RespireRx Pharmaceuticals Inc.
Form 10-K
April 17, 2018

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, 2017

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)

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, a smaller reporting company or an emerging growth company. See the definitions of “large accelerated filer,” “accelerated filer,” “smaller reporting company” and “emerging growth company” in Rule 12b-2 of the Exchange Act.

Large accelerated filer [ ] Accelerated filer [ ] Non-accelerated filer [ ] Smaller reporting company [X] Emerging growth co
(Do not check if a smaller reporting company)

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

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

The aggregate market value of the voting stock held by non-affiliates as of June 30, 2017 was approximately $3,567,000 (based on the closing sale price of the common stock as reported by the OTC QB) on June 30, 2017.

As of March 31, 2018, there were 3,123,332 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 of RespireRx Pharmaceuticals Inc. (“RespireRx” or the “Company”) 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 the Company intends that such forward-looking statements be subject to the safe harbor 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.” These might include statements regarding the Company’s future plans, targets, estimates, assumptions, financial position, business strategy and other plans and objectives for future operations, and assumptions and predictions about research and development efforts, including, but not limited to, preclinical and clinical research design, execution, timing, costs and results, future product demand, supply, manufacturing, costs, marketing and pricing factors are all forward-looking statements.

In some cases, forward-looking statements may be identified by words including “anticipates,” “believes,” “intends,” “estimates,” “expects,” “plans,” “contemplates,” “targets,” “continues,” “budgets,” “may” and similar expressions include, but limited to, statements regarding (i) future research plans, expenditures and results, (ii) potential collaborative arrangements, (iii) the potential utility of the Company’s 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 the Company’s 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 the Company’s control. Although the Company believes 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 the Company or any other person that the Company’s objectives or plans will be achieved.

Factors that could cause or contribute to such differences include, but are not limited to, regulatory policies or changes thereto, available cash, research and development results, competition from other similar businesses, and market and general economic factors.

For more information about the risks and uncertainties the Company faces, 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. The Company does not undertake and specifically declines 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 sleep apneas and respiratory depression produced by drugs and neural damage, 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.

There is a substantial unmet need for new drug treatments for breathing disorders. According to a study commissioned by the American Academy of Sleep Medicine, published in August 2016 ("AASM Commissioned Study"), there are approximately 29.4 million adults with obstructive sleep apnea, of whom 5.9 million are diagnosed. Sleep apnea places a considerable burden on society and the health care system because of its association with co-morbidities and adverse events ranging from vehicular (for example: cars, trucks, trains, buses) and industrial accidents, and loss of productivity to increased risk of cardiopulmonary illness and related death. According to the AASM Commissioned Study, the estimated overall cost of obstructive sleep apnea in the United States in 2015 was $162 billion, of which $12.4 billion relates to diagnosis and treatment and the balance relates to all other categories. 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 which is a form of apnea. 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 opioid antagonists such as 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 opioids. 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 and respiratory failure is the most common cause of death. In both of these indications, symptomatic treatment for the respiratory depression is severely lacking.

Accordingly, there is a considerable need for pharmaco-therapeutic 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 neurological indications, such as spinal injury and Pompe Disease. 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 treatment.

The most common type of sleep apnea is obstructive sleep apnea ("OSA"), which occurs by 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 patient compliance with CPAP devices is extremely low. Alternative treatments include surgical intervention, dental appliances, hypoglossal nerve stimulation (via surgical implant) and other physical interventions. Given the large patient population and the limited 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 patients taking chronic opioids and in heart failure patients and is a major correlate for mortality in these 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.

Cannabinoids

RespireRx is developing dronabinol, a synthetic derivative of a naturally occurring substance in the cannabis plant, otherwise known as Δ9-THC or Δ9-tetrahydrocannabinol, for the treatment of OSA which is discussed above. OSA has been linked to increased risk for hypertension, heart failure, depression, and diabetes. There are no approved drug treatments for OSA.

RespireRx holds the exclusive world-wide license to a family of patents for the use of cannabinoids, a family of compounds found naturally in the cannabis plant, including the synthetic cannabinoid dronabinol, in the treatment of sleep disordered breathing from the University of Illinois at Chicago ("UIC"). In addition, RespireRx has several extensions and pending applications that, if issued, will extend patent protection for over a decade. With approximately $5 million in funding from the National Heart, Lung and Blood Institute of the National Institutes of Health, UIC completed a Phase 2B multi-center, double-blind, placebo-controlled clinical trial of dronabinol in patients with OSA. Entitled **P**harmacotherapy of **A**pnea with **C**annabimimetic **E**nhancement ("PACE"), this study replicated an earlier Phase 2A RespireRx sponsored clinical trial and demonstrated statistically significant improvements in respiration, daytime sleepiness, and patient satisfaction after administration of dronabinol and is discussed in more detail below.

RespireRx believes that the most direct route to commercialization is to proceed directly to a Phase 3 pivotal trial using the currently available dronabinol formulation (2.5, 5 and 10 mg gel caps) and to then commercialize a RespireRx branded dronabinol capsule ("RBDC").

The Company also believes that there are numerous opportunities for reformulation of dronabinol to produce a second generation proprietary, branded product for the treatment of OSA with an improved profile. Therefore, simultaneously with its development of the RBDC, RespireRx plans to develop a proprietary dronabinol formulation to optimize the dose and duration of action for treating OSA.

RespireRx initiated its dronabinol program when it acquired 100% of the issued and outstanding equity securities of Pier Pharmaceuticals, Inc. ("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 OSA and had been engaged in research and clinical development activities.

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.

Through the merger, RespireRx gained access to a 2007 Exclusive License Agreement (as amended, the "Old License") that Pier had entered into with the University of Illinois on October 10, 2007. The Old License covered certain patents and patent applications in the United States and other countries claiming the use of cannabinoids, including dronabinol, for the treatment of sleep-related breathing disorders (including sleep apnea).

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 505(b)(2) new drug application, an efficient regulatory pathway.

The Old License was terminated effective March 21, 2013, due to the Company's failure to make a required payment. Subsequently, current management opened negotiations with the University of Illinois, and as a result, the Company entered into a new license agreement (the "2014 License Agreement") with the University of Illinois on June 27, 2014, the material terms of which were similar to the Old License.

Similar to the Old License, the 2014 License Agreement grants the Company, among other provisions, exclusive rights: (i) to practice certain patents and patent applications, as defined in the 2014 License Agreement, that are 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 2014 License Agreement, subject to the provisions of the 2014 License Agreement. The Company is required under the 2014 License Agreement, among other terms and conditions, to pay the University of Illinois a license fee, royalties, patent costs and certain milestone payments.

On November 30, 2017, the Company announced the publication by the principal investigators, Dr. Phyllis Zee of Northwestern University and Dr. David Carley of the University of Illinois at Chicago, in the peer-reviewed journal SLEEP, the official publication of the Sleep Research Society, of the positive results of the potentially pivotal, PACE (Pharmacotherapy of Apnea by Cannabimimetic Enhancement) Phase 2B OSA clinical trial, that was fully funded by the National Institutes of Health. The results from PACE were published in the journal Sleep Vol. 41. No. 1, 2018. The results of the PACE clinical trial were previously presented by Dr. Carley at the SLEEP 2017 annual meeting in June 2017. In the PACE trial, dronabinol significantly improved the primary outcome measures of Apnea Hypopnea Index (“AHI”), daytime sleepiness as measured by the Epworth Sleepiness Scale (“ESS”), and overall patient satisfaction as measured by the Treatment Satisfaction Questionnaire for Medications (“TSQM”).

The recently completed PACE trial was a fully-blinded, two-center, Phase II, randomized placebo-controlled trial of dronabinol in 56 adult patients with moderate to severe OSA. By random assignment, 56 adult subjects with BMI<45, Epworth Sleepiness Scale (ESS)>7 and PSG-documented AHI between 15 and 50 received either placebo (N=17), 2.5mg (N=19) or 10.0mg (N=20) of dronabinol daily, one hour before bedtime for 6 weeks. Repeat in- laboratory PSG followed by maintenance of wakefulness (MWT) testing was completed every 2-weeks during the treatment period. At each visit, the ESS and Treatment Satisfaction Questionnaire for Medications also were completed.

Overall, baseline AHI was 26.0±11.6 (SD) and this was equivalent among all treatment groups. In comparison to placebo, statistically significant end of treatment declines in AHI were observed for both the 2.5 and 10 mg doses (-9.7±4.1, p=0.02 and -13.2±4.0, p=0.001, respectively). Statistically significant declines in ESS were observed for subjects receiving 10 mg dronabinol (-4.0±0.8 units, p=0.001) but not those receiving 2.5 mg or placebo. Subjects receiving 10 mg dronabinol also expressed the greatest overall satisfaction with treatment (p=0.02).

The PACE trial enrolled 73 subjects of which 56 were evaluable with moderate to severe OSA who met all inclusion and exclusion criteria for the study. At baseline, overall apnea/hypopnea index (AHI) was 25.9±11.3, Epworth Sleepiness Scale score (ESS) was 11.45±3.8, maintenance of wakefulness test (MWT) mean latency was 19.2±11.8 min, body mass index (BMI) was 33.4±5.4 kg/m2 and age was 53.6±9.0 years. Subjects were randomized to receive placebo, 2.5 mg or 10 mg dronabinol. Randomized subjects completed daily self-administration of study drug for 6 weeks, and returned to the laboratory every 2 weeks for overnight polysomnography (PSG), physical examination, and completion of clinical study procedures.

Subjects receiving 10mg/day of dronabinol expressed the highest overall satisfaction with treatment (p=0.04). In comparison to placebo, dronabinol dose-dependently reduced AHI by 10.7±4.4 (p=0.02) and 12.9±4.3 (p=0.003) events/hour at doses of 2.5 and 10 mg/day, respectively. Dronabinol at 10 mg/day reduced ESS score by -3.8±0.8 points from baseline (p<0.0001) and by -2.3±1.2 points in comparison to placebo (p=0.05). Body weights, MWT sleep latencies, gross sleep architecture and overnight oxygenation parameters were unchanged from baseline in any treatment group. The number and severity of adverse events, and treatment adherence (0.3±0.6 missed doses/week) were equivalent among all treatment groups.

Drug-induced Respiratory Depression or Drug-induced apnea

Drug-induced respiratory depression ("RD") or drug-induced apnea 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. According to data from the National Center for Health Statistics, 48 million surgical inpatient procedures were performed in the United States in 2009. It is notable that, according to the HealthGrades Inc. Patient Safety in American Hospitals Study released in 2011, post-operative respiratory failure produces the third highest number of patient safety events, the fourth highest mortality rate, and the second largest overall excess cost to the Medicare system, when compared to other patient safety indicators. The Company believes that, in these patients, the major risk factor for the appearance of RD is a history of sleep apnea.

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. In post-surgical patients taking opioids for pain management, sleep apnea is a major risk factor for the occurrence of RD. If patients with sleep apnea are receiving combination therapies, they are at even higher risk for complications and extended hospital stays.

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 due to normal outpatient pain management, 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. In patients chronically consuming opioids, CSA is a major correlate for overdose and most likely represents an early and sensitive form of opioid induced RD. In August 2017, the Centers for Disease Control and Prevention ("CDC") reported that approximately 42,000 people died in 2016 from opioid overdoses, including prescription opioids and illegally made fentanyl and heroin. The CDC reported that the common prescription drugs involved in overdoses were methadone, oxycodone (such as OxyContin®) and hydrocodone (such as Vicodin®). In 2016, the CDC reported that 40% of all US opioid deaths involved a prescription opioid. There were 13,000 heroin deaths in 2015. There are two types of fentanyl, pharmaceutical fentanyl used to manage acute and chronic pain and non-pharmaceutical fentanyl that is illicitly manufactured and is often mixed with heroin or cocaine. The CDC also reported that most of the increases in fentanyl deaths involved the illicit fentanyl and not the pharmaceutical fentanyl.

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Drug Abuse

On January 19, 2016, the Company announced that that it had 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 is evaluating the compounds using pharmacologic, pharmacokinetic and toxicologic protocols to determine the potential effectiveness of the ampakines for the treatment of drug abuse and addiction. The Company retains all intellectual property as well as proprietary and commercialization rights to the Company's compounds. Initial studies focus on cocaine and methamphetamine addiction and abuse and are contracted to outside testing facilities and/or government laboratories, with all costs paid by NIDA. In experiments conducted by NIDA, CX717 antagonized the stimulatory effects of methamphetamine. NIDA is in the process of testing CX717 on the interoceptive effects (determinants of addiction liability) of both cocaine and methamphetamine in models of drug discrimination in rats.

Ampakines

RespireRx is developing a class of proprietary compounds known as ampakines, a term used to designate their actions as positive allosteric modulators of the alpha-amino-3-hydroxy-5-methyl-4-isoxazolepropionic acid ("AMPA") glutamate receptor. Ampakines are small molecule compounds that enhance the excitatory actions of the neurotransmitter, glutamate at the AMPA receptor complex, which mediates most excitatory transmission in the central nervous system ("CNS"). These drugs do not have agonistic or antagonistic properties but instead modulate the receptor rate constants for transmitter binding, channel opening, and desensitization

Through an extensive translational research effort from the cellular level through Phase 2 clinical trials, the Company has developed a family of ampakines, including CX717, CX1739 and CX1942 that have clinical application in the treatment of CNS-driven respiratory disorders, neurobehavioral disorders, spinal cord injury, neurological diseases, and orphan indications. In particular, we are addressing CNS-driven respiratory disorders that affect millions of people, but for which there are few treatment options and no drug therapies, including opioid induced respiratory disorders, such as apnea (transient cessation of breathing) and hypopnea (transient reduction in breathing). When these symptoms become severe, as in opioid overdose, they are the primary cause of opioid lethality. In addition, we are developing our ampakines for the treatment of disordered breathing and motor impairment resulting from spinal cord injury.

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 do 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, their actions as ampakines and their use in the treatment of various disorders. Patents claiming a family of chemical structures, including CX1739 and CX1942, as well as their use in the treatment of various disorders, extend through at least 2028. Additional patents claiming a family of chemical structures, including CX717, as well as their use in the treatment of various disorders, expired in 2017 in the U.S. and will expire in 2018 internationally. The Company is developing potential market exclusivity strategies for CX717 which may include new patent applications and identifying market opportunities and strategies that may provide exclusivity without patents.

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, including drug induced respiratory depression. These patents extend through at least 2028 and, 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 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.

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Despite the loss in 2017 and impending loss in 2018, of U.S. patents and international patents claiming composition-of-matter and certain non-respiratory uses for CX717, the Company believes that CX717 stills retains considerable value as a potential, commercial product, for the following reasons. The Company owns or controls patents claiming the use of CX717 for the treatment of various respiratory disorders that are in effect in the United States and elsewhere at least through 2028, 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 for six months. In nine Phase 1 and Phase 2 clinical studies, CX717 was safe and well tolerated. CX717 has demonstrated the ability to antagonize the respiratory effects of fentanyl, a potent opioid, in two clinical trials, demonstrating target site engagement as well as proof of principle. Promising results also have been observed in clinical trials of attention deficit hyperactivity disorder and cognition. Finally, while CX717 was put on temporary clinical hold by the FDA due to potential neurotoxicity, this hold was completely removed and the Company was allowed to re-initiate clinical trials. This lifting of the clinical hold resulted from the Company obtaining what it believes to be conclusive data showing that the presumed neurotoxicity observed after administration of very high doses of CX717 results from a post-mortem artifact. On December 18, 2017, the Company announced that a paper detailing the neurobiologic safety of CX717 had been accepted for publication by Toxicological Sciences, the Journal of the American Society of Toxicology. The paper, co-authored by RespireRx scientists in conjunction with expert pathologists from around the country who contributed to an extensive neuropathology research program, presents clear scientific evidence that vacuoles that were discovered upon histological evaluation of brain tissue samples from animals treated with high doses of CX717, and which halted the company’s promising CX717 clinical development effort, were actually an artifact of tissue processing rather than a toxic drug effect.

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 50 mg to 1200 mg was linear and predictable, with an approximate half-life of 8 hours.

The Company filed an IND with the FDA in September 2015 to conduct a randomized, double-blind, placebo-controlled, crossover, Phase 2A study of CX1739 (300 mg) versus placebo, followed by dose escalation of CX1739 to 600 and 900 mg, with open-label administration of the IV opioid remifentanil in approximately 18 healthy subjects to assess the ability of CX1739 to antagonize the respiratory depressive effect of remifentanil without altering the analgesic effect of the opioid. The clinical protocol was designed to evaluate the safety and efficacy of CX1739 to antagonize respiratory depression in two models of opioid use and abuse. During REMI-INFUSION, a model of chronic (steady state) opioid use, respiration, pain, pulmometry, and safety were measured during a 30-minute intravenous infusion of remifentanil that produced stable blood levels. During REMI-BOLUS, a model of acute, intravenous opioid overdose, a single, intravenous bolus injection of remifentanil was administered at a dose calculated to achieve significant respiratory depression.

On each study day, REMI-BOLUS was initiated with an intravenous, bolus injection of remifentanil 3 hours after subjects received either placebo or CX1739. Respiration was measured for 20 minutes and then compared to the baseline respiration recorded 5 minutes prior to the bolus injection. REMI-INFUSION was initiated 3.5 hours after placebo or CX1739, with an intravenous infusion protocol designed to maintain stable remifentanil blood levels and

calculated to produce approximately 50% respiratory depression. The ClinicalTrials.gov identifier is NCT02735629.

The commencement of this clinical trial was subject to the 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, 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. In March 2016, upon Institutional Review Board approval, the trial was initiated at the Duke Clinical Research Unit, Duke University Medical Center, Durham NC. The dosing and data acquisition phase of the clinical trial was completed in June 2016 and the clinical trial was formally completed on July 11, 2016.

On September 12, 2016, the Company announced preliminary top-line analysis of safety and efficacy data from this clinical trial. On October 3, 2016, the Company discovered an error in the preliminary data reported to it and accordingly, on October 4, 2016, the Company issued a press release retracting the efficacy data contained in the September 12, 2016 press release. On December 15, 2016, the Company announced the corrected results of the trial, and presented the re-analyzed data, as follows.

During REMI-INFUSION, the model of chronic opioid use, CX1739 antagonized the respiratory rate depression produced by remifentanil, with statistically significant effects observed at 300 mg ($p<.005$) and 900 mg ($p<.001$). The antagonism produced by the 600 mg dose did not achieve statistical significance. This lack of a linear, dose response effect is not unusual in early stage clinical trials. During this period, CX1739 did not alter the analgesic and sedative effects of remifentanil. During REMI-BOLUS, the model of IV opioid overdose, CX1739 treatment did not prevent respiratory depression, or improve time to recovery at any of the doses tested.

Overall, CX1739 was found to be safe and well tolerated, both prior to and during administration of remifentanil. Treatment-related adverse events ("AEs") for the various doses of CX1739 were mild, with an incidence comparable to that reported for placebo. The great majority of AEs occurred after remifentanil administration, including nausea and vomiting, which are common side effects associated with opioid administration.

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 a Small Business Innovation Research 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 Dr. David Fuller of the University of Florida, studies with RespireRx's ampakines have determined that these compounds improve breathing in animal models of spinal cord injury and Pompe Disease.

Development Goals

To achieve our short-and long-term development goals, as well as to provide for our day-to-day operations, we will need additional capital, the availability of which is subject to uncertainly. Should sufficient financing be available, the Company's short-term development goals consist of the following:

1. The Company intends to have a pre-IND meeting with the FDA in order to identify a Phase 3 plan, a clear pathway for the commercial development of dronabinol for the treatment of OSA, which also may include a request for some form of an accelerated review.

2.

After establishing a clear development strategy, the Company intends to execute a Phase 3 clinical study of dronabinol for the treatment of OSA.

3. The Company intends to initiate a multi-center clinical trial investigating the ability of CX717 or CX1739 to improve breathing in patients with spinal cord injury. Assuming FDA allowance and appropriate approvals by institutional review boards, we intend to have this study conducted at the University of Miami, the University of Florida, the Detroit Medical Center and the Detroit Veterans Administration Hospital.

4. Upon issuance of the final clinical report of the CX1739 Phase 2A trial, the Company intends to seek FDA allowance to conduct a Phase 2 clinical trial investigating the safety and efficacy of CX1739 in chronic opioid patients who have central apnea.

The Company believes that these goals can be achieved in a timely and cost-effective manner. To meaningfully advance any of the above goals, however, the Company must secure sufficient additional financing or enter into one or more arrangements with strategic partner(s). Although the Company is engaged in a number of discussions with potential strategic partners and is periodically involved in financing activities, the Company has not entered into a strategic partnership and does not have sufficient financing resources to pursue these goals, and can provide no assurance that available or future sources of financing or a strategic partner will be secured to enable the Company to pursue or achieve these goals.

See "Risk Factors—*Risks related to our business*—We will need additional capital in the near term and 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."

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 Phase 3 or pivotal 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 such as the filing for an NDA under Section 505(b)(2). Another example would be a Supplementary NDA (“SNDA”). A third example would be an Abbreviated NDA (“ANDA”) claiming bio-equivalence to an already approved drug and claiming the same indications such as in the case of generic drugs. Other opportunities allow for accelerated review and approval based upon several factors, including potential fast-track status for serious medical conditions and unmet medical needs, potential breakthrough therapy designation of the drug for serious conditions where preliminary evidence shows that the drug may show substantial improvement over available therapy 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*—We are at an early stage of development and we may not be able to successfully develop and commercialize our products and technologies."

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, 2017 and as of the date of filing of this Annual Report on Form 10-K, the Company employed four people (all officers), three of whom were full time. The Company also engages certain contractors who provide

substantial services to the Company. In February 2017, one employee (officer), the Company's Chief Financial Officer resigned, and his responsibilities were subsequently assigned to one of the remaining officers.

Technology Rights

University of Illinois License Agreement

Through the merger with Pier, the Company gained access to the Old License that Pier had entered into with the University of Illinois on October 10, 2007. The Old License 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 Old License 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 Old License. In exchange for certain milestone and royalty payments, patent costs and license fees, the 2014 License Agreement grants the Company (i) exclusive rights to several issued and pending patents, 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.

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 any expected to be due in the near future.

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 (approximately US$108,000), consisting of approximately CAD$85,000 (approximately US$63,000) of personnel funding in cash in four installments during 2016, to provide approximately CAD$21,000 (approximately US$16,000) in equipment, to pay patent costs of CAD$20,000 (approximately US$15,000), and to underwrite additional budgeted costs of CAD$20,000 (approximately US$15,000). As of December 31, 2017, the Company had recorded amounts payable in respect to this Research Contract of US$16,207 (CAD$21,222) which amount was paid in US dollars on January 24, 2018. The conversion to US dollars above utilizes an exchange rate of approximately US$0.76 for every CAD$1.00.

The University of Alberta received matching funds through a grant from the Canadian Institutes of Health Research in support of this research. The Company retains the rights to research results and any patentable intellectual property generated by the research. Dr. John Greer, Ph.D., faculty member of the Department of Physiology, Perinatal Research Centre, and Women & Children’s Health Research Institute at the University of Alberta, collaborated on this research. The studies were completed in 2016. Any patentable intellectual property developed in the Research Agreement will be covered by the existing license agreement described above.

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, 2017 and 2016.

Research and Development Expenses

The Company invested $1,731,565 and $3,176,197 in research and development in 2017 and 2016, respectively. Of those amounts, $633,088 and $1,646,092 were incurred with related parties in 2017 and 2016 respectively. See our consolidated financial statements for the years ended December 31, 2017 and 2016 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, 2017 and 2016 and our statements of operations, stockholders' equity (deficiency), and cash flows for the years ended December 31, 2017 and 2016, 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, 2017, we have generated only minimal operating revenues. For the fiscal year ended December 31, 2017, our net loss was $4,291,483 and as of December 31, 2017, we had an accumulated deficit of $161,802,262. For the year ended December 31, 2016, our net loss was $9,229,760 and as of December 31, 2016, we had an accumulated deficit of $157,510,779. 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 continue to incur significant net losses over the next several years. As with other biotechnology companies, it is possible that we will never achieve profitable operations.

We will need additional capital in the near term and 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, 2017, we estimated that our existing cash resources will not be sufficient to meet our requirements for 2018. We also need additional capital in the near term to fund on-going operations including basic 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 funding or other 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. 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.

Through the merger with Pier, the Company gained access to a 2007 Exclusive License Agreement (as amended, the "Old License"), that Pier had entered into with the University of Illinois on October 10, 2007. The Old License 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 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 Old License 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 Old License 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.

On May 8, 2007, the Company entered into a license agreement with The Governors of the University of Alberta, 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.

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.

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 cannabinoid products and ampakine 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 those described above under PART I. Item 1. Business-Development Goals.

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 strategic partners if we do.

We are seeking pharmaceutical company partners to participate with us in the development of major indications for the cannabinoids and ampakine compounds. 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.

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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, some of which have been converted or exercised, 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 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 cannabinoid or ampakine 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, and our competitors may develop products that are superior to those 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. In particular, 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) James S. Manuso, Ph.D., our President and Chief Executive Officer since 2015 who succeeded Dr. Lippa in those roles, Jeff E. Margolis, our Vice President, Treasurer and Secretary, and Richard Purcell, our Senior Vice President of Research and development. 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 prospects. Additionally, in February 2017, Robert N. Weingarten resigned as our Chief Financial Officer and member of our Board of Directors, although he remains a consultant to the Company. Jeff E. Margolis has been appointed Chief Financial Officer. There can be no assurance that we will be able to attract and retain a qualified long-term replacement for Mr. Weingarten.

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, 2017 and 2016, as quoted on the OTC QB, was $0.80 to $4.20 and $1.50 to $12.34, respectively as adjusted for our 325-to-1 reverse stock split, effective September 1, 2016. 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, 2017, we had 3,065,261 shares of our common stock outstanding.

If all warrants and options outstanding as of December 31, 2017 are exercised prior to their expiration, up to 5,460,582 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.

In 2014, we issued shares of our Series G 1.5% Convertible Preferred Stock, which were convertible into shares of our common stock (see Note 6 to our consolidated financial statements for the years ended December 31, 2017 and 2016). On November 5, December 9 and December 31, 2014, and again on February 2, 2015 we issued convertible notes and warrants that are convertible and exercisable, respectively, into shares of our common stock (see Note 6 to our consolidated financial statements for the years ended December 31, 2017 and 2016). We may in the future issue additional equity or equity-based securities. All of our Series G 1.5% Convertible Preferred Stock had converted to common stock by April 17, 2016, and some of our convertible notes and related warrants have converted into or been exercised for common stock, and any unexercised warrants associated with our unconverted convertible notes have expired. As of December 31, 2017, however, there were remaining outstanding convertible notes totaling $374,646 of principal and accrued interest that may convert into 32,941 shares of common stock. If we issue additional equity or equity-based securities, the number of shares of our common stock outstanding could increase substantially, 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.

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, allows the Board of Directors of the Company, referred to as the Board or Board of Directors, to issue, as of December 31, 2017, up to 5,000,000 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, 2017, the Company did not own any real property or maintain any leases with respect to real property. The Company periodically contracts for services provided at the facilities owned by third parties and may, from time-to-time, have employees who work in these facilities.

Item 3. Legal Proceedings

By letter dated February 5, 2016, the Company received a demand from a law firm representing a professional services vendor of the Company alleging an amount due and owing for unpaid services rendered. On January 18, 2017, following an arbitration proceeding, an arbitrator awarded the vendor the full amount sought in arbitration of $146,082. Additionally, the arbitrator granted the vendor attorneys' fees and costs of $47,937. All such amounts have been accrued at December 31, 2017.

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, 2017 and 2016—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, 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 closing prices of the common stock furnished by the OTC QB for the fiscal years ended December 31, 2017 and 2016. The quotations on the OTC QB reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not necessarily represent actual transactions. The prices shown in the table below have been conformed to reflect the Company's 325-to-1 reverse stock split, which was effective September 1, 2016.

	High	Low
Fiscal Year ended December 31, 2017		
Fourth Quarter	$2.10	$0.80
Third Quarter	2.00	0.95
Second Quarter	3.79	1.80
First Quarter	4.20	2.80
Fiscal Year ended December 31, 2016		
Fourth Quarter	$4.25	$1.50
Third Quarter	12.01	3.00
Second Quarter	8.12	4.97
First Quarter	12.34	3.31

As of December 31, 2017, there were 90 stockholders of record of our common stock, and approximately 1,200 beneficial owners. The high and low sales prices for our common stock on December 29, 2017, as quoted on the OTC QB market, were 1.35 and $1.03, 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, 2017, we did not repurchase any of our securities. During the fiscal year ended December 31, 2016, we did not repurchase any of our securities, except in connection with our 325-to-1 reverse stock split in which we provided cash in lieu of issuing fractional shares, for a total of $1,298 in the aggregate.

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. Throughout this section, references to number of shares, share price and exercise price have generally been conformed to reflect the effects of the Company's 325-to-1 reverse stock split, effective September 1, 2016.

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, now are being developed by the Company for the treatment of a variety of breathing disorders, particularly sleep apneas and respiratory depression produced by drugs and neural damage.

This focus on respiratory disorders provided the impetus for RespireRx's acquisition of, Pier Pharmaceuticals, Inc. ("Pier") in August 2012. The acquisition of Pier added the dronabinol cannabinoid program for obstructive sleep apnea described below.

The Company underwent a change in management in March 2013, and since then the Company's current management has continued 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 the discovery and development of innovative pharmaceuticals for the treatment of respiratory disorders.

There is a substantial unmet need for new drug treatments for breathing disorders. According to a study commissioned by the American Academy of Sleep Medicine, published in August 2016 ("AASM Commissioned Study"), there are approximately 29.4 million adults with obstructive sleep apnea, of which 5.9 million are diagnosed. Sleep apnea places a considerable burden on society and the health care system because of its association with co-morbidities and adverse events ranging from vehicular (for example: cars, trucks, trains, buses) and industrial accidents, loss of productivity to increased risk of cardiopulmonary illness and related death. According to the AASM Commissioned Study, the estimated overall cost of obstructive sleep apnea in the United States in 2015 was $162 billion, of which $12.4 billion relates to diagnosis and treatment and the balance relates to all other categories. 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 which is a form of apnea. 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 opioid antagonists such as 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 opioids. 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 and respiratory failure is the most common cause of death. In both of these indications, symptomatic treatment for the respiratory depression is severely lacking.

Accordingly, there is a considerable need for pharmaco-therapeutic 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 neurological indications, such as spinal injury and Pompe Disease. 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 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 patient compliance with CPAP devices is extremely low. Alternative treatments include surgical intervention, dental appliances, hypoglossal nerve stimulation (via surgical implant) and other physical interventions. Given the large patient population and the limited 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 patients taking chronic opioids and in heart failure patients and is a major correlate for mortality in these 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.

Cannabinoids

RespireRx is developing dronabinol, a synthetic derivative of a naturally occurring substance in the cannabis plant, otherwise known as Δ9-THC or Δ9-tetrahydrocannabinol, for the treatment of OSA, a serious respiratory disorder that impacts an estimated 30 million people in the United States. OSA has been linked to increased risk for hypertension, heart failure, depression, and diabetes, and has an annual economic cost of $162 billion according to the American Academy of Sleep Medicine. There are no approved drug treatments for OSA.

RespireRx holds the exclusive world-wide license to a family of patents for the use of cannabinoids, a family of compounds found naturally in the cannabis plant, including the synthetic cannabinoid dronabinol, in the treatment of sleep disordered breathing from the University of Illinois at Chicago ("UIC"). In addition, RespireRx has several extensions and pending applications that, if issued, will extend patent protection for over a decade. With approximately $5 million in funding from the National Heart, Lung and Blood Institute of NIH, UIC recently completed a Phase 2B multi-center, double-blind, placebo-controlled clinical trial of dronabinol in patients with OSA. Entitled **P**harmacotherapy of **A**pnea with **C**annabimimetic **E**nhancement ("PACE"), this study replicated an earlier Phase 2A RespireRx sponsored clinical trial and demonstrated statistically significant improvements in respiration, daytime sleepiness, and patient satisfaction after administration of dronabinol. The results from PACE were published in the journal Sleep Vol. 41. No. 1, 2018.

RespireRx believes that the most direct route to commercialization is to proceed directly to a Phase 3 pivotal trial using the currently available dronabinol formulation (2.5, 5 and 10 mg gel caps) and to then commercialize a RespireRx branded dronabinol capsule (RBDC).

The Company also believes that there are numerous opportunities for reformulation of dronabinol to produce a second generation proprietary, branded product for the treatment of OSA with an improved profile. Therefore, simultaneous with its development of the RBDC, RespireRx plans to develop a proprietary dronabinol formulation to optimize the dose and duration of action for treating OSA.

RespireRx initiated its dronabinol program when it 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 OSA and had been engaged in research and clinical development activities.

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.

Through the merger, RespireRx gained access to a 2007 Exclusive License Agreement (as amended, the “Old License”) that Pier had entered into with the University of Illinois on October 10, 2007. The Old License covered certain patents and patent applications in the United States and other countries claiming the use of cannabinoids, including dronabinol, for the treatment of sleep-related breathing disorders (including sleep apnea).

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 505(b)(2) new drug application, an efficient regulatory pathway.

The Old License was terminated effective March 21, 2013, due to the Company's failure to make a required payment. Subsequently, current management opened negotiations with the University of Illinois, and as a result, the Company entered into a new license agreement (the "2014 License Agreement") with the University of Illinois on June 27, 2014, the material terms of which were similar to the Old License.

Similar to the Old License, the 2014 License Agreement grants the Company, among other provisions, exclusive rights: (i) to practice certain patents and patent applications, as defined in the 2014 License Agreement, that are 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 2014 License Agreement, subject to the provisions of the 2014 License Agreement. The Company is required under the 2014 License Agreement, among other terms and conditions, to pay the University of Illinois a license fee, royalties, patent costs and certain milestone payments.

The recently completed PACE trial is described in more detail below in *Recent Developments*.

Drug-induced Respiratory Depression or Drug-induced apnea

Drug-induced respiratory depression ("RD") or drug-induced apnea 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. According to data from the National Center for Health Statistics, 48 million surgical inpatient procedures were performed in the United States in 2009. It is notable that, according to the HealthGrades Inc. Patient Safety in American Hospitals Study released in 2011, post-operative respiratory failure produces the third highest number of patient safety events, the fourth highest mortality rate, and the second largest overall excess cost to the Medicare system, when compared to other patient safety indicators. The Company believes that, in these patients, the major risk factor for the appearance of RD is a history of sleep apnea.

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. In post-surgical patients taking opioids for pain management, sleep apnea is a major risk factor for the occurrence of RD. If patients with sleep apnea are receiving combination therapies, they are at even higher risk for complications and extended hospital stays.

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 due to normal outpatient pain management, 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. In patients chronically consuming opioids, CSA is a major correlate for overdose and most likely represents an early and sensitive form of opioid induced RD. In August 2017, the Centers for Disease Control and Prevention (CDC) reported that approximately 42,000 people died in 2016 from opioid overdoses, including prescription opioids and illegally made fentanyl and heroin. The CDC reported that the common prescription drugs involved in overdoses were methadone, oxycodone (such as OxyContin®) and hydrocodone (such as Vicodin®). In 2016, the CDC reported that 40% of all US opioid deaths involved a prescription opioid. There were 13,000 heroin deaths in 2015. There are two types of fentanyl, pharmaceutical fentanyl used to manage acute and chronic pain and non-pharmaceutical fentanyl that is illicitly manufactured and is often mixed with heroin or cocaine. The CDC also reported that most of the increases in fentanyl deaths involved the illicit fentanyl and not the pharmaceutical fentanyl.

Drug Abuse

On January 19, 2016, the Company announced that that it had 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 is evaluating the compounds using pharmacologic, pharmacokinetic and toxicologic protocols to determine the potential effectiveness of the ampakines for the treatment of drug abuse and addiction. The Company retains all intellectual property as well as proprietary and commercialization rights to the Company's compounds. Initial studies focus on cocaine and methamphetamine addiction and abuse, and are contracted to outside testing facilities and/or government laboratories, with all costs paid by NIDA. In experiments conducted by NIDA, CX717 antagonized the stimulatory effects of methamphetamine. NIDA is in the process of testing CX717 on the interoceptive effects (determinants of addiction liability) of both cocaine and methamphetamine in models of drug discrimination in rats.

Ampakines

RespireRx is developing a class of proprietary compounds known as ampakines, a term used to designate their actions as positive allosteric modulators of the alpha-amino-3-hydroxy-5-methyl-4-isoxazolepropionic acid ("AMPA") glutamate receptor. Ampakines are small molecule compounds that enhance the excitatory actions of the neurotransmitter, glutamate at the AMPA receptor complex, which mediates most excitatory transmission in the central nervous system ("CNS"). These drugs do not have agonistic or antagonistic properties but instead modulate the receptor rate constants for transmitter binding, channel opening, and desensitization

Through an extensive translational research effort from the cellular level through Phase 2 clinical trials, the company has developed a family of ampakines, including CX717, CX1739 and CX1942 that have clinical application in the treatment of CNS-driven respiratory disorders, neurobehavioral disorders, spinal cord injury, neurological diseases, and orphan indications. In particular, we are addressing CNS-driven respiratory disorders that affect millions of people, but for which there are few treatment options and no drug therapies, including opioid induced respiratory disorders, such as apnea (transient cessation of breathing) and hypopnea (transient reduction in breathing). When these symptoms become severe, as in opioid overdose, they are the primary cause of opioid lethality. In addition, we are developing our ampakines for the treatment of disordered breathing and motor impairment resulting from spinal cord injury.

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 do 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, their actions as ampakines and their use in the treatment of various disorders. Patents claiming a family of chemical structures, including CX1739 and CX1942, as well as their use in the treatment of various disorders, extend through at least 2028. Additional patents claiming a family of chemical structures, including CX717, as well as their use in the treatment of various disorders, expired in 2017 in the U.S. and will expire in 2018 internationally. The Company is developing potential market exclusivity strategies for CX717 which may include new patent applications and identifying market opportunities and strategies that may provide exclusivity without patents.

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, including drug induced respiratory depression. These patents extend through at least 2028 and, 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 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.

The Company owns patents and patent applications for certain families of chemical compounds that claim the chemical structures, their actions as ampakines and their use in the treatment of various disorders. Patents claiming a family of chemical structures, including CX1739 and CX1942, as well as their use in the treatment of various disorders extend through at least 2028. Additional patents claiming a family of chemical structures, including CX717,

as well as their use in the treatment of various disorders, expired in 2017 in the U.S. and will expire in 2018 internationally, though certain patents regarding the use of these chemical structures extend through 2028.

Recent Developments

PACE Clinical Trial with Dronabinol

On November 30, 2017, the Company announced the publication by the principal investigators, Dr. Phyllis Zee of Northwestern University and Dr. David Carley of the University of Illinois at Chicago, in the peer-reviewed journal SLEEP, the official publication of the Sleep Research Society, of the positive results of the potentially pivotal, PACE (Pharmacotherapy of Apnea by Cannabimimetic Enhancement) Phase 2B OSA clinical trial, that was fully funded by the National Institutes of Health. The results from PACE were published in the journal Sleep Vol. 41. No. 1, 2018. The results of the PACE clinical trial were previously presented by Dr. Carley at the SLEEP 2017 annual meeting in June 2017. In the PACE trial, dronabinol significantly improved the primary outcome measures of Apnea Hypopnea Index ("AHI"), daytime sleepiness as measured by the Epworth Sleepiness Scale ("ESS"), and overall patient satisfaction as measured by the Treatment Satisfaction Questionnaire for Medications ("TSQM").

The recently completed PACE trial was a fully-blinded, two-center, Phase II, randomized placebo-controlled trial of dronabinol in 56 adult patients with moderate to severe OSA. By random assignment, 56 adult subjects with BMI<45, Epworth Sleepiness Scale (ESS)>7 and PSG-documented AHI between 15 and 50 received either placebo (N=17), 2.5mg (N=19) or 10.0mg (N=20) of dronabinol daily, one hour before bedtime for 6 weeks. Repeat in- laboratory PSG followed by maintenance of wakefulness (MWT) testing was completed every 2-weeks during the treatment period. At each visit, the ESS and Treatment Satisfaction Questionnaire for Medications also were completed.

Overall, baseline AHI was 26.0±11.6 (SD) and this was equivalent among all treatment groups. In comparison to placebo, statistically significant end of treatment declines in AHI were observed for both the 2.5 and 10 mg doses (-9.7±4.1, p=0.02 and -13.2±4.0, p=0.001, respectively). Statistically significant declines in ESS were observed for subjects receiving 10 mg dronabinol (-4.0±0.8 units, p=0.001) but not those receiving 2.5 mg or placebo. Subjects receiving 10 mg dronabinol also expressed the greatest overall satisfaction with treatment (p=0.02).

The PACE trial enrolled 73 subjects of which 56 were evaluable with moderate to severe OSA who met all inclusion and exclusion criteria for the study. At baseline, overall apnea/hypopnea index (AHI) was 25.9±11.3, Epworth Sleepiness Scale score (ESS) was 11.45±3.8, maintenance of wakefulness test (MWT) mean latency was 19.2±11.8 min, body mass index (BMI) was 33.4±5.4 kg/m2 and age was 53.6±9.0 years. Subjects were randomized to receive placebo, 2.5 mg or 10 mg dronabinol. Randomized subjects completed daily self-administration of study drug for 6 weeks, and returned to the laboratory every 2 weeks for overnight polysomnography (PSG), physical examination, and completion of clinical study procedures.

Subjects receiving 10mg/day of dronabinol expressed the highest overall satisfaction with treatment (p=0.04). In comparison to placebo, dronabinol dose-dependently reduced AHI by 10.7±4.4 (p=0.02) and 12.9±4.3 (p=0.003) events/hour at doses of 2.5 and 10 mg/day, respectively. Dronabinol at 10 mg/day reduced ESS score by -3.8±0.8 points from baseline (p<0.0001) and by -2.3±1.2 points in comparison to placebo (p=0.05). Body weights, MWT sleep latencies, gross sleep architecture and overnight oxygenation parameters were unchanged from baseline in any treatment group. The number and severity of adverse events, and treatment adherence (0.3±0.6 missed doses/week) were equivalent among all treatment groups.

CX1739 Clinical Trial

The Company filed an IND with the FDA in September 2015 to conduct a randomized, double-blind, placebo-controlled, crossover, Phase 2A study of CX1739 (300 mg) versus placebo, followed by dose escalation of CX1739 to 600 and 900 mg, with open-label administration of the IV opioid remifentanil in approximately 18 healthy subjects to assess the ability of CX1739 to antagonize the respiratory depressive effect of remifentanil without altering the analgesic effect of the opioid. The clinical protocol was designed to evaluate the safety and efficacy of CX1739 to antagonize respiratory depression in two models of opioid use and abuse. During REMI-INFUSION, a model of chronic (steady state) opioid use, respiration, pain, pulmometry, and safety were measured during a 30-minute intravenous infusion of remifentanil that produced stable blood levels. During REMI-BOLUS, a model of acute, intravenous opioid overdose, a single, intravenous bolus injection of remifentanil was administered at a dose calculated to achieve significant respiratory depression.

On each study day, REMI-BOLUS was initiated with an intravenous, bolus injection of remifentanil 3 hours after subjects received either placebo or CX1739. Respiration was measured for 20 minutes and then compared to the baseline respiration recorded 5 minutes prior to the bolus injection. REMI-INFUSION was initiated 3.5 hours after placebo or CX1739, with an intravenous infusion protocol designed to maintain stable remifentanil blood levels and calculated to produce approximately 50% respiratory depression. The ClinicalTrials.gov identifier is NCT02735629.

The commencement of this clinical trial was subject to the 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, 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. In March 2016, upon Institutional Review Board approval, the trial was initiated at the Duke Clinical Research Unit, Duke University Medical Center, Durham NC. The dosing and data acquisition phase of the clinical trial was completed in June 2016 and the clinical trial was formally completed on July 11, 2016.

On September 12, 2016, the Company announced preliminary top-line analysis of safety and efficacy data from this clinical trial. On October 3, 2016, the Company discovered an error in the preliminary data reported to it and accordingly, on October 4, 2016, the Company issued a press release retracting the efficacy data contained in the September 12, 2016 press release. On December 15, 2016, the Company announced the corrected results of the trial, and presented the re-analyzed data, as follows.

During REMI-INFUSION, the model of chronic opioid use, CX1739 antagonized the respiratory rate depression produced by remifentanil, with statistically significant effects observed at 300 mg ($p<.005$) and 900 mg ($p<.001$). The antagonism produced by the 600 mg dose did not achieve statistical significance. This lack of a linear, dose response effect is not unusual in early stage clinical trials. During this period, CX1739 did not alter the analgesic and sedative effects of remifentanil. During REMI-BOLUS, the model of IV opioid overdose, CX1739 treatment did not prevent respiratory depression, or improve time to recovery at any of the doses tested.

Overall, CX1739 was found to be safe and well tolerated, both prior to and during administration of remifentanil. Treatment-related adverse events ("AEs") for the various doses of CX1739 were mild, with an incidence comparable to that reported for placebo. The great majority of AEs occurred after remifentanil administration, including nausea and vomiting, which are common side effects associated with opioid administration.

The study was conducted at the Duke Clinical Research Unit of the Duke Clinical Research Institute. The ClinicalTrials.gov identifier is NCT02735629.

The Company intends to initiate a multi-center clinical trial investigating the ability of CX717 or CX1739 to improve breathing in patients with spinal cord injury. Assuming FDA allowance and appropriate approvals by institutional review boards, we intend to have this study conducted at the University of Miami, the University of Florida, the Detroit Medical Center and the Detroit Veterans Administration Hospital.

Upon issuance of the final clinical report of the CX1739 Phase 2A trial, the Company intends to seek FDA allowance to conduct a Phase 2 clinical trial investigating the safety and efficacy of CX1739 in chronic opioid patients who have central apnea.

National Institute of Drug Abuse Agreement

On January 19, 2016, the Company announced that that it had 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 is evaluating the compounds using pharmacologic, pharmacokinetic and toxicologic protocols to determine the potential effectiveness of the ampakines for the treatment of drug abuse and addiction. The Company retains all intellectual property as well as proprietary and commercialization rights to the Company’s compounds. Initial studies focus on cocaine and methamphetamine addiction and abuse, and are contracted to outside testing facilities and/or government laboratories, with all costs paid by NIDA. In experiments conducted by NIDA, CX717 antagonized the stimulatory effects of methamphetamine. NIDA is in the process of testing CX717 on the interoceptive effects (determinants of additions liability) of both cocaine and methamphetamine in models of drug discrimination in rats.

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 (approximately US$108,000), consisting of approximately CAD$85,000 (approximately US$63,000) of personnel funding in cash in four installments during 2016, to provide approximately CAD$21,000 (approximately US$16,000) in equipment, to pay patent costs of CAD$20,000 (approximately US$15,000), and to underwrite additional budgeted costs of CAD$20,000 (approximately US$15,000). As of December 31, 2017, the Company had recorded amounts payable in respect to this Research Contract of US$16,207 (CAD$21,222) which amount was paid in US dollars on January 24, 2018. The conversion to US dollars above utilizes an exchange rate of approximately US$0.76 for every CAD$1.00.

The University of Alberta received matching funds through a grant from the Canadian Institutes of Health Research in support of this research. The Company retains 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 at the University of Alberta, collaborated on this research. The studies were completed in 2016. Any patentable intellectual property developed in the Research Agreement will be covered by the existing license agreement.

Common Stock and Warrant Financings

1st 2017 Unit Offering

On August 29, 2017, September 27, 2017, September 28, 2017, October 5, 2017, October 25, 2017, November 29, 2017, December 13, 2017, December 21, 2017, December 22, 2017 and December 29, 2017 the Company sold units to investors in the 2nd 2017 Unit Offering for aggregate gross proceeds of $404,500, with each unit consisting of one share of the Company's common stock and one common stock purchase warrant to purchase one share of the Company's common stock. Units were sold for $1.00 per unit and the warrants issued in connection with the units are exercisable through September 29, 2022 at a fixed price $1.10 per share of the Company's common stock. The warrants contain a cashless exercise provision and certain blocker provisions preventing exercise if the investor would beneficially own more than 4.99% of the Company's outstanding shares of common stock as a result of such exercise. The warrants are also subject to redemption by the Company at $0.001 per share upon ten (10) days written notice if the Company's common stock closes at 250% or more of the unit purchase price for any five (5) consecutive trading days. The investors in the offering were not affiliates of the Company. Investors also received an unlimited number of piggy-back registration rights. Investors also received an unlimited number of exchange rights, which are options and

not obligations, to exchange such investor's entire investment (and not less than the entire investment) into one or more subsequent equity financings (consisting solely of convertible preferred stock or common stock or units containing preferred stock or common stock and warrants exercisable only into preferred stock or common stock) that would be considered as "permanent equity" under United States Generally Accepted Accounting Principles and the rules and regulations of the United States Securities and Exchange Commission, and therefore classified as stockholders' equity, and excluding any form of debt or convertible debt (each such financing a "Subsequent Equity Financing" as in the 1st 2017 Unit Offering). These exchange rights were effective until the earlier of: (i) the completion of any number of subsequent financings aggregating at least $15 million gross proceeds to the Company, or (ii) December 30, 2017 and therefore have expired. The dollar amount used to determine the amount invested or exchanged into the subsequent financing would have been 1.2 times the amount of the original investment. Under certain circumstances, the ratio might have been 1.4 instead of 1.2. The exchange right did not permit the investors to exchange into a debt offering or into redeemable preferred stock, therefore, unlike the 2nd 2016 Unit Offering, the 2nd 2017 Unit Offering resulted in the issuance of permanent equity.

The Company evaluated whether the warrants or the exchange rights met criteria to be accounted for as a derivative in accordance with Accounting Standard Codification Topic (ASC) 815 and determined that the derivative criteria were not met. Therefore, the Company determined no bifurcation and separate valuation was necessary and that the warrants and exchange right should be accounted for with the host instrument. The closing market prices of the Company's common stock on March 10, 2017 and March 28, 2017 were $4.05 and $3.80 respectively. In connection with this transaction, Aurora Capital LLC ("Aurora") served as a placement agent and earned $20,000 fees and 8,000 placement agent common stock warrants associated with the closing of the 1st 2017 Unit Offering. The fees were unpaid as of December 31, 2017 and have been accrued in accounts payable and accrued expenses and charged against Additional paid-in capital as of March 31, 2017, June 30, 2017, September 30, 2017 and December 31, 2017. The placement agent common stock warrants were valued at $27,648 and were accounted for in Additional paid-in capital as of March 31, 2017 and remain valued at that amount as of December 31, 2017.

On July 26, 2017, the Company's Board approved an offering of securities conducted via private placement (the "2nd 2017 Unit Offering" as described below) that, because of the terms of the 2nd 2017 Unit Offering as compared to the terms of the 2nd 2016 Unit offering as well as the 1st 2017 Unit Offering, resulted in an exchange of all outstanding units from each of the 2nd 2016 Unit Offering and the 1st 2017 Unit Offering for new equity securities of the Company into the 2nd 2017 Unit Offering by all of the investors in the 2nd 2016 Unit Offering and all of the investors in the 1st 2017 Unit Offering.

2nd 2017 Unit Offering

On August 29, 2017, September 27, 2017, September 28, 2017, October 5, 2017, October 25, 2017, November 29, 2017, December 13, 2017, December 21, 2017, December 22, 2017 and December 29, 2017 the Company sold units to investors in the 2nd 2017 Unit Offering for aggregate gross proceeds of $404,500, with each unit consisting of one share of the Company's common stock and one common stock purchase warrant to purchase one share of the Company's common stock. Units were sold for $1.00 per unit and the warrants issued in connection with the units are exercisable through September 29, 2022 at a fixed price $1.10 per share of the Company's common stock. The warrants contain a cashless exercise provision and certain blocker provisions preventing exercise if the investor would beneficially own more than 4.99% of the Company's outstanding shares of common stock as a result of such exercise. The warrants are also subject to redemption by the Company at $0.001 per share upon ten (10) days written notice if the Company's common stock closes at 250% or more of the unit purchase price for any five (5) consecutive trading days. The investors in the offering were not affiliates of the Company. Investors also received an unlimited number of piggy-back registration rights. Investors also received an unlimited number of exchange rights, which are options and not obligations, to exchange such investor's entire investment (and not less than the entire investment) into one or more subsequent equity financings (consisting solely of convertible preferred stock or common stock or units containing preferred stock or common stock and warrants exercisable only into preferred stock or common stock) that would be considered as "permanent equity" under United States Generally Accepted Accounting Principles and the rules and regulations of the United States Securities and Exchange Commission, and therefore classified as stockholders' equity, and excluding any form of debt or convertible debt (each such financing a "Subsequent Equity Financing" as in the 1st 2017 Unit Offering). These exchange rights were effective until the earlier of: (i) the completion of any number of subsequent financings aggregating at least $15 million gross proceeds to the Company, or (ii) December 30, 2017 and therefore have expired. The dollar amount used to determine the amount invested or exchanged into the subsequent financing would have been 1.2 times the amount of the original investment. Under certain circumstances, the ratio might have been 1.4 instead of 1.2. The exchange right did not permit the investors to exchange into a debt offering or into redeemable preferred stock, therefore, unlike the 2nd 2016 Unit Offering, the 2nd 2017 Unit Offering resulted in the issuance of permanent equity.

The Company evaluated whether the warrants or the exchange rights met criteria to be accounted for as a derivative in accordance with Accounting Standard Codification Topic (ASC) 815, and determined that the derivative criteria were not met. Therefore, the Company determined no bifurcation and separate valuation was necessary and the warrants and exchange right should be accounted for with the host instrument. The closing market prices of the Company's common stock on August 29, 2017, September 27, 2017, September 28, 2017, October 5, 2017, October 25, 2017, November 29, 2017, December 13, 2017, December 21, 2017, December 22, 2017 and December 29, 2017 were

$1.00, $1.40, $1.40, $1.50, $0.80, $1.05, $1.45, $1.51, $1.45 and $1.14 respectively. There was no placement agent and therefore no fees associated with the 2nd 2017 Unit Offering.

The terms of the 2nd 2017 Unit Offering, as compared to the terms of the 2nd 2016 Unit Offering and the 1st 2017 Unit Offering, were such that all of the units from each of the 2nd 2016 Unit Offering and the 1st 2017 Unit Offering were exchanged into securities of the 2nd 2017 Unit Offering. Because the 1st 2017 Unit Offering and the 2nd 2017 Unit Offering were both originally accounted for as equity, a reclassification similar to the 2nd 2016 Unit Offering was not required.

The shares of common stock and warrants in each of the private placements discussed above were offered and sold without registration under the Securities Act of 1933, as amended (the “Securities Act”) in reliance on the exemptions provided by Section 4(a)(2) of the Securities Act as provided in Rule 506(b) of Regulation D promulgated thereunder. None of the shares of common stock issued as part of the units, the warrants, the common stock issuable upon exercise of the warrants or any warrants issued to a qualified referral source have been registered under the Securities Act or any other applicable securities laws, and unless so registered, may not be offered or sold in the United States except pursuant to an exemption from the registration requirements of the Securities Act.

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 $4,291,483 and $9,229,760 and negative operating cash flows of $697,009 and $1,328,684 for the fiscal years ended December 31, 2017 and 2016, respectively, had a stockholders' deficiency of $4,355,384 at December 31, 2017, 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 its report on the Company's consolidated financial statements for the year ended December 31, 2017, 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.

In January 2016, 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 18,400 shares of Common Stock in the aggregate.

During April and May 2016, the Company entered into Note Exchange Agreements with certain note holders representing an aggregate of $303,500 of principal amount of the Notes (out of a total of $579,500 of original principal amount of the Notes). Pursuant to the Note Exchange Agreements, an aggregate of $344,483, which included accrued interest of $40,983, of the Notes were exchanged (together with original warrants to purchase 26,681 shares of the Company's common stock, New Warrants to purchase 14,259 shares of the Company's common stock, and the payment of an aggregate of $232,846 in cash) into a total of 101,508 shares of the Company's common stock. None of the Notes had previously been converted into shares of the Company's common stock.

During April and May 2016, the Company also entered into Unit Exchange Agreements with certain warrant holders who had acquired units in connection with the Second Amended and Restated Common Stock and Warrant Purchase Agreement on August 28, 2015, September 28, 2015 or November 2, 2015. The Unit Exchange Agreements provided for the warrant holders to exchange (i) existing warrants to purchase an aggregate of 217,187 shares of the Company's common stock, plus (ii) an aggregate of $529,394 in cash, in return for (i) an aggregate of 108,594 shares of the Company's common stock with a total market price of $728,859 (average $6.7275 per share), and (ii) new warrants to purchase an aggregate of 108,594 shares of the Company's common stock with an exercise price of $4.8750 per share,

exercisable for cash or on a cashless basis through the original expiration date of September 30, 2020.

In September 2016, the Company's Chief Executive Officer and Chief Scientific Officer each advanced an additional $25,000 to the Company for working capital purposes under secured short-term promissory notes payable aggregating $50,000 and three year warrants exercisable into 10,155 shares of common stock in the aggregate.

On December 29, 2016 and December 30, 2016, the Company sold units comprised of one share of Common Stock and one Common Stock Purchase Warrant to purchase one share of Common Stock in a private placement ("2nd 2016 Unit Offering") for gross proceeds of $185,000. The per unit purchase price was $1.42. The warrant exercise price was $1.562 per share of Common Stock. The warrants were exercisable until December 31, 2021. The warrants had a cashless exercise provision, "blocker" provisions similar to those described above and may be redeemed or called by the Company for a price of $0.001 per share if the closing price of the Company's Common Stock is equal to or greater than 200% of the unit purchase price or $2.82 for five consecutive trading days. The Company has had the right to call or redeem these warrants several times since issuance, but has chosen not to do so through the date of the issuance of this Form 10-K. Investors in the 2nd 2016 Unit Offering had an exchange right, that under certain circumstances permitted such investors to exchange their investment in the 2nd 2016 Unit Offering into subsequent financings until December 30, 2017 with an exchange ratio of 1.2 times the amount invested in the 2nd 2016 Unit Offering and under certain circumstances, a ratio of 1.4.

On March 10, 2017 and March 28, 2017, the Company sold units to investors in the 1st 2017 Unit Offering for aggregate gross proceeds of $350,000, with each unit consisting of one share of the Company's common stock and one common stock purchase warrant to purchase one share of the Company's common stock. Units were sold for $2.50 per unit and the warrants issued in connection with the units are exercisable through December 31, 2021 at a fixed price $2.75 per share of the Company's common stock. The warrants contain a cashless exercise provision and certain blocker provisions preventing exercise if the investor would beneficially own more than 4.99% of the Company's outstanding shares of common stock as a result of such exercise. The warrants were also subject to redemption by the Company at $0.001 per share upon ten (10) days written notice if the Company's common stock closes at 200% or more of the unit purchase price for any five (5) consecutive trading days. The investors were not affiliates of the Company. Investors received an unlimited number of piggy-back registration rights. Investors also received an unlimited number of exchange rights, which are options and not obligations, to exchange such investor's entire investment (and not less than the entire investment) into one or more subsequent equity financings (consisting solely of convertible preferred stock or common stock or units containing preferred stock or common stock and warrants exercisable only into preferred stock or common stock) that would be considered as "permanent equity" under United States Generally Accepted Accounting Principles and the rules and regulations of the United States Securities and Exchange Commission, and therefore classified as stockholders' equity, and excluding any form of debt or convertible debt (each such financing a "Subsequent Equity Financing"). These exchange rights were effective until the earlier of: (i) the completion of any number of subsequent financings aggregating at least $15 million gross proceeds to the Company, or (ii) December 30, 2017. The dollar amount used to determine the amount invested or exchanged into the subsequent financing would have been 1.2 times the amount of the original investment. Under certain circumstances, the ratio might have been 1.4 instead of 1.2. The exchange right did not permit the investors to exchange into a debt offering or into redeemable preferred stock. In connection with this transaction, Aurora Capital LLC ("Aurora") served as a placement agent and earned $20,000 of cash fees and 8,000 placement agent common stock warrants associated with the closing of 1st 2017 Unit Offering. The cash fees were unpaid as of December 31, 2017.

On July 26, 2017, the Company's Board approved the "2nd 2017 Unit Offering. The terms of the 2nd 2017 Unit Offering as compared to the terms of the 1st 2017 Unit Offering were such, that it resulted in an exchange of units from the 1st 2017 Unit Offering for new equity securities and warrants of the Company in the 2nd 2017 Unit Offering by the Company by all of the investors in the 1st 2017 Unit Offering.

On August 29, 2017, September 27, 2017, September 28, 2017, October 5, 2017, October 25, 2017, November 29, 2017, December 13, 2017, December 21, 2017, December 22, 2017 and December 29, 2017 the Company sold units to investors in the 2nd 2017 Unit Offering for aggregate gross proceeds of $404,500, with each unit consisting of one share of the Company's common stock and one common stock purchase warrant to purchase one share of the Company's common stock (2nd 2017 Unit Offering). Units were sold for $1.00 per unit and the warrants issued in connection with the units are exercisable through September 29, 2022 at a fixed price $1.10 per share of the Company's common stock. The warrants contain a cashless exercise provision and certain blocker provisions preventing exercise if the investor would beneficially own more than 4.99% of the Company's outstanding shares of common stock as a result of such exercise. The warrants are also subject to redemption by the Company at $0.001 per share upon ten (10) days written notice if the Company's common stock closes at 250% or more of the unit purchase price for any five (5) consecutive trading days. Investors were not affiliates of the Company. Investors also received an unlimited number of piggy-back registration rights. Investors received an unlimited number of exchange rights, which were options and not obligations, to exchange such investor's entire investment (and not less than the entire investment) into one or more subsequent equity financings (consisting solely of convertible preferred stock or common stock or units containing preferred stock or common stock and warrants exercisable only into preferred stock or common stock) that would be considered as "permanent equity" under United States Generally Accepted Accounting Principles and the rules and regulations of the United States Securities and Exchange Commission, and therefore classified as stockholders' equity, and excluding any form of debt or convertible debt (each such financing a "Subsequent Equity Financing"). These exchange rights were effective until the earlier of: (i) the completion of any number of subsequent financings aggregating at least $15 million gross proceeds to the Company, or (ii) December 30, 2017, and have therefore expired. The dollar amount used to determine the amount invested or exchanged into the subsequent financing would have been 1.2 times the amount of the original investment. Under certain circumstances, the ratio might have been 1.4 instead of 1.2. The exchange right did not permit the investors to exchange into a debt offering or into redeemable preferred stock. There was no placement agent and therefore no fees associated with the 2nd 2017 Unit Offering.

The terms of the 2nd 2017 Unit Offering as compared to the terms of the 2nd 2016 Unit Offering and the 1st 2017 Unit Offering, has resulted in an exchange of all of the units from each of the 2nd 2016 Unit Offering and the 1st 2017 Unit Offering into equity securities and warrants of the 2nd 2017 Unit Offering.

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 August 2017, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update No. 2017-12 —Derivatives and Hedging (Topic 815): Targeted Improvements to Accounting for Hedging Activities. The new standard is intended to improve and simplify accounting rules around hedge accounting. The new standard refines and expands hedge accounting for both financial (e.g., interest rate) and commodity risks. Its provisions create more transparency around how economic results are presented, both on the face of the financial statements and in the footnotes, for investors and analysts. The new standard takes effect for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2018, for public companies and for fiscal years beginning after December 15, 2019 (and interim periods for fiscal years beginning after December 15, 2020), for private companies. Early adoption is permitted in any interim period or fiscal years before the effective date of the standard. The adoption of ASU 2017-12 is not expected to have any impact on the Company's financial statement presentation or disclosures.

In July 2017, the FASB issued Accounting Standards Update No. 2017-11 (ASU 2017-11), Earnings Per Share (Topic 260): Distinguishing Liabilities from Equity (Topic 480): Derivatives and Hedging (Topic 815). The relevant section for the Company is Tock 815 where it pertains to accounting for certain financial instruments with down round features. Until the issuance of this ASU, financial instruments with down round features required fair value measurement and subsequent changes in fair value were recognized in earnings. As a result of the ASU, financial instruments with down round features are no longer treated as a derivative liability measured at fair value. Instead, when the down round feature is triggered, the effect is treated as a dividend and as a reduction of income available to common shareholders in basic earnings per share. For public entities, the ASU is effective for fiscal years beginning after December 15, 2018. Early adoption is permitted including adoption in an interim period. The adoption of ASU 2017-11 is not expected to have any impact on the Company's financial statement presentation or disclosures.

In May 2017, the FASB issued ASU No. 2017-09, "Compensation – Stock Compensation (Topic 718)." The amendments in in this update provide guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting in Topic 718. An entity should account for the effects of a modification unless all the following are met: (i) the fair value (or calculated value or intrinsic value, if such an alternative measurement method is used) of the modified award is the same as the fair value (or calculated value or intrinsic value, if such an alternative measurement method is used) of the original award immediately before the original award is modified, (ii) the vesting conditions of the modified award are the same as the vesting conditions of the original award immediately before the original award is modified and (iii) the classification off the modified award as an equity instrument or a liability instrument is the same as the classification of the original award immediately before the original award is modified. The amendments in this update are effective for annual periods beginning after December 15, 2017 and for interim periods within those annual periods and are not expected to have any impact on the Company's financial statement presentation or disclosures.

In April 2016, the FASB issued ASU 2016-10, "Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing." The amendments in this update affect the guidance in Accounting Standards

Update 2014-09, Revenue from Contracts with Customers (Topic 606), which we are required to apply for annual and interim periods beginning after December 15, 2017. Management's current analysis is that the new guidelines currently will not substantially impact our revenue recognition. The adoption of the ASU is not expected to have any impact on the Company's financial statement presentation or disclosure.

In March 2016, the FASB issued Accounting Standards Update No. 2016-09 (ASU 2016-09), Compensation – Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting. ASU 2016-09 requires, among other things, that all income tax effects of awards be recognized in the statement of operations when the awards vest or are settled. ASU 2016-09 also allows for an employer to repurchase more of an employee's shares than it can today for tax withholding purposes without triggering liability accounting and allows for a policy election to account for forfeitures as they occur. ASU 2016-09 is effective for fiscal years beginning after December 15, 2016 and therefore is effective for this annual period. The adoption of ASU 2016-09 has not had a significant impact 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 Old License that Pier had entered into with the University of Illinois on October 10, 2007. The Old License 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 Old License 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 Old License 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.

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Convertible Notes Payable and Related Warrants

The Company accounted for the beneficial conversion features with respect to the sale of the convertible notes and the issuance of the warrants in 2015 and 2016 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 were 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 accounted for such costs as a discount to the notes and amortized 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 accounted for such costs as a discount to the notes and amortized 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 $10.075 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 $11.375 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 convertible note obligation. The aggregate debt discount is being amortized as interest expense over the extended 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.

Note Exchange Agreements and Unit Exchange Agreements

See Note 3 to our consolidated financial statements for the years ended December 31, 2017 and 2016 for information on our “Note Exchange Agreements” and “Unit Exchange Agreements.”

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. Payments of grants receivable are based on progress reports provided to the grant provider by the Company.

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 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 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,	
	2017	2016
Operating expenses:		
General and administrative	2,515,846	5,295,683
Research and development	1,731,565	3,176,207
Total operating expenses	4,247,411	8,471,890
Loss from operations	(4,247,411)	(8,471,890)
Gain on settlements with service providers	-	1,076
Fair value of inducement cost to effect exchange of convertible notes	-	(188,274)
Interest income	-	8
Interest expense	(102,225)	(586,346)
Foreign currency transaction gain	58,153	15,666
Net loss	(4,291,483)	(9,229,760)
Adjustment related to Series G 1.5% Convertible Preferred Stock:		
Dividends on Series G 1.5% Convertible Preferred Stock	-	(1,165)
Net loss attributable to common stockholders	$(4,291,483)	$(9,230,295)
Net loss per common share - basic and diluted	$(1.77)	$(4.95)
Weighted average common shares outstanding - basic and diluted	2,418,271	1,864,045

Years Ended December 31, 2017 and 2016

Revenues. The Company had no research grant revenues or other revenues during the years ended December 31, 2017 and December 31, 2016.

General and Administrative. For the year ended December 31, 2017, general and administrative expenses were $2,515,846, a decrease of $2,779,837, as compared to $5,295,683 for the year ended December 31, 2016. The decrease in general and administrative expenses for the year ended December 31, 2017, as compared to the year ended December 31, 2016, is primarily due to decreases of $2,227,310 in stock-based compensation, $198,811 in administrative salaries and employee benefits and Board of Directors fees, $209,560 in corporate legal expenses and $59,820 in investor relations expenses. There were also decreases in accounting and consulting costs, offset by increases in insurance and a number of other smaller offsetting increases and decreases.

Stock-based compensation costs included in general and administrative expenses were $1,164,538 for the year ended December 31, 2017, as compared to $3,391,848 for the year ended December 31, 2016. Salaries, employee benefits and board fees included in general and administrative expenses were $696,445 for the year ended December 31, 2017, as compared to $895,256 for the year ended December 31, 2016. The net change reflects the effects of the termination of employment of the Company's former Chief Financial Officer in February 2017, partially offset by the increase in base compensation of the officer taking over the Chief Financial Officer responsibilities. It also reflects of the gain experienced by the Company upon the forgiveness of accrued compensation by certain officers, a former officer and the independent members of the Board of Directors, partially offset by the value of options granted to those individuals on the same date.

The Company experienced a net benefit of $59,338 when, on December 9, 2017, certain officers, one former officer, two independent members of the Board of Directors and two vendors forgave $1,861,221 of compensation, benefits and other expenses and received, on the same date, options valued at $1,801,883.

In addition, during 2017, the Company experienced an increase in the costs of directors and officers liability insurance and general office insurance.

Research and Development. For the year ended December 31, 2017, research and development expenses were $1,731,565, a decrease of $1,444,642, as compared to $3,176,207 for the year ended December 31, 2016. The decrease in research and development expenses for the year ended December 31, 2017, as compared to the year ended December 31, 2016, is primarily a result of a $580,325 decrease in stock-based compensation and a $566,222 decrease in research contract related expenses, most of which is related to the CX1739 clinical trial at Duke University School

of Medicine, a $264,426 decrease in research and development expenses at other research institutes and vendors, as well as a $42,572 decrease in patent legal and other fees.

The Company experienced a net benefit of $25,742 when, on December 9, 2017, an officer whose compensation and related benefit expenses that are included in research and development expenses forgave $807,497 of such compensation and related expenses, and received in exchange options valued at $781,755.

Interest Expense. During the year ended December 31, 2017, interest expense was $102,225 (including $15,220 to related parties), a decrease of $484,121, as compared to $586,346 (including $151,958 to related parties) for the year ended December 31, 2016. The decrease in interest expense resulted primarily from the exchanges of certain convertible notes for common stock.

Foreign Currency Transaction Gain. Foreign currency transaction gain was $58,153 for the year ended December 31, 2017, as compared to a foreign currency transaction gain of $15,666 for the year ended December 31, 2016. 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, 2017, the Company incurred a net loss of $4,291,483, as compared to a net loss of $9,229,760 for the year ended December 31, 2016.

Dividends on Series G 1.5% Convertible Preferred Stock. There were no dividends on the Series G 1.5% Convertible Preferred Stock for the year ended December 31, 2017, as compared to dividends of $1,165 for the year ended December 31, 2016. On April 17, 2016, all remaining previously unconverted outstanding shares of Series G 1.5% Convertible Preferred Stock were automatically and mandatorily redeemed by conversion into shares of common stock at a conversion price of $1.0725 per share.

Net Loss Attributable to Common Stockholders. For the year ended December 31, 2017, the Company incurred a net loss attributable to common stockholders of $4,291,483, as compared to a net loss attributable to common stockholders of $9,230,925 for the year ended December 31, 2016.

Liquidity and Capital Resources

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 $4,291,483 and $9,229,760 and negative operating cash flows of $697,009 and $1,328,684 for the fiscal years ended December 31, 2017 and 2016, respectively, had a stockholders’ deficiency of $4,355,384 at December 31, 2017, 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 its report on the Company’s consolidated financial statements for the year ended December 31, 2017, has expressed substantial doubt about the Company’s ability to continue as a going concern.

At December 31, 2017, the Company had a working capital deficit of $4,373,443, as compared to a working capital deficit of $5,493,377 at December 31, 2016, reflecting an increase in working capital (a decrease in working capital deficit) of $1,119,934 for the year ended December 31, 2017. The decrease in the working capital deficit during the year ended December 31, 2017 is comprised primarily of a decrease in accrued compensation and related expenses of $1,465,259 arising primarily by the forgiveness described above partially offset by increases in accounts payable and accrued expenses of $427,284, and a net decrease of other current liabilities of $139,095 (inclusive of accrued interest), partially offset by net decrease of $11,827 in current prepaid expenses.

At December 31, 2017, the Company had cash aggregating $84,902, as compared to $92,040 at December 31, 2016, reflecting a decrease in cash of $7,138 for the year ended December 31, 2017. The decrease in cash at December 31, 2017 was primarily the result of principal amounts of short-term notes repaid of $64,629 and $697,009 of cash used in operating activities, partially offset by $ 754,500 of cash raised in financing activities.

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.

From January 8, 2016 through June 30, 2016, the Company sold units comprised of one share of Common Stock and one Common Stock Purchase Warrant to purchase two shares of Common Stock in a private placement ("1st 2016 Unit Offering"). The per unit purchase price was $7.2085 and the warrant exercise price is $7.93. The warrants are exercisable until January 31, 2021. The warrants have a cashless exercise provision and certain "blocker" provisions that prevent or postpone exercise if such exercise would cause the investor to own more than 4.99% of the shares of Common Stock of the Company offer exercise. Gross proceeds were $307,985. In connection with the 1st 2016 Unit Offering, 43,003 shares of Common Stock were issued and 86,005 warrants to purchase Common Stock were issued. No fees were paid to qualified referral sources in connection with the 1st 2016 Unit Offering.

On December 29, 2016 and December 30, 2016, the Company sold units comprised of one share of Common Stock and one Common Stock Purchase Warrant to purchase one share of Common Stock in a private placement ("2nd 2016 Unit Offering") for gross proceeds of $185,000. The per unit purchase price was $1.42. The warrant exercise price was $1.562 per share of Common Stock. The warrants were exercisable until December 31, 2021. The warrants had a cashless exercise provision, "blocker" provisions similar to those described above and may be redeemed or called by the Company for a price of $0.001 per share if the closing price of the Company's Common Stock is equal to or greater than 200% of the unit purchase price or $2.82 for five consecutive trading days. The Company had the right to call or redeem these warrants several times since issuance but has chosen not to do so. Investors in the 2nd 2016 Unit Offering had an exchange right, that under certain circumstances permitted such investors to exchange their investment in the 2nd 2016 Unit Offering into subsequent financings until December 30, 2017 with an exchange ratio of 1.2 times the amount invested in the 2nd 2016 Unit Offering and under certain circumstances, a ratio of 1.4.

The exchange right permitted the investors to exchange into a subsequent debt offering. The Company accounts for non-permanent equity as a liability and such portion of that liability due or to be outstanding for one year or less as a current liability. The Company determined that until the earlier of the completion of aggregate subsequent financings of at least $15 million or December 30, 2017, because the exchange right permitted an exchange into a subsequent debt instrument, this financing should be accounted for as non-permanent equity and had therefore classified the total amount of the gross proceeds of the offering as a current liability as of December 31, 2016. In 2017, all of the investors in the 2nd 2016 Unit Offering exchanged into the 2nd 2017 Unit Offering described below, which was an equity offering at which time the Company determined than any further exchanges into anything other than a permanent equity offering was highly unlikely and reclassified the $185,000 from a current liability to permanent equity. As of December 31, 2017, investors in the 2nd 2016 Unit Offering had no further exchange rights.

On March 10, 2017 and March 28, 2017, the Company sold units to investors in the 1st 2017 Unit Offering for aggregate gross proceeds of $350,000, with each unit consisting of one share of the Company's common stock and one common stock purchase warrant to purchase one share of the Company's common stock. Units were sold for $2.50 per unit and the warrants issued in connection with the units were exercisable through December 31, 2021 at a fixed price $2.75 per share of the Company's common stock. The warrants contained a cashless exercise provision and certain blocker provisions preventing exercise if the investor would beneficially own more than 4.99% of the Company's outstanding shares of common stock as a result of such exercise. The warrants were also subject to redemption by the Company at $0.001 per share upon ten (10) days written notice if the Company's common stock closed at 200% or more of the unit purchase price for any five (5) consecutive trading days. The investors in the offering were not

affiliates of the Company. Investors also received an unlimited number of piggy-back registration rights. Investors also received an unlimited number of exchange rights, which were options and not obligations, to exchange such investor's entire investment (and not less than the entire investment) into one or more subsequent equity financings (consisting solely of convertible preferred stock or common stock or units containing preferred stock or common stock and warrants exercisable only into preferred stock or common stock) that would be considered as "permanent equity" under United States Generally Accepted Accounting Principles and the rules and regulations of the United States Securities and Exchange Commission, and therefore classified as stockholders' equity, and excluding any form of debt or convertible debt (each such financing a "Subsequent Equity Financing"). These exchange rights were effective until the earlier of: (i) the completion of any number of subsequent financings aggregating at least $15 million gross proceeds to the Company, or (ii) December 30, 2017. The dollar amount used to determine the amount invested or exchanged into the subsequent financing was 1.2 times the amount of the original investment. Under certain circumstances, the ratio might have been 1.4 instead of 1.2. The exchange right did not permit the investors to exchange into a debt offering or into redeemable preferred stock, therefore, unlike the 2nd 2016 Unit Offering, the 2017 Unit Offering resulted in the issuance of permanent equity.

The Company evaluated whether the warrants or the exchange rights met criteria to be accounted for as a derivative in accordance with Accounting Standard Codification Topic (ASC) 815 and determined that the derivative criteria were not met. Therefore, the Company determined no bifurcation and separate valuation was necessary and that the warrants and exchange right should be accounted for with the host instrument. The closing market prices of the Company's common stock on March 10, 2017 and March 28, 2017 were $4.05 and $3.80 respectively. In connection with this transaction, Aurora Capital LLC ("Aurora") served as a placement agent and earned $20,000 fees and 8,000 placement agent common stock warrants associated with the closing of 1st 2017 Unit Offering. The fees were unpaid as of December 31, 2017 and have been accrued in accounts payable and accrued expenses and charged against Additional paid-in capital as of March 31, 2017, June 30, 2017 and September 30, 2017 and December 31, 2017. The placement agent common stock warrants were valued at $27,648 and were accounted for in Additional paid-in capital as of March 31, 2017 and remain valued at that amount as of December 31, 2017.

On July 26, 2017, the Company's Board approved the 2nd 2017 Unit Offering, an offering of securities conducted via private placement that, because of the terms of the 2nd 2017 Unit Offering as compared to the terms of the 2nd 2016 Unit offering as well as the 1st 2017 Unit Offering, resulted in an exchange of all outstanding units from each of the 2nd 2016 Unit Offering and the 1st 2017 Unit Offering for new equity securities of the Company into the 2nd 2017 Unit Offering by all of the investors in the 2nd 2016 Unit Offering and all of the investors in the 1st 2017 Unit Offering.

On August 29, 2017, September 27, 2017, September 28, 2017, October 5, 2017, October 25, 2017, November 29, 2017, December 13, 2017, December 21, 2017, December 22, 2017 and December 29, 2017 the Company sold units to investors in the 2nd 2017 Unit Offering for aggregate gross proceeds of $404,500, with each unit consisting of one share of the Company's common stock and one warrant to purchase one share of the Company's common stock. Units were sold for $1.00 per unit and the warrants issued in connection with the units are exercisable through September 29, 2022 at a fixed price $1.10 per share of the Company's common stock. The warrants contain a cashless exercise provision and certain blocker provisions preventing exercise if the investor would beneficially own more than 4.99% of the Company's outstanding shares of common stock as a result of such exercise. The warrants are also subject to redemption by the Company at $0.001 per share upon ten (10) days written notice if the Company's common stock closes at 250% or more of the unit purchase price for any five (5) consecutive trading days. The investors in the offering were not affiliates of the Company. Investors received an unlimited number of piggy-back registration rights. Investors also received an unlimited number of exchange rights, which are options and not obligations, to exchange such investor's entire investment (and not less than the entire investment) into one or more subsequent equity financings (consisting solely of convertible preferred stock or common stock or units containing preferred stock or common stock and warrants exercisable only into preferred stock or common stock) that would be considered as "permanent equity" under United States Generally Accepted Accounting Principles and the rules and regulations of the United States Securities and Exchange Commission, and therefore classified as stockholders' equity, and excluding any form of debt or convertible debt (each such financing a "Subsequent Equity Financing"). These exchange rights were effective until the earlier of: (i) the completion of any number of subsequent financings aggregating at least $15 million gross proceeds to the Company, or (ii) December 30, 2017, and therefore have expired. The dollar amount used to determine the amount invested or exchanged into the subsequent financing would have been 1.2 times the amount of the original investment. Under certain circumstances, the ratio might have been 1.4 instead of 1.2. The exchange right did not permit the investors to exchange into a debt offering or into redeemable preferred stock, therefore, unlike the 2nd 2016 Unit Offering, the 2nd 2017 Unit Offering resulted in the issuance of permanent equity.

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The Company evaluated whether the warrants or the exchange rights met criteria to be accounted for as a derivative in accordance with Accounting Standard Codification Topic (ASC) 815, and determined that the derivative criteria were not met. Therefore, the Company determined no bifurcation and separate valuation was necessary and the warrants and exchange right should be accounted for with the host instrument. The closing market prices of the Company's common stock on August 29, 2017, September 27, 2017, September 28, 2017, October 5, 2017, October 25, 2017, November 29, 2017, December 13, 2017, December 21, 2017, December 22, 2017 and December 29, 2017 were $1.00, $1.40, $1.40, $1.50, $0.80, $1.05, $1.45, $1.51, $1.45 and $1.14 respectively. There was no placement agent and therefore no fees associated with the 2nd 2017 Unit Offering.

The terms of the 2nd 2017 Unit Offering, as compared to the terms of the 2nd 2016 Unit Offering and the 1st 2017 Unit Offering, were such that all of the units from each of the 2nd 2016 Unit Offering and the 1st 2017 Unit Offering were exchanged into securities of the 2nd 2017 Unit Offering. Because the 1st 2017 Unit Offering and the 2nd 2017 Unit Offering were both originally accounted for as equity, a reclassification similar to the 2nd 2016 Unit Offering was not required.

The shares of common stock and warrants in each of the private placements discussed above were offered and sold without registration under the Securities Act of 1933, as amended (the "Securities Act") in reliance on the exemptions provided by Section 4(a)(2) of the Securities Act as provided in Rule 506(b) of Regulation D promulgated thereunder. None of the shares of common stock issued as part of the units, the warrants, the common stock issuable upon exercise of the warrants or any warrants issued to a qualified referral source. have been registered under the Securities Act or any other applicable securities laws, and unless so registered, may not be offered or sold in the United States except pursuant to an exemption from the registration requirements of the Securities Act.

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, 2017, operating activities utilized cash of $697,009, as compared to utilizing cash of $1,328,684 for the year ended December 31, 2016, to support the Company's ongoing operations, including legal and accounting fees and costs related to the preparation of financial statements and SEC filings, research and development activities, patent fees and related legal costs, and settlement agreements.

Investing Activities. The Company did not generate cash from investing activities in 2017 or 2016.

Financing Activities. For the year ended December 31, 2017, financing activities generated cash of $689,871 comprised of $754,500 from the sale of units comprised of common stock and warrants and which was partially offset by principal paid on short-term notes of $64,629. For the year ended December 31, 2016, financing activities generated $494,985 from the sale of units comprised of common stock and warrants, $762,240 from warrant exchanges, $155,200 from notes payable to officers, partially offset by cash used to pay principal amounts of short-term notes payable of $39,602, cash paid in lieu of the issuance of fractional shares associated with the reverse stock split of $1,298 and fees associated with financings of $4,000.

Principal Commitments

Employment Agreements

On August 18, 2015, the Company entered into an employment agreement with Dr. James S. Manuso to be its new President and Chief Executive Officer. In connection therewith, and in addition to other provisions, the Board of Directors of the Company awarded Dr. Manuso stock options to purchase a total of 261,789 shares of common stock, of which options for 246,154 shares were granted pursuant to the Company's 2015 Plan and options for 15,635 shares were granted pursuant to the Company's 2014 Plan. The stock options vested 50% on August 18, 2015 (at issuance), 25% on February 18, 2016, and 25% on August 18, 2016, and will expire on August 18, 2025. The exercise price of the stock options was established on the grant date at $6.4025 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 the OTC markets, as compared to the closing market price of the Company's common stock on August 18, 2015 of $7.02 per share. The aggregate grant date fair value of these stock options calculated pursuant to the Black-Scholes option-pricing model was $1,786,707. Additional information with respect to other provisions of the employment agreement is provided in the Company's Consolidated Financial Statements at Note 9.

On August 18, 2015, the Company also entered into employment agreements with Dr. Arnold S. Lippa, its new Chief Scientific Officer, Robert N. Weingarten, its Vice President and Chief Financial Officer, and Jeff E. Margolis, its Vice President, Treasurer and Secretary. In connection therewith, and in addition to other provisions, the Board of Directors of the Company awarded to each of those officers stock options to purchase a total of 30,769 shares of common stock pursuant to the Company's 2015 Plan. The stock options vested 25% on December 31, 2015, 25% on March 31, 2016, 25% on June 30, 2016, and 25% on September 30, 2016, and will expire on August 18, 2022. The exercise price of the stock options was established on the grant date at $6.4025 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 the OTC Markets, as compared to the closing market price of the Company's common stock on August 18, 2015 of $7.0200 per share. The aggregate grant date fair value of these stock options calculated pursuant to the Black-Scholes option-pricing model was $609,000. During the years ended December 31, 2016 and 2015, the Company recorded charges to operations of $569,222 and $1,223,772, respectively, with respect to these stock option and the stock options issued to Dr. Manuso described in the prior paragraph. Additional information with respect to

other provisions of the employment agreement is provided in the Company's Consolidated Financial Statements at Note 9.

In February 2017, Robert N. Weingarten resigned as the Company's Vice President and Chief Financial Officer and resigned as a member of the Company's Board of Directors. The Board of Directors accepted Mr. Weingarten's resignation and appointed Mr. Margolis to the additional title of Chief Financial Officer. Other than the additional title and responsibilities, there were no changes to Mr. Margolis' compensation arrangements at that time. Mr. Weingarten remains a consultant to the Company.

Jeff E. Margolis' employment agreement was amended effective July 1, 2017 and he was named Chief Financial Officer (no longer interim). The employment agreement amendment called for payment in three installments in cash of the $60,000 bonus granted on June 30, 2015. A minimum of $15,000 was to be payable in cash as follows: (a) $15,000 payable in cash upon the next closing (after July 1, 2017) of any financing in excess of $100,000 (b) $15,000 payable by the end of the following month assuming cumulative closings (beginning with the closing that triggered (a)) in excess of $200,000 and (c) $30,000 payable in cash upon the next closing of any financing in excess of an additional $250,000. The conditions of (a), (b) and (c) above were met as of December 31, 2017, however Mr. Margolis has waived the Company's obligation to make any payments of the cash bonus until the Board of Directors of the Company determines that sufficient capital has been raised by the Company or is otherwise available to fund the Company's operations on an ongoing basis. Obligations through September 30, 2017 were forgiven by Mr. Margolis as described below.

On March 31, 2016, the Board of Directors of the Company awarded stock options for a total of 523,075 shares of common stock in various quantities to twelve individuals who are members of management, the Company's Scientific Advisory Board, independent members of the Board of Directors, or outside service providers pursuant to the Company's 2015 Plan. The stock options vested 25% on each of March 31, 2016, June 30, 2016, September 30, 2016, and December 31, 2016, and will expire on March 31, 2021. The exercise price of the stock options was established on the grant date at $7.3775 per share, which was the closing market price of the Company's common stock on such date. The aggregate grant date fair value of these stock options, as calculated pursuant to the Black-Scholes option-pricing model, was $3,774,000. During the three months and nine months ended September 30, 2016, the Company recorded a charge to operations of $844,650 and $2,686,800, respectively, with respect to these stock options.

On September 12, 2016, the Company entered into an agreement for consulting services, which provided for the payment of a fee through the grant of a non-qualified stock option to purchase a total of 2,608 shares of common stock pursuant to the Company's 2015 Plan. The stock option was fully vested on the date of grant and will expire on September 12, 2021. The exercise price of the stock option was established on the grant date at $5.7500 per share, which was the closing market price of the Company's common stock on the date of grant. The aggregate grant date fair value of the stock option, calculated pursuant to the Black-Scholes option-pricing model, was $14,384, which was charged to operations on the date of grant.

On January 17, 2017, the Board of Directors further increased the number of shares that may be issued under the 2015 Plan to 3,038,461 shares of the Company's common stock. On December 9, 2017, the Board of Directors further increased the number of shares that may be issued under the 2015 Plan to 6,985,260 shares of the Company's common stock.

On January 17, 2017, the Board of Directors of the Company awarded stock options for a total of 395,000 shares of Common Stock in various quantities to seventeen individuals or their designees pursuant to the Company's 2015 Plan. The individuals are members of management, the Company's Scientific Advisory Board, independent members of the

Board of Directors or outside service providers. The stock options vested 25% on the date of the grant, and will vest 50% on March 31, 2017 and 25% on June 30, 2017, and are exercisable for five years at $3.90 per share of Common Stock.

On July 26, 2017, the Company granted Jeff E. Margolis, 25,000 non-qualified stock options from the 2015 Plan, all of which vested by December 31, 2017. The options have an exercise price of $2.00 per share and expire on July 26, 2022.

On July 28, 2017, the Board of Directors awarded 34,000 non-qualified stock options from the 2015 Plan to two consultants totaling. The options have an exercise price of $1.35 per share of common stock and expire on July 28, 2022. All of these options were vested by December 31, 2017.

On December 9, 2017, the Company accepted offers from Dr. Arnold S. Lippa, Dr. James S. Manuso, Jeff E. Margolis, James E. Sapirstein, Kathryn MacFarlane and Robert N. Weingarten (former Chief Financial Officer) pursuant to which such individuals would forgive accrued compensation and related accrued expenses as of September 30, 2017 in the following amounts: $807,497; $878,360; $560,876; $55,000; $55,000 and $200,350, respectively, for a total of $2,557,083. On the same date, the Board of Directors of the Company granted to the same individuals, or designees of such individuals from the 2015 Plan, non-qualified stock options, exercisable for 10 years with an exercise price of $1.45 per share of common stock, among other terms and features as follows: 559,595; 608,704; 388,687; 38,114; 38,114 and 138,842, respectively, for options exercisable into a total of 1,772,055 shares of common stock.

On December 9, 2017, the Board of Directors of the Company awarded 100,000 non-qualified stock options from the 2015 Plan to Richard Purcell, the Company’s Senior Vice President of Research and Development as a bonus. These options vested upon grant, have an exercise price of $1.45 and are exercisable for 10 years.

Information with respect to the issuance of common stock options in connection with the settlement of debt obligations and as payment for consulting services is provided in the Company's Consolidated Financial Statements at Note 5.

Information with respect to common stock awards issued to officers and directors as compensation is provided above under "Common Stock."

Information with respect to the Black-Scholes variables used in connection with the evaluation of the fair value of stock-based compensation is provided in the Company's Consolidated Financial Statements at Note 2.

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 minimum annual royalty of $100,000 was paid as scheduled in December 2017 and 2016, respectively. 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 2017 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, 2017.

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 (approximately US$108,000), consisting of approximately CAD$85,000 (approximately US$63,000) of personnel funding in cash in four installments during 2016, to provide approximately CAD$21,000 (approximately US$16,000) in equipment, to pay patent costs of CAD$20,000 (approximately US$15,000), and to underwrite additional budgeted costs of CAD$20,000 (approximately US$15,000). As of December 31, 2017, the Company had recorded amounts payable in respect to this Research Contract of US$16,207 (CAD$21,222) which amount was paid in US dollars in January 2018. The conversion to US dollars above utilizes an exchange rate of approximately US$0.76 for every CAD$1.00.

The University of Alberta received matching funds through a grant from the Canadian Institutes of Health Research in support of this research. The Company will retain the rights to research results and any patentable intellectual property generated by the research. Dr. John Greer, Ph.D., faculty member of the Department of Physiology, Perinatal Research Centre, and Women & Children's Health Research Institute at the University of Alberta, collaborated on this research. The studies were 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. There were no direct costs in 2017 with respect to this clinical trial. The Company incurred $602,642 of direct costs in 2016 with respect to this clinical trial, which was completed in 2016.

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. The Company incurred $28,467 and $83,081 of such services in 2017 and 2016, respectively.

Contractual Obligations and Commitments

The following table sets forth the Company's principal cash obligations and commitments for the next five fiscal years as of December 31, 2017, aggregating $1,340,350.

		Payments Due By Year				
	Total	2018	2019	2020	2021	2022
Research and development contracts	$-	$-	$-	$-	$-	$-
Clinical trial agreements	-	-	-	-	-	-
License agreements	500,000	100,000	100,000	100,000	100,000	100,000
Digital media consulting agreement						