RespireRx Pharmaceuticals Inc.
Form 10-K
March 29, 2016

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

[X] Annual Report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

For the fiscal year ended December 31, 2015

OR

[ ] Transition Report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Commission file number 1-16467

RespireRx Pharmaceuticals Inc.

(Exact name of registrant as specified in its charter)

(formerly known as Cortex Pharmaceuticals, Inc.)

Delaware	**33-0303583**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**

126 Valley Road, Suite C

Glen Rock, New Jersey 07452

(Address of principal executive offices, including zip code)

(201) 444-4947

(Registrant's telephone number, including area code)

Securities registered under Section 12(b) of the Act: None

Securities registered under Section 12(g) of the Act:

Common Stock, $0.001 par value

(Title of Class)

Indicate by check mark whether the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES [ ] NO [X]

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. YES [ ] NO [X]

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act during the preceding 12 months (or for such shorter period that the registrant was required to file such reports); and (2) has been subject to such filing requirements for the past 90 days. YES [X] NO [ ]

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). YES [X] NO [ ]

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy

or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. [ ]

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See definitions of “accelerated filer,” “large 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 [X]

Indicate by check mark whether the registrant is a shell company (as defined in Exchange Act Rule 12b-2). YES [ ] NO [X]

The aggregate market value of the voting stock held by non-affiliates as of June 30, 2015 was approximately $5,454,000 (based on the closing sale price of the common stock as reported by the OTC QB) on June 30, 2015. As of March 23, 2016, there were 498,622,133 shares of the registrant’s common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE: NONE

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In this Annual Report on Form 10-K, the terms “RespireRx,” the “Company,” “we,” “us” and “our” refer to RespireRx Pharmaceuticals Inc. (f/k/a Cortex Pharmaceuticals, Inc.), a Delaware corporation, and, unless the context indicates otherwise, its consolidated subsidiaries.

INTRODUCTORY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 (the “Exchange Act”) and we intend that such forward-looking statements be subject to the safe harbors created thereby. These forward-looking statements are contained principally in the sections entitled “Business,” “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations.” In some cases, forward-looking statements may be identified by words including “anticipates,” “believes,” “intends,” “estimates,” “expects,” “plans,” and similar expressions include, but are not limi to, statements regarding (i) future research plans, expenditures and results, (ii) potential collaborative arrangements, (iii) the potential utility of our proposed products, and (iv) the need for, and availability of, additional financing.

The forward-looking statements included herein are based on current expectations that involve a number of risks and uncertainties. These forward-looking statements are based on assumptions regarding our business and technology, which involve judgments with respect to, among other things, future scientific, economic and competitive conditions, and future business decisions, all of which are difficult or impossible to predict accurately and many of which are beyond our control. Although we believe that the assumptions underlying the forward-looking statements are reasonable, actual results may differ materially from those set forth in the forward-looking statements. In light of the significant uncertainties inherent in the forward-looking information included herein, the inclusion of such information should not be regarded as a representation by us or any other person that our objectives or plans will be achieved.

For more information about the risks and uncertainties we face, see “Item 1A. Risk Factors” of this Annual Report on Form 10-K. Forward-looking statements speak only as of the date they are made. We do not undertake and specifically decline any obligation to update any forward-looking statements or to publicly announce the results of any revisions to any statements to reflect new information or future events or developments.

PART I

Item 1. Business

Since its formation in 1987, the Company has engaged in the discovery, development and commercialization of innovative pharmaceuticals for the treatment of neurological and psychiatric disorders. In 2011, however, we conducted a re-evaluation of our strategic focus and determined that clinical development in the area of respiratory disorders, particularly respiratory depression and sleep apnea, provided the most cost-effective opportunities for potential rapid development and commercialization of our compounds. As a result of our scientific discoveries and the acquisition of strategic, exclusive license agreements, we believe we are now a leader in the discovery and development of innovative pharmaceuticals for the treatment of respiratory disorders.

Saying that there exists an unmet need for new drug treatments for breathing disorders is an understatement. According to the Centers for Disease Control and Prevention, the rate of respiratory disorders is reaching epidemic proportions, with estimates that 1 in 4 men and 1 in 10 women in this country have sleep apnea. Sleep apnea places a considerable burden on society and the health care system because of its association with adverse events ranging from loss of productivity to increased risk of cardiopulmonary illness and related death. No drugs currently are approved for the treatment of sleep apnea.

Even in patients without sleep apneas, the use of drugs such as propofol, used as an anesthetic during surgery, and opioid analgesics such as morphine and oxycodone, used during anesthesia and for the treatment of post-surgical and chronic pain, are well known for producing respiratory depression. In fact, while respiratory depression is the leading cause of death from the overdose of most classes of abused drugs, it also arises during normal, physician-supervised procedures such as surgical anesthesia, post-operative analgesia and as a result of normal outpatient management of pain.

Although naloxone (Narcan) and nalmefene (Revex) can reverse respiratory depression associated with opioids, they have several major shortcomings. First and foremost, these opioid antagonists do not reverse the respiratory depression produced by other classes of drugs often given/taken either alone or in combination with narcotics. Second, while these drugs reverse the serious side effects of the opioids, they also dramatically reduce their analgesic effectiveness. Third, the side effects of opioid antagonists are themselves serious and include seizures, agitation, convulsions, tachycardia, hypotension, nausea, and vomiting.

Furthermore, respiratory depression can arise as a result of a number of other illnesses that involve neural and muscular disorders. For example, certain spinal injuries can interfere with normal neural communication between the

brain and the lungs resulting in reduced respiratory capacity. Pompe Disease is an autosomal, recessive, metabolic disorder that damages muscle and nerve cells throughout the body. One of the first symptoms is a progressive decrease in the strength of muscles such as the diaphragm and other muscles required for breathing. Respiratory failure is the most common cause of death. In both of these orphan indications, symptomatic treatment for the respiratory depression is severely lacking.

Clearly, considerable need exists for pharmacotherapeutic agents to (i) treat sleep apnea, (ii) prevent and reverse the respiratory depression produced by different classes of drugs, and (iii) relieve the respiratory depression produced in a number of orphan indications, such as Pompe and spinal injury. The Company currently has two drug platforms, each with a clinical stage compound directed at these needs.

Sleep Apnea

Sleep apnea is a serious disorder in which breathing repeatedly stops long enough to disrupt sleep, and temporarily decreases the amount of oxygen and increases the amount of carbon dioxide in the blood. Apnea is defined by more than five periods per hour of ten seconds or longer without breathing. The repetitive cessation of breathing during sleep has substantial impact on the affected individuals. The disorder is associated with major co-morbidities including excessive daytime sleepiness and increased risk of cardiovascular disease (such as hypertension, stroke and heart failure), diabetes and weight gain. Sleep apnea is often made worse by central nervous system depressants such as opioids, benzodiazepines, barbiturates and alcohol. It is therefore important for these patients to seek therapy.

The most common type of sleep apnea is obstructive sleep apnea ("OSA"), which occurs by repetitive narrowing or collapse of the pharyngeal airway during sleep. There is currently no approved pharmacotherapy, and the most common treatment is to use continuous positive airway pressure ("CPAP") delivered via a nasal or full-face mask, as long as patients are able to tolerate the treatment. We believe that long term patient compliance with CPAP devices is extremely low. Given the large patient population and a lack of suitable treatment options, there is a very large opportunity for pharmacotherapy to treat this disorder.

Central sleep apnea ("CSA"), a less frequently diagnosed type of sleep apnea, is caused by alterations in the brain mechanisms responsible for maintaining normal respiratory drive. CSA is most frequently observed in heart failure patients and in patients taking chronic opioids. CSA is a predictor of mortality in heart failure patients. There are no therapeutic options for patients with CSA; CPAP is contra-indicated for the treatment of CSA and no drugs are currently approved for this indication.

In addition, many patients present with a pattern of sleep apnea that has both obstructive and central components.

Drug-induced Respiratory Depression

Drug-induced respiratory depression ("RD") is a life-threatening condition caused by a variety of depressant drugs, including analgesic, hypnotic, and anesthesia medications. We believe that RD is a leading cause of death from the overdose of some classes of abused drugs, yet it also arises during normal, physician-supervised procedures such as surgical anesthesia and post-operative pain management. For example, in the hospital setting, anesthetics, such as propofol, are well known for their propensity to produce RD, particularly when combined with opioids. The Center for Disease Control and Prevention has published that there are approximately 51.4 million inpatient surgical procedures performed annually. It is notable that according to the HealthGrades Inc. Patient Safety in American Hospitals Study, post-operative respiratory failure produces the highest mortality rate, the second highest attributable number of deaths and the second largest overall excess cost to the Medicare system, when compared to other patient safety indicators.

In the hospital setting, one of the most serious complications of patient-controlled analgesia is RD and, despite nurses' vigilance, adverse events associated with opioids continue to increase. Drug-induced RD is associated with a high mortality rate relative to other adverse drug events. If high-risk patients are receiving combination therapies, they are at even higher risk.

Outside the hospital, the primary risk factor for RD is the use of a single opioid in large doses or concomitant use of opioids and sedative agents. Whether as a result of normal outpatient management of pain or as a result of substance

abuse, RD has been reported to be the leading cause of death from drug overdose, with the drug overdose death rate tripling since 1991. According to the Centers for Disease Control and Prevention, approximately 15,000 people die every year as a result of overdoses involving prescription painkillers. Oxycodone and fentanyl have been reported to be the two most frequently reported drugs associated with death and serious nonfatal outcomes from 1998 to 2005, exceeding the number of deaths from heroin and cocaine combined. Opioid use has increased significantly along with a dramatic increase in unintentional poisoning deaths from opioids. Unintentional deaths from opioids are not only related to diversion for nonmedical use and misuse by patients, but by prescriber's error as well.

Drug Abuse

On January 19, 2016, the Company announced that that it has reached an agreement with the Medications Development Program of the National Institute of Drug Abuse ("NIDA") to conduct research on the Company's ampakine compounds CX717 and CX1739. The agreement was entered into as of October 19, 2015, and on January 14, 2016, the Company and NIDA approved the proposed protocols, allowing research activities to commence. NIDA will evaluate the compounds using pharmacologic, pharmacokinetic and toxicological protocols to determine the potential effectiveness of the ampakines for the treatment of drug abuse and addiction. Initial studies will focus on cocaine and methamphetamine addiction and abuse, and will be contracted to outside testing facilities and/or government laboratories, with all costs to be paid by NIDA. The Company will provide NIDA with supplies of CX717 and CX1739 and will work with the NIDA staff to refine the protocols and dosing parameters. The Company will retain all intellectual property, as well as proprietary and commercialization rights to these compounds.

Cannabinoids

In order to expand the Company's respiratory disorders program, on August 10, 2012, pursuant to an Agreement and Plan of Merger by and among Pier Pharmaceuticals Inc., a privately-held corporation, ("Pier") Pier Acquisition Corp., a Delaware corporation ("Merger Sub") and a wholly-owned subsidiary of the Company, and the Company, Merger Sub merged with and into Pier (the "Merger") and Pier became a wholly-owned subsidiary of the Company. Pier had been formed in June 2007 (under the name SteadySleep Rx Co.) as a clinical stage pharmaceutical company to develop a pharmacologic treatment for obstructive sleep apnea and had been engaged in research and clinical development activities since formation.

Through the Merger, the Company gained access to an Exclusive License Agreement, as amended (the "License Agreement"), that Pier had entered into with the University of Illinois on October 10, 2007. The License Agreement covered certain patents and patent applications in the United States and other countries claiming the use of certain compounds referred to as cannabinoids for the treatment of sleep related breathing disorders (including sleep apnea), of which dronabinol is a specific example of one type of cannabinoid. Dronabinol is a synthetic derivative of the naturally occurring substance in the cannabis plant, otherwise known as Δ9-THC (Δ9-tetrahydrocannabinol). Dronabinol is currently approved by the U. S. Food and Drug Administration ("FDA") and is sold generically for use in refractory chemotherapy-induced nausea and vomiting, as well as for anorexia in patients with AIDS. The License Agreement was terminated effective March 21, 2013 due to the Company's failure to make a required payment.

However, on June 27, 2014, the Company entered into a new license agreement with the Board of Trustees of the University of Illinois (the "2014 License Agreement"). In exchange for certain milestone and royalty payments, the 2014 License Agreement grants the Company (i) exclusive rights to several issued and pending patents in numerous jurisdictions and (ii) the non-exclusive right to certain technical information that is generated by the University of Illinois in connection with certain clinical trials as specified in the 2014 License Agreement, all of which relate to the use of cannabinoids for the treatment of sleep related breathing disorders. The Company is developing dronabinol for the treatment of OSA, the most common form of sleep apnea.

The Company previously conducted a 21 day, randomized, double-blind, placebo-controlled, dose escalation Phase 2 clinical study in 22 patients with OSA, in which dronabinol produced a statistically significant reduction in the Apnea-Hypopnea Index (AHI), the primary therapeutic end-point, and was observed to be safe and well tolerated. Dronabinol is currently under investigation, at the University of Illinois and other centers, in a potentially pivotal Phase 2 OSA clinical trial, fully funded by the National Institutes of Health.

Dronabinol is a Schedule III, controlled generic drug with a relatively low abuse potential that is approved by the FDA for the treatment of AIDS related anorexia and chemotherapy induced emesis. The use of dronabinol for the treatment of OSA is a novel indication for an already approved drug and, as such, the Company expects that only FDA approval of a supplemental new drug application will be required.

Ampakines

Since its founding, the Company has been engaged in the research and clinical development of a class of compounds referred to as ampakines. By acting as positive allosteric modulators of AMPA glutamate receptors, ampakines increase the excitatory effects of the neurotransmitter glutamate. Early preclinical and clinical research suggested that these ampakines might have therapeutic potential for the treatment of memory and cognitive disorders, depression, attention deficit disorder and schizophrenia. Given our current focus on respiratory disorders, we may seek to partner, out-license or sell our rights to the use of ampakine compounds for the treatment of neurological and psychiatric indications, as we focus on the development of our compounds for the treatment of breathing disorders.

The early ampakines discovered by the Company, Eli Lilly and Company, and others were ultimately abandoned due to the presence of undesirable side effects, particularly convulsive activity. Subsequently, Company scientists discovered a new, chemically distinct series of molecules termed “low impact” as opposed to the “high impact” designation given to the earlier compounds. While these low impact compounds share many pharmacological properties with the high impact compounds, they did not produce convulsive effects in animals. These low impact compounds do not bind to the same molecular site as the high impact compounds and, as a result, do not produce the undesirable electrophysiological and biochemical effects that lead to convulsive activity.

The Company owns patents and patent applications for certain families of chemical compounds that claim the chemical structures and their use in the treatment of various disorders. These patents cover, among other compounds, the Company's lead ampakines CX1739 and CX1942 and extend through at least 2028.

In order to broaden the use of the Company's ampakine technology into the area of respiratory disorders, on May 8, 2007, the Company entered into a license agreement, as subsequently amended, with the University of Alberta granting the Company exclusive rights to practice patents held by the University of Alberta claiming the use of ampakines for the treatment of various respiratory disorders. These patents, along with the Company's own patents claiming chemical structures, comprise the Company's principal intellectual property supporting the Company's research and clinical development program in the use of ampakines for the treatment of respiratory disorders.

The Company has obtained preclinical results indicating that several of its low impact ampakines, including CX717, CX1739 and CX1942, were able to antagonize the respiratory depression caused by opioids, barbiturates and anesthetics without offsetting the analgesic effects of the opioid or the sedative effects of the anesthetics. Dr. John Greer, faculty member of the Department of Physiology, Perinatal Research Centre, and Women & Children's Health Research Institute and Alberta Innovates Health Sciences Senior Scientist with the Neuroscience and Mental Health Institute at the University of Alberta, has shown that these ampakine effects are due to a direct action on neurons in pre-Botzinger's complex, a brain stem region responsible for regulating respiratory drive.

After several Phase 1 and 2 studies to demonstrate safety and tolerability, the first of these low impact compounds, CX717, was tested in two Phase 2A clinical studies to determine its ability to antagonize the respiratory depressant effects of fentanyl, a potent opioid analgesic. In both of these studies, one of which was published in a peer-reviewed journal, CX717 antagonized the respiratory depression produced by fentanyl without altering the analgesia produced by this drug.

Although the development of CX717 has been delayed due to regulatory issues with the FDA, and despite the impending loss of U.S. patents in 2017 and international patents in 2018 claiming composition-of-matter and certain non-respiratory uses, nevertheless, the Company believes that CX717 stills retains considerable value as a potential commercial product, for the following reasons. Patents claiming the use of CX717 for the treatment of various respiratory disorders are in effect in the United States and elsewhere at least through 2027 and additional method of treatment patents are planned and are being prepared. Long term preclinical safety studies have been completed and are sufficient to support chronic dosing of CX717 in humans. CX717 has demonstrated the ability to antagonize the respiratory effects of fentanyl, a potent opioid, in two clinical trials. Promising results have also been observed in clinical trials of attention deficit hyperactivity disorder and cognition. Finally, the Company has obtained what it believes to be conclusive data showing that the presumed neurotoxicity observed after administration of very high doses of CX717 (i.e., appearance of vacuoles in certain brain regions) is a post-mortem artifact due to the exposure of a CX717 metabolite to formaldehyde, the chemical agent used to fix the brain tissue. The Company is preparing this data for publication in a peer-reviewed journal and intends to submit a new Investigational New Drug ("IND") application to the FDA in the second half of 2016.

In several Phase 1 clinical studies, the Company's present lead ampakine, CX1739, has demonstrated good safety and tolerability after single doses up to 1200 mg for seven days, as well as two doses per day of 600 mg each for ten days. Pharmacokinetic results to date from the volunteers who have taken CX1739 show that drug absorption over the range of 50mg to 1200mg was linear and predictable, with an approximate half-life of 8 hours.

The Company has conducted a single dose, randomized, double-blind, placebo-controlled study with CX1739 in 20 subjects with moderate to severe sleep apnea. Analysis of a range of sleep apnea parameters assessed by overnight polysomnography revealed that, while a single dose of CX1739 improved a number of sleep apnea parameters across most of the patients who were given the drug, the primary effects were observed within a sub-group of patients diagnosed with either central or mixed sleep apnea. There were no serious adverse events and no clinically relevant changes in vital signs, cardiovascular or other safety assessments.

The Company filed an IND application with the FDA in September 2015 to conduct a double-blind, placebo-controlled, dose-ascending Phase 2A clinical trial in approximately 18 subjects to determine the ability of orally administered CX1739, the Company's proprietary lead ampakine, to prevent the respiratory depression produced by remifentanil, a potent opioid, without altering remifentanil's analgesic properties. The clinical protocol was designed to evaluate the safety and efficacy of three escalating doses of CX1739 versus placebo when administered prior to remifentanil, with respiration, analgesia and a number of other clinical measures being taken after administration of both drugs. The commencement of this clinical trial was subject to resolution of two deficiencies raised by the FDA in its clinical hold letter issued in November 2015, which were satisfactorily resolved in early 2016, as a result of which the FDA removed the clinical hold on the Company's IND for CX1739 on February 25, 2016, thus allowing for the initiation of the clinical trial. During March 2016, upon receiving unconditional approval from the Institutional Review Board ("IRB") of the Duke Clinical Research Unit, this Phase 2A clinical trial at Duke University School of Medicine was initiated. The Company expects to complete the clinical trial in approximately four months.

In addition to CX1739, the Company is developing CX1942, a soluble ampakine, as an injectable formulation in a hospital or surgical setting to be used in conjunction with opioids and anesthetics either during or after surgery. Animal studies conducted in collaboration with investigators at the University of Florida and funded by an Small Business Innovation Research ("SBIR") contract from the National Institute of Drug Abuse have indicated that CX1942 injected intravenously, intramuscularly or subcutaneously can reverse the respiratory depression produced by fentanyl. Such data will be used to develop an injectable formulation with the flexibility to be administered via different routes.

As part of its preclinical research program, the Company, through Dr. John Greer, Chairman of the RespireRx Scientific Advisory Board, has engaged in research collaborations with a number of academic institutions. As part of its collaborative program with the University of Florida, studies with RespireRx's ampakines have determined that these compounds improve breathing in animal models of Pompe Disease and spinal injury.

The Company's short term commercial goals are to obtain FDA approval for the use of orally administered CX1739 for the following indications: (i) peri- and post-operative administration in a hospital setting for the prevention of respiratory depression produced by opioids, (ii) central sleep apnea, and (iii) another indication, possibly respiratory distress associated with spinal cord injury or Pompe Disease. The Company believes that these goals can be achieved in a timely and cost-effective manner. Longer term goals include obtaining FDA approval for the oral administration of CX1739 given concomitantly with an opioid analgesic for the safe management of pain in a home setting. The Company believes that successful commercial implementation of these goals will require corporate partnership.

Competition

The pharmaceutical industry is characterized by intensive research efforts, rapidly advancing technologies, intense competition and a strong emphasis on proprietary therapeutics. Our competitors include many companies, research institutes and universities that are working in a number of pharmaceutical or biotechnology disciplines to develop therapeutic products similar to those we are currently investigating. Most of these competitors have substantially greater financial, technical, manufacturing, marketing, distribution and/or other resources than we do. In addition, many of our competitors have experience in performing human clinical trials of new or improved therapeutic products and obtaining approvals from the FDA and other regulatory agencies. We have no experience in conducting and managing later-stage clinical testing or in preparing applications necessary to obtain regulatory approvals. We expect that competition in this field will continue to intensify.

Regulation

The FDA and other similar agencies in foreign countries have substantial requirements for therapeutic products. Such requirements often involve lengthy and detailed laboratory, clinical and post-clinical testing procedures and are expensive to complete. It often takes companies many years to satisfy these requirements, depending on the complexity and novelty of the product. The review process is also extensive, which may delay the approval process further. Failure to comply with applicable FDA or other requirements may subject a company to a variety of administrative or judicial sanctions, such as the FDA’s refusal to approve pending applications, a clinical hold, warning letters, recall or seizure of products, partial or total suspension of production, withdrawal of the product from the market, injunctions, fines, civil penalties or criminal prosecution.

FDA approval is required before any new drug or dosage form, including the new use of a previously approved drug, can be marketed in the United States. Other similar agencies in foreign countries also impose substantial requirements.

The process of developing drug candidates normally begins with a discovery process of potential candidates that are then initially tested in *in vitro* and *in vivo* non-human animal (preclinical) studies which include, but are not limited to toxicity and other safety related studies, pharmacokinetics, pharmacodynamics and ADME (absorption, distribution, metabolism, excretion). Once sufficient preclinical data are obtained, a company must submit an IND and receive authorization from the FDA in order to begin clinical trials in the United States. Successful drug candidates then move into human studies that are characterized generally as Phase 1, Phase 2 and Phase 3. Phase 1 studies seeking safety and other data normally utilize healthy volunteers. Phase 2 studies utilize one or more prospective patient populations and are designed to establish safety and preliminary measures of efficacy. Sometimes studies may be referred to as Phase 2A and 2B depending on the size of the patient population. Phase 3 studies are large trials in the targeted patient population, performed in multiple centers, often for longer periods of time and are designed to establish statistically significant efficacy as well as safety in the larger population. Most often the FDA and similar regulatory agencies in other countries require two confirmatory studies. Upon completion of both the preclinical and clinical phases, an NDA (New Drug Application) is filed with the FDA or a similar filing is made to the regulatory authority in other countries. NDA filings are extensive and include the data from all prior studies. These filings are reviewed by the FDA and, only if approved, may the company or its partners commence marketing of the new drug in the United States.

There also are variations of these procedures. For example, companies seeking approval for new indications for an already approved drug may choose to pursue an abbreviated approval process by filing a Supplementary NDA (SNDA). Another example would be an Abbreviated NDA (ANDA) claiming bio-equivalence to an already approved drug. Other opportunities allow for accelerated review and approval based upon several factors, including potential breakthrough status of the drug or orphan designation (generally, an orphan indication in the United States is one with a patient population of less than 200,000).

As of yet, we have not obtained any approvals to market our products. Further, we cannot assure you that the FDA or other regulatory agency will grant us approval for any of our products on a timely basis, if at all. Even if regulatory clearances are obtained, a marketed product is subject to continual review, and later discovery of previously unknown problems may result in restrictions on marketing or withdrawal of the product from the market. See “Risk Factors - *Risks related to our business.*

Manufacturing

We have no experience or capability to either manufacture bulk quantities of the new compounds that we develop, or to produce finished dosage forms of the compounds, such as tablets or capsules. We rely, and presently intend to continue to rely, on the manufacturing and quality control expertise of contract manufacturing organizations or current

and prospective corporate partners. There is no assurance that we will be able to enter into manufacturing arrangements to produce bulk quantities of our compounds on favorable financial terms. There is, however, substantial availability of both bulk chemical manufacturing and dosage form manufacturing capability throughout the world that we believe we can readily access. See “Risk Factors - *Risks related to our business* - We are at an early stage of development and we may not be able to successfully develop and commercialize our products and technologies” for a discussion of certain risks related to the development and commercialization of our products.

Marketing

We have no experience in the marketing of pharmaceutical products and do not anticipate having the resources to distribute and broadly market any products that we may develop. We will therefore continue to seek commercial development arrangements with other pharmaceutical companies for our proposed products for those indications that require significant sales forces to effectively market. In entering into such arrangements, we may seek to retain the right to promote or co-promote products for certain of the orphan drug indications in North America. We believe that there is a significant expertise base for such marketing and sales functions within the pharmaceutical industry and expect that we could recruit such expertise if we choose to directly market a drug. See “Risk Factors-*Risks related to our business*-We are at an early stage of development and we may not be able to successfully develop and commercialize our products and technologies” for a discussion of certain risks related to the marketing of our products.

Employees

As of December 31, 2015 and as of the date of filing of this Annual Report on Form 10-K, the Company employed five people (all officers), two of whom were full time. The Company also engages certain contractors who provide substantial services to the Company.

Technology Rights

University of California, Irvine License Agreements

The Company entered into a series of license agreements in 1993 and 1998 with the University of California, Irvine ("UCI") that granted the Company proprietary rights to certain chemical compounds that acted as ampakines and their therapeutic uses. These agreements granted the Company, among other provisions, exclusive rights: (i) to practice certain patents and patent applications, as defined in the license agreement, that were then held by UCI; (ii) to identify, develop, make, have made, import, export, lease, sell, have sold or offer for sale any related licensed products; and (iii) to grant sub-licenses of the rights granted in the license agreements, subject to the provisions of the license agreements. The Company was required, among other terms and conditions, to pay UCI a license fee, royalties, patent costs and certain additional payments.

Under such license agreements, the Company was required to make minimum annual royalty payments of approximately $70,000. The Company was also required to spend a minimum of $250,000 per year to advance the ampakine compounds until the Company began to market an ampakine compound. At December 31, 2012, the Company was not in compliance with its minimum annual payment obligations and believed that this default constituted a termination of the license agreements. On April 15, 2013, the Company received a letter from UCI indicating that the license agreements between UCI and the Company had been terminated due to the Company's failure to make certain payments required to maintain the agreements. Since the patents covered in these license agreements had begun to expire and the therapeutic uses described in these patents were no longer germane to the Company's new focus on respiratory disorders, the loss of these license agreements is not expected to have a material impact on the Company's current drug development programs. In the opinion of management, the Company has made adequate provision for any liability relating to this matter in its financial statements at December 31, 2015 and 2014.

University of Alberta License Agreement and Research Agreement

On May 8, 2007, the Company entered into a license agreement, as subsequently amended, with the University of Alberta granting the Company exclusive rights to practice patents held by the University of Alberta claiming the use of ampakines for the treatment of various respiratory disorders. The Company agreed to pay the University of Alberta a licensing fee and a patent issuance fee, which were paid, and prospective payments consisting of a royalty on net sales, sublicense fee payments, maintenance payments and milestone payments. The prospective maintenance payments commence on the enrollment of the first patient into the first Phase 2B clinical trial and increase upon the successful completion of the Phase 2B clinical trial. As the Company does not at this time anticipate scheduling a Phase 2B clinical trial in the near term, no maintenance payments to the University of Alberta are currently due and payable, nor are expected to be due in the near future in connection with the license agreement.

On January 12, 2016, the Company entered into a Research Contract with the University of Alberta in order to test the efficacy of ampakines at a variety of dosage and formulation levels in the potential treatment of Pompe Disease, apnea of prematurity and spinal cord injury, as well as to conduct certain electrophysiological studies to explore the ampakine mechanism of action for central respiratory depression. The Company agreed to pay the University of Alberta total consideration of approximately CAD$146,000 (currently approximately US$110,000), consisting of approximately CAD$85,000 (currently approximately US$64,000) of personnel funding in cash in four installments during 2016, to provide approximately CAD$21,000 (currently approximately US$16,000) in equipment, to pay patent costs of CAD$20,000 (currently approximately US$15,000), and to underwrite additional budgeted costs of CAD$20,000 (currently approximately US$15,000). All but US$64,000 of the total consideration has already been incurred and paid for directly or in-kind. The conversion to US dollars above utilizes an exchange rate of US$0.7548 for every CAD$1.00.

The University of Alberta will receive matching funds through a grant from the Canadian Institutes of Health Research in support of the research. The Company will retain the rights to research results and any patentable intellectual property generated by the research. Dr. John Greer, Ph.D., Chairman of the Company's Scientific Advisory Board and faculty member of the Department of Physiology, Perinatal Research Centre, and Women & Children's Health Research Institute and Alberta Innovates Health Sciences Senior Scientist with the Neuroscience and Mental Health Institute at the University of Alberta, will collaborate on this research. The studies are expected to be completed in 2016. Any patentable intellectual property developed in the Research Agreement will be covered by the existing license agreement described above.

University of Illinois License Agreement

Through the merger with Pier, the Company gained access to the License Agreement that Pier had entered into with the University of Illinois on October 10, 2007. The License Agreement covered certain patents and patent applications in the United States and other countries claiming the use of certain compounds referred to as cannabinoids for the treatment of sleep related breathing disorders (including sleep apnea), of which dronabinol is a specific example of one type of cannabinoid. The License Agreement was terminated effective March 21, 2013 due to the Company's failure to make a required payment.

On June 27, 2014, the Company entered into the 2014 License Agreement with the Board of Trustees of the University of Illinois that was similar, but not identical, to the License Agreement between the parties that had been terminated on March 21, 2013. In exchange for certain milestone and royalty payments, the 2014 License Agreement grants the Company (i) exclusive rights to several issued and pending patents in numerous jurisdictions and (ii) the non-exclusive right to certain technical information that is generated by the University of Illinois in connection with certain clinical trials as specified in the 2014 License Agreement, all of which relate to the use of cannabinoids for the treatment of sleep related breathing disorders. The Company is developing dronabinol for the treatment of OSA, the most common form of sleep apnea.

Research and Development Expenses

The Company invested $1,706,603 and $591,768 in research and development in 2015 and 2014 respectively. Of those amounts, $555,425 and $28,529 were incurred with related parties in 2015 and 2014 respectively. See our consolidated financial statements for the years ended December 31, 2015 and 2014 included in this Annual Report on Form 10-K.

Item 1A. Risk Factors

In addition to the other matters set forth in this Annual Report on Form 10-K, our continuing operations and the price of our common stock are subject to the following risks:

Risks related to our business

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

In its audit opinion issued in connection with our balance sheets as of December 31, 2015 and 2014 and our statements of operations, stockholders' equity (deficiency), and cash flows for the years ended December 31, 2015 and 2014, our independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern given our limited working capital, recurring net losses and negative cash flows from operations. The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. The consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or amounts of liabilities that might be necessary should we be unable to continue in existence. While we have relied principally in the past on external financing to provide liquidity and capital resources for our operations, we can provide no assurance that cash generated from our operations together with cash received in the future from external financing, if any, will be sufficient to enable us to continue as a going concern.

We have a history of net losses; we expect to continue to incur net losses and we may never achieve or maintain profitability.

Since our formation on February 10, 1987 through the end of our most recent fiscal year ended December 31, 2015, we have generated only modest operating revenues. For the fiscal year ended December 31, 2015, our net loss was $5,961,892 and as of December 31, 2015, we had an accumulated deficit of $148,279,854. For the year ended December 31, 2014, our net loss was $2,707,535 and as of December 31, 2014, we had an accumulated deficit of $142,311,095. We have not generated any revenue from product sales to date, and it is possible that we will never generate revenues from product sales in the future. Even if we do achieve significant revenues from product sales, we expect to incur significant net losses over the next several years. As with other companies in the biotechnology industry, it is possible that we will never achieve profitable operations.

We will need additional capital in the future and, if such capital is not available on terms acceptable to us or available to us at all, we may need to scale back our research and development efforts and may be unable to continue our business operations.

We will require substantial additional funds to advance our research and development programs and to continue our operations, particularly if we decide to independently conduct later-stage clinical testing and apply for regulatory approval of any of our proposed products, and if we decide to independently undertake the marketing and promotion of our products. Additionally, we may require additional funds in the event that we decide to pursue strategic acquisitions of or licenses for other products or businesses. Based on our operating plan as of December 31, 2015, we estimated that our existing cash resources will not be sufficient to meet our requirements for 2016. We believe that we will require additional capital to fund on-going operations. Additional funds may come from the sale of common equity, preferred equity, convertible preferred equity or equity-linked securities, debt, including debt convertible into equity, or may result from agreements with larger pharmaceutical companies that include the license or rights to the technologies and products that we are currently developing, although there is no assurance that we will secure any such transaction in a timely manner, or at all.

Our cash requirements in the future may differ significantly from our current estimates, depending on a number of factors, including:

- the results of our clinical trials;
- the time and costs involved in obtaining regulatory approvals;
- the costs of setting up and operating our own marketing and sales organization;

the ability to obtain funding under contractual and licensing agreements;

the costs involved in obtaining and enforcing patents or any litigation by third parties regarding intellectual property;

the costs involved in meeting our contractual obligations including employment agreements; and

our success in entering into collaborative relationships with other parties.

To finance our future activities, we may seek funds through additional rounds of financing, including private or public equity or debt offerings and collaborative arrangements with corporate partners. We may also seek to exchange or restructure some of our outstanding securities to provide liquidity, strengthen our balance sheet and provide flexibility. We cannot say with any certainty that these measures will be successful, or that we will be able to obtain the additional needed funds on reasonable terms, or at all. The sale of additional equity or convertible debt securities could result in additional and possibly substantial dilution to our stockholders. If we issued preferred equity or debt securities, these securities could have rights superior to holders of our common stock, and such instruments entered into in connection with the issuance of securities could contain covenants that will restrict our operations. We might have to obtain funds through arrangements with collaborative partners or others that may require us to relinquish rights to our technologies, product candidates or products that we otherwise would not relinquish. In 2012, several members of management departed. In March 2013 the then-current remaining members of management were removed by our newly elected board of directors and new officers were appointed. If adequate funds are not available in the future, as required, we could lose our key employees and might have to further delay, scale back or eliminate one or more of our research and development programs, which would impair our future prospects. In addition, we may be unable to meet our research spending obligations under our existing licensing agreements and may be unable to continue our business operations.

Our product opportunities rely on licenses from research institutions and if we lose access to these technologies or applications, our business could be substantially impaired.

Under our agreements with The Regents of the University of California, we had exclusive rights to certain ampakine compounds for all applications for which the University had patent rights, other than endocrine modulation. The license securing these rights has since been terminated.

Under a patent license agreement with The Governors of the University of Alberta, we have exclusive rights to the use of certain ampakine compounds to prevent and treat respiratory depression induced by opioid analgesics, barbiturates and anesthetic and sedative agents.

On May 8, 2007, the Company entered into a license agreement, as subsequently amended, with the University of Alberta granting the Company exclusive rights to practice patents held by the University of Alberta claiming the use of ampakines for the treatment of various respiratory disorders. The Company agreed to pay the University of Alberta a licensing fee and a patent issuance fee, which were paid, and prospective payments consisting of a royalty on net sales, sublicense fee payments, maintenance payments and milestone payments. The prospective maintenance payments commence on the enrollment of the first patient into the first Phase 2B clinical trial and increase upon the successful completion of the Phase 2B clinical trial. As the Company does not at this time anticipate scheduling a Phase 2B clinical trial in the near term, no maintenance payments are currently due and payable nor are expected to be due in the near future, to the University of Alberta in connection with the license agreement.

Through the merger with Pier, the Company gained access to an Exclusive License Agreement (as amended, the Pier License Agreement), that Pier had entered into with the University of Illinois on October 10, 2007. The Pier License Agreement covered certain patents and patent applications in the United States and other countries claiming the use of certain compounds referred to as cannabinoids for the treatment of sleep related breathing disorders (including sleep apnea), of which dronabinol is a specific example of one type of cannabinoid. Dronabinol is a synthetic derivative of the naturally occurring substance in the cannabis plant, otherwise known as Δ9-THC (Δ9-tetrahydrocannabinol). Dronabinol is currently approved by the FDA and is sold generically for use in refractory chemotherapy-induced nausea and vomiting, as well as for anorexia in patients with AIDS. Pier's business plan was to determine whether dronabinol would significantly improve subjective and objective clinical measures in patients with obstructive sleep apnea. In addition, Pier intended to evaluate the feasibility and comparative efficacy of a proprietary formulation of dronabinol. The Pier License Agreement was terminated effective March 21, 2013 due to the Company's failure to make a required payment and on June 27, 2014, the Company entered into the 2014 License Agreement with the University of Illinois that was similar, but not identical, to the Pier License Agreement that had been terminated. If we are unable to comply with the terms of the 2014 License Agreement, such as required payments thereunder, the 2014 License Agreement might be terminated.

We are at an early stage of development and we may not be able to successfully develop and commercialize our products and technologies.

The development of ampakine products and cannabinoid products is subject to the risks of failure commonly experienced in the development of products based upon innovative technologies and the expense and difficulty of obtaining approvals from regulatory agencies. Drug discovery and development is time consuming, expensive and unpredictable. On average, only one out of many thousands of chemical compounds discovered by researchers proves to be both medically effective and safe enough to become an approved medicine. All of our proposed products are in the preclinical or early clinical stage of development and will require significant additional funding for research, development and clinical testing, which may not be available on favorable terms or at all, before we are able to submit them to any of the regulatory agencies for clearances for commercial use.

The process from discovery to development to regulatory approval can take several years and drug candidates can fail at any stage of the process. Late stage clinical trials often fail to replicate results achieved in earlier studies. Historically, in our industry more than half of all compounds in development failed during Phase 2 trials and 30% failed during Phase 3 trials. We cannot assure you that we will be able to complete successfully any of our research and development activities, including the recently initiated trials with Duke University described above under "Business - *Ampakines*." Even if we do complete them, we may not be able to market successfully any of the products or be able to obtain the necessary regulatory approvals or assure that healthcare providers and payors will accept our products. We also face the risk that any or all of our products will not work as intended or that they will be unsafe, or that, even if they do work and are safe, that our products will be uneconomical to manufacture and market on a large scale. Due to the extended testing and regulatory review process required before we can obtain marketing clearance, we do not expect to be able to commercialize any therapeutic drug for several years, either directly or through our corporate partners or licensees.

We may not be able to enter into the strategic alliances necessary to fully develop and commercialize our products and technologies, and we will be dependent on our corporate partners if we do.

We are seeking pharmaceutical company partners to develop other major indications for the ampakine compounds and cannabinoids. These agreements would potentially provide us with additional funds in exchange for exclusive or non-exclusive license or other rights to the technologies and products that we are currently developing. Competition between biopharmaceutical companies for these types of arrangements is intense. We cannot give any assurance that our discussions with candidate companies will result in an agreement or agreements in a timely manner, or at all. Additionally, we cannot assure you that any resulting agreement will generate sufficient revenues to offset our operating expenses and longer-term funding requirements.

If our third-party manufacturers' facilities do not follow current good manufacturing practices, our product development and commercialization efforts may be harmed.

There are a limited number of manufacturers that operate under the FDA's and European Union's good manufacturing practices regulations and are capable of manufacturing products like those we are developing. Third-party manufacturers may encounter difficulties in achieving quality control and quality assurance and may experience shortages of qualified personnel. A failure of third-party manufacturers to follow current good manufacturing practices or other regulatory requirements and to document their adherence to such practices may lead to significant delays in the availability of products for commercial use or clinical study, the termination of, or hold on, a clinical study, or may delay or prevent filing or approval of marketing applications for our products. In addition, we could be subject to sanctions, including fines, injunctions and civil penalties. Changing manufacturers may require additional clinical trials and the revalidation of the manufacturing process and procedures in accordance with FDA mandated current good manufacturing practices and would require FDA approval. This revalidation may be costly and time consuming. If we are unable to arrange for third-party manufacturing of our products, or to do so on commercially reasonable terms, we may not be able to complete development or marketing of our products.

Our ability to use our net operating loss carry forwards will be subject to limitations upon a change in ownership, which could reduce our ability to use those loss carry forwards following any change in Company ownership.

Generally, a change of more than 50% in the ownership of a Company's stock, by value, over a three-year period constitutes an ownership change for U.S. federal income tax purposes. An ownership change may limit our ability to use our net operating loss carry forwards attributable to the period prior to such change. We have sold or otherwise issued shares of our common stock in various transactions sufficient to constitute an ownership change, including the issuance of the Series G 1.5% Convertible Preferred Stock (as defined below), and the issuance of convertible notes and warrants, as well as the issuance of additional shares of our Common Stock and warrants. As a result, if we earn net taxable income in the future, our ability to use our pre-change net operating loss carry forwards, which amounted to approximately $87,287,000 as of December 31, 2015, to offset U.S. federal taxable income will be subject to limitations, which would restrict our ability to reduce future tax liability. Future shifts in our ownership, including transactions in which we may engage, may cause additional ownership changes, which could have the effect of imposing additional limitations on our ability to use our pre-change net operating loss carry forwards.

Risks related to our industry

If we fail to secure adequate intellectual property protection, it could significantly harm our financial results and ability to compete.

Our success will depend, in part, on our ability to obtain and maintain patent protection for our products and processes in the United States and elsewhere. We have filed and intend to continue to file patent applications as we need them. However, additional patents that may issue from any of these applications may not be sufficiently broad to protect our technology. Also, any patents issued to us or licensed by us may be designed around or challenged by others, and if such design or challenge is effective, it may diminish our rights and negatively affect our financial results.

If we are unable to obtain and maintain sufficient protection of our proprietary rights in our products or processes prior to or after obtaining regulatory clearances, our competitors may be able to obtain regulatory clearance and market similar or competing products by demonstrating at a minimum the equivalency of their products to our products. If they are successful at demonstrating at least the equivalency between the products, our competitors would not have to conduct the same lengthy clinical tests that we have or will have conducted.

We also rely on trade secrets and confidential information that we protect by entering into confidentiality agreements with other parties. Those confidentiality agreements could be breached, and our remedies may be insufficient to protect the confidential information. Further, our competitors may independently learn our trade secrets or develop similar or superior technologies. To the extent that our consultants, key employees or others apply technological information independently developed by them or by others to our projects, disputes may arise regarding the proprietary rights to such information or developments. We cannot assure you that such disputes will be resolved in our favor.

We may be subject to potential product liability claims. One or more successful claims brought against us could materially affect our business and financial condition.

The clinical testing, manufacturing and marketing of our products may expose us to product liability claims. We have never been subject to a product liability claim, and we require each patient in our clinical trials to sign an informed consent agreement that describes the risks related to the trials, but we cannot assure you that the coverage limits of our insurance policies will be adequate or that one or more successful claims brought against us would not have a material adverse effect on our business, financial condition and result of operations. Further, if one of our ampakine or cannabinoid compounds is approved by the FDA for marketing, we cannot assure you that adequate product liability insurance will be available, or if available, that it will be available at a reasonable cost. Any adverse outcome resulting

from a product liability claim could have a material adverse effect on our business, financial condition and results of operations.

We face intense competition that could result in products that are superior to the products that we are developing.

Our business is characterized by intensive research efforts. Our competitors include many companies, research institutes and universities that are working in a number of pharmaceutical or biotechnology disciplines to develop therapeutic products similar to those we are currently investigating. Most of these competitors have substantially greater financial, technical, manufacturing, marketing, distribution and/or other resources than we do. In addition, many of our competitors have experience in performing human clinical trials of new or improved therapeutic products and obtaining approvals from the FDA and other regulatory agencies. We have no experience in conducting and managing later-stage clinical testing or in preparing applications necessary to obtain regulatory approvals. Accordingly, it is possible that our competitors may succeed in developing products that are safer or more effective than those that we are developing and/or may obtain FDA approvals for their products faster than we can. We expect that competition in this field will continue to intensify.

We may be unable to recruit and retain our senior management and other key technical personnel on whom we are dependent.

We are highly dependent upon senior management and key technical personnel and currently do not carry any insurance policies on such persons. Since our change in management in March 2013, we are highly dependent on Arnold S. Lippa, Ph.D., our Chief Scientific Officer and Executive Chairman (and formerly our President and Chief Executive Officer), Jeff E. Margolis, our Vice President, Treasurer and Secretary, and since his appointment in April 2013, our Vice President and Chief Financial Officer, Robert N. Weingarten. In addition, in 2014 we appointed John Greer, Ph.D. as the Chairman of our Science Advisory Board and hired Richard Purcell as our Senior Vice President of Research and development, and in 2015, we hired James S. J. Manuso, Ph.D. to succeed Dr. Lippa as the Company's President and Chief Executive Officer and to be Vice Chairman. Competition for qualified employees among pharmaceutical and biotechnology companies is intense. The loss of any of our senior management or other key employees, or our inability to attract, retain and motivate the additional or replacement highly-skilled employees and consultants that our business requires, could substantially hurt our business and prospects.

The regulatory approval process is expensive, time consuming, uncertain and may prevent us from obtaining required approvals for the commercialization of some of our products.

The FDA and other similar agencies in foreign countries have substantial requirements for therapeutic products. Such requirements often involve lengthy and detailed laboratory, clinical and post-clinical testing procedures and are expensive to complete. It often takes companies many years to satisfy these requirements, depending on the complexity and novelty of the product. The review process is also extensive, which may delay the approval process even more.

As of yet, we have not obtained any approvals to market our products. Further, we cannot assure you that the FDA or other regulatory agency will grant us approval for any of our products on a timely basis, if at all. Even if regulatory clearances are obtained, a marketed product is subject to continual review, and later discovery of previously unknown problems may result in restrictions on marketing or withdrawal of the product from the market.

Risks related to capital structure

Our stock price may be volatile and our common stock could decline in value.

The market price of securities of life sciences companies in general has been very unpredictable. The range of sales prices of our common stock for the fiscal years ended December 31, 2015 and 2014, as quoted on the OTC Markets, OTC QB since mid-May 2015 and on the OTC Markets, OTC BB prior to that, was $0.0100 to $0.0610 and $0.0240 to $0.0900, respectively. The following factors, in addition to factors that affect that market generally, could significantly affect our business, and the market price of our common stock could decline:

- competitors announcing technological innovations or new commercial products;
- competitors' publicity regarding actual or potential products under development;
- regulatory developments in the United States and foreign countries;
- developments concerning proprietary rights, including patent litigation;
- public concern over the safety of therapeutic products; and
- changes in healthcare reimbursement policies and healthcare regulations.

Our common stock is thinly traded and you may be unable to sell some or all of your shares at the price you would like, or at all, and sales of large blocks of shares may depress the price of our common stock.

Our common stock has historically been sporadically or "thinly-traded," meaning that the number of persons interested in purchasing shares of our common stock at prevailing prices at any given time may be relatively small or nonexistent. As a consequence, there may be periods of several days or more when trading activity in shares of our common stock is minimal or non-existent, as compared to a seasoned issuer that has a large and steady volume of trading activity that will generally support continuous sales without an adverse effect on share price. This could lead to wide fluctuations in our share price. You may be unable to sell your common stock at or above your purchase price, which may result in substantial losses to you. Also, as a consequence of this lack of liquidity, the trading of relatively small quantities of shares by our stockholders may disproportionately influence the price of shares of our common stock in either direction. The price of shares of our common stock could, for example, decline precipitously in the event a large number of share of our common shares are sold on the market without commensurate demand, as compared to a seasoned issuer which could better absorb those sales without adverse impact on its share price.

There is a large number of shares of the Company's common stock that may be issued or sold, and if such shares are issued or sold, the market price of our common stock may decline.

As of December 31, 2015, we had 489,846,883 shares of our common stock outstanding.

If all warrants and options outstanding as of December 31, 2015 are exercised prior to their expiration, up to 408,567,190 additional shares of our common stock could become freely tradable. The issuance of such shares would dilute the interests of the current stockholders and sales of substantial amounts of common stock in the public market could adversely affect the prevailing market price of our common stock and could also make it more difficult for us to raise funds through future offerings of common stock.

On March 18 and April 17, 2014, we issued shares of our Series G 1.5% Convertible Preferred Stock, which are convertible into shares of our common stock (see Note 6 to our consolidated financial statements for the years ended December 31, 2015 and 2014). On November 5, December 9 and December 31, 2014, and again on February 2, 2015 we issued convertible notes and warrants, both of which are convertible into shares of our common stock (see Note 3 to our consolidated financial statements for the years ended December 31, 2015 and 2014) and may in the future issue additional equity or equity-based securities. If some or all of our Series G 1.5% Convertible Preferred Stock, convertible notes or warrants converts to common stock, or if we issue additional equity or equity-based securities, the number of shares of our common stock outstanding could increase substantially (as of December 31, 2015, by approximately 78,400,000 shares if all of our Series G 1.5% Convertible Preferred Stock converted and by approximately 18,300,000 if all of our convertible notes converted), which could adversely affect the prevailing market price of our common stock and could also make it more difficult for us to raise funds through future offerings of common stock. By their terms, the remaining shares of our Series G 1.5% Convertible Preferred Stock will mandatorily convert on April 17, 2016.

Our charter document may prevent or delay an attempt by our stockholders to replace or remove management.

Certain provisions of our restated certificate of incorporation, as amended, could make it more difficult for a third party to acquire control of our business, even if such change in control would be beneficial to our stockholders. Our restated certificate of incorporation, as amended, allowed the Board of Directors of the Company, referred to as the Board or Board of Directors, to issue as of December 31, 2015 up to 3,506,470 shares of preferred stock, with characteristics to be determined by the board, without stockholder approval. The ability of our Board of Directors to issue additional preferred stock may have the effect of delaying or preventing an attempt by our stockholders to replace or remove existing directors and management.

If our common stock is determined to be a "penny stock," a broker-dealer may find it more difficult to trade our common stock and an investor may find it more difficult to acquire or dispose of our common stock in the secondary market.

In addition, our common stock may be subject to the so-called "penny stock" rules. The United States Securities and Exchange Commission ("SEC") has adopted regulations that define a "penny stock" to be any equity security that has a market price per share of less than $5.00, subject to certain exceptions, such as any securities listed on a national securities exchange. For any transaction involving a "penny stock," unless exempt, the rules impose additional sales practice requirements on broker-dealers, subject to certain exceptions. If our common stock is determined to be a "penny stock," a broker-dealer may find it more difficult to trade our common stock and an investor may find it more difficult to acquire or dispose of our common stock on the secondary market.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

As of December 31, 2015, the Company did not own any real property or maintain any leases with respect to real property. The Company does contract for services provided at the facilities owned by third parties and has employees who work in these facilities.

Item 3. Legal Proceedings

We were not a party to any material legal proceedings, nor has any material proceeding been terminated during the fiscal year ended December 31, 2015.

We are periodically subject to various pending and threatened legal actions and claims. See Note 9 to our consolidated financial statements for the years ended December 31, 2015 and 2014-Commitments and Contingencies-*Pending or Threatened Legal Actions and Claims* for details regarding these matters.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

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

Our common stock is quoted on the OTC QB since mid-May 2015 and prior to that on the OTC BB, now under the symbol "RSPI" (and prior to the Company's name change in December 2015, under the symbol "CORX"). The following table presents quarterly information on the high and low sales prices of the common stock furnished by the OTC QB and OTC BB for the fiscal years ended December 31, 2015 and 2014. The quotations on the OTC QB and OTC BB reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not necessarily represent actual transactions.

	High	Low
Fiscal Year ended December 31, 2015		
Fourth Quarter	$0.0299	$0.0100
Third Quarter	0.0400	0.0150
Second Quarter	0.0610	0.0150
First Quarter	0.0610	0.0410
Fiscal Year ended December 31, 2014		
Fourth Quarter	$0.0900	$0.0300
Third Quarter	0.0790	0.0295
Second Quarter	0.0430	0.0240
First Quarter	0.0500	0.0260

As of December 31, 2015, there were 429 stockholders of record of our common stock, and approximately 6,500 beneficial owners. The high and low sales prices for our common stock on December 31, 2015, as quoted on the OTC QB and OTC BB market, were $0.0200 and $0.0183, respectively.

We have never paid cash dividends on our common stock and do not anticipate paying such dividends in the foreseeable future. The payment of dividends, if any, will be determined by the Board in light of conditions then existing, including our financial condition and requirements, future prospects, restrictions in financing agreements, business conditions and other factors deemed relevant by the Board.

During the fiscal year ended December 31, 2015, we did not repurchase any of our securities.

Item 6. Selected Financial Data

Not applicable to smaller reporting companies.

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

The following discussion and analysis should be read in conjunction with the audited financial statements and notes related thereto appearing elsewhere in this document.

Overview

Since its formation in 1987, RespireRx Pharmaceuticals Inc. ("RespireRx") has been engaged in the research and clinical development of a class of compounds referred to as ampakines, which act to enhance the actions of the excitatory neurotransmitter glutamate at AMPA glutamate receptors. Several ampakines, in both oral and injectable form, are being developed by the Company for the treatment of a variety of breathing disorders. In clinical studies, select ampakines have shown preliminary efficacy in central sleep apnea and in the control of respiratory depression produced by opioids, without altering their analgesic effects. In animal models of orphan disorders, such as Pompe Disease, spinal cord damage and perinatal respiratory distress, it has been demonstrated that certain ampakines improve breathing function. The Company's compounds belong to a new class of ampakines that do not display the undesirable side effects previously reported in animal models of earlier generations

In 2011, prior management conducted a re-evaluation of RespireRx's strategic focus and determined that clinical development in the area of respiratory disorders, particularly sleep apnea and drug-induced respiratory depression, provided the most cost-effective opportunities for potential rapid development and commercialization of RespireRx's compounds. Accordingly, RespireRx narrowed its clinical focus at that time and sidelined other avenues of scientific inquiry. This re-evaluation provided the impetus for RespireRx's acquisition of Pier Pharmaceuticals, Inc. ("Pier") in August 2012. RespireRx and its wholly-owned subsidiary, Pier, are collectively referred to herein as the "Company."

The Company underwent a change in management in March 2013, and since then the Company's current management has continued to implement this strategic focus, including seeking the capital to fund such efforts. As a result of the Company's scientific discoveries and the acquisition of strategic, exclusive license agreements, management believes that the Company is now a leader in developing drugs for respiratory disorders, particularly sleep apneas and drug-induced respiratory depression.

The Company owns patents and patent applications for certain families of chemical compounds, including ampakines, which claim the chemical structures and their use in the treatment of various disorders. These patents cover, among other compounds, the Company's lead ampakines CX1739 and CX1942, and extend through at least 2028.

On May 8, 2007, RespireRx entered into a license agreement, as subsequently amended, with the University of Alberta granting RespireRx exclusive rights to method of treatment patents held by the University of Alberta claiming the use of ampakines for the treatment of various respiratory disorders. These patents, along with RespireRx's own patents claiming chemical structures, comprise RespireRx's principal intellectual property supporting RespireRx's research and clinical development program in the use of ampakines for the treatment of respiratory disorders. RespireRx has completed preclinical studies indicating that several of its ampakines, including CX717, CX1739 and CX1942, were efficacious in treating drug induced respiratory depression caused by opioids or certain anesthetics without offsetting the analgesic effects of the opioids or the anesthetic effects of the anesthetics. In two clinical Phase 2 studies, one of which was published in a peer-reviewed journal, CX717, a predecessor compound to CX1739 and CX1942, antagonized the respiratory depression produced by fentanyl, a potent narcotic, without affecting the analgesia produced by this drug. In addition, RespireRx has conducted a Phase 2A clinical study in which patients with sleep apnea were administered CX1739, RespireRx's lead clinical compound. The results suggested that CX1739 might have use for the treatment of central sleep apnea ("CSA") and mixed sleep apnea, but not obstructive sleep apnea ("OSA").

In order to expand RespireRx's respiratory disorders program, RespireRx acquired 100% of the issued and outstanding equity securities of Pier effective August 10, 2012 pursuant to an Agreement and Plan of Merger. Pier was formed in June 2007 (under the name SteadySleep Rx Co.) as a clinical stage pharmaceutical company to develop a pharmacologic treatment for the respiratory disorder known as OSA and had been engaged in research and clinical development activities since formation.

Through the merger, RespireRx gained access to an Exclusive License Agreement (as amended, the "License Agreement") that Pier had entered into with the University of Illinois on October 10, 2007. The License Agreement covered certain patents and patent applications in the United States and other countries claiming the use of certain compounds referred to as cannabinoids, of which dronabinol is a specific example, for the treatment of sleep-related breathing disorders (including sleep apnea). Dronabinol is a synthetic derivative of the naturally occurring substance in the cannabis plant, otherwise known as Δ9-THC (Δ9-tetrahydrocannabinol). Pier's business plan was to determine whether dronabinol would significantly improve subjective and objective clinical measures in patients with OSA. In addition, Pier intended to evaluate the feasibility and comparative efficacy of a proprietary formulation of dronabinol.

The License Agreement granted Pier, among other provisions, exclusive rights: (i) to practice certain patents and patent applications, as defined in the License Agreement, that were then held by the University of Illinois; (ii) to identify, develop, make, have made, import, export, lease, sell, have sold or offer for sale any related licensed products; and (iii) to grant sub-licenses of the rights granted in the License Agreement, subject to the provisions of the License Agreement. Pier was required under the License Agreement, among other terms and conditions, to pay the University of Illinois a license fee, royalties, patent costs and certain milestone payments.

Prior to the merger, Pier conducted a 21 day, randomized, double-blind, placebo-controlled, dose escalation Phase 2 clinical study in 22 patients with OSA, in which dronabinol produced a statistically significant reduction in the Apnea-Hypopnea Index, the primary therapeutic end-point, and was observed to be safe and well tolerated. The University of Illinois and three other research centers are currently investigating dronabinol in a potentially pivotal, six week, double-blind, placebo-controlled Phase 2B clinical trial in 120 patients with OSA. This study, which the University of Illinois expects to be completed during the second quarter of 2016, is fully funded by the National Heart, Lung and Blood Institute of the National Institutes of Health. The Company is not managing or funding this ongoing clinical trial.

Dronabinol is a Schedule III, controlled generic drug with a relatively low abuse potential that is approved by the U.S. Food and Drug Administration (the "FDA") for the treatment of AIDS-related anorexia and chemotherapy-induced emesis. The use of dronabinol for the treatment of OSA is a novel indication for an already approved drug and, as such, the Company believes that it would only require approval by the FDA of a supplemental new drug application.

Subsequent to the termination of the License Agreement effective March 21, 2013, due to the Company's failure to make a required payment, current management opened negotiations with the University of Illinois. As a result, the Company ultimately entered into the 2014 License Agreement with the University of Illinois on June 27, 2014, the material terms of which were similar to the License Agreement that was terminated on March 21, 2013.

Recent Developments

Clinical Trial

The Company filed an Investigational New Drug ("IND") application with the FDA in September 2015 to conduct a double-blind, placebo-controlled, dose-ascending Phase 2A clinical trial in approximately 18 subjects to determine the ability of orally administered CX1739, the Company's proprietary lead ampakine, to prevent the respiratory depression produced by remifentanil, a potent opioid, without altering remifentanil's analgesic properties. The clinical protocol was designed to evaluate the safety and efficacy of three escalating doses of CX1739 versus placebo when administered prior to remifentanil, with respiration, analgesia and a number of other clinical measures being taken after administration of both drugs. The commencement of this clinical trial was subject to resolution of two deficiencies raised by the FDA in its clinical hold letter issued in November 2015, which were satisfactorily resolved in early 2016, as a result of which the FDA removed the clinical hold on the Company's IND for CX1739 on February 25, 2016, thus allowing for the initiation of the clinical trial. During March 2016, upon receiving unconditional approval from the Institutional Review Board ("IRB") of the Duke Clinical Research Unit, this Phase 2A clinical trial at Duke University School of Medicine was initiated. The Company expects to incur approximately $750,000 of direct costs in 2016 with respect to this clinical trial, and to complete the clinical trial in approximately four months.

National Institute of Drug Abuse Agreement

On January 19, 2016, the Company announced that that it has reached an agreement with the Medications Development Program of the National Institute of Drug Abuse ("NIDA") to conduct research on the Company's ampakine compounds CX717 and CX1739. The agreement was entered into as of October 19, 2015, and on January 14, 2016, the Company and NIDA approved the proposed protocols, allowing research activities to commence. NIDA will evaluate the compounds using pharmacologic, pharmacokinetic and toxicologic protocols to determine the potential effectiveness of the ampakines for the treatment of drug abuse and addiction. Initial studies will focus on cocaine and methamphetamine addiction and abuse, and will be contracted to outside testing facilities and/or government laboratories, with all costs to be paid by NIDA. The Company will provide NIDA with supplies of CX717 and CX1739 and will work with the NIDA staff to refine the protocols and dosing parameters. The Company will retain all intellectual property, proprietary and commercialization rights to these compounds.

Research Contract with the University of Alberta

On January 12, 2016, the Company entered into a Research Contract with the University of Alberta in order to test the efficacy of ampakines at a variety of dosage and formulation levels in the potential treatment of Pompé Disease, apnea of prematurity and spinal cord injury, as well as to conduct certain electrophysiological studies to explore the ampakine mechanism of action for central respiratory depression. The Company agreed to pay the University of Alberta total consideration of approximately CAD$146,000 (currently approximately US$110,000), consisting of approximately CAD$85,000 (currently approximately US$64,000) of personnel funding in cash in four installments during 2016, to provide approximately CAD$21,000 (currently approximately US$16,000) in equipment, to pay patent costs of CAD$20,000 (currently approximately US$15,000), and to underwrite additional budgeted costs of CAD$20,000 (currently approximately US$15,000). All but US$64,000 of the total consideration has already been incurred and paid for directly or in-kind. The conversion to US dollars above utilizes an exchange rate of US$0.7548 for every CAD$1.00.

The University of Alberta will receive matching funds through a grant from the Canadian Institutes of Health Research in support of the research. The Company will retain the rights to research results and any patentable intellectual property generated by the research. Dr. John Greer, Ph.D., Chairman of the Company's Scientific Advisory Board and faculty member of the Department of Physiology, Perinatal Research Centre, and Women & Children's Health Research Institute and Alberta Innovates Health Sciences Senior Scientist with the Neuroscience and Mental Health Institute at the University of Alberta, will collaborate on this research. The studies are expected to be completed in 2016.

Common Stock and Warrant Financing

On January 6, 2016, the Company entered into a Common Stock and Warrant Purchase Agreement (the "Purchase Agreement") with an investor, pursuant to which, in a closing on January 8, 2016, the Company sold units for aggregate cash consideration of $100,000, with each unit consisting of (i) one share of common stock, representing an aggregate of 4,508,567 shares of common stock, and (ii) one warrant to purchase two additional shares of common stock, representing an aggregate of 9,017,133 warrants. This financing represented the initial closing of a private placement of up to $2,500,000 (the "Private Placement").

The price per unit in the initial closing of the Private Placement was $0.02218. The warrants are exercisable at $0.0244, for each share of common stock to be acquired, and expire on February 28, 2021. The warrants have a cashless exercise provision and contain certain "blocker" provisions limiting the percentage of shares of the Company's common stock that the purchaser can beneficially own upon conversion to not more than 4.99% of the issued and outstanding shares immediately after giving effect to the warrant exercise. The purchaser was an accredited, non-affiliated investor.

In addition, from January 29, 2016 through March 3, 2016, the Company received subscriptions totaling $94,635 for the purchase of units, representing an aggregate of 4,266,683 shares of common stock and warrants to purchase an additional 8,533,366 shares of common stock. The purchasers were accredited, non-affiliated investors.

In the case of an acquisition, as defined in the Purchase Agreement, in which the Company is not the surviving entity, the holder of the warrant would receive from any surviving entity or successor to the Company, in exchange for the warrant, a new warrant from the surviving entity or successor to the Company, substantially in the form of the existing warrant and with an exercise price adjusted to reflect the nearest equivalent exercise price of common stock (or other applicable equity interest) of the surviving entity that would reflect the economic value of the warrant, but in the surviving entity.

No registration rights were granted to the purchaser in the Private Placement with respect to (i) the shares of common stock issued as part of the units, (ii) the warrants, or (ii) the shares of common stock issuable upon exercise of the warrants.

No placement agent fees, brokerage commissions, finder’s fees or similar payments were made in the form of cash and warrants to qualified referral sources in connection with the sale of the shares of common stock and warrants.

Going Concern

The Company's consolidated financial statements have been presented on the basis that it is a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The Company has incurred net losses of $5,961,892 and $2,707,535 and negative operating cash flows of $1,296,100 and $885,869 for the fiscal years ended December 31, 2015 and 2014, respectively, had a stockholders' deficiency of $2,862,209 at December 31, 2015, and expects to continue to incur net losses and negative operating cash flows for at least the next few years. As a result, management has concluded that there is substantial doubt about the Company's ability to continue as a going concern, and the Company's independent registered public accounting firm, in their report on the Company's consolidated financial statements for the year ended December 31, 2015, has expressed substantial doubt about the Company's ability to continue as a going concern.

The Company is currently, and has for some time, been in significant financial distress. It has limited cash resources and current assets and has no ongoing source of revenue. Current management is continuing to address various aspects of the Company's operations and obligations, including, without limitation, debt obligations, financing requirements, intellectual property, licensing agreements, legal and patent matters and regulatory compliance, and has continued to raise new debt and equity capital to fund the Company's business activities.

From June 2013 through March 2014, the Company's Chairman and then Chief Executive Officer advanced short-term loans to the Company aggregating $150,000 for working capital purposes. In March and April 2014, the Company completed a private placement by selling 928.5 shares of its Series G 1.5% Convertible Preferred Stock for gross proceeds of $928,500 and repaid the aggregate advances. The Company's Chairman and then Chief Executive Officer invested $250,000 in the Series G 1.5% Convertible Preferred Stock private placement. During November and December 2014, the Company sold short-term convertible notes and warrants in an aggregate principal amount of $369,500 to various accredited investors and an additional $210,000 of such short-term convertible notes and warrants in February 2015. The Company terminated this financing, which generated aggregate gross proceeds of $579,500, effective February 18, 2015. In June 2015, the Company's Chairman and then Chief Executive Officer advanced $40,000 to the Company in the form of a short-term loan for working capital purposes. In August through November 2015, the Company completed three closings of a private placement, which terminated on December 31, 2015, by selling 56,809,802 units of its common stock and warrants for gross proceeds of $1,194,710 and repaid the short-term loan of $40,000 plus accrued interest of $877. The Company's current President and Chief Executive Officer invested $250,000 in the August 2015 closing of this private placement. The Company initiated a new private placement of common stock and warrants in January 2016, selling to date 8,775,250 units of its common stock and warrants for gross proceeds of $194,635. Subsequent to December 31, 2015, the Company's Chief Executive Officer and Chief Scientific Officer each advanced an additional $52,600 to the Company for working capital purposes under secured short-term promissory notes payable aggregating $105,200 and three year warrants exercisable into 5,980,319 shares of Common Stock in the aggregate.

The Company is continuing its efforts to raise additional capital in order to be able to pay its liabilities and fund its business activities on a going forward basis, including an increase in the Company's research and development activities. As a result of the Company's current financial situation, the Company has limited access to external sources of debt and equity financing. Accordingly, there can be no assurances that the Company will be able to secure additional financing in the amounts necessary to fully fund its operating and debt service requirements. If the Company is unable to access sufficient cash resources, the Company may be forced to discontinue its operations entirely and liquidate.

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update No. 2014-09 (ASU 2014-09), Revenue from Contracts with Customers. ASU 2014-09 will eliminate transaction- and industry-specific revenue recognition guidance under current GAAP and replace it with a principle based approach for determining revenue recognition. ASU 2014-09 will require that companies recognize revenue based on the value of transferred goods or services as they occur in the contract. ASU 2014-09 also will require additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. Based on the FASB's Exposure Draft Update issued on April 29, 2015, and approved in July 2015, Revenue from Contracts With Customers (Topic 606): Deferral of the Effective Date, ASU 2014-09 is now effective for reporting periods beginning after December 15, 2017, with early adoption permitted only as of annual reporting periods beginning after December 15, 2016, including interim reporting periods within that reporting period. Entities will be able to transition to the standard either retrospectively or as a cumulative-effect adjustment as of the date of adoption. The adoption of ASU 2014-09 is not expected to have any impact on the Company's financial statement presentation or disclosures.

In August 2014, the FASB issued Accounting Standards Update No. 2014-15 (ASU 2014-15), Presentation of Financial Statements - Going Concern (Subtopic 205-10). ASU 2014-15 provides guidance as to management's responsibility to evaluate whether there is substantial doubt about an entity's ability to continue as a going concern and to provide related footnote disclosures. In connection with preparing financial statements for each annual and interim reporting period, an entity's management should evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued (or within one year after the date that the financial statements are available to be issued when applicable). Management's evaluation should be based on relevant conditions and events that are known and reasonably knowable at the date that the financial statements are issued (or at the date that the financial statements are available to be issued when applicable). Substantial doubt about an entity's ability to continue as a going concern exists when relevant conditions and events, considered in the aggregate, indicate that it is probable that the entity will be unable to meet its obligations as they become due within one year after the date that the financial statements are issued (or available to be issued). ASU 2014-15 is effective for the annual period ending after December 15, 2016, and for annual periods and interim periods thereafter. Early application is permitted. The adoption of ASU 2014-15 is not expected to have any impact on the Company's financial statement presentation and disclosures.

In January 2015, the FASB issued Accounting Standards Update No. 2015-01 (ASU 2015-01), Income Statement - Extraordinary and Unusual Items (Subtopic 225-20). ASU 2015-01 eliminates from GAAP the concept of extraordinary items. Subtopic 225-20, Income Statement - Extraordinary and Unusual Items, required that an entity separately classify, present, and disclose extraordinary events and transactions. Presently, an event or transaction is presumed to be an ordinary and usual activity of the reporting entity unless evidence clearly supports its classification as an extraordinary item. Paragraph 225-20-45-2 contains the following criteria that must both be met for extraordinary classification: (1) Unusual nature. The underlying event or transaction should possess a high degree of abnormality and be of a type clearly unrelated to, or only incidentally related to, the ordinary and typical activities of the entity, taking into account the environment in which the entity operates. (2) Infrequency of occurrence. The underlying event or transaction should be of a type that would not reasonably be expected to recur in the foreseeable future, taking into account the environment in which the entity operates. If an event or transaction meets the criteria for extraordinary classification, an entity is required to segregate the extraordinary item from the results of ordinary operations and show the item separately in the income statement, net of tax, after income from continuing operations. The entity also is required to disclose applicable income taxes and either present or disclose earnings-per-share data applicable to the extraordinary item. ASU 2015-01 is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2015. A reporting entity may apply the guidance prospectively. A reporting entity also may apply the guidance retrospectively to all prior periods presented in the financial statements. Early adoption is permitted provided that the guidance is applied from the beginning of the fiscal year of adoption. The adoption of ASU 2015-01 is not expected to have any impact on the Company's financial statement presentation or disclosures.

In February 2015, the FASB issued Accounting Standards Update No. 2015-02 (ASU 2015-02), Consolidation (Topic 810). ASU 2015-02 changes the guidance with respect to the analysis that a reporting entity must perform to determine whether it should consolidate certain types of legal entities. All legal entities are subject to reevaluation under the revised consolidation mode. ASU 2015-02 affects the following areas: (1) limited partnerships and similar legal entities; (2) evaluating fees paid to a decision maker or a service provider as a variable interest; (3) the effect of

fee arrangements on the primary beneficiary determination; (4) the effect of related parties on the primary beneficiary determination; and (5) certain investment funds. ASU 2015-02 is effective for public business entities for fiscal years, and for interim periods within those fiscal years, beginning after December 15, 2015. Early adoption is permitted, including adoption in an interim period. If an entity early adopts the guidance in an interim period, any adjustments should be reflected as of the beginning of the fiscal year that includes that interim period. A reporting entity may apply the amendments in this guidance using a modified retrospective approach by recording a cumulative-effect adjustment to equity as of the beginning of the fiscal year of adoption. A reporting entity also may apply the amendments retrospectively. The adoption of ASU 2015-02 is not expected to have any impact on the Company’s financial statement presentation or disclosures.

In April 2015, the FASB issued Accounting Standards Update No. 2015-03 (ASU 2015-03), Interest - Imputation of Interest (Subtopic 835-30). ASU 2015-03 simplifies the presentation of debt issuance costs and requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. The recognition and measurement guidance for debt issuance costs are not affected by the new guidance. ASU 2015-3 is effective for financial statements issued for fiscal years beginning after December 15, 2015, and interim periods within that fiscal year. Early adoption is permitted for financial statements that have not been previously issued. An entity is required to apply the new guidance on a retrospective basis, wherein the balance sheet of each individual period presented is adjusted to reflect the period-specific effects of applying the new guidance. Upon transition, an entity is required to comply with the applicable disclosures for a change in an accounting principle. These disclosures include the nature of and reason for the change in accounting principle, the transition method, a description of the prior-period information that has been retrospectively adjusted, and the effect of the change on the financial statement line items (i.e., debt issuance cost asset and the debt liability). The adoption of ASU 2015-03 is expected to have an impact on the presentation of the Company’s current and future debt issuance costs beginning in 2016.

In November 2015, the FASB issued Accounting Standards Update No. 2015-17 (ASU 2015-17), Income Taxes (Topic 740): Balance Sheet Classification of Deferred Taxes. ASU 2015-17 requires that deferred tax liabilities and assets be classified as noncurrent in a classified statement of financial position. ASU 2015-17 is effective for financial statements issued for annual periods beginning after December 15, 2016, and interim periods within those annual periods. Earlier application is permitted as of the beginning of an interim or annual reporting period. The adoption of ASU 2015-17 is not expected to have any impact on Company’s financial statement presentation or disclosures.

In February 2016, the FASB issued Accounting Standards Update No. 2016-02 (ASU 2016-02), Leases (Topic 842). ASU 2016-02 requires a lessee to record a right-of-use asset and a corresponding lease liability, initially measured at the present value of the lease payments, on the balance sheet for all leases with terms longer than 12 months, as well as the disclosure of key information about leasing arrangements. ASU 2016-02 requires recognition in the statement of operations of a single lease cost, calculated so that the cost of the lease is allocated over the lease term, generally on a straight-line basis. ASU 2016-02 requires classification of all cash payments within operating activities in the statement of cash flows. Disclosures are required to provide the amount, timing and uncertainty of cash flows arising from leases. A modified retrospective transition approach is required for lessees for capital and operating leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, with certain practical expedients available. ASU 2016-02 is effective for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Early application is permitted. The Company has not yet evaluated the impact of the adoption of ASU 2016-02 on the Company’s financial statement presentation or disclosures.

Management does not believe that any other recently issued, but not yet effective, authoritative guidance, if currently adopted, would have a material impact on the Company’s financial statement presentation or disclosures.

Concentration of Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash and cash equivalents. The Company limits its exposure to credit risk by investing its cash with high credit quality financial institutions.

The Company’s research and development efforts and potential products rely on licenses from research institutions and if the Company loses access to these technologies or applications, its business could be substantially impaired.

Under a patent license agreement with The Governors of the University of Alberta, the Company has exclusive rights to the use of certain ampakine compounds to prevent and treat respiratory depression induced by opioid analgesics, barbiturates and anesthetic and sedative agents.

On May 8, 2007, the Company entered into a license agreement, as subsequently amended, with the University of Alberta granting the Company exclusive rights to practice patents held by the University of Alberta claiming the use of ampakines for the treatment of various respiratory disorders. The Company agreed to pay the University of Alberta a licensing fee and a patent issuance fee, which were paid, and prospective payments consisting of a royalty on net sales, sublicense fee payments, maintenance payments and milestone payments. The prospective maintenance payments commence on the enrollment of the first patient into the first Phase 2B clinical trial and increase upon the successful completion of the Phase 2B clinical trial. As the Company does not at this time anticipate scheduling a Phase 2B clinical trial, no maintenance payments are currently due and payable to the University of Alberta. In addition, no other prospective payments are currently due and payable to the University of Alberta.

Through the merger with Pier, the Company gained access to the License Agreement that Pier had entered into with the University of Illinois on October 10, 2007. The Pier License Agreement covered certain patents and patent applications in the United States and other countries claiming the use of certain compounds referred to as cannabinoids for the treatment of sleep related breathing disorders (including sleep apnea), of which dronabinol is a specific example of one type of cannabinoid. Dronabinol is a synthetic derivative of the naturally occurring substance in the cannabis plant, otherwise known as Δ9-THC (Δ9-tetrahydrocannabinol). Dronabinol is currently approved by the FDA and is sold generically for use in refractory chemotherapy-induced nausea and vomiting, as well as for anorexia in patients with AIDS. Pier’s business plan was to determine whether dronabinol would significantly improve subjective and objective clinical measures in patients with OSA. In addition, Pier intended to evaluate the feasibility and comparative efficacy of a proprietary formulation of dronabinol. The Pier License Agreement was terminated effective March 21, 2013 due to the Company’s failure to make a required payment and on June 27, 2014, the Company entered into the 2014 License Agreement with the University of Illinois, the material terms of which were similar to the Pier License Agreement that had been terminated. If the Company is unable to comply with the terms of the 2014 License Agreement, such as required payments thereunder, the Company risks the 2014 License Agreement being terminated.

Critical Accounting Policies and Estimates

The Company prepared its consolidated financial statements in accordance with accounting principles generally accepted in the United States of America. The preparation of these consolidated financial statements requires the use of estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amount of revenues and expenses during the reporting period. Management periodically evaluates the estimates and judgments made. Management bases its estimates and judgments on historical experience and on various factors that are believed to be reasonable under the circumstances. Actual results may differ from these estimates as a result of different assumptions or conditions.

The following critical accounting policies affect the more significant judgments and estimates used in the preparation of the Company's consolidated financial statements.

Series G 1.5% Convertible Preferred Stock

The Company accounted for the beneficial conversion features associated with the Series G 1.5% Convertible Preferred Stock in accordance with Accounting Standards Codification ("ASC") 470-20, Accounting for Debt with Conversion and Other Options. The Company calculated a deemed dividend on the Series G 1.5% Convertible Preferred Stock of $8,376,719 in March 2014 and $1,673,127 in April 2014, which equals the amount by which the estimated fair value of the common stock issuable upon conversion of the issued Series G 1.5% Convertible Preferred Stock exceeded the proceeds from such issuances. The deemed dividend on the Series G 1.5% Convertible Preferred Stock was amortized on the straight-line basis from the respective issuance dates through the earliest conversion date of June 16, 2014, in accordance with ASC 470-20. The difference between the amortization of the deemed dividend calculated based on the straight-line method and the effective yield method was not material.

10% Convertible Notes Payable

The Company accounted for the beneficial conversion features with respect to the sale of the convertible notes and the issuance of the warrants in 2014 and 2015 in accordance with ASC 470-20, Accounting for Debt with Conversion and Other Options.

The Company considered the face value of the convertible notes to be representative of their fair value. The Company determined the fair value of the warrants based on the Black-Scholes option-pricing model. The relative fair value method generated respective fair values for each of the convertible notes and the warrants of approximately 50% for the convertible notes and approximately 50% for the warrants. Once these values were determined, the fair value of the warrants and the fair value of the beneficial conversion feature (which were calculated based on the effective conversion price) were recorded as a reduction to the face value of the promissory note obligation. As a result, this aggregate debt discount reduced the carrying value of the convertible notes to zero at each issuance date. The excess amount generated from this calculation was not recorded, as the carrying value of a convertible note cannot be reduced below zero. The aggregate debt discount is being amortized as interest expense over the original term of the convertible notes. The difference between the amortization of the debt discount calculated based on the straight-line method and the effective yield method was not material.

The cash fees paid to placement agents and for legal costs were deferred and capitalized as deferred offering costs and are being amortized to interest expense over the original term of the convertible notes on the straight-line method. The placement agent warrants were considered as an additional cost of the offering and were included in deferred offering costs at fair value. The difference between the amortization of the deferred offering costs calculated based on the straight-line method and the effective yield method was not material.

On August 13, 2015, the Company elected to extend the maturity date of the convertible notes to September 15, 2016. As a consequence of this election, under the terms of the convertible notes, the Company was required to issue to convertible note holders additional warrants (the “New Warrants”). In connection with the extension of the maturity date of the convertible notes, the Board of Directors of the Company determined to extend the termination date of the original warrants (the “Old Warrants”), so that they are coterminous with the new maturity date of the convertible notes.

The Company reviewed the guidance in ASC 405-20, Extinguishment of Liabilities, and determined that the notes had not been extinguished. The Company therefore concluded that the guidance in ASC 470-50, Modifications and Extinguishments, should be applied, which states that if the exchange or modification is not to be accounted for in the same manner as a debt extinguishment, then the fees shall be associated with the replacement or modified debt instrument and, along with any existing unamortized premium or discount, amortized as an adjustment of interest expense over the remaining term of the replacement or modified debt instrument using the interest method.

With regard to the modification of the convertible notes and the issuance of the New Warrants, the Company deferred the debt modification costs over the remaining term of the extended notes. The Company is accounting for such costs as a discount to the notes and is amortizing such costs to interest expense over the extended term of the notes on the straight-line method. The difference between the amortization of these costs calculated based on the straight-line method and the effective yield method was not material.

With regard to the extension of the Old Warrants, the Company deferred the debt modification costs over the remaining term of the extended convertible notes. The Company is accounting for such costs as a discount to the notes and is amortizing such costs to interest expense over the extended term of the convertible notes on the straight-line method. The difference between the amortization of these costs calculated based on the straight-line method and the effective yield method was not material.

The closing market price of the Company’s common stock on the extension date of September 15, 2015 was $0.031 per share, as compared to the fixed conversion price of the convertible notes and the fixed exercise price of both the Old Warrants and the New Warrants of $0.035 per share. The Company has accounted for the beneficial conversion features with respect to the extension of the convertible notes and the extension of the Old Warrants and the issuance of the New Warrants in accordance with ASC 470-20, Accounting for Debt with Conversion and Other Options.

The Company considered the face value of the convertible notes, plus the accrued interest thereon, to be representative of their fair value. The relative fair value method generated respective fair values for each of the convertible notes, including accrued interest, and the New Warrants and extension of the Old Warrants, of approximately 55% for the convertible notes, including accrued interest, and approximately 45% for the New Warrants and extension of the Old Warrants. Once these values were determined, the fair value of the New Warrants and extension of the Old Warrants and the fair value of the beneficial conversion feature (which were calculated based on the effective conversion price) were recorded as a reduction to the face value of the promissory note obligation. The aggregate debt discount is being amortized as interest expense over the extended term of the promissory notes. The difference between the amortization of the debt discount calculated based on the straight-line method and the effective yield method was not material.

Research Grants

The Company recognizes revenues from research grants as earned based on the percentage-of-completion method of accounting and issues invoices for contract amounts billed based on the terms of the grant agreement. Revenues recorded under research grants in excess of amounts earned are classified as unearned grant revenue liability in the Company's consolidated balance sheet. Grant receivable reflects contractual amounts due and payable under the grant agreement. The payment of grants receivables are based on progress reports provided to the grant provider by the Company. The research grant was completed in April 2015. The Company has filed all required progress reports.

Research grants are generally funded and paid through government or institutional programs. Amounts received under research grants are nonrefundable, regardless of the success of the underlying research project, to the extent that such amounts are expended in accordance with the approved grant project.

Stock-Based Compensation

The Company periodically issues common stock and stock options to officers, directors, Scientific Advisory Board members and consultants for services rendered. Such issuances vest and expire according to terms established at the issuance date of each grant.

The Company accounts for stock-based payments to officers and directors by measuring the cost of services received in exchange for equity awards based on the grant date fair value of the awards, with the cost recognized as compensation expense on the straight-line basis in the Company's financial statements over the vesting period of the awards. The Company accounts for stock-based payments to Scientific Advisory Board members and consultants by determining the value of the stock compensation based upon the measurement date at either (a) the date at which a

performance commitment is reached, or (b) at the date at which the necessary performance to earn the equity instruments is complete.

Stock grants, which are generally time vested, are measured at the grant date fair value and charged to operations ratably over the vesting period.

Stock options granted to members of the Company's Scientific Advisory Board and to outside consultants are revalued each reporting period until vested to determine the amount to be recorded as an expense in the respective period. As the stock options vest, they are valued on each vesting date and an adjustment is recorded for the difference between the value already recorded and the value on the date of vesting.

The fair value of stock options is determined utilizing the Black-Scholes option-pricing model, and is affected by several variables, the most significant of which are the life of the equity award, the exercise price of the security as compared to the fair market value of the common stock on the grant date, and the estimated volatility of the common stock over the term of the equity award. Estimated volatility is based on the historical volatility of the Company's common stock. The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of grant. The fair value of common stock is determined by reference to the quoted market price of the Company's common stock.

Stock options and warrants issued to non-employees as compensation for services to be provided to the Company or in settlement of debt are accounted for based upon the fair value of the services provided or the estimated fair value of the stock option or warrant, whichever can be more clearly determined. Management utilizes the Black-Scholes option-pricing model to determine the fair value of the stock options and warrants issued by the Company. The Company recognizes this expense over the period in which the services are provided.

The Company recognizes the fair value of stock-based compensation in general and administrative costs and in research and development costs, as appropriate, in the Company's consolidated statements of operations. The Company issues new shares of common stock to satisfy stock option exercises.

Research and Development Costs

Research and development costs consist primarily of fees paid to consultants and outside service providers and organizations (including research institutes at universities), patent fees and costs, and other expenses relating to the acquisition, design, development and testing of the Company's treatments and product candidates.

Research and development costs incurred by the Company under research grants are expensed as incurred over the life of the underlying contracts, unless the terms of the contract indicate that a different expensing schedule is more appropriate.

The Company reviews the status of its research and development contracts on a quarterly basis.

License Agreements

Obligations incurred with respect to mandatory payments provided for in license agreements are recognized ratably over the appropriate period, as specified in the underlying license agreement, and are recorded as liabilities in the Company's consolidated balance sheet, with a corresponding charge to research and development costs in the Company's consolidated statement of operations. Obligations incurred with respect to milestone payments provided for in license agreements are recognized when it is probable that such milestone will be reached, and are recorded as liabilities in the Company's consolidated balance sheet, with a corresponding charge to research and development costs in the Company's consolidated statement of operations. Payments of such liabilities are made in the ordinary course of business.

Patent Costs

Due to the significant uncertainty associated with the successful development of one or more commercially viable products based on the Company's research efforts and any related patent applications, all patent costs, including patent-related legal and filing fees, are expensed as incurred.

Results of Operations

The Company's consolidated statements of operations as discussed herein are presented below.

	Years Ended December 31,	
	2015	2014
Grant revenues	$86,916	$61,667
Operating expenses:		
General and administrative	3,619,929	3,823,434
Research and development	1,706,603	591,768
Total operating expenses	5,326,532	4,415,202
Loss from operations	(5,239,616)	(4,353,535)
Gain on settlements with former management	91,710	1,038,270
Gain on settlements with service providers	75,375	393,590
Gain on settlement of project advance	-	287,809
Interest income	9	-
Interest expense	(902,698)	(117,306)
Foreign currency transaction gain	13,328	43,637
Net loss	(5,961,892)	(2,707,535)
Adjustments related to Series G 1.5% Convertible Preferred Stock:		
Amortization of deemed dividend on Series G 1.5% Convertible Preferred Stock	-	(10,049,846)
Dividends on Series G 1.5% Convertible Preferred Stock	(6,867)	(10,926)
Net loss attributable to common stockholders	$(5,968,759)	$(12,768,307)
Net loss per common share - basic and diluted	$(0.02)	$(0.07)
Weighted average common shares outstanding - basic and diluted	384,451,048	192,739,814

Years Ended December 31, 2015 and 2014

Revenues. During the years ended December 31, 2015 and 2014, the Company had research grant revenues of $86,916 and $61,667, respectively, related to a contract with the National Institute on Drug Abuse entered into on September 18, 2014 and completed in early 2015.

General and Administrative. For the year ended December 31, 2015, general and administrative expenses were $3,619,929, a decrease of $203,505, as compared to $3,823,434 for the year ended December 31, 2014. The decrease in general and administrative expenses for the year ended December 31, 2015, as compared to the year ended December 31, 2014, is primarily due to a decrease in stock-based compensation of $805,112, offset by an increase in salaries, employee benefits and board fees of $591,970.

Stock-based compensation costs included in general and administrative expenses were $2,326,388 for the year ended December 31, 2015, as compared to $3,131,500 for the year ended December 31, 2014, reflecting a decrease of $805,112. Salaries, employee benefits and board fees included in general and administrative expenses were $591,970 for the year ended December 31, 2015, as compared to $0 for the year ended December 31, 2014, reflecting an increase of $591,970. The net change reflects the Company's shift in compensation philosophy for its officers and directors beginning in mid-2015 from entirely stock-based compensation to a combination of stock-based compensation and compensation payable in cash.

Additionally, during the year ended December 31, 2015, as compared to the year ended December 31, 2014, the Company incurred an increase of $50,141 in professional fees and other costs incurred in connection with management's efforts to reestablish and update the Company's accounting systems and records and prepare various delinquent financial reports and public filings.

The Company periodically reviews its estimates for accounts payable and accrued expenses, as a result of which the Company reduced accounts payable and accrued expenses by $55,778, which was recorded as a reduction to general and administrative expenses for the year ended December 31, 2015.

Research and Development. For the year ended December 31, 2015, research and development expenses were $1,706,603, an increase of $1,114,835, as compared to $591,768 for the year ended December 31, 2014. The increase in research and development expenses for the year ended December 31, 2015, as compared to the year ended December 31, 2014, is primarily a result of $118,439 in compensation paid to Dr. Lippa as the Company's new Chief Scientific Officer, an increase in stock-based compensation of $281,058, primarily as a result of $67,170 attributable to the amortization of fair value of stock options that were awarded to Dr. Lippa as the Company's new Chief

Scientific Officer and $210,550 to Richard Purcell in connection with his appointment as the Company's Senior Vice President of Research and Development, $14,102 in fees and expenses for the newly formed Scientific Advisory Board, $551,034 of costs related to the planning for an upcoming clinical study of CX1739, an increase in consulting fees of $136,045 paid to the Company's Senior Vice President of Research and Development, an increase in royalties and license fees of $9,160 to the University of Illinois, an increase in patent related legal fees of $14,708, and $35,664 in salaries and other costs incurred in connection with work performed relating to the grant from the National Institute on Drug Abuse entered into on September 18, 2014.

Gain (Loss) on Settlements with Former Management. During the year ended December 31, 2015, the Company recorded a gain of $91,710 as a result of a settlement agreement with its former Vice President and Chief Financial Officer that resulted in the settlement of potential claims.

In conjunction with such settlement agreement, the Company paid a total of $26,000 (including $775 of interest) in cash and issued stock options to purchase 500,000 shares of common stock exercisable at $0.512 per share for a period of five years, which were valued pursuant to the Black-Scholes option-pricing model at $25,450. The Company also issued stock options to purchase 50,000 shares of common stock exercisable at $0.018 per share for a period of five years, which were valued pursuant to the Black-Scholes option-pricing model at $840.

During the year ended December 31, 2014, the Company recorded a gain of $1,038,270 as a result of settlement agreements with four former executives. The Company settled potential claims totaling $1,336,264 for cash payments of $118,084 and the issuance of stock options to purchase 4,300,000 shares of common stock exercisable at $0.04 per share for periods ranging from five to ten years. The stock options were valued pursuant to the Black-Scholes option-pricing model at $179,910.

Gain on Settlements with Service Providers. During the year ended December 31, 2015, the Company recorded a gain of $75,375 as a result of agreements with four current professional service providers that resulted in the partial settlement of amounts owed to them by the Company. Obligations in the amount of $916,827 were settled for $15,000 in cash, the issuance of a note payable in the amount of $59,763, the issuance of 9,064,286 shares of common stock valued at $158,625 ($0.0175 per share), and the issuance of stock options to purchase 31,618,470 shares of common stock valued pursuant to the Black-Scholes option-pricing model at $608,064.

During the year ended December 31, 2014, the Company recorded a gain of $393,590 as a result of settlement agreements with two former service providers. The Company settled potential claims totaling $496,514 for cash payments of $60,675 plus the issuance of stock options to purchase 1,250,000 shares of common stock exercisable at $0.04 per share for a period of five years. The stock options were valued pursuant to the Black-Scholes option-pricing model at $42,250.

Gain on Settlement of Project Advance. During the year ended December 31, 2014, the Company recorded a gain of $287,809 as the result of a settlement agreement reached with the Institute for the Study of Aging on September 2, 2014. The Company settled a claim of $336,809 through the issuance of 1,000,000 shares of the Company’s common stock valued at $49,000.

Interest Expense. During the year ended December 31, 2015, interest expense was $902,698 (including $49,516 to related parties), an increase of $785,392, as compared to $117,306 (including $48,692 to related parties) for the year ended December 31, 2014. The increase in interest expense resulted primarily from costs associated with the convertible note and warrant financing conducted during November 2014 through February 2015, as well as the extension of the convertible notes in September 2015. Such costs charged to interest expense during the year ended December 31, 2015 totaled $846,447 and consisted of the amortization of capitalized financing costs of $114,128, the amortization of debt discount costs of $675,025, and accrued interest of $57,294.

Foreign Currency Transaction Gain. Foreign currency transaction gain was $13,328 for the year ended December 31, 2015, as compared to a foreign currency transaction gain of $43,637 for the year ended December 31, 2014. The foreign currency transaction gain relates to the $399,774 loan from SY Corporation Co., Ltd., formerly known as Samyang Optics Co. Ltd., made in June 2012, which is denominated in the South Korean Won.

Net Loss. For the year ended December 31, 2015, the Company incurred a net loss of $5,961,892, as compared to a net loss of $2,707,535 for the year ended December 31, 2014.

Amortization of Deemed Dividend on Series G 1.5% Convertible Preferred Stock. For the year ended December 31, 2015, there was no amortization of the deemed dividend on the shares of Series G 1.5% Convertible Preferred Stock, as the deemed dividend was fully amortized as of June 16, 2014. For the year ended December 31, 2014, amortization of the deemed dividend on the shares of Series G 1.5% Convertible Preferred Stock issued in the March 18, 2014 and the April 17, 2014 closings was $10,049,846.

Dividends on Series G 1.5% Convertible Preferred Stock. For the year ended December 31, 2015, dividends accrued on the shares of Series G 1.5% Convertible Preferred Stock issued in the March 18, 2014 and the April 17, 2014 closings were $6,867. For the year ended December 31, 2014, dividends accrued on the shares of Series G 1.5% Convertible Preferred Stock issued in the March 18, 2014 and April 17, 2014 closings were $10,926. The decrease in dividends accrued on the shares of Series G 1.5% Convertible Preferred Stock of $4,059 is due to conversions of Series G 1.5% Convertible Preferred Stock into common stock that have occurred since issuance in 2014. On April 17, 2016, the remaining outstanding shares of Series G 1.5% Convertible Preferred Stock will be automatically and mandatorily redeemed by conversion into shares of common stock at a conversion price of $0.0033 per share.

Net Loss Attributable to Common Stockholders. For the year ended December 31, 2015, the Company incurred a net loss attributable to common stockholders of $5,968,759, as compared to a net loss attributable to common stockholders of $12,768,307 for the year ended December 31, 2014.

Liquidity and Capital Resources - December 31, 2015

The Company’s consolidated financial statements have been presented on the basis that it is a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The Company has incurred net losses of $5,961,892 and $2,707,535 and negative operating cash flows of $1,296,100 and $885,869 for the fiscal years ended December 31, 2015 and 2014, respectively, had a stockholders’ deficiency of $2,862,209 at December 31, 2015, and expects to continue to incur net losses and negative operating cash flows for at least the next few years. As a result, management has concluded that there is substantial doubt about the Company’s ability to continue as a going concern, and the Company’s independent registered public accounting firm, in their report on the Company’s consolidated financial statements for the year ended December 31, 2015, has expressed substantial doubt about the Company’s ability to continue as a going concern.

At December 31, 2015, the Company had a working capital deficit of $2,922,279, as compared to a working capital deficit of $2,280,035 at December 31, 2014, reflecting a decrease in working capital of $642,244 for the year ended December 31, 2015. The decrease in the working capital deficit during the year ended September 30, 2015 is comprised primarily of a net decrease in total current assets of $234,901 and a net increase in total current liabilities of $407,343. The net increase in total current liabilities of $407,343 consists of a net increase in notes payable of $286,713, a net increase in accounts payable and accrued liabilities, including accrued compensation, of $154,963, and a decrease in unearned grant revenue of $34,333.

At December 31, 2015, the Company had cash aggregating $53,199, as compared to $162,752 at December 31, 2014, reflecting a decrease in cash of $109,553 for the year ended December 31, 2015. The decrease in cash during the year ended December 31, 2015 was primarily the result of cash utilized in operating activities and debt settlements partially funded with net proceeds totaling $1,089,896 from the closings of the private placement of units of common stock and

warrants, and net proceeds of $194,300 from the closing of the convertible note and warrant financing.

The Company is currently, and has for some time, been in significant financial distress. It has limited cash resources and current assets and has no ongoing source of revenue. Current management is continuing to address numerous aspects of the Company's operations and obligations, including, without limitation, debt obligations, financing requirements, intellectual property, licensing agreements, legal and patent matters and regulatory compliance, and has continued to raise new debt and equity capital to fund the Company's business activities.

To meet minimum operating needs, from June 2013 through March 2014, the Company's Chairman and then Chief Executive Officer advanced short-term loans to the Company aggregating $150,000. In March and April 2014, the Company completed a private placement by selling 928.5 shares of its Series G 1.5% Convertible Preferred Stock for gross proceeds of $928,500 and repaid the aggregate advances. The Company's Chairman and then Chief Executive Officer invested $250,000 in the Series G Private Placement. During November and December 2014, the Company sold short-term convertible notes and warrants in an aggregate principal amount of $369,500 to various accredited investors and an additional $210,000 of such short-term convertible notes and warrants in February 2015. The Company terminated this financing, which generated aggregate gross proceeds of $579,500, effective February 18, 2015. In June 2015, the Company's Chairman and then Chief Executive Officer advanced $40,000 to the Company in the form of a short-term loan for working capital purposes. In August, September and November 2015, the Company completed three closings of a private placement by selling 56,809,802 units of its common stock and warrants for gross proceeds of $1,194,710 and repaid the short-term loan of $40,000 plus accrued interest of $877. The Company's current President and Chief Executive Officer invested $250,000 in the August 2015 closing of this private placement.

On August 13, 2015, the Company elected to extend the maturity date of the convertible notes with an aggregate principal amount of $579,500 to September 15, 2016. As a consequence of this election, under the terms of the notes, the Company was required to issue to convertible note holders 8,903,684 additional warrants (the "New Warrants") that are exercisable through September 15, 2016. As set forth in the convertible notes, the New Warrants are exercisable for that number of shares of common stock of the Company calculated as the principal amount of the convertible notes (an aggregate amount of $579,500), plus any accrued and unpaid interest (an aggregate amount of $43,758), multiplied by 50%, and then divided by $0.035. The New Warrants otherwise have terms substantially similar to the 16,557,142 original warrants issued to the investors. In connection with the extension of the maturity date of the convertible notes, the Board of Directors of the Company determined to extend the termination date of the 16,557,142 original warrants to September 15, 2016 (the "Old Warrants"), so that they are coterminous with the new maturity date of the notes.

The Company is continuing its efforts to raise additional capital in order to be able to pay its liabilities and fund its business activities on a going forward basis and regularly evaluates various measures to satisfy the Company's liquidity needs, including developing agreements with collaborative partners and seeking to exchange or restructure some of the Company's outstanding securities. As a result of the Company's current financial situation, the Company has limited access to external sources of debt and equity financing. Accordingly, there can be no assurances that the Company will be able to secure additional financing in the amounts necessary to fully fund its operating and debt service requirements. If the Company is unable to access sufficient cash resources, the Company may be forced to discontinue its operations entirely and liquidate.

Operating Activities. For the year ended December 31, 2015, operating activities utilized cash of $1,296,100, as compared to utilizing cash of $885,869 for the year ended December 31, 2014, to support the Company's ongoing operations, including legal and accounting fees and costs related to the preparation of delinquent financial statements and SEC filings, research and development activities, patent fees and related legal costs, and settlement agreements.

Investing Activities. For the year ended December 31, 2015, investing activities utilized cash of $2,497 for the acquisition of equipment, as compared to $18,400 during the year ended December 31, 2014.

Financing Activities. For the year ended December 31, 2015, financing activities generated cash of $1,189,044, consisting of $1,194,710 in proceeds from the common stock and warrant unit financing, $210,000 in proceeds from the convertible note and warrant financing and $40,000 in proceeds from a note payable issued to the Company's Chairman and then Chief Executive Officer, offset by principal paid on other notes payable of $95,152, the payment of financing costs of $120,514 relating to various financings, and the repayment of the $40,000 note payable from the Company's Chairman and then Chief Executive Officer. For the year ended December 31, 2014, financing activities generated cash of $1,052,669, consisting of $928,500 in proceeds from the sale of the Series G 1.5% Convertible Preferred Stock, $369,500 in proceeds from the convertible note and warrant financing, and $75,000 in proceeds from notes payable issued to the Company's Chairman and then Chief Executive Officer, offset by the payment of financing costs of $170,331 relating to various financings, and the repayment of notes payable to the Chairman and then Chief

Executive Officer totaling $150,000.

On April 17, 2016, the remaining outstanding shares of Series G 1.5% Convertible Preferred Stock will be automatically and mandatorily redeemed by conversion into shares of common stock at a conversion price of $0.0033 per share, which will not generate any new capital for the Company.

Principal Commitments

Employment Agreements

On August 18, 2015, the Company entered into an employment agreement with Dr. James S. J. Manuso to be its new President and Chief Executive Officer. Pursuant to the agreement, which is for an initial term of three years, Dr. Manuso is to receive an initial annual base salary of $375,000, subject to certain conditions, which will increase to $450,000 annually upon the first anniversary of his contract, again subject to certain conditions being met. Dr. Manuso will also be eligible to receive bonuses ranging from $100,000 to $300,000, once certain conditions have been met or at the discretion of the Board of Directors. Additionally, Dr. Manuso was granted stock options to acquire 85,081,300 shares of common stock of the Company and is eligible to receive additional awards under the Company's Plans in the discretion of the Board of Directors. Dr. Manuso had also agreed to purchase newly issued securities of the Company in an amount of $250,000, which was accomplished by Dr. Manuso's participation in the first closing of the unit offering of common stock and warrants on August 28, 2015. Dr. Manuso will also receive, beginning on the first anniversary of the agreement, additional compensation to cover automobile lease expenses (up to a maximum of $16,000 annually, on a tax-equalized basis) if certain conditions are met, and, until such time as the Company establishes a group health plan for its employees, $1,200 per month, on a tax-equalized basis, to cover the cost of health coverage and up to $1,000 per month, on a tax-equalized basis, for a term life insurance policy and disability insurance policy. He will also be reimbursed for business expenses. The payment obligation associated with the first year base salary is to accrue, but no payments are to be made, until at least $2,000,000 of net proceeds from any offering or financing of debt or equity, or a combination thereof, is received by the Company, at which time, scheduled payments are to commence. Compensation accrued pursuant to this agreement totaled $146,060 for the period August 18, 2015 through December 31, 2015 and is included in accrued compensation and related expenses in the Company's consolidated balance sheet at December 31, 2015, and in general and administrative expenses in the Company's consolidated statement of operations for the year ended December 31, 2015. Dr. Manuso was also appointed to the Company's Board of Directors and elected as Vice Chairman of the Board of Directors. Dr. Manuso will not receive any additional compensation for serving as Vice Chairman and on the Board of Directors.

On August 18, 2015, concurrently with the hiring of Dr. James S. J. Manuso as its new President and Chief Executive Officer, the Company accepted the resignation of Dr. Arnold S. Lippa, as President and Chief Executive Officer. Dr. Lippa will continue to serve as the Company's Executive Chairman and a member of the Board of Directors. Also on August 18, 2015, Dr. Lippa was named Chief Scientific Officer of the Company, and the Company entered into an employment agreement with Dr. Lippa in that capacity. Pursuant to the agreement, which is for an initial term of three years, Dr. Lippa is to receive an initial annual base salary of $300,000, subject to certain conditions, which will increase to $375,000 annually upon the first anniversary of his contract, again subject to certain conditions being met. Dr. Lippa will also be eligible to receive bonuses ranging from $75,000 to $150,000, once certain conditions have been met or at the discretion of the Board of Directors. Additionally, Dr. Lippa was granted stock options to acquire 10,000,000 shares of common stock of the Company and is eligible to receive additional awards under the Company's Plans at the discretion of the Board of Directors. Dr. Lippa will also receive, beginning on the first anniversary of the agreement, additional compensation to cover automobile lease expenses (up to a maximum of $12,000 annually, on a tax-equalized basis) if certain conditions are met, and, until such time as the Company establishes a group health plan

for its employees, $1,200 per month, on a tax-equalized basis, to cover the cost of health coverage and up to $1,000 per month, on a tax-equalized basis, for a term life insurance policy and disability insurance policy. He will also be reimbursed for business expenses. The payment obligation associated with the first year base salary is to accrue, but no payments are to be made, until at least $2,000,000 of net proceeds from any offering or financing of debt or equity, or a combination thereof, is received by the Company, at which time, scheduled payments are to commence. Compensation accrued pursuant to this agreement totaled $118,439 for the period August 18, 2015 through December 31, 2015 and is included in accrued compensation and related expenses in the Company's consolidated balance sheet at December 31, 2015, and in research and development expenses in the Company's consolidated statement of operations for the year ended December 31, 2015. Compensation accrued to Dr. Lippa under a prior superseded arrangement, while still serving as the Company's President and Chief Executive Officer, totaled $19,758 for the period July 1, 2015 through August 17, 2015 and is included in accrued compensation and related expenses in the Company's consolidated balance sheet at December 31, 2015, and in general and administrative expenses in the Company's consolidated statement of operations for the year ended December 31, 2015. Dr. Lippa will not receive any additional compensation for serving as Executive Chairman and on the Board of Directors.

On August 18, 2015, the Company also entered into employment agreements with Jeff E. Margolis, in his continuing role as Vice President, Secretary and Treasurer, and Robert N. Weingarten, in his continuing role as Vice President and Chief Financial Officer. Pursuant to the agreements, which are for initial terms of one year, Mr. Margolis and Mr. Weingarten are each to receive an initial annual base salary of $195,000, subject to certain conditions, and each will also be eligible to receive bonuses ranging from $65,000 to $125,000, once certain conditions have been met or at the discretion of the Board of Directors. Additionally, Mr. Margolis and Mr. Weingarten each were granted stock options to acquire 10,000,000 shares of common stock of the Company and both are eligible to receive additional awards under the Company's Plans at the discretion of the Board of Directors. Mr. Margolis and Mr. Weingarten will also each receive, beginning on the first anniversary of the agreement, additional compensation to cover automobile lease expenses (up to a maximum of $9,000 annually, on a tax-equalized basis) if certain conditions are met, and, until such time as the Company establishes a group health plan for its employees, $1,200 per month, on a tax-equalized basis, to cover the cost of health coverage and up to $1,000 per month, on a tax-equalized basis, for a term life insurance policy and disability insurance policy. Both will also be reimbursed for business expenses. The payment obligations associated with both of their first year base salaries is to accrue, but no payments are to be made, until at least $2,000,000 of net proceeds from any offering or financing of debt or equity, or a combination thereof, is received by the Company, at which time, scheduled payments are to commence. Total compensation accrued pursuant to these agreements totaled $159,540 ($79,770 each) for the period August 18, 2015 through December 31, 2015 and is included in accrued compensation and related expenses in the Company's consolidated balance sheet at December 31, 2015, and in general and administrative expenses in the Company's consolidated statement of operations for the year ended December 31, 2015. Compensation accrued to Mr. Margolis and Mr. Weingarten under prior superseded arrangements totaled $31,612 ($15,806 each) for the period July 1, 2015 through August 17, 2015 and is also included in accrued compensation and related expenses in the Company's consolidated balance sheet at December 31, 2015, and in general and administrative expenses in the Company's consolidated statement of operations for the year ended December 31, 2015. Mr. Margolis and Mr. Weingarten also continue to serve as Directors of the Company, but will not receive any additional compensation for serving on the Board of Directors.

University of Alberta License Agreement

On May 8, 2007, the Company entered into a license agreement, as amended, with the University of Alberta granting the Company exclusive rights to practice patents held by the University of Alberta claiming the use of ampakines for the treatment of various respiratory disorders. The Company agreed to pay the University of Alberta a licensing fee and a patent issuance fee, which were paid, and prospective payments consisting of a royalty on net sales, sublicense fee payments, maintenance payments and milestone payments. The prospective maintenance payments commence on the enrollment of the first patient into the first Phase 2B clinical trial and increase upon the successful completion of the Phase 2B clinical trial. As the Company does not at this time anticipate scheduling a Phase 2B clinical trial, no maintenance payments are currently due and payable to the University of Alberta. In addition, no other prospective payments are currently due and payable to the University of Alberta.

University of Illinois 2014 Exclusive License Agreement

On June 27, 2014, the Company entered into an Exclusive License Agreement (the "2014 License Agreement") with the University of Illinois, the material terms of which were similar to the License Agreement between the parties that had been previously terminated on March 21, 2013. The 2014 License Agreement became effective on September 18, 2014, upon the completion of certain conditions set forth in the 2014 License Agreement, including: (i) the payment by the Company of a $25,000 licensing fee, (ii) the payment by the Company of outstanding patent costs aggregating $15,840, and (iii) the assignment to the University of Illinois of rights the Company held in certain patent applications, all of which conditions were fulfilled.

The 2014 License Agreement granted the Company (i) exclusive rights to several issued and pending patents in numerous jurisdictions and (ii) the non-exclusive right to certain technical information that is generated by the University of Illinois in connection with certain clinical trials as specified in the 2014 License Agreement, all of which relate to the use of cannabinoids for the treatment of sleep related breathing disorders. The Company is developing dronabinol (Δ9-tetrahydrocannabinol), a cannabinoid, for the treatment of OSA, the most common form of sleep apnea.

The 2014 License Agreement provides for various commercialization and reporting requirements commencing on June 30, 2015. In addition, the 2014 License Agreement provides for various royalty payments, including a royalty on net sales of 4%, payment on sub-licensee revenues of 12.5%, and a minimum annual royalty beginning in 2015 of $100,000, which is due and payable on December 31 of each year beginning on December 31, 2015. The 2015 minimum annual royalty of $100,000 was paid as scheduled in December 2015. In the year after the first application for market approval is submitted to the FDA and until approval is obtained, the minimum annual royalty will increase to $150,000. In the year after the first market approval is obtained from the FDA and until the first sale of a product, the minimum annual royalty will increase to $200,000. In the year after the first commercial sale of a product, the minimum annual royalty will increase to $250,000. The Company recorded a charge to operations of $100,000 with respect to its 2015 minimum annual royalty obligation, which is included in research and development expenses in the Company's consolidated statement of operations for the year ended December 31, 2015.

The 2014 License Agreement also provides for certain one-time milestone payments. A payment of $75,000 is due within five days after any one of the following: (a) dosing of the first patient with a product in a Phase 2 human clinical study anywhere in the world that is not sponsored by the University of Illinois, (b) dosing of the first patient in a Phase 2 human clinical study anywhere in the world with a low dose of dronabinol, or (c) dosing of the first patient in a Phase 1 human clinical study anywhere in the world with a proprietary reformulation of dronabinol. A payment of $350,000 is due within five days after dosing of the first patient with a product in a Phase 3 human clinical trial anywhere in the world. A payment of $500,000 is due within five days after the first new drug application filing with the FDA or a foreign equivalent for a product. A payment of $1,000,000 is due within 12 months after the first commercial sale of a product.

Research Contract with the University of Alberta

On January 12, 2016, the Company entered into a Research Contract with the University of Alberta in order to test the efficacy of ampakines at a variety of dosage and formulation levels in the potential treatment of Pompe Disease, apnea of prematurity and spinal cord injury, as well as to conduct certain electrophysiological studies to explore the ampakine mechanism of action for central respiratory depression. The Company agreed to pay the University of Alberta total consideration of approximately CAD$146,000 (currently approximately US$110,000), consisting of approximately CAD$85,000 (currently approximately US$64,000) of personnel funding in cash in four installments during 2016, to provide approximately CAD$21,000 (currently approximately US$16,000) in equipment, to pay patent costs of CAD$20,000 (currently approximately US$15,000), and to underwrite additional budgeted costs of CAD$20,000 (currently approximately US$15,000). All but US$64,000 of the total consideration has already been incurred and paid for directly or in-kind. The conversion to US dollars above utilizes an exchange rate of US$0.7548 for every CAD$1.00.

The University of Alberta will receive matching funds through a grant from the Canadian Institutes of Health Research in support of the research. The Company will retain the rights to research results and any patentable intellectual property generated by the research. Dr. John Greer, Ph.D., Chairman of the Company's Scientific Advisory

Board and faculty member of the Department of Physiology, Perinatal Research Centre, and Women & Children's Health Research Institute and Alberta Innovates Health Sciences Senior Scientist with the Neuroscience and Mental Health Institute at the University of Alberta, will collaborate on this research. The studies are expected to be completed in 2016.

Duke University Clinical Trial Agreement

On January 27, 2015, the Company entered into a Clinical Study and Research Agreement (the "Agreement") with Duke University to develop and conduct a protocol for a program of clinical study and research at a total cost of $50,579, which was completed in March 2015. On October 30, 2015, the Agreement was amended to provide for certain additional services related to the Company's Phase 2A clinical trial of CX1739. The commencement of this clinical trial was subject to resolution of two deficiencies raised by the FDA in its clinical hold letter issued in November 2015, which were satisfactorily resolved in early 2016, as a result of which the FDA removed the clinical hold on the Company's IND for CX1739 on February 25, 2016, thus allowing for the initiation of the clinical trial. During March 2016, upon receiving unconditional approval from the Institutional Review Board of the Duke Clinical Research Unit, this Phase 2A clinical trial at Duke University School of Medicine was initiated. The Company expects to incur approximately $750,000 of direct costs in 2016 with respect to this clinical trial, and to complete the clinical trial in approximately four months.

Sharp Clinical Services, Inc. Agreement

On August 31, 2015, the Company entered into an agreement with Sharp Clinical Services, Inc. to provide packaging, labeling, distribution and analytical services for the Company with respect to CX1739 at a budgeted cost of $109,833, of which $45,041 of such services is expected to be provided in 2016.

The following table sets forth the Company's principal cash obligations and commitments for the next five fiscal years as of December 31, aggregating $3,641,259.

		Payments Due By Year				
	Total	2016	2017	2018	2019	2020
Research and development contracts	$157,041	$157,041	$-	$-	$-	$-
Clinical trial agreements	558,268	558,268	-	-	-	-
License agreements	500,000	100,000	100,000	100,000	100,000	100,000
Employment and consulting agreements*	2,425,950	1,106,100	754,200	565,650	-	-
Total	$3,641,259	$1,921,409	$854,200	$665,650	$100,000	$100,000

*The payment of such amounts is subject to the Company reaching certain financing milestones, as described above.

Off-Balance Sheet Arrangements

At December 31, 2015, the Company did not have any transactions, obligations or relationships that could be considered off-balance sheet arrangements.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Not applicable for smaller reporting companies.

Item 8. Financial Statements and Supplementary Data

Our financial statements and other information required by this item are set forth herein in a separate section beginning with the Index to Consolidated Financial Statements on page F-1.

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

Not applicable.

Item 9A. Controls and Procedures

Disclosure Controls and Procedures

The Company maintains disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act") that are designed to ensure that information required to be disclosed in the reports that the Company files with the Securities and Exchange Commission (the "SEC") under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to the Company's management, including its Chief Executive Officer and Chief Financial Officer, to allow for timely decisions regarding required disclosures.

The Company carried out an evaluation, under the supervision and with the participation of its management, consisting of its principal executive officer and principal financial officer, of the effectiveness of the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act). Based upon that evaluation, the Company's principal executive officer and principal financial officer concluded that, as of the end of the period covered in this Annual Report on Form 10-K, the Company's disclosure controls and procedures were not effective to ensure that information required to be disclosed in reports filed under the Exchange Act is recorded, processed, summarized and reported within the required time periods and is accumulated and communicated to the Company's management, consisting of the Company's principal executive officer and principal financial officer, to allow timely decisions regarding required disclosure.

The Company failed to complete and file various periodic reports in 2012, 2013 and 2014 in a timely manner because the Company's accounting and financial staff had resigned by October 26, 2012 and its financial and accounting systems had been shut-down at December 31, 2012. Current management, most of which joined the Company in March and April 2013, has been focusing on developing replacement controls and procedures that are adequate to ensure that information required to be disclosed in reports filed under the Exchange Act is recorded, processed, summarized and reported within the required time periods and is accumulated and communicated to the Company's management to allow timely decisions regarding required disclosure. Current management has instituted a program to reestablish the Company's accounting and financial staff and install new accounting and internal control systems, and has retained accounting personnel, established accounting and internal control systems, addressed the preparation of delinquent financial statements, and worked diligently to bring current delinquent SEC filings as promptly as reasonably possible under the circumstances. The Company is now current in its SEC periodic reporting obligations, but as of the date of the filing of this Annual Report on Form 10-K, the Company had not yet completed the process to establish adequate internal controls over financial reporting.

In addition, in July 2015, the Company determined that it had inadvertently omitted to record charges from, and a related liability to, a third party vendor for research and development services rendered during the three months ended March 31, 2015, in part as a result of the delayed receipt of information and invoicing from the vendor. Accordingly, the Company amended its Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2015 to restate its condensed consolidated financial statements as of and for the three months ended March 31, 2015, and to amend the related footnotes and other disclosures included therein. The Company has instituted certain additional internal control procedures to prevent a recurrence of such an event.

The Company's management, consisting of its principal executive officer and principal financial officer, does not expect that its disclosure controls and procedures or its internal controls will prevent all error or fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Furthermore, the design of a control system must reflect the fact that there are resource constraints and the benefits of controls must be considered relative to their costs. Due to the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, have been detected. In addition, as conditions change over time, so too may the effectiveness of internal controls. However, management believes that the financial statements included in this Annual Report on Form 10-K fairly present, in all material respects, the Company's financial condition, results of operations and cash flows for the periods presented.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. Our internal control over financial reporting is designed to ensure that material information regarding our operations is made available to management and the board of directors to provide them reasonable assurance that the published financial statements are fairly presented. There are limitations inherent in any internal control, such as the possibility of human error and the circumvention or overriding of controls. As a result, even effective internal controls can provide only reasonable assurance with respect to financial statement preparation. As conditions change over time so too may the effectiveness of internal controls.

Our management, consisting of our Chief Executive Officer and our Chief Financial Officer, has evaluated our internal control over financial reporting as of December 31, 2015 based on the 2013 Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations ("COSO") of the Treadway Commission. Based on this assessment, and taking into account the operating structure of the Company as it has existed from October 2012 through December 2015, as well as the various factors discussed herein, our management has concluded that material weaknesses in the Company's internal control over financial reporting existed as of December 31, 2015, as a result of which our internal control over financial reporting was not effective at December 31, 2015.

Prior management, which had essentially ceased business operations and was preparing to shut down the Company and cause it to file for liquidation under Chapter 7 of the United States Bankruptcy Code, was replaced on March 22, 2013 in conjunction with the change in control of the Board of Directors on such date. Since that date, new management has instituted a program to reestablish the Company's accounting and financial staff functions, as well as to install new accounting and internal control systems.

Within the constraints of the Company's limited financial resources, new management has retained accounting personnel, established accounting and internal control systems, addressed the preparation of delinquent SEC financial filings, and filed all delinquent SEC filings. As of the date of the filing of this Annual Report on Form 10-K, the Company has not yet completed this process of reestablishing adequate internal controls over financial reporting.

This Annual Report on Form 10-K does not include an attestation report of the Company's independent registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the Company's independent registered public accounting firm pursuant to rules of the SEC that permit the Company to provide only management's report in this Annual Report on Form 10-K.

Changes in Internal Control over Financial Reporting

The Company's management, consisting of its principal executive officer and principal financial officer, has determined that no change in the Company's internal control over financial reporting (as that term is defined in Rules 13(a)-15(f) and 15(d)-15(f) of the Securities Exchange Act of 1934) occurred during or subsequent to the fourth quarter of the year ended December 31, 2015 that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

Item 9B. Other Information

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

Directors

The names of each of the directors and certain biographical information about them are set forth below:

Name	Age	Director Since	Principal Occupation
James S.J. Manuso	67	2015	President, Chief Executive Officer and Vice Chairman of the Company
Arnold S Lippa, Ph.D.	69	2013	Chief Scientific Officer and Chairman of the Board of the Company
Jeff E. Margolis	60	2013	President of Aurora Capital, LLC
Robert N. Weingarten	63	2013	Business and financial consultant and advisor
James Sapirstein, RPh. M.B.A.	54	2014	CEO ContraVir Pharmaceuticals, Inc.
Kathryn MacFarlane, PharmD	50	2014	Owner and Managing Partner of SmartPharma LLC

James S. J. Manuso: Dr. Manuso is the former Chairman of the Board of Directors and Chief Executive Officer of Astex Pharmaceuticals, Inc. (“Astex”) (NASDAQ: ASTX), having served in such positions from July 2011 through October 2013. Dr. Manuso had previously served as the President and Chief Executive Officer, as well as Chairman of the Board of Directors, of Astex (formerly SuperGen, Inc.: NASDAQ: SUPG) from January 2004 to July 2011, and as a director of Astex since February 2001. Dr. Manuso currently serves on the board of directors of privately-held KineMed, Inc. Previously, Dr. Manuso served on the boards of directors of The Biotechnology Industry Organization (BIO) and its Health Section Governing Board, Novelos Therapeutics, Inc. (NVLT.OB; now Cellectar Biosciences, Inc.), Symbiontics, Inc., Quark Pharmaceuticals, Inc., EuroGen, Ltd. (London, UK), where he was chairman, and other industry companies.

We believe that Dr. Manuso’s qualifications to serve on our Board include his position as the Company’s President and Chief Executive Officer, and his experience working in management roles in other pharmaceutical companies as described above, including overseeing the successful efforts to sell Astex for approximately $886 million. In addition

to being knowledgeable regarding public markets, especially in the pharmaceutical industry, Dr. Manuso provides the Board with both technical and scientific expertise in drug discovery and drug development, research management, governmental regulations and strategic planning expertise that is important to the advancement of our research platforms as well as to the overall success of the Company. Dr. Manuso was appointed to our board of directors in August 2015.

Arnold S. Lippa, Ph.D.: Dr. Lippa is a Senior Managing Director and founder of T Morgen Capital LLC through which he administers his family's assets. T Morgen Capital LLC is a significant equity owner and managing member of Aurora Capital LLC ("Aurora"), a boutique investment bank and securities firm of which Mr. Margolis is the president and founder, which has served as a placement agent with respect to the Company's recent financings. Dr. Lippa and Mr. Margolis jointly manage, since 2004, Atypical BioCapital Management LLC and Atypical BioVentures Fund LLC, a life sciences fund management company and venture fund, respectively. Since 2006, Dr. Lippa has also been the Executive Chairman of the board of Xintria Pharmaceutical Corporation, a Delaware corporation, as well as a member of its board of directors. Dr. Lippa was co-founder of DOV Pharmaceutical, Inc., where he served as Chairman of the Board and Chief Executive Officer from its inception in 1995 through 2005. Dr. Lippa stepped down as a director of DOV Pharmaceuticals, Inc. in 2006.

We believe that Dr. Lippa's qualifications to serve on our Board include his position as the Company's Chief Scientific Officer, and his experience working in management roles in other pharmaceutical companies as described above. Dr. Lippa provides the Board with both technical and scientific expertise in drug discovery and drug development, research management, governmental regulations and strategic planning expertise that is important to the advancement of our research platforms as well as to the overall success of the Company. Dr. Lippa was appointed to our board of directors in March 2013.

Jeff E. Margolis: Mr. Margolis is the president and founder of Aurora, and has been since its inception in 1994. Aurora Capital Corp., a corporation wholly owned by Mr. Margolis, is a significant equity owner and managing member of Aurora. Dr. Lippa and Mr. Margolis jointly manage, since 2004, Atypical BioCapital Management LLC and Atypical BioVentures Fund LLC, a life sciences fund management company and venture fund, respectively. Since 2006, Mr. Margolis has also been the Chief Financial Officer of Xintria Pharmaceutical Corporation, a Delaware corporation, as well as a member of its board of directors.

We believe that Mr. Margolis's qualifications to serve on our Board include his significant experience in operational and management roles within pharmaceutical companies as described above. He also has extensive prior experience working in business development and provides the Company with extremely useful expertise in financing and capital markets, knowledge gained though his position as President of Aurora. Mr. Margolis also provides broad financial expertise. Mr. Margolis was appointed to our board of directors in March 2013.

Robert N. Weingarten: Mr. Weingarten is an experienced business consultant and advisor with an ongoing consulting practice. Since 1979 he has provided financial consulting and advisory services to numerous public companies in various stages of development, operation or reorganization. Mr. Weingarten received a B.A. Degree (Accounting) from the University of Washington in 1974, and an M.B.A. Degree (Finance) from the University of Southern California in 1975. Mr. Weingarten is a Certified Public Accountant (inactive) in the State of California. Mr. Weingarten was appointed as a director of Staffing 360, Inc. on February 25, 2014 and resigned this position on April 20, 2014. Mr. Weingarten was the Non-Executive Chairman of New Dawn Mining Corp. ("New Dawn") from August 31, 2005 through September 30, 2010, and was named the Executive Chairman of New Dawn in October 2010. On July 8, 2010, Mr. Weingarten was appointed to the board of directors of Central African Gold Limited (formerly known as Central African Gold Plc and listed on the Alternative Investment Market of the London Stock Exchange at that time). Central African Gold Limited is an indirect, wholly-owned subsidiary of New Dawn. Both New Dawn and Central African Gold Limited have ceased to be publicly traded reporting companies in their respective jurisdictions. Since June 30, 2015, Mr. Weingarten has served as a director of Guardion Health Sciences, Inc., a company that on February 11, 2016 filed a registration statement on Form S-1 with the SEC. Mr. Weingarten is a Certified Public Accountant (inactive) in the State of California.

We believe that Mr. Weingarten's qualifications to serve on our Board include his breadth of experience with public companies, especially those in the development phase and those undergoing restructuring or reorganization. He has also served in managements capacities at other public companies and as a result brings a wealth of experience on financial matters. Mr. Weingarten was appointed to our board of directors in April 2013.

James Sapirstein, RPh. M.B.A.: Mr. Sapirstein has been the Chief Executive Officer and director of ContraVir Pharmaceuticals, Inc., a public reporting company, since March 20, 2014. Prior to joining Contravir, Mr. Sapirstein served as the Chief Executive Officer of Alliqua Biomedical, Inc., a public reporting company. He is considered a start-up and turnaround specialist, with 30 years of pharmaceutical and biotechnology industry experience. He was a founder and Chief Executive Officer and President of Tobira Therapeutics, Inc. from October 2006 to April, 2011, a company that was recently approved for listing on NASDAQ. At Tobira Therapeutics, Inc. Mr. Sapirstein led an experienced biotechnology development team. He has launched several HIV/AIDS agents worldwide during his career in the biotechnology and pharmaceutical industry. Mr. Sapirstein was with Bristol-Myers Squibb from 1996-2000. While at Bristol-Myers Squibb he served as the Head of the International HIV business as well as working in its Infectious Disease marketing teams. In 2002, he accepted the position of Executive Vice President for Serono Laboratories, where he led a team of over 100 professionals in the HIV and pediatric growth hormone business. He had held positions at Gilead Sciences (where he was responsible for the product Viread®), Bristol-Myers Squibb, Hoffmann-LaRoche Ltd. and Eli Lilly and Company. He serves as a member of the Advisory Board at MusclePharm Corp., a public reporting company and a member of the Board of Directors of Clinical Supplies Management, Inc., a private company. He currently serves as an Advisory Board Director at the Fairleigh Dickinson School of Pharmacy. Mr. Sapirstein previously served as a Director of Tobira Therapeutics, Inc. as well as a Director of Alliqua, Inc. He has also previously served as a Director of BioNJ and BIO’s Emerging Company Board. Mr. Sapirstein received his Pharmacy degree from the Ernest Mario School of Pharmacy at the Rutgers University, and his Masters of Business Administration degree from Farleigh Dickinson University.

We believe that Mr. Sapirstein's qualifications to serve on our Board include his experience working in management roles in other biopharmaceutical companies as described above, as well as his service on both public and private boards. Mr. Sapirstein provides the Board with additional technical and scientific expertise in drug discovery and drug development, as well as expertise in all phases of start-ups and turnarounds of biopharmaceutical companies, all of which is important to the advancement of our research platforms as well as to the overall success of the Company. Mr. Sapirstein was appointed to our board of directors in September 2014.

Kathryn MacFarlane, PharmD: Ms. MacFarlane has over 25 years of experience in the pharmaceutical industry, with expertise in marketing, new product planning, and commercialization. Ms. MacFarlane is currently an owner and Managing Partner of SmartPharma LLC, a pharmaceutical consulting firm specializing in commercial consulting for emerging pharmaceutical companies. She also serves as the Chief Commercial Officer at Agile Therapeutics, Inc., a public reporting company, where she played an integral role in two financing rounds and the recent IPO. Her expertise includes market assessment and commercial planning for products in development as well as evaluating products for licensing or acquisition. Her experience spans multiple therapeutic areas including Women's Health, Central Nervous System, Cardiology, Vaccines, and Dermatology. Before joining Agile Therapeutics, Ms. MacFarlane served as President and Chief Executive Officer at Xintria Pharmaceutical Corporation, a private company from 2006 through 2007, a company for which Arnold S. Lippa and Jeff E. Margolis served as officers and directors, and prior to that as Vice President of Women's Health and New Product Planning at Warner Chilcott from 2001 through 2006, now part of Activis plc. Ms. MacFarlane had responsibility for the launches of Lipitor®, Celexa®, and Loestrin® 24. In 1999, she was named a Distinguished Alumna and in 2012, was named the Eaton Entrepreneur of the Year by the Purdue University School of Pharmacy. She has completed a Postdoctoral Fellowship in Industrial Pharmacy Practice with Rutgers University and Hoffmann-LaRoche. Ms. MacFarlane currently serves on the Purdue University School of Pharmacy Dean's Advisory Council and is a Founding Member and Advisor to IPhO. She also serves on the Board of Directors for INMED Partnerships for Children, an NGO dedicated to providing food security and health services to women and children. Ms. MacFarlane received her Bachelor of Science in Pharmacy and Doctor of Pharmacy degrees from Purdue University.

We believe Ms. MacFarlane's qualifications to serve on our Board include both her biopharmaceutical consulting background and her familiarity with the biopharmaceutical regulatory and commercialization environment, as well as the breadth of her technical and therapeutic knowledge, as discussed above. Ms. Macfarlane has also served in numerous senior executive positions at various biopharmaceutical companies. Ms. MacFarlane was appointed to our board of directors in September 2014.

Executive Officers

Each executive officer of the Company serves at the discretion of the Board of Directors. The names of the Company's executive officers are set forth below. At December 31, 2015, each of our executive officers except Richard Purcell was also a member of our board of directors, and the biographical information of those officers appears above in the immediately prior section.

Name	Position with Company
James S.J. Manuso	President, Chief Executive Officer and Vice Chairman
Arnold S. Lippa, Ph.D.	Chief Scientific Officer and Chairman of the Board
Jeff E. Margolis	Vice President, Secretary and Treasurer
Robert N. Weingarten	Vice President and Chief Financial Officer
Richard Purcell	Senior Vice President of Research and Development

Richard Purcell: In addition to his role at the Company, Richard Purcell (Age: 55) is the Acting President & Chief Operating Officer and a director of Cynvec, LLC, a private company. He is also the President and CEO of intelliSantè, Inc., a private company. He is a biopharmaceutical development specialist, with extensive experience in providing consulting services to financial, venture capital, and start-up companies to concentrate on new business strategy and clinical development of novel compounds. Previously, Mr. Purcell was president of ClinPro, Inc., a mid-sized clinical research organization (CRO), where he led this full-service, technology driven CRO specializing in Phase I, II, and III clinical trial management. His work included the design and implementation of a number of early stage clinical development programs. Prior to joining ClinPro, Mr. Purcell worked for SCP Communications, a medical communications company, where he served as Corporate Vice President and General Manager of the Clinical Programs Division. Mr. Purcell previously headed the Life Sciences Consulting Group for Kline and Company. Mr. Purcell started his career as a molecular biologist, where he developed and patented a second generation TPA (tissue plasminogen activator) with increased half-life. He has also conducted primary research and published manuscripts on the topics of AIDS and immunomodulators. Mr. Purcell graduated with a degree in Biochemical Sciences from Princeton University, and attended Rutgers Graduate School of Management focusing in marketing and finance.

Other key personnel

On September 18, 2014, John Greer, Ph.D. was appointed to the position of Chairman of the Company's Scientific Advisory Board. Dr. Greer is a faculty member of the Department of Physiology, Perinatal Research Centre, and Women & Children's Health Research Institute and Alberta Innovates Health Sciences Senior Scientist with the Neuroscience and Mental Health Institute at the University of Alberta. He holds two grants regarding research into neuromuscular control of breathing and is the inventor on the use patents licensed by the Company with respect to ampakines. Dr. Greer is assisting the Company in forming the rest of its Scientific Advisory Board, a process that is ongoing.

BOARD COMMITTEES

The board of directors has historically maintained a standing Audit Committee, Compensation Committee, and Governance and Nominations Committee. Since the changes in the composition of our board of directors on March 22, 2013, the functions of each of the committees described below have been and are currently being addressed by the full board of directors.

***Audit Committee*.** Traditionally, the Audit Committee meets with the Company's independent registered public accountants and management to prepare for and to review the results of the annual audit and to discuss the annual and quarterly financial statements, earnings releases and related matters. The Audit Committee, among other things, (i) selects and retains the independent registered public accountants, (ii) reviews with the independent registered public accountants the scope and anticipated cost of their audit, and their independence and performance, (iii) reviews accounting practices, financial structure and financial reporting, (iv) receives and considers the independent registered

public accountants' comments as to controls, adequacy of staff and management performance and procedures in connection with audit and financial controls, (v) reviews and pre-approves all audit and non-audit services provided to the Company by the independent registered public accountants, and (vi) reviews and pre-approves all related-party transactions. The Audit Committee does not itself prepare financial statements or perform audits, and its members are not auditors or certifiers of the Company's financial statements.

Since the change in composition of our board of directors in March 2013, the composition of an Audit Committee has not been determined, nor has the current board of directors adopted an amended written charter. Company records indicate that the Audit Committee previously operated under a written charter adopted by the previous board of directors. When an Audit Committee is reestablished along with a written charter, such charter will be made available on the Company's website at www.respirerx.com.

Compensation Committee. The traditional functions of the Compensation Committee include, without limitation, administering the Company's incentive ownership programs and approving the compensation to be paid to the Company's directors and executive officers. The Compensation Committee typically meets no less frequently than annually as circumstances dictate to discuss and determine executive officer and director compensation. Historically, the Company's Chief Executive Officer annually reviews the performance of each executive officer (other than the Chief Executive Officer, whose performance is reviewed by the Compensation Committee). The conclusions reached and recommendations based on these reviews, including with respect to salary adjustments and annual award amounts, are presented to the Compensation Committee, who can exercise its discretion in modifying any recommended adjustments or awards to executive officers. The Compensation Committee is entitled to, but generally does not, retain the services of any compensation consultants. Neither the Compensation Committee nor management has engaged a compensation consultant in the past fiscal year. The Compensation Committee has the power to form and delegate authority to subcommittees when appropriate, provided that such subcommittees are composed entirely of directors who would qualify for membership on the Compensation Committee.

Since the change in composition of our board of directors in March 2013, the members of the board of directors have performed the functions of the Compensation Committee and the composition of a Compensation Committee has not been determined nor has the current board of directors adopted a written charter. Company records indicate that the Compensation Committee previously operated under a written charter adopted by the board of directors. When a Compensation Committee is reestablished along with a written charter, such charter will be made available on the Company's website at www.respirerx.com.

Governance and Nominations Committee. The traditional functions of the Governance and Nominations Committee include, without limitation, (i) identifying individuals qualified to become members of the board of directors, (ii) recommending director nominees for the next annual meeting of stockholders and to fill vacancies that may be created by the expansion of the number of directors serving on the board of directors and by resignation, retirement or other termination of services of incumbent directors, (iii) developing and recommending to the board of directors corporate governance guidelines and changes thereto, (iv) ensuring that the board of directors and the Company's Certificate of Incorporation and Bylaws are structured in a way that best serves the Company's practices and objectives, (v) leading the board of directors in its annual review of the board of directors' performance; and (vi) recommending to the board of directors nominees for each committee. Accordingly, the Governance and Nominations Committee annually reviews the composition of the board of directors as a whole and makes recommendations, if deemed necessary, to enhance the composition of the board of directors. The Governance and Nominations Committee first considers a candidate's management experience and then considers issues of judgment, background, conflicts of interest, integrity, ethics and commitment to the goal of maximizing stockholder value when considering director candidates. The Governance and Nominations Committee also focuses on issues of diversity, such as diversity of gender, race and national origin, education, professional experience and differences in viewpoints and skills. The Governance and Nominations Committee does not have a formal policy with respect to diversity; however, the board of directors and Governance and Nominations Committee believe that it is essential that the members of the board of directors represent diverse viewpoints. In considering candidates for the board of directors, the Governance and Nominations Committee considers the entirety of each candidate's credentials in the context of these standards. With respect to the nomination of continuing directors for re-election, the individual's contributions to the board of directors are also considered.

Since the change in composition of our board of directors in March 2013, the members of the board of directors have performed the functions of the Governance and Nominations Committee and the composition of a Governance and Nominations Committee has not been determined nor has the current board of directors adopted a written charter. When a Governance and Nominations Committee is reestablished along with a written charter, such charter will be made available on the Company's website at www.respirerx.com.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires the Company's executive officers and directors and persons who beneficially own more than 10% of the Company's outstanding common stock, whom the Company refers to

collectively as the “reporting persons,” to file reports of ownership and changes in ownership with the SEC, and to furnish the Company with copies of these reports.

Based solely on the Company’s review of the copies of these reports received by it and written representations received from certain of the reporting persons with respect to the filing of reports on Forms 3, 4 and 5, the Company believes that all such filings required to be made by the reporting persons for the fiscal year ended December 31, 2015 were made on a timely basis, except (i) the initial Form 3 and Form 4 in connection with the transfer of Series G preferred stock to the Arnold Lippa Family Trust of 2007, causing it to become a 10% holder on a fully diluted basis, Form 4s in connection with subsequent acquisitions by the Trust or its subsidiaries of certain warrants in connection with various offerings of the Company, and any Form 3 or Form 4 that may be required for any of the beneficial holders listed in Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

Code of Ethics

We have previously adopted a Code of Business Conduct and Ethics, which covers all of our directors and employees, including our principal executive and financial officers. Any amendment to, or waiver from, any applicable provision (related to elements listed under Item 406(b) of Regulation S-K) of our Code of Business Conduct and Ethics that applies to our directors or executive officers will be posted on our website at www.respirerx.com or in a report filed with the SEC on a Current Report on Form 8-K. The Company is in the process of updating its Code of Business Conduct and Ethics. Any amendment or waiver to its Code of Business Conduct and Ethics that applies to its directors or executive officers will be posted on its website at www.respirerx.com and/or filed in a report with the Securities and Exchange Commission on a Current Report on Form 8-K.

Item 11. Executive Compensation

Summary Compensation Table for 2015

The table below summarizes the total compensation paid or earned by each of the named executive officers for the fiscal years ended December 31, 2015 and 2014. The information contained under the heading "All Other Compensation" for all named executive officers includes the estimated value of equity awards using the Black-Scholes option-pricing model and does not reflect actual cash payments or actual dollars awarded.

Name and Principal Position	Year	Salary ($)	Bonus ($)	**Stock Awards ($)(1)**	All Other Compensation ($)(2)	Total ($)
James S. J. Manuso, Ph.D President, Chief Executive Officer and Vice Chairman	2015	146,060	-	1,786,707	-	1,932,767
Arnold S Lippa, Ph.D.	2015	138,197	75,000	461,000	-	674,197
Executive Chairman and Chief Scientific Officer	2014	-	-	818,500	-	818,500
Jeff E. Margolis	2015	95,576	60,000	461,000	-	616,576
Vice President, Secretary and Treasurer	2014	-	-	818,500	-	818,500
Robert N. Weingarten	2015	95,576	60,000	461,000	-	616,576

Vice President, Chief Financial Officer	2014	-	-	818,500	-	818,500

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(1) On June 30, 2015, the Board of Directors of the Company awarded non- qualified stock options with respect to a total of 55,000,000 shares of common stock of the Company, consisting of options for 15,000,000 shares to each of the Company's three executive officers at that time, who were also all of the directors of the Company at that time, and options for 2,000,000 shares to each of five others including the Company's two independent directors. These awards were made with an exercise price ofs $0.0250 per share, as compared to the closing market price of the Company's common stock on such date of $0.0175 per share, reflecting an exercise price premium of $0.0075 per share or 42.9%. These awards were made to those individuals on that date as partial compensation for services rendered through December 31, 2015. During the year ended December 31, 2015, the Company recorded an aggregate charge to operations of $774,000 with respect to these stock options awarded to named executive officers, or $258,000 per individual, reflecting the grant date fair value of the stock options calculated pursuant to the Black-Scholes option-pricing model.

Subsequently, on August 18, 2015, the Company awarded stock options to certain officers and independent directors to purchase an aggregate of 51,000,000 shares of common stock of the Company, consisting of options for 10,000,000 shares to each of the Company's three executive officers at that time (excluding Dr. Manuso who is discussed separately below), who were also all of the directors of the Company at that time, and options for 3,000,000 shares to each of seven others, including the Company's two independent directors. The exercise price of the stock options was established on the grant date at $0.0197 per share, which is equal to the simple average of the most recent four full trading weeks, weekly VWAPs of the Company's common stock price immediately preceding the date of grant as reported by OTC IQ, as compared to the closing market price of the Company's common stock on August 18, 2015 of $0.0216 per share. The stock options were awarded partially as compensation for those individuals through December 31, 2015 and partially as 2016 compensation. During the year ended December 31, 2015, the Company recorded an aggregate charge to operations of $201,510 with respect to these stock options, or $67,170 per individual. The balance of the total aggregate amount of $609,000 ($203,000 per individual) reflecting the grant date fair value of the stock options calculated pursuant to the Black-Scholes option-pricing model, will be recorded as a charge to operations in 2016.

Pursuant to his employment agreement, upon commencement of his employment with the Company, Dr. Manuso received options with respect to 85,081,300 shares of the company, of which 5,081,300 were incentive stock options. The options have a term of 10 years and vest 50% on the Effective Date (as defined in the employment agreement, 25% on the date six months after the Effective Date and 25% on the first Anniversary of the effective date. The exercise price of the stock options was established on the grant date at $0.0197 per share, which is equal to the simple average of the most recent four full trading weeks, weekly Volume Weighted Average Prices ("VWAPs") of the Company's common stock price immediately preceding the date of grant as reported by OTC IQ, as compared to the closing market price of the Company's common stock on August 18, 2015 of $0.0216 per share. During the year ended December 31, 2015, the Company recorded an aggregate charge to operations of $1,223,772 with respect to these stock options. The balance of the total aggregate amount of $1,786,707, reflecting the grant date fair value of the stock options calculated pursuant to the Black-Scholes option-pricing model will be recorded as a charge to operations in 2016.

On April 14, 2014, the Board of Directors of the Company awarded a total of 57,000,000 shares of common stock of the Company, including awards of 15,000,000 shares to each of the Company's three executive officers, who were also all of the directors of the Company at that time, and 4,000,000 shares and 8,000,000 shares to two other individuals. The individual who received the 8,000,000 shares was an associated person of Aurora Capital LLC, a related party. These awards were made to those individuals on that date as compensation for services rendered through March 31, 2014. As the initial closing of the Series G 1.5% Convertible Preferred Stock was completed on March 18, 2014, and such closing represented approximately 81% of the total amount of such financing, the Company's Board of Directors determined that it was appropriate at that time to compensate such officers for the period since they joined the Company in March and April 2013 through March 31, 2014. Such compensation was concluded on April 14, 2014 with the issuance of the aforementioned stock awards. Accordingly, as a result of these factors, the fair value of these stock awards of $2,280,000, $600,000 for each of the executive officers, was charged to operations effective as of March 18, 2014. The stock awards were valued at $0.04 per share, which was the closing price of the Company's common stock on March 18, 2014.

Subsequently the Company awarded stock options to purchase an aggregate of 15,000,000 shares of common stock of the Company, consisting of options for 5,000,000 shares to each of the Company's three executive officers at an exercise price of $0.05 per share, as compared to the closing market price of the Company's common stock on such date of $0.044 per share, reflecting an exercise price premium of $0.006 per share or 13.6%. The stock options were awarded as compensation for those individuals through December 31, 2014. During the year ended December 31, 2014, the Company recorded an aggregate charge to operations of $655,500 with respect to these stock options, or $218,500 per individual, reflecting the grant date fair value of the stock options calculated pursuant to the Black-Scholes option-pricing model.

(2) In accordance with Securities and Exchange Commission rules, "Other Annual Compensation" in the form of perquisites and other personal benefits has been omitted where the aggregate amount of such perquisites and other personal benefits was less than $10,000.

Narrative to Summary Compensation Table

In 2015, bonuses were awarded and accrued, but not paid, to named executive officers in the following amounts as of June 30 2015: Arnold S. Lippa - $75,000, Jeff E. Margolis - $60,000, Robert N. Weingarten - $60,000. No performance bonuses were awarded to the named executive officers for the years ended December 31, 2014.

The options that were awarded to our named executive officers in June 2015 vested in three installments, 50% on June 30, 2015 (at issuance), 25% at September 30, 2015, and 25% at December 31, 2015, and expire on June 30, 2022. The options that were awarded to our named executive officers in August 2015 vest in four equal installments on December 31, 2015, March 31, 2016, June 30, 2016 and September 30, 2016, and expire on August 18, 2022. These awards were made under the Company's 2015 Stock and Stock Option Plan. Accordingly, the options will provide a return to the named executive officer only if the market price of the Company's common stock appreciates over the option term. In 2014, the Company awarded stock options to purchase an aggregate of 15,000,000 shares of common stock of the Company, consisting of options for 5,000,000 shares to each of the Company's three named executive officers at an exercise price of $0.05 per share, as compared to the closing market price of the Company's common stock on such date of $0.044 per share, reflecting an exercise price premium of $0.006 per share or 13.6%.

In connection with the recent changes to our board membership and taking into account the Company's current operating structure and business plans, management is currently reevaluating the compensation policies of the Company and, as a result of that reassessment, and in light of the Company's current financial circumstances, has made departures from the Company's historic compensation policies and will likely make substantial adjustments to such policies, including the termination of such policies, in the future.

On June 30, 2015, the Board of Directors of the Company awarded non- qualified stock options with respect to a total of 55,000,000 shares of common stock of the Company, consisting of options for 15,000,000 shares to each of the Company's three executive officers at that time, who were also all of the directors of the Company at that time, and options for 2,000,000 shares to each of five others including the Company's two independent directors. These awards were made to those individuals on that date as partial compensation for services rendered through December 31, 2015. Subsequently, on August 18, 2015, the Company awarded stock options to certain officers and independent directors to purchase an aggregate of 51,000,000 shares of common stock of the Company, consisting of options for 10,000,000 shares to each of the Company's three executive officers at that time (excluding Dr. Manuso who is discussed separately below), who were also all of the directors of the Company at that time, and options for 3,000,000 shares to each of seven others, including the Company's two independent directors. The stock options were awarded partially as compensation for those individuals through December 31, 2015 and partially as 2016 compensation.

Pursuant to his employment agreement, upon commencement of his employment with the Company, Dr. Manuso received options with respect to 85,081,300 shares of the company, of which 5,081,300 were incentive stock options. The options have a term of 10 years and vest 50% on the Effective Date (as defined in the employment agreement,

25% on the date six months after the Effective Date and 25% on the first Anniversary of the effective date. This award was made to Dr. Manuso on that date as partially as compensation through December 31, 2015 and partially as 2016 compensation.

On April 14, 2014, the board of directors of the Company awarded a total of 57,000,000 shares of common stock of the Company, including awards of 15,000,000 shares to each of the Company's three executive officers, who were also all of the directors of the Company at that time, and 4,000,000 shares and 8,000,000 shares to two other individuals. These awards were made to those individuals on that date as compensation for services rendered through March 31, 2014. Subsequently, on July 17, 2014, the Board approved an award to each of these named executive officers of options to purchase 5,000,000 shares of the company's common stock, as described above, in compensation for the balance of 2014 following the stock award.

Outstanding Equity Awards at Fiscal Year-End

The following table shows information concerning outstanding equity awards at December 31, 2015, made by The Company to its named executive officers.

	Option Awards				
Name	**Number of Securities Underlying Unexercised Options Exercisable (#)**	**Number of Securities Underlying Unexercised Options Unexercisable (#)**	**Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)**	**Option Exercise Price ($)**	**Option Expiration Date**
James S. D. Manuso	42,540,650	0	42,540,650	$0.0197	8/18/25
Arnold S. Lippa	15,000,000	0			