

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

FORM 10
Amendment No. 1

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
(State or Other Jurisdiction of
Incorporation or Organization)

47-4113275
(I.R.S. Employer
Identification No.)

3 Columbus Circle, 15th Floor
New York, New York
(Address of Principal Executive Offices)

01803
(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)
n/a

(Name of exchange on which registered)
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 company.

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 HCl ("**IV Tramadol**"), for the treatment of moderate to moderately severe post-operative pain. Avenue Therapeutics plans to initiate a Phase 3 development program of IV Tramadol for the management of post-operative pain in 2016 following a pharmacokinetics or PK study. Under the terms of certain agreements described herein, Avenue Therapeutics has an exclusive license to develop and commercialize IV Tramadol in the United States. Avenue Therapeutics 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.

IV Tramadol and the U.S. IV Analgesic Market Opportunity

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 U.S., tramadol is approved and marketed as an oral agent for moderate to moderately severe pain in adults. Tramadol was first approved in the U.S. 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 U.S. (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 U.S. 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 U.S. 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 U.S. 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.

CORPORATE INFORMATION

Avenue Therapeutics, Inc. incorporated in Delaware on February 9, 2015. Our executive offices are located at 3 Columbus Circle, 15th Floor, New York, NY 10019. 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). We have not received revenue from operations since our incorporation, which is less than three fiscal years immediately before the filing of this registration statement.

COSTS AND TIME TO COMPLETE PRODUCT DEVELOPMENT

The information below provides estimates regarding the costs associated with the completion of the current development phase and our current estimated range of the time that will be necessary to complete that development phase for IV Tramadol. We also direct your attention to the Risk Factors, which could significantly affect our ability to meet these cost and time estimates found in this report in Item 1A.

Product Candidate	Target Indication	Clinical Development Plan and Timing	NDA Submission	Estimated Cost to Complete Development
<i>IV Tramadol HCl</i>	Moderate to Moderately Severe Post-Operative Pain	PK study, followed by Phase 3 program in 2016	Early 2019	Approximately \$20 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

Our goal is to obtain, maintain and enforce patent protection for our products, formulations, processes, methods and other proprietary technologies, preserve our trade secrets, and 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, broad intellectual property protection for our product candidates, proprietary information and proprietary technology through a combination of contractual arrangements and patents, both in the U.S. and elsewhere in the world.

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, consultants, advisors and other contractors to enter into confidentiality agreements, which prohibit the disclosure of confidential information and, where applicable, require disclosure and assignment to us of the ideas, developments, discoveries and inventions important to our business.

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 a few patents and patent applications related to our compounds and other 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 U.S. 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 U.S. 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 to 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. 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 HCl

Pursuant to our license for IV Tramadol with Revogenex Ireland Ltd. (**“Revogenex”**), which is described further in the following section, we have the rights to U.S. Patent Serial No. 14/550,729, entitled “Intravenous Administration of Tramadol,” which was issued November 21, 2014 (the **“729 Patent”**), a continuation of U.S. 8,895,622 “Intravenous Administration of Tramadol”. This patent is scheduled to expire in 2032.

The 729 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. This method of treatment is different and provides significant benefits (e.g., reduced side effects) over prior administration of intravenous tramadol, in which the dose was typically accomplished over a 2-3 minute period. Additional claims of the 729 Patent focus on the intravenous administration of tramadol over 15 (\pm 2) minutes, which represents the preferred method of administration that we will be pursuing in obtaining approval of our product through the FDA. The 729 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.). We believe that our patent will prevent third parties from marketing a generic version of the product without infringing claims of the patent(s) it is 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

LICENSING AGREEMENTS AND COLLABORATIONS

Revogenex Ireland Ltd.

Effective as of February 17, 2015, Fortress obtained a worldwide exclusive license to make, market and sell IV Tramadol in the U.S. market pursuant to an agreement with Revogenex, a privately held company in Dublin, Ireland (the **“License Agreement”**). Under the terms of the License Agreement, Fortress paid Revogenex an up-front licensing fee of two million dollars (\$2,000,000), with an additional one million (\$1,000,000) due upon Revogenex’s full transfer of all Acquired Assets. In turn, Fortress obtained the exclusive worldwide rights to the 729 Patent. 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 (**“Manufacturing Agreement”**).

Fortress transferred the Revogenex license and all other rights and obligations of Fortress under the License Agreement and the Manufacturing Agreement to Avenue Therapeutics pursuant to the Founders Agreement between Fortress and Avenue Therapeutics (the **“Founders Agreement”**). Through the assignment of the License Agreement, we acquired a worldwide exclusive license to IV Tramadol’s intellectual property, to make, have made, use, offer to sell, sell and import IV Tramadol for all therapeutic, preventive, palliative and diagnostic uses and applications for humans and animals. As part of the consideration for the Founders Agreement, we assumed \$3.0 million in debt that Fortress accumulated under the NSC Note (described below) for the License Agreement. Additionally, Fortress has provided us with a working capital loan of up to \$2.5 million, in connection with which we have executed a promissory note (the **“Fortress Note”**). See Item 2. Financial Information – Liquidity and Capital Resources. Under the License Agreement, we will also be required to remit two payments totaling four million dollars (\$4,000,000) to Revogenex upon submission of the New Drug Application (the **“NDA”**) to the FDA and subsequent approval for the commercial sale of IV Tramadol. In addition, we will be required to remit royalty payments to Revogenex equal to a percentage of net sales of IV Tramadol ranging from the high single-digits to low double-digits, depending on annual net sales. The license 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. For more information about the Founders Agreement, see Item 7 – Certain Relationships and Related Transactions, and Director Independence.

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

International Regulation

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

Our Development and Regulatory Strategy for IV Tramadol

As of the date of this registration statement, Revogenex had 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.

Based upon correspondence and meetings with the U.S. FDA, we anticipate that we will perform a pharmacokinetics (PK) study, followed by a Phase 3 program in 2016. We will perform a PK study to determine a dosing regimen for IV Tramadol that provides a similar exposure profile to that of oral tramadol. This dosing regimen will be utilized 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 program consists of two double-blind, placebo-controlled, multicenter, randomized studies to evaluate the efficacy and safety of IV Tramadol in the management of post-operative pain. One of the Phase 3 studies will be done in orthopedic surgeries and the other one in soft tissue surgeries. We anticipate each of these studies will enroll approximately 300 subjects, with at least one study targeted to commence in 2016.

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 the Section 505(b)(2) applicant is relying on the FDA's findings for an already-approved product, the applicant is required to certify to the FDA concerning 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 may also 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 patent 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 has 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 on 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 approval 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 EMA and similar regulatory authorities outside the United States. Failure to obtain marketing approval for our product candidate or any future product candidate will prevent us from commercializing the product candidates. We have not received approval to market our product candidate 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 or any future product candidate 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 obtained 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 candidate, 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 candidate 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 candidate.

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 or be unable to meet market demand, and may lose potential revenues.

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 current cGMP. We also plan to qualify a backup manufacturer.

All of our contract manufacturers must comply with strictly enforced federal, state and foreign regulations, including cGMP requirements enforced by the FDA through its facilities inspection program, 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 product candidate or any future product candidate 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 candidate 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 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.

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

- 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 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 product candidates 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;
- 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, the President 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 in additional downward pressure on the price that we receive for any approved drug. Any reduction in reimbursement from Medicare or other government healthcare programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our drugs.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for 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. Patient enrollment is affected by other factors including:

- 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:

- 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.

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 coverage and 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 products on our own include:

- 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 terminate, 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:

- 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, or 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, a privately held company in Dublin, Ireland. Fortress transferred the Revogenex license 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.

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. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents.

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 United States Patent Office 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 U.S. Patent and Trademark Office, or become involved in opposition, derivation, reexamination, *inter partes* review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, 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 729 Patent provides a strong protection, our market opportunity would be limited, if a generic manufacturer can 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 commercially viable 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 products or 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 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 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 our ability to establish the necessary 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;
- there are any regulatory developments affecting IV Tramadol or the product candidates of our competitors; and
- IV Tramadol or other product candidate receives regulatory approval, the level of underlying hospital demand for this product candidate and wholesalers' buying patterns.

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 will need additional funding and may be unable to raise capital when needed, which would force us to delay, reduce or eliminate our product development programs or commercialization efforts.

Developing products for use in the hospital setting, conducting clinical trials, establishing outsourced manufacturing relationships and successfully manufacturing and marketing drugs that we may develop is expensive. We will need to raise additional capital to:

- fund our operations and continue our efforts to hire additional personnel;
- qualify and outsource the commercial-scale manufacturing of our products under cGMP; and
- in-license and develop additional product candidates.
- Our future funding requirements will depend on many factors, including, but not limited to:
- the potential for delays in our efforts to seek regulatory approval for IV Tramadol, and any costs associated with such delays;
- the costs of establishing a commercial organization to sell, market and distribute IV Tramadol;
- 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 IV Tramadol from our contract manufacturers 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 IV Tramadol is 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 intravenous synthetic opioid analgesic; and
- the success of the commercialization of IV Tramadol.

Future capital requirements will also depend on the extent to which we acquire or invest in additional complementary businesses, products and technologies, but we currently have no commitments or agreements relating to any of these types of transactions.

Until we can generate a sufficient amount of product revenue, if ever, we expect to finance future cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements, as well as through interest income earned on cash and investment balances. We cannot be certain that additional funding will be available on acceptable terms, or at all. If adequate funds are not available, we may be required to delay, reduce the scope of or eliminate one or more of our development programs or our commercialization efforts.

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 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. 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.

We intend to become a public company. As a public company, we will incur significant legal, accounting and other expenses under Section 404 of the Sarbanes-Oxley Act of 2002 requires that we evaluate and report on our system of internal controls and may require us to have such system audited by an independent registered public accounting firm. If we fail to maintain the adequacy of our internal controls, we could be subject to regulatory scrutiny, civil or criminal penalties and/or shareholder litigation. Any inability to provide reliable financial reports could harm our business. A target business may also 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 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 one billion (\$1,000,000,000), or the market value of our ordinary shares that are held by non-affiliates exceeds seven hundred million (\$700,000,000) 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 December 29, 2015, on our financial statements for the period ended October 31, 2015, included an explanatory paragraph indicating that there is substantial doubt about our ability to continue as a going concern. Our auditors' doubts are based on our working capital deficit of approximately \$1.6 million and our shareholders' deficit of approximately \$4.3 million, and the Company has incurred losses of approximately \$4.4 million since inception. 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 the Common Stock.

Pursuant to the terms of the Class A Common Stock held by Fortress, Fortress will be entitled to cast, for each share of Class A Common 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 the shares of outstanding Common Stock and the denominator of which is the number of shares of outstanding Class A Common Stock. Thus, Fortress will at all times have voting control 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 Founders Agreement (See Item 7 - Certain Relationships and Related Transactions, and Director Independence), Fortress has the right to receive a grant of shares of our Common Stock equal to 2.5% of the fully-diluted outstanding equity at the time of issuance, annually on the anniversary of the date of the Founders Agreement, which became effective as of February 17, 2015. This annual issuance of shares to Fortress will dilute your holdings in our equity, and, if the value of Avenue has not grown over the prior year, would result in a reduction in the value of your shares.

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 and 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 that could potentially be of interest to Avenue, and they are not required to notify Avenue prior to pursuing these opportunities. 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 harm our results of operations.

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.

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. We plan to initiate a Phase 3 development program of IV Tramadol for the management of post-operative pain in 2016 following completion of our pharmacokinetics or PK study. Under the terms of our license agreement, 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 majority controlled subsidiary of Fortress.

Avenue Therapeutics, Inc. was incorporated in Delaware on February 9, 2015. Our executive offices are located at 3 Columbus Circle, 15th Floor, New York, NY 10019. 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. We believe the following accounting policies to be most critical to the judgments and estimates used in the preparation of our financial statements.

Research and Development

Research and development costs are expensed as incurred. Advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made. Upfront and milestone payments due to third parties that perform research and development services on our behalf will be expensed as services are rendered or when the milestone is achieved. Costs incurred in obtaining technology licenses are charged to research and development expense if the technology licensed has not reached technological feasibility and has no alternative future use. Research and development costs primarily consist of personnel related expenses, including salaries, benefits, travel, and other related expenses, stock-based compensation, payments made to third parties for license and milestone costs related to in-licensed products and technology, payments made to third party contract research organizations for preclinical and clinical studies, investigative sites for clinical trials, consultants, the cost of acquiring and manufacturing clinical trial materials, costs associated with regulatory filings and patents, laboratory costs and other supplies.

Fair Value Measurement

We follow 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. Our 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

We expense 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, we measure the fair value of the non-employee awards at each reporting period prior to vesting and finally at the vesting date of the award. Changes in the estimated fair value of these nonemployee 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.

Results of Operations

General

At October 31, 2015, we had an accumulated deficit of \$4.4 million, primarily as a result of expenditures for licenses acquired, for research and development and for general and administrative purposes. While we may in the future generate revenue from a variety of sources, including license fees, milestone payments, research and development payments in connection with strategic partnerships and/or product sales, our product candidate is in early stages of development and may never be successfully developed or commercialized. Accordingly, we expect to continue to incur substantial losses from operations for the foreseeable future, and there can be no assurance that we will ever generate significant revenues.

Research and Development Expenses

Research and development is central to our business. For the period from February 9, 2015 through October 31, 2015, research and development expenses were \$3.6 million, of which \$3.0 million was related to the acquisition of the license and rights to IV Tramadol and an additional \$0.6 million relates to activities in connection with the development of IV Tramadol inclusive of 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 October 31, 2015, general and administrative expenses were \$0.6 million, which consisted of expense related to the Management Services Agreement with Fortress, effective as of February 17, 2015, and approximately \$0.3 million was related to legal expenses in connection with the acquisition of the license from Revogenex as well as formation 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 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. 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. Our liquidity needs, to date, have been satisfied by \$3.0 million from the NSC Note and approximately \$1.0 million of the Fortress Note.

Operating Activities

From the period from February 9, 2015 to October 31, 2015, cash provided under the NSC Note was \$3.0 million and cash provided under the Fortress Note was approximately \$1.0 million. From these amounts, \$3.0 million was used to make up-front payments to acquire IV Tramadol, while \$0.7 million was used to fund operating activities related to our formation, including \$0.3 million of fees related to the NSC Note, as well as preliminary research and development activities.

Recently Issued Accounting Pronouncements

There are no recently issued accounting pronouncements that have not yet been adopted that are expected, when adopted, to have a material impact on our consolidated financial statements or notes thereto.

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 3 Columbus Circle, 15th Floor, New York, New York 10019. We are not currently under a lease agreement at 3 Columbus Circle. 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 common stock and vested warrants, as of October 31, 2015, for:

- e a c h of our named executive officers;
- e a c h 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., 3 Columbus Circle, 15th Floor, New York, NY 10019.

Name and Address of Beneficial Owner	Common Stock Beneficially Owned	
	Number of Shares and Nature of Beneficial Ownership	Percentage of Total Common Stock
Lucy Lu, M.D.	1,000,000	50.0%
Michael S. Weiss	500,000(1)	25.0%(1)
Lindsay A. Rosenwald, M.D.	500,000(1)	25.0%(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)	50.0%(2)

5% or Greater Stockholders:

Fortress Biotech, Inc.	1,000,000	50.0%
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- (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 Common Stock Beneficially Owned	
	Number of Shares and Nature of Beneficial Ownership	Percentage of Total Class A Common Stock
Fortress Biotech, Inc.	7,000,000	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.	60	Executive Chairman of the Board of Directors
Lucy Lu, M.D.	40	Interim President, Chief Executive Officer
Scott A. Reines, M.D., Ph.D.	69	Interim Chief Medical Officer
David Horin, CPA	47	Interim Chief Financial Officer
Michael S. Weiss	49	Director
Neil Herskowitz	58	Director
Jeffrey Paley, MD	47	Director
Akhtar Samad, MD, PhD	56	Director

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

Executive Officers

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

Dr. Rosenwald has served as our Executive Chairman of the Board of Directors since inception. From November 2014 to August 2015, he also was our Chief Executive Officer and President. 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. Dr. Rosenwald is also Co-Chairman of the Board of Directors and Chief Executive Officer of CB Pharma Acquisition Corp., which he joined in 2014. 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

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 August 31, 2015. Pursuant to such agreement, 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 for its back office accounting support and accounting policy and financial reporting services that it provides to us, including the services of Mr. Horin. We do not have information or 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 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 a member of our Board of Directors since February, 2015. Mr. Weiss has served in several capacities at Fortress, most recently as Executive Vice Chairman since February 2014. He has also been Co-Chairman of the Board of Directors of CB Pharma Acquisition Corp. since 2014. Mr. Weiss is currently Co-Portfolio Manager and Partner of Opus Point Partners, LLC, which he co-founded in 2009. He has also served as Executive Chairman, Interim Chief Executive Officer and President of TG Therapeutics, Inc., a company he founded in 2011. 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 served as Chairman of the board of directors of National Holdings Corporation from 2011 to 2012. 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. Mr. Weiss has been selected to serve on our Board of Directors based on his experience, including as an executive of biotech companies and Fortress.

Neil Herskowitz

Mr. Herskowitz joined our Board of Directors in December 2015. Mr. Herskowitz has served as the managing member of the ReGen Group of companies, located in New York, since 1998, which include ReGen Capital Investments LLC and Riverside Claims Investments LLC. He has also served as the President of its affiliate, Riverside Claims LLC, since June 2004. Mr. Herskowitz currently serves as director of CB Pharma Acquisition Corp, along with being the Chairman of its Audit Committee. He also serves as Chairman of the board of directors of Starting Point Services for Children, a not-for-profit corporation. Mr. Herskowitz received a B.B.A. in Finance from Bernard M. Baruch College in 1978. Mr. Herskowitz has been selected to serve on our Board of Directors based on his experience, including experience serving as a director of other public companies.

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 five (5) 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 3 Columbus Circle, 15th Floor, New York, New York 10019. 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 3 Columbus Circle, 15th Floor, New York NY 10019.

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⁾ Interim Chief Executive Officer and President	2015	40,155	20,047	60,202
Scott A. Reines Interim Chief Medical Officer	2015	25,780 ⁽³⁾	--	25,780
David J. Horin 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 [X] 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 with will commence upon a public offering. 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 March 2015 through October 31, 2015 Dr. Lu spent 19% of her time devoted to us.

(3) This represents the amount paid to Dr. Reines during 2015 for services rendered. He provided us with 64.45 hours of work, and we pay him \$400.00 per hour for his work pursuant to our Consulting Agreement with him.

(4) This represents the amount paid to Chord during 2015, for services rendered, including those of Mr. Horin. We do not have information or any influence over Mr. Horin's direct compensation from Chord.

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 agreement will terminate on July 22, 2016, but can be extended for one year terms upon mutual written consent of Dr. Reines and Avenue.

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 for the year ended October 31, 2015.

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 (10th) 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 (10th) 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.

Effective as of February 17, 2015, we entered into a Founders Agreement with Fortress pursuant to which Fortress assigned to Avenue all of its right and interest under the License Agreement with Revogenex. As consideration for the Founders Agreement, we assumed \$3.0 million in debt that Fortress accumulated under the NSC Note, for the initial license payment in February for \$2.0 million and the additional payment in June of \$1.0 million related to obtaining the License Agreement. As additional consideration for the transfer of rights under the Founders Agreement, we shall 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 2.50% of the gross amount of any such equity or debt financing; and (iii) 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) monthly net sales for the twelve (12) months immediately preceding the change in control and (ii) four and one-half percent (4.5%).

Effective February 17, 2015, we entered into a Management Services Agreement (the "MSA") with Fortress and 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. Pursuant to the terms of the MSA, for a period of five (5) years, Fortress will render advisory and consulting services to us. 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"). 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 shall not be liable for any of our actions or inactions based upon their advice. Fortress and its affiliates, including all members of our Board of Directors, have been contractually exempt from their fiduciary duties to our Company relating to corporate opportunities. In consideration for the Services, we will pay Fortress an annual consulting 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 one million dollars (\$1,000,000) for each calendar year in which we have net assets in excess of one hundred million dollars (\$100,000,000) at the beginning of the calendar year.

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 no further advances can be made if the outstanding principal and interest exceed \$2.5 million. Interest on the Fortress Note is being accrued at 8% interest 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.

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 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. In the near future and prior to the effectiveness of this registration statement we intend to add two additional non-executive directors to our board in order to fully satisfy the NASDAQ and SEC requirements.

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.

Holdings

As of October 31, 2015, there were 2,150,000 shares of Common Stock outstanding held by four record holders, and 7,000,000 shares of Class A Common 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 resale 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.

None.

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 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, of which 15,000,000 have been designated as Class A Common Stock. Of the Class A Common Stock, 7,000,000 has been issued to Fortress Biotech, Inc. Only our Common Stock is being registered hereby. The description of our Class A Common Stock in this Item is for informational purposes only. Class A Common Stock is identical to Common Stock other than as to voting rights, the election of directors for a definite period, and conversion rights. 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 Common Stock shall be entitled to cast for each share of Class A Common 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 the shares of outstanding Common Stock and the denominator of which is number of shares of outstanding Class A Common Stock. Thus, the Class A Common 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 Common Stock (the "**Class A Director Period**"), the holders of record of the shares of Class A Common Stock (or other capital stock or securities issued upon conversion of or in exchange for the Class A Common 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 Common Stock will be entitled to elect the majority of the board of directors during the Class A Director Period. Finally, each share of Class A Common 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 Avenue at any time effects a subdivision of the outstanding Common Stock (or other capital stock or securities at the time issuable upon conversion of the Class A Common Stock) (by any stock split, stock dividend, recapitalization or otherwise), the applicable Conversion Ratio in effect immediately before that subdivision is 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 Common Stock) issuable on conversion of each share of Class A Common 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 Common Stock) outstanding. If Avenue at any time combines the outstanding shares of Common Stock, the applicable Conversion Ratio in effect immediately before the combination is 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 Common Stock) issuable on conversion of each share of Class A Common 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 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 Common Stock) is converted into or exchanged for securities, cash or other property (other than a transaction involving the subdivision or combination of the Common Stock), then, following any such reorganization, recapitalization, reclassification, consolidation or merger, each share of Class A Common Stock becomes 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 Avenue issuable upon conversion of one share of the applicable Class A Common Stock immediately prior to such reorganization, recapitalization, reclassification, consolidation or merger would have been entitled to receive pursuant to such transaction. In such case, appropriate adjustment (as determined in good faith by the Board of Directors of Avenue) will be made in the application of the provisions of Avenue's Amended and Restated Certificate of Incorporation relating the subdivision or combination of the Common Stock with respect to the rights and interests thereafter of the holders of the Class A Common Stock, to the end that the provisions set forth in of Avenue's Amended and Restated Certificate of Incorporation relating the subdivision or combination of the Common Stock (including the 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 Common Stock. Avenue is not authorized to issue preferred stock.

Other features of our common stock include:

- *Dividend Rights.* The holders of outstanding shares of our Common Stock, including Class A common 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. 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 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 Amended and Restated Certificate of Incorporation and Bylaws do not provide for cumulative voting rights. The voting rights of holders of our Class A Common Stock are described above.
- *No Preemptive or Similar Rights.* The holders of our common stock have no preemptive, conversion, or subscription rights, and there are no redemption or sinking fund provisions applicable to our common stock.
- *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 common stock, including Class A common stock, outstanding at that time after payment of other claims of creditors, if any.
- *Fully Paid and Non-Assessable.* All of the outstanding shares of our common stock, including Class A common stock, are, and the shares of our common stock to be issued pursuant to this offering will be, duly issued, fully paid and non-assessable.

Item 12. Indemnification of Directors and Officers.

We have adopted provisions in our 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 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 EisnerAmper LLP to audit our initial financial statements on June 1, 2015. There have been no changes since or any disagreements with EisnerAmper 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:

Report of Independent Registered Public Accounting Firm	F-2
Financial Statements:	
Balance Sheet	F-3
Statement of Operations	F-4
Statement of Shareholders' Deficit	F-5
Statement of Cash Flows	F-6
Notes to Financial Statements	F-7 – F-16

(b) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
3.1	Amended and Restated Certificate of Incorporation of Avenue Therapeutics, Inc. (filed with the Company's Form 10 on December 30, 2015).
3.2	Certificate of Amendment of Amended and Restated Certificate of Incorporation of Avenue Therapeutics, Inc. (filed with the Company's Form 10 on December 30, 2015).
3.3	Bylaws of Avenue Therapeutics, Inc. (filed with the Company's Form 10 on December 30, 2015).
4.1	Specimen certificate evidencing shares of Common Stock. (filed with the Company's Form 10 on December 30, 2015).
4.2	Form of warrant agreement. (filed with the Company's Form 10 on December 30, 2015).
10.1	Asset Transfer and License Agreement between Fortress Biotech, Inc. and Revogenex Ireland Limited dated February 17, 2015.*
10.2	Founders Agreement between Fortress Biotech, Inc., and Avenue Therapeutics, Inc. effective as of February 17, 2015. (filed with the Company's Form 10 on December 30, 2015).
10.3	Promissory Note from Avenue Therapeutics, Inc. to NSC Biotech Venture Fund I, LLC, effective as of February 27, 2015. (filed with the Company's Form 10 on December 30, 2015).
10.4	Promissory Note from Avenue Therapeutics, Inc. to Fortress Biotech, Inc. (filed with the Company's Form 10 on December 30, 2015).
10.5	Management Services Agreement between Fortress Biotech, Inc. and Avenue Therapeutics, Inc. effective as of February 17, 2015. (filed with the Company's Form 10 on December 30, 2015).
10.6	Employment Agreement with Dr. Lucy Lu, MD, dated June 10, 2015. (filed with the Company's Form 10 on December 30, 2015).
10.7	Avenue Therapeutics, Inc. 2015 Incentive Plan. (filed with the Company's Form 10 on December 30, 2015).
10.8	First Amendment to Consulting Agreement with Dr. Scott A. Reines, dated January 25, 2016 (includes copy of original Consulting Agreement dated July 22, 2015).

* Subject to a request for confidential treatment.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders
Avenue Therapeutics, Inc.

We have audited the accompanying balance sheet of Avenue Therapeutics, Inc. (the "Company") as of October 31, 2015 and the related statements of operations, changes in shareholders' deficit, and cash flows for the period from February 9, 2015 through October 31, 2015. The financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). 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 audits 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 includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide 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. as of October 31, 2015, and the results of its operations and its cash flows for the period from February 9, 2015 through October 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 discussed in Note 1 to the financial statements, the Company has a working capital deficit of approximately \$1.6 million and a shareholders' deficit of approximately \$4.3 million, and has incurred losses of approximately \$4.4 million since inception. Further, the Company expects to continue to incur significant costs in pursuit of its financing plans and product development. These conditions raise substantial doubt about the Company's 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/ EisnerAmper LLP

New York, NY
December 29, 2015

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

ASSETS	
Current Assets:	
Due from related party	\$ 1
Prepaid consulting	16
Total Assets	\$ 17
LIABILITIES AND STOCKHOLDERS' DEFICIT	
Current Liabilities:	
Accounts payable and accrued expenses	\$ 118
Accrued expenses - related party	378
Accrued interest	19
Accrued interest - related party	49
Notes payable - related party	973
Derivative warrant liability	114
Total current liabilities	1,651
NSC notes payable, long-term (net of debt discount of \$316)	2,684
Total Liabilities	4,335
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 October 31, 2015	1
Common shares; 2,150,000 shares issued and outstanding as of October 31, 2015	-
Additional paid-in capital	42
Accumulated deficit	(4,361)
Total Stockholders' Deficit	(4,318)
Total Liabilities and Stockholders' Deficit	\$ 17

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 October 31, 2015
(In thousands, except share and per share amounts)

Operating expenses:		
Research and development	\$	556
Research and development – licenses acquired		3,000
General and administration		598
Loss from operations		<u>(4,154)</u>
Interest expense		207
Net Loss	\$	<u>(4,361)</u>
Net loss per common share outstanding, basic and diluted	\$	(0.50)
Weighted average number of common shares outstanding, basic and diluted		8,640,755

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 October 31, 2015
(In thousands, except share amounts)

	Class A Common Shares		Common Shares		Additional paid-in capital	Accumulated deficit	Total Stockholders' deficit
	Shares	Amount	Shares	Amount			
Issuance of Class A common shares to Fortress on February 9, 2015	7,000,000	\$ 1	-	\$ -	-	-	\$ 1
Issuance of common shares to Fortress on February 9, 2015	-	-	1,000,000	-	-	-	-
Issuance of common shares for services	-	-	150,000	-	22	-	22
Share based compensation	-	-	1,000,000	-	20	-	20
Net loss	-	-	-	-	-	(4,361)	(4,361)
Balance at October 31, 2015	7,000,000	\$ 1	2,150,000	\$ -	\$ 42	\$ (4,361)	\$ (4,318)

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 October 31, 2015
(In thousands)

Cash flows from operating activities:	
Net loss	\$ (4,361)
Adjustments to reconcile net loss to net cash used in operating activities:	
Common stock issuance for services	22
Share based compensation	20
Debt discount amortization	54
Changes in operating assets and liabilities:	
Prepaid consulting	(16)
Accounts payable and accrued expenses	118
Accrued expenses - related party	378
Accrued interest	19
Accrued interest - related party	49
Net cash used in operating activities	<u>(3,717)</u>
Cash flows from financing activities:	
Proceeds from notes payable - related party	973
Proceeds from NSC notes payable	3,000
Debt issue costs associated with NSC Note	(256)
Net cash provided by financing activities	<u>3,717</u>
Net change in cash	-
Cash and cash equivalents, beginning of the period	-
Cash and cash equivalents, ending of the period	<u>\$ -</u>
Supplemental disclosure of cash flow information:	
Cash paid for interest	\$ 85
Supplemental disclosure of noncash investing and financing activities:	
Issuance of Class A common shares to Fortress - founder shares	\$ 1
Warrant liability associated with NSC Note	\$ 114

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

AVENUE THERAPEUTICS, INC.
Notes to 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 October 31, 2015. The shares were issued pursuant to the Founders Agreement effective February 17, 2015.

Intravenous formulation of Tramadol HCl (“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 4).

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 October 31, 2015 the allocated expenses related to Lucy Lu were approximately \$44,800.

Going Concern Consideration

As of October 31, 2015 the Company’s working capital deficit was approximately \$1.6 million and the Company’s stockholders’ deficit was \$4.3 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.

AVENUE THERAPEUTICS, INC.
Notes to Financial Statements

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 October 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.

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.

AVENUE THERAPEUTICS, INC.
Notes to Financial Statements

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.

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.

AVENUE THERAPEUTICS, INC.
Notes to Financial Statements

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 October 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 October 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 October 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 were 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 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 beginning after December 15, 2015, early adoption is permitted. The Company adopted ASU 2015-03 and such adoption resulted in debt issuance costs for all periods presented in notes payable, long-term, net.

AVENUE THERAPEUTICS, INC.
Notes to Financial Statements

In August 2014, the FASB issued *ASU 2014-15, Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern* ("ASU 2014-2015") ASU 2014-15 provides guidance on management's responsibility in evaluating whether there is substantial doubt about a company's ability to continue as a going concern and about related footnote disclosures. For each reporting period, management will be required to evaluate whether there are conditions or events that raise substantial doubt about a company's ability to continue as a going concern within one year from the date the financial statements are issued. The amendments in ASU 2014-15 are effective for annual reporting periods ending after December 15, 2016, and for annual and interim periods thereafter. Early adoption is permitted. The Company will adopt the methodologies prescribed by ASU 2014-15 by the date required, and does not anticipate that the adoption of ASU 2014-15 will have a material effect on its financial position or results of operations.

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 October 31, 2015 the allocated expenses related to Lucy Lu were approximately \$44,800 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 October 31, 2015, the Company paid the Consultant approximately \$42,000 and as of October 31, 2015, the Company prepaid approximately \$17,000 to the Consultant.

AVENUE THERAPEUTICS, INC.
Notes to Financial Statements

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 October 31, 2015, the Company recognized approximately \$333,000 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. The Fortress Note is a future advance promissory note under which no further advances can be made if the outstanding principal and interest exceed \$2.5 million. 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 October 31, 2015, the loan approximated \$1.0 million and the Company recognized approximately \$49,000 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 \$7,500 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 October 31, 2015, the Company recognized \$13,500 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 through National Securities Corporation (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.

AVENUE THERAPEUTICS, INC.
Notes to Financial Statements

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 a 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 October 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 \$256,000. For the period from February 9, 2015 (Inception) to October 31, 2015, the Company recorded costs of approximately \$54,000 related to the amortization of the debt discount and approximately \$104,000 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 October 31, 2015 (in thousands).

	<u>Note Payable</u>	<u>Discount</u>	<u>Note Payable, Net</u>
February 9, 2015 balance	\$ -	\$ -	\$ -
Proceeds from issuance of NSC Note	3,000	(256)	2,744
Amortization of debt discount	-	54	54
Derivative warrant liability	-	(114)	(114)
October 31, 2015 balance	<u>\$ 3,000</u>	<u>\$ (316)</u>	<u>\$ 2,684</u>

Fortress Note

As of October 31, 2015, the Fortress Note totaled approximately \$1.0 million. For the period from February 9, 2015 (Inception) to October 31, 2015, the Company recorded costs of approximately \$49,000 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 October 31, 2015, there was no litigation against the Company.

AVENUE THERAPEUTICS, INC.
Notes to Financial Statements

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. Scott 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 October 31, 2015.

	Number of Units	Weighted Average Grant Date Fair Value
Nonvested at February 9, 2015 (Inception)	-	\$ -
Granted	1,150,000	0.15
Vested	<u>(150,000)</u>	<u>0.15</u>
Nonvested at October 31, 2015	<u>1,000,000</u>	<u>\$ 0.15</u>

For the period from February 9, 2015 (Inception) through October 31, 2015, stock-based compensation expenses associated with the amortization of restricted stock award for employees and non-employees were approximately \$20,000 and \$22,000, respectively.

At October 31, 2015, the Company had unrecognized stock-based compensation expense related to restricted stock awards of \$60,000, which is expected to be recognized over the remaining weighted-average vesting period of 1.93 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 October 31, 2015 the Contingently Issuable Warrant balance of \$113,727 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:

	Contingently Issuable Warrants
Fair value at the beginning of period:	\$ -
Additions	113,727
Change in fair value:	-
Fair value at end of period:	<u>\$ 113,727</u>

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 October 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 October 31, 2015 for \$3.0 million and on February 17, 2015 for \$2.0 million 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:

	October 31, 2015	February 17, 2015
Risk-free interest rate	1.46%	1.97%
Expected dividend yield	-	-
Expected term in years	10.00	10.00
Expected volatility	83%	83%
Probability of issuance of the warrant	25%	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 October 31, 2015
Statutory federal income tax rate	(34.0)%
State taxes, net of federal tax benefit	(11.5)%
Change in valuation allowance	45.5%
Income tax provision (benefit)	<u>0.0%</u>

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

	As of October 31, 2015
Deferred tax assets:	
Net operating loss carryovers	\$ (645)
Stock based compensation	(19)
In process research and development	(1,320)
Total deferred tax assets	(1,984)
Valuation allowance	1,984
Deferred tax asset, net of allowance	<u>-</u>

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 \$2.0 million for the period ended October 31, 2015 was recorded.

As of October 31, 2015, the Company had federal and state net operating loss carryforwards of approximately \$1.4 million. The federal and state net operating loss carryforwards will expire, if not utilized, by 2035. 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.

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 and Chief Executive Officer

February 18, 2016

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.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Lindsay A. Rosenwald, M.D.</u> Lindsay A. Rosenwald, M.D.	Executive Chairman of the Board	February 18, 2016
<u>/s/ Lucy Lu, M.D.</u> Lucy Lu, M.D.	Interim President and Chief Executive Officer	February 18, 2016
<u>/s/ Scott A. Reines, M.D., Ph.D.</u> Scott A. Reines, M.D., Ph.D.	Interim Chief Medical Officer	February 18, 2016
<u>/s/ David J. Horin</u> David J. Horin	Interim Chief Financial Officer	February 18, 2016
<u>/s/ Michael S. Weiss</u> Michael S. Weiss	Director	February 18, 2016
<u>/s/ Neil Herskowitz</u> Neil Herskowitz	Director	February 18, 2016
<u>/s/ Jeffrey Paley, M.D.</u> Jeffrey Paley, M.D.	Director	February 18, 2016
<u>/s/ Akhtar Samad, M.D., PhD.</u> Akhtar Samad, M.D., PhD.	Director	February 18, 2016

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 HCl ("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 policies 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 HCl 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, reissues, 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 HCl.

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 business 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

13.1 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 deemed 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.]

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]

Exhibit B-2

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 ("Assignee"), 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]

Exhibit C-2

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(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(b)

Schedule 3.1(c)
Claims

1. None

Schedule 3.1(c)

Schedule 4.2(b)
Required Consents

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

Schedule 4.2(b)

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:

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 terms 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:

AVENUE:

AVENUE THERAPEUTICS, INC.

By: /s/ _____
Scott A. Reines, MD, PhD

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.

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: _____