbus Circle, 15th Floor, New York, NY 10019 ("**Avenue**").

WITNESSETH:

WHEREAS, Consultant and Avenue entered into a Consulting Agreement (the "**Consulting Agreement**") as of July 22, 2015;

WHEREAS, Consultant and Avenue wish to amend the Consulting Agreement to alter certain provisions regarding the services to be provided by Consultant; and

WHEREAS, in light of the foregoing, Consultant and Avenue desire to mutually and voluntarily amend the Consulting Agreement, pursuant to the turns set forth herein.

NOW, THEREFORE, in consideration of the foregoing, the mutual promises herein contained, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto, intending to be legally bound, agree as follows.

1. AMENDMENT TO SECTION 2 OF THE CONSULTING AGREEMENT. Section 2 of the Consulting Agreement is modified by replacing the existing Section 2 with the following:

> **Section 2. Services.** Commencing on the Effective Date, Avenue hereby retains Consultant, and Consultant hereby agrees to serve, as a consultant to Avenue to provide services with respect to Avenue's business as may be mutually agreed upon by the Parties including, without limitation, meeting or telephone consultation with Avenue management and consultants, providing advice and support for the Avenue's clinical product development activities as requested by the Avenue. Without limiting the preceding sentence, Consultant will serve as Avenue's Interim Chief Medical Officer and may be so identified publicly by Avenue. Consultant agrees to exercise the highest degree of professionalism and to utilize Consultant's expertise and creative talents to the fullest in performing these services. As an independent contractor, Consultant will at all times retain sole and absolute discretion and judgment in the manner and means of carrying out the services Consultant performs hereunder. Avenue shall own all rights, title and interest in any Work Product, which will be deemed Avenue Confidential Information as defined in Section 5 herein.

2. REMAINDER OF CONSULTING AGREEMENT. Except as expressly set forth in this Amendment, the provisions of the Consulting Agreement will remain in full force and effect, in their entirety, in accordance with their terms.

3 . MISCELLANEOUS. This Amendment shall be governed, construed, and interpreted in accordance with the laws of the State of New York, without giving effect to conflicts of laws principles of any jurisdiction. The parties agree that this Amendment may only be modified in a signed writing executed by each of the parties hereto. This Amendment shall be binding upon and shall inure to the benefit of the parties hereto and their respective heirs, successors and assigns. This Amendment may be executed in separate counterparts, each of which is deemed to be an original and all of which taken together constitute one agreement. Facsimile or PDF reproductions of original signatures will be deemed binding for the purpose of the execution of this Amendment.

IN WITNESS WHEREOF, the parties hereto have executed this Amendment to be effective as of the date set forth above.

CONSULTANT:

By: /s/
Scott A. Reines, MD, PhD

AVENUE:

AVENUE THERAPEUTICS, INC.

By: /s/
Lucy Lu, MD President

The undersigned does hereby consent that this document be filed with the minutes of the Company, and that the actions set forth in the foregoing resolutions shall have the same force and effect as if taken at a duly constituted meeting of the Board of Directors of the Company as indicated by his signature hereto, effective as of the date first set forth above.

SOLE DIRECTOR

/s/ Lindsay A. Rosenwald
Lindsay A. Rosenwald, M.D.