RespireRx Pharmaceuticals Inc.
Form 10-K
April 16, 2019

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, 2018

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 every Interactive Data File required to be submitted 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 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	Emerging growth company
[ ]	[ ]	[ ]	[X]	[ ]

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 29, 2018 was approximately $3,164,690 (based on the closing sale price of the common stock as reported by the OTC QB) on June 29, 2018.

As of April 11, 2019, there were 3,872,076 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 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.

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 and such sta may include, but are not 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, (iv) reorganization plans, and (v) 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, regulatory and competitive conditions, collaborations with third parties, 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, interest of third parties in collaborations with us, 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

The Company's mission is to develop innovative and revolutionary treatments to combat diseases caused by disruption of neuronal signaling. We are developing treatment options that address conditions that affect millions of people, but for which there are few or poor treatment options, including obstructive sleep apnea ("OSA"), attention deficit hyperactivity disorder ("ADHD") and recovery from spinal cord injury ("SCI"), as well as certain neurological orphan diseases such as Fragile X Syndrome. RespireRx is developing a pipeline of new drug products based on our broad patent portfolios for two drug platforms: ampakines, proprietary compounds that positively modulate AMPA-type glutamate receptors to promote neuronal function and cannabinoids, including dronabinol ("Δ9-THC").

Ampakines

Since its formation in 1987, RespireRx Pharmaceuticals Inc. (formerly known as Cortex Pharmaceuticals, Inc.) has been engaged in the research and clinical development of 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 positively modulate the receptor rate constants for transmitter binding, channel opening, and desensitization. We currently are developing two lead clinical compounds, CX717 and CX1739, and one pre-clinical compound, CX1942. These compounds belong to a new class of ampakines that do not display the electrophysiological and biochemical effects that lead to undesirable side effects, namely convulsive activities, previously reported in animal models of earlier generations.

The Company owns patents and patent applications, or the rights thereto, for certain families of chemical compounds, including ampakines, which 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 patent applications claiming the use of ampakines in the treatment of certain neurological and neuropsychiatric disorders, such as Attention Deficit Hyperactivity Disorder ("ADHD") have been or are expected to be filed in the near future.

In 2007, we determined that expansion of our strategic development into the areas of central respiratory dysfunction, including drug-induced respiratory dysfunction, represented cost-effective opportunities for potentially rapid development and commercialization of RespireRx's compounds. On May 8, 2007, RespireRx entered into a license

agreement, as subsequently amended, with the University of Alberta granting RespireRx exclusive rights to method of treatment patents held by the University of Alberta claiming the use of ampakines for the treatment of various respiratory disorders. These patents, along with RespireRx's own patents claiming chemical structures, comprise RespireRx's principal intellectual property supporting RespireRx's research and clinical development program in the use of ampakines for the treatment of central and drug-induced respiratory disorders.

On May 18, 2018, the Company received a letter from counsel claiming to represent TEC Edmonton and The Governors of the University of Alberta that purported to terminate, effective December 12, 2017, the license agreement dated May 9, 2007 (as subsequently amended) between the Company and The Governors of the University of Alberta. The Company, through its counsel, disputed any grounds for termination and notified the representative that it invoked Section 13 of that license agreement, which mandates a meeting to be attended by individuals with decision-making authority to attempt in good faith to negotiate a resolution to the dispute. In February 2019, the Company and TEC Edmonton tentatively agreed to terms acceptable to all parties to establish a new license agreement and the form of a new license agreement. However, the parties have not signed the draft new license agreement pending the Company's payment of the agreed amount of historical unreimbursed patent fees of approximately CAD$23,000 (approximately US$17,000 as of December 31, 2018). No assurance can be provided that the Company will or will not be able to remit the historical license fees or that the draft new license agreement will be executed and become effective. If we do not remit the historical fees and the new license agreement does not become effective, we cannot estimate the possible adverse impact on the Company's operations or business prospects.

Through an extensive translational research effort from the cellular level through Phase 2 clinical trials, the Company has developed a family of novel, low impact ampakines, including CX717, CX1739 and CX1942 that have clinical application in the treatment of neurobehavioral disorders, CNS-driven respiratory disorders, spinal cord injury, neurological diseases, and orphan indications. We have been addressing CNS-driven respiratory disorders that affect millions of people, but for which there are few treatment options and limited drug therapies, including opioid induced respiratory disorders, such as apnea (transient cessation of breathing) or hypopnea (transient reduction in breathing). When these symptoms become severe, as in opioid overdose, they are the primary cause of opioid lethality.

RespireRx has completed pre-clinical studies indicating that several of its ampakines, including CX717, CX1739 and CX1942, were efficacious in treating drug induced respiratory depression caused by opioids or certain anesthetics without altering the analgesic effects of the opioids or the anesthetic effects of the anesthetics. The results of our preclinical research studies have been replicated in three separate Phase 2A human clinical trials with two ampakines, CX717 and CX1739, confirming the translational mechanism and target site engagement and demonstrating proof of principle that ampakines act as positive allosteric modulators of AMPA receptors in humans and can be used in humans for the prevention of opioid induced apnea. In addition, RespireRx has conducted a Phase 2A clinical study in which patients with sleep apnea were administered CX1739, RespireRx's lead clinical compound. The results suggested that CX1739 might have use as a treatment for central sleep apnea ("CSA") and mixed sleep apnea, but not OSA.

RespireRx is committed to advancing the ampakines through the clinical and regulatory path to approval and commercialization. Until recently, RespireRx has focused on the ampakines' ability to antagonize opioid induced respiratory depression both as a translational tool to verify target engagement, as well as an eventual commercial indication. We believe the loss of over 70,000 lives in our country last year alone demands that new solutions for opioid induced deaths be developed to ensure the public health.

To this end, the Company has conducted preclinical and clinical research with CX1739, CX717 and CX1942 in the prevention, treatment, and management of opioid induced apnea, the primary cause of overdose deaths. In particular, we have conducted several Phase 2 clinical trials demonstrating that both CX717 and CX1739 significantly reduced opioid induced respiratory depression ("OIRD") without altering analgesia. Since one of the primary risk factors for opioid overdose is CSA, it is significant that a Phase 2A clinical study with CX1739 produced data suggesting a possible reduction in central sleep apnea.

As there are neither drugs nor devices approved to treat CSA, Company management believes there is the potential for a rapid path to commercialization. Unfortunately, rather than support novel approaches for opioid treatment, the recent public and governmental discourses regarding the "opioid epidemic" has focused almost entirely on the distribution of naloxone, an opioid antagonist used for acute emergency situations, so-called "non-abuseable" opioid formulations, as well as on means of reducing opioid consumption by limiting production of opioids and access to legal opioid prescriptions. It remains to be seen whether these approaches will have an impact on the situation. Nevertheless, as a result, we believe that there is an ongoing industry-wide pullback from opioids, as evidenced by a reduction in opioid prescriptions and a major reduction in manufacturing by two of the largest opioid manufactures in the United States.

These factors have made it difficult to raise capital or find strategic partners for the development of ampakines for the treatment of opioid induced respiratory depression and we are assessing whether to continue with this program. In addition, as noted above, we have been notified by the University of Alberta ("TEC Edmonton") that they consider our license agreement to be terminated and we are in discussions with them to determine whether and under what conditions a resolution to the dispute can be achieved. At the present time, we are suspending the development of this program until we reach an understanding with the University of Alberta, the political climate is clarified and we are able to either raise funding or enter into a strategic relationship for this purpose. Nevertheless, the valuable data derived from these translational studies have established antagonism of OIRD as a biomarker for demonstrating proof of principle and target engagement in support of continued ampakine development for other indications.

In addition, the Company is pursuing potentially promising clinical development programs in neuro-behavioral and cognitive disorders, with translational and clinical research programs focused on the use of ampakines for the treatment of ADHD and, together with our academic collaborators, for motor impairment resulting from SCI and for Fragile X Autism.

ADHD is one of the most common neurobehavioral disorders, with 6.1% of American children taking medication for treatment, and ADHD is estimated to affect 7.8% of U.S. children aged 4 to 17, which is approximately 4.5 million children, according to the U.S. Centers for Disease Control and Prevention ("CDC"). The principal characteristics of ADHD are inattention, hyperactivity and impulsivity. ADHD symptoms are known to persist into adulthood. In a study published in *Psychiatry Res in May 2010,* up to 78% of children affected by this disorder showed at least one of the major symptoms of ADHD when followed up 10 years later. According to the CDC, approximately 4% of the US adult population has ADHD, which can negatively impair many aspects of daily life, including home, school, work and interpersonal relationships.

Currently available treatments for ADHD include amphetamine-type stimulants and non-stimulant agents targeting the monoaminergic receptor systems in the brain. However, these receptors are not restricted to the brain and are widely found throughout the body. Thus, while these agents can be effective in ameliorating ADHD symptoms, they also can produce adverse cardiovascular effects, such as increased heart rate and blood pressure. Existing treatments also affect eating habits and can reduce weight gain and growth in children and have been associated with suicidal ideation in adolescents and adults. In addition, approved stimulant treatments are DEA classified as controlled substances and present logistical issues for distribution and protection from diversion. Approved non-stimulant treatments, such as atomoxetine, can take four to eight weeks to become effective and undesirable side effects have been observed.

Various investigators have generated data supporting the concept that alterations in AMPA receptor function might underlie the production of some of the symptoms of ADHD. In rodent and primate models of cognition, ampakines have been demonstrated to reduce inattention and impulsivity, two of the cardinal symptoms of ADHD. Furthermore, ampakines do not stimulate spontaneous locomotor activity in either mice or rats, unlike the stimulants presently used for the treatment of ADHD, nor do they increase the stimulation produced by amphetamine or cocaine. These preclinical considerations prompted us to conduct a randomized, double-blind, placebo controlled, two period crossover study to assess the efficacy and safety of CX717 in adults with ADHD.

In a repeated measures analysis, a statistically significant treatment effect on ADHD Rating Scale (ADHD-RS), the primary outcome measure, was observed after a three-week administration of CX717, 800 mg BID. Differences between this dose of CX717 and placebo were seen as early as week one of treatment and continued throughout the remainder of the study. The low dose of CX717, 200 mg BID, did not differ from placebo. In general, results from both the ADHD-RS hyperactivity and inattentiveness subscales, which were secondary efficacy variables, paralleled the results of the total score. CX717 was considered safe and well tolerated.

Based on these clinical results, ampakines such as CX717 might represent a breakthrough opportunity to develop a non-stimulating therapeutic for ADHD with the rapidity of onset normally seen with stimulants. Subject to raising sufficient financing (of which no assurance can be provided), we are planning to continue this program with a Phase 2B clinical trial in patients with adult ADHD.

Ampakines also may have potential utility in the treatment and management of SCI to enhance motor functions and improve the quality of life for SCI patients. An estimated 17,000 new cases of SCI occur each year in the United States, most a result of automobile accidents. Currently, there are roughly 282,000 people living with spinal cord injuries, which often produce impaired motor function.

SCI can profoundly impair neural plasticity leading to significant morbidity and mortality in human accident victims. Plasticity is a fundamental property of the nervous system that enables continuous alteration of neural pathways and synapses in response to experience or injury. One frequently studied model of plasticity is long-term facilitation of motor nerve output ("LTF"). A large body of literature exists regarding the ability of ampakines to stimulate neural plasticity, possibly due to an enhanced synthesis and secretion of various growth factors.

Recently, studies of acute intermittent hypoxia ("AIH") in patients with SCI demonstrate that neural plasticity can be induced to improve motor function. This LTF is based on physiological mechanisms associated with the ability of spinal circuitry to learn how to adjust spinal and brainstem synaptic strength following repeated hypoxic bouts. Because AIH induces spinal plasticity, the potential exists to harness repetitive AIH as a means of inducing functional recovery of motor function following SCI.

RespireRx has been working with Dr. David Fuller, at the University of Florida with funding from the National Institutes of Health, to evaluate the use of ampakines for the treatment of compromised motor function in SCI. Using mice that have received spinal hemisections, CX717 was observed to increase motor nerve activity bilaterally. The effect on the hemisected side was greater than that measured on the intact side, with the recovery approximating that seen on the intact side prior to administration of ampakine. In addition, CX717 was observed to produce a dramatic and long-lasting effect on LTF produced by AIH. The doses of ampakines active in SCI were comparable to those demonstrating antagonism of OIRD, indicating target engagement of the AMPA receptors.

These animal models of motor nerve function following SCI support proof of concept for a new treatment paradigm using ampakines to improve motor functions in patients with SCI. With additional funding recently granted by NIH to Dr. Fuller, RespireRx is continuing its collaborative preclinical research with Dr. Fuller while it is planning a clinical trial program focused on developing ampakines for the restoration of certain motor functions in patients with SCI. The Company is working with our Clinical Advisory Panel and with researchers at highly regarded clinical sites to finalize a Phase 2 clinical trial protocol. Subject to raising sufficient financing (of which no assurance can be provided), we believe that a clinical study could be initiated as early as 2019.

According to the Autism Society, more than 3.5 million Americans live with an Autism Spectrum Disorder (“ASD”), a complex neurodevelopmental disorder. Fragile X Syndrome (“FXS”) is the most common identifiable single-gene cause of autism, affecting approximately 1.4 in every 10,000 males and 0.9 in every 10,000 females, according to the CDC. Individuals with FXS and ASD exhibit a range of abnormal behaviors comprising hyperactivity and attention problems, executive function deficits, hyper-reactivity to stimuli, anxiety and mood instability. Also, according the Autism Society, the prevalence rate of ASD has risen from 1 in 150 children in 2000 to 1 in 68 children in 2010, with current estimates indicating a significant rise in ASD diagnosis to 1 in 59 births, placing a significant emotional and economic burden on families and educational systems. The Autism Society estimates the economic cost to U.S. citizens of autism services to be between $236 and $262 billion annually.

Since “autistic disturbances” were first identified in children in 1943, extensive research efforts have attempted to identify the genetic, molecular, environmental, and clinical causes of ASD, but until recently the underlying etiology of the disorder remained elusive. Today, there are no medications that can treat ASD or its core symptoms, and only two anti-psychotic drugs, aripiprazole and risperidone, are approved by the United States Food and Drug Administration (“FDA”) for the treatment of irritability associated with ASD.

Thanks to wide ranging translational research efforts, FXS and ASD are currently recognized as disorders of the synapse with alterations in different forms of synaptic communication and neuronal network connectivity. Focusing on the proteins and subunits of the AMPA receptor complex, autism researchers at the University of San Diego (“UCSD”) have proposed that AMPA receptor malfunction and disrupted glutamate signal transmission may play an etiologic role in the behavioral, emotional and neurocognitive phenotypes that remain the standard for ASD diagnosis. For example, Stargazin, also known as CACNG2 (Ca^{2+} channel 2 subunit), is one of four closely related proteins recently categorized as transmembrane AMPA receptor regulating proteins (“TARPs”).

Researchers at the UCSD have been studying genetic mutations in the AMPA receptor complex that lead to cognitive and functional deficiencies along the autism spectrum. They work with patients and their families to conduct detailed genetic analyses in order to better understand the underlying mechanisms of autism. In one case, they have been working with a teenage patient who has an autism diagnosis, with a phenotype that is characterized by subtle Tourette-like behaviors, extreme aggression, and verbal and physical outbursts with disordered thought. Despite the behaviors, his language is normal. Using next generation sequencing and genome editing technologies, the researchers identified a specific mutation in stargazin, a transmembrane AMPA receptor regulatory protein that alters the configuration and kinetics of the AMPA receptor. When the aberrant sequence was introduced into C57bL6 mice using CRISPR (Clustered Regulatory Interspaced Short Palindromic Repeats), the heterozygous allele had a dominant negative effect on the trafficking of post-synaptic AMPA receptors and produced behaviors consistent with a glutamatergic deficit and similar to what has been observed in the teenage patient.

With funding from the National Institutes of Health to UCSD, RespireRx is working with UCSD to explore the use of ampakines for the amelioration of the cognitive and other deficits associated with AMPA receptor gene mutations. Because CX1739 has an open investigational new drug (“IND”) application, subject to securing sufficient outside funding (of which no assurance can be provided), we are considering a Phase 2A clinical trial sometime in 2019.

Cannabinoids

OSA is a sleep-related breathing disorder that afflicts an estimated 29 million people in the United States according to the American Academy of Sleep Medicine ("AASM"), and an additional 26 million in Germany and 8 million in the United Kingdom, as presented at the European Respiratory Society's ("ERS") annual Congress in Paris, France in September 2018. OSA involves a decrease or complete halt in airflow despite an ongoing effort to breathe during sleep. When the muscles relax during sleep, soft tissue in the back of the throat collapses and obstructs the upper airway. OSA remains significantly under-recognized, as only 20% of cases in the United States according to the AASM and 20% of cases globally have been properly diagnosed. About 24 percent of adult men and 9 percent of adult women have the breathing symptoms of OSA with or without daytime sleepiness. OSA significantly impacts the lives of sufferers who do not get enough sleep; their quality of sleep is deteriorated such that daily function is compromised and limited. OSA is associated with decreased quality of life, significant functional impairment, and increased risk of road traffic accidents, especially in professions like transportation and shipping.

Research has established links between OSA and several important co-morbidities, including hypertension, type II diabetes, obesity, stroke, congestive heart failure, coronary artery disease, cardiac arrhythmias, and even early mortality. The consequences of undiagnosed and untreated OSA are medically serious and economically costly. According to the AASM, the estimated economic burden of OSA in the United States is approximately $162 billion annually. We believe that a new drug therapy that is effective in reducing the medical and economic burden of OSA would have significant advantages for optimal pricing in this costly disease indication.

Continuous Positive Airway Pressure ("CPAP") is the most common treatment for OSA. CPAP devices work by blowing pressurized air into the nose (or mouth and nose), which keeps the pharyngeal airway open. CPAP is not curative, and patients must use the mask whenever they sleep. Reduction of the apnea/hypopnea index ("AHI") is the standard objective measure of therapeutic response in OSA. Apnea is the cessation of breathing for 10 seconds or more and hyponea is a reduction in breathing. AHI is the sum of apnea and hypopnea events per hour. In the sleep laboratory, CPAP is highly effective at reducing the AHI. However, the device is cumbersome and difficult for many patients to tolerate. Most studies describe that 25-50% of patients refuse to initiate or completely discontinue CPAP use within the first several months and that most patients who continue to use the device do so only intermittently.

Oral devices may be an option for patients who cannot tolerate CPAP. Several dental devices are available including the Mandibular Advancement Device ("MAD") and the Tongue Retaining Device ("TRD"). The MAD is the most widely used dental device for sleep apnea and is similar in appearance to a sports mouth guard. It forces the lower jaw forward and down slightly which keeps the airway more open. The TRD is a splint that holds the tongue in place to keep the airway as open as possible. Like CPAP, oral devices are not curative for patients with OSA. The cost of these devices tends to be high and side effects associated with them include night time pain, dry lips, tooth discomfort, and excessive salivation.

Patients with clinically significant OSA who cannot be treated adequately with CPAP or oral devices can elect to undergo surgery. The most common surgery is uvulopalatopharyngoplasty which involves the removal of excess tissue in the throat to make the airway wider. Other possible surgeries include tracheostomies, rebuilding of the lower jaw, and nose surgery. Patients who undergo surgery for the treatment of OSA risk complications, including infection, changes in voice frequency, and impaired sense of smell. Surgery is often unsuccessful and, at present, no method exists to reliably predict therapeutic outcome from these forms of OSA surgery.

Recently, another surgical option has become available based on upper airway stimulation. It is a combination of an implantable nerve stimulator and an external remote controlled by the patient. The hypoglossal nerve is a motor nerve that controls the tongue. The implanted device stimulates the nerve with every attempted breath, regardless of whether such stimulation is needed for that breath, to increase muscle tone to prevent the tongue and other soft tissues from collapsing. The surgically implanted device is turned on at night and off in the morning by the patient with the remote.

The poor tolerance and long-term adherence to CPAP, as well as the limitations of mechanical devices and surgery, make discovery of therapeutic alternatives clinically relevant and important. RespireRx's translational research results demonstrate that dronabinol, a synthetic cannabinoid, has the potential to become the first drug treatment for this large and underserved market.

In order to expand RespireRx's respiratory disorders program and develop cannabinoids for the treatment of OSA, RespireRx 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 had been 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.

Through the merger, RespireRx gained access to an Exclusive License Agreement (as amended, the "Old License Agreement") that Pier had entered into with the University of Illinois Chicago (the "UIC") on October 10, 2007. The Old License Agreement covered certain patents and patent applications in the United States and other countries claiming the use of certain compounds referred to as cannabinoids, of which dronabinol is a specific example, for the treatment of sleep-related breathing disorders (including sleep apnea). Pier's business plan was to determine whether dronabinol would significantly improve subjective and objective clinical measures in patients with OSA.

The Old License Agreement was terminated effective March 21, 2013 and the Company entered into a new license agreement (the "2014 License Agreement") with the UIC on June 27, 2014, the material terms of which were substantially similar to the Old License Agreement. The 2014 License Agreement grants the Company, among other provisions, exclusive rights: (i) to practice certain patents in the United States, Germany and the United Kingdom, as defined in the 2014 License Agreement, that are held by the UIC; (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 UIC a license fee, royalties, patent costs and certain milestone payments.

Dronabinol is a synthetic derivative of Δ9-THC, one of the pharmacologically active substances naturally occurring in the cannabis plant. Dronabinol is a Schedule III, controlled generic drug that has been approved by the FDA for the treatment of AIDS-related anorexia and chemotherapy-induced nausea and vomiting. Dronabinol is available in the United States as the branded prescription drug product Marinol® capsules. Marinol®, together with numerous generic formulations, is available in 2.5, 5, and 10 mg capsules, with a maximum labelled dosage of 20 mg/day for the AIDS indication, or 15 mg/m^2 per dose for chemotherapy-induced nausea and vomiting.

The Company conducted a 21 day, randomized, double-blind, placebo-controlled, dose escalation Phase 2A clinical study in 22 patients with OSA, in which dronabinol produced a statistically significant reduction in AHI, the primary therapeutic end-point, and was observed to be safe and well tolerated, with the frequency of side effects no different from placebo (Prasad *et al, Frontiers in Psychiatry*, 2013).

With approximately $5 million in funding from the National Heart, Lung and Blood Institute of National Institutes of Health ("NIH"), Dr. David Carley of UIC, along with his colleagues at UIC and Northwestern University, recently completed a Phase 2B multi-center, double-blind, placebo-controlled clinical trial of dronabinol in patients with OSA.

Entitled Pharmacotherapy of Apnea with Cannabimimetic Enhancement (“PACE”), this study replicated the earlier Phase 2A study. The authors reported (Carley *et al*, *Sleep*, 2018) that, in a dose dependent fashion, treatment with 2.5mg and 10mg of dronabinol once a day at night, significantly reduced, compared to placebo, the AHI during sleep in 56 evaluable patients with moderate to severe OSA who completed the study. Additionally, treatment with 10mg of dronabinol significantly improved daytime sleepiness as measured by the Epworth Sleepiness Scale and achieved the greatest overall patient satisfaction. As in the previous study, dronabinol was observed to be safe and well tolerated, with the frequency of side effects no different from placebo. The Company did not manage or fund this clinical trial which was funded by the National Heart, Lung and Blood Institute of NIH.

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 allow us or a development partner to submit a 505(b)(2) New Drug Application ("NDA") to the FDA for approval of a new dronabinol label, as opposed to the submission and approval of a full 505(b)(1) NDA. The 505(b)(2) NDA was created by the Hatch-Waxman Amendments to the Federal Food, Drug and Cosmetic Act, in part, to help avoid unnecessary duplication of studies already performed on a previously approved drug; the section gives the FDA express permission to rely on data not developed by the NDA applicant. A 505(b)(2) NDA contains full safety and effectiveness reports but allows at least some of the information required for NDA approval, such as safety and efficacy information on the active ingredient, to come from studies not conducted by or for the applicant. This can result in a less expensive and faster route to approval, compared with a traditional development path, such as 505(b)(1), while creating new, differentiated products. This regulatory path offers market protections under Hatch-Waxman provisions for market exclusivity at the FDA. Other regulatory routes are available to pursue proprietary formulations of dronabinol that will provide further market protections. In Europe, a regulatory approval route similar to the 505(b)(2) pathway is the hybrid procedure based on Article 10 of Directive 2001/83/EC.

In conjunction with its management and consultants, RespireRx has developed a regulatory strategy in which we intend to file a new NDA under Section 505(b)(2) claiming the efficacy of dronabinol in the treatment of OSA and, in the process, create a new branded product. We have engaged Camargo Pharmaceutical Services, LLC to act as regulatory consultants and assist with FDA filings and regulatory strategy.

Unlike a standard 505(b)(1) NDA, the 505(b)(2) Abbreviated New Drug Application ("ANDA") process begins with a pre-IND meeting with the FDA, then moves to formulation development (and nonclinical studies, if necessary) and then to the IND (investigational new drug) filing. Since we intend to utilize an already approved or equivalent dronabinol product from manufacturers that have approved Drug Master Files, we believe that the pre-IND meeting will forego discussions of CMC (chemistry, manufacturing and controls), formulation and safety, as well as Phase 1 and 2 studies. Instead, we believe that the focus will be on the Phase 3 clinical development program. When a Phase 3 study is required for a 505(b)(2), usually only one study with fewer patients is necessary versus the two, large scale, confirmatory studies generally required for 505(b)(1). While no assurance can be provided, with an extensive safety database tracking chronic, long-term use of Marinol® and generics, we believe that FDA should not have major safety concerns with dronabinol in the treatment of OSA.

We anticipate requesting a pre-IND meeting with the FDA possibly during the second quarter of 2019, which would functionally serve as the equivalent of an end-of-Phase 2 meeting. The FDA responses to this meeting will be incorporated into an IND, which we believe we could be in a position to submit within 60 days of receiving their communication.

RespireRx has worked with the PACE investigators and staff, as well as with our Clinical Advisory Panel to design a Phase 3 protocol that, based on the experience and results from the Phase 2A and Phase 2B trials, we believe will provide sufficient data for FDA approval of a RespireRx dronabinol branded capsule for OSA. Subject to raising sufficient financing (of which no assurance can be provided). RespireRx intends to submit the Phase 3 protocol to the FDA. The current version of the protocol is designed as a 90-day randomized, blinded, placebo controlled study of

dronabinol in the treatment of OSA. Depending on feedback from the FDA, RespireRx estimates that the Phase 3 trial would require between 120 and 300 patients at 15 to 20 sites, and take 18 to 24 months to complete, at a cost of between $10 million and $14 million.

Subject to raising sufficient financing (of which no assurance can be provided), RespireRx intends to hire Clinilabs Drug Development Corporation, a full-service CRO, to consult and potentially provide clinical site management, monitoring, data management, and centralized sleep monitoring services for the Phase 3 OSA trial. Dr. Gary Zammitt, CEO of Clinilabs, serves on the RespireRx Clinical Advisory Panel, and his management team has provided guidance on study design and CNS drug development that will be relevant for the Phase 3 program. For example, Clinilabs offers specialized clinical trial services for CNS drug development through an alliance with Neuroclinics, including clinical trials examining the effects of drugs on driving, cognitive effects of food and (medicinal) drugs, and sleep and sleep disordered breathing.

On September 4, 2018, RespireRx entered into a dronabinol Development and Supply Agreement with Noramco Inc., one of the world’s major dronabinol manufacturers. Under the terms of the Agreement, Noramco agreed to (i) provide all of the active pharmaceutical ingredient (“API”) estimated to be needed for the clinical development process for both the first- and second-generation products (each a “Product” and collectively, the “Products”), three validation batches for NDA filing(s) and adequate supply for the initial inventory stocking for the wholesale and retail channels, subject to certain limitations, (ii) maintain or file valid drug master files (“DMFs”) with the FDA or any other regulatory authority and provide the Company with access or a right of reference letter entitling the Company to make continuing reference to the DMFs during the term of the agreement in connection with any regulatory filings made with the FDA by the Company, (iii) participate on a development committee, and (iv) make available its regulatory consultants, collaborate with any regulatory consulting firms engaged by the Company and participate in all FDA or Drug Enforcement Agency (“DEA”) meetings as appropriate and as related to the API.

In consideration for these supplies and services, the Company has agreed (i) to purchase exclusively from Noramco, during the commercialization phase, all API for its Products (as defined in the Development and Supply Agreement) at a pre-determined price subject to certain producer price adjustments and (ii) Noramco's participation in the economic success of the commercialized Product or Products up to the earlier of the achievement of a maximum dollar amount or the expiration of a period of time.

We plan to establish strategic relationships with appropriate companies to complete formulation and packaging. RespireRx has identified several candidates to perform the encapsulation. Some of these already supply finished product to generic pharmaceutical companies marketing dronabinol for its current non-OSA indications. In addition, as described below, RespireRx has been in discussions with several companies that have considerable expertise in developing novel formulations for dronabinol and have expressed interest in helping us develop a proprietary controlled release formulation. No assurance can be provided that encapsulation or formulation agreements will be consummated on terms acceptable to us; the failure to consummate these agreements would materially adversely affect the Company.

After considerable research and discussions with consultants, we believe the most direct route to commercialization is to proceed directly to a Phase 3 pivotal clinical trial using the currently available dronabinol formulation (2.5, 5 and 10 mg gel caps) and to commercialize a RespireRx branded dronabinol capsule ("RBDC") with an NDA. To that end, RespireRx plans to complete the Phase 3 trial and submit a 505(b)(2) application to FDA for approval of a new, branded, once per day dronabinol gel capsule for the treatment of OSA estimated to occur in 2020. Under the provisions of the Hatch-Waxman Act, the RBDC would have 3-year market exclusivity, as well as further protection from generic substitution through 2025 due to our patents and an anticipated listing in the ***Approved Drug Products with Therapeutic Equivalence Evaluations*** publication (the "Orange Book"), which identifies drug products approved on the basis of safety and effectiveness by the FDA and related patent and exclusivity information.

In addition, management believes there are numerous opportunities for reformulation of dronabinol to produce a proprietary, branded product for the treatment of OSA. Therefore, simultaneous with the development of the RBDC, RespireRx plans to develop a proprietary dronabinol formulation to optimize the dose and duration of action for treating OSA. An analysis of the time-related efficacy results provides potential guidance on development. We have identified several formulation companies with existing dronabinol formulations, expertise, and licensure to develop a proprietary formulation of dronabinol for RespireRx based on RespireRx's pending patents for low-dose and extended release dronabinol, which we expect would enable brand extensions and market protections through 2036.

Since RBDC is expected, if approved, to be approved under a 505(b)(2) NDA, it would be considered a new, proprietary, branded dronabinol product, with a specific label for OSA. It would be non-identical to any other dronabinol product and there would be no generic equivalents or AB substitutions. There are many examples of branded products that might ordinarily have applied for an ANDA as a branded generic, but which have successfully utilized this 505(b)(2) NDA approach to grant them new product status and protect them from generic substitution.

Because the 505(b)(2) NDA requires clinical data for approval of a new indication, we anticipate that our RBDC would be eligible for market protection under the Hatch-Waxman Amendment clause for “other significant changes” and we expect would therefore be eligible for 3-years of market exclusivity. At the end of these 3 years, if a generic company wished to challenge our issued patents, they would have to file an ANDA with bioequivalence data to our RBDC and, if our patents were listed in the Orange Book, they would have to simultaneously file a Paragraph 4 certification stating that they are challenging our patent. At that point, we would receive a 30-months stay of the patent challenge.

We believe the 5.5 years of market exclusivity expected to result from the Hatch-Waxman Act and the Orange Book listing will provide adequate time for the development and approval of a novel, proprietary formulation of dronabinol, optimized for all-night treatment of OSA, with patent protections through 2036. If the new formulation is approved, we plan to rescind the 505(b)(2) NDA for RBDC and replace the branded product with the new and improved formulation on the market, with the intention of preventing ANDA competition and protecting market share.

With guidance based on the product launch experience of Dr. MacFarland, a member of our Board of Directors, and Richard Purcell, our senior vice-president of research and development, and the managed markets experience of our consultant, Commercialization Consulting, LLC, we have prepared an approach to marketing and commercialization of both the RBDC and the proprietary dronabinol formulation. Based upon an extensive analysis conducted by Commercialization Consulting, LLC, we believe that if we were to execute our strategy, we should not experience a loss of more than approximately 15% of sales due to off-label generic dronabinol sales.

On February 13, 2019, the Company entered into a non- binding memorandum of understanding ("MOU") and exclusivity agreement with Impression Healthcare Limited (ASX: IHL)("Impression") for the purpose of negotiating terms by which the parties would enter in an arrangement, such as a license, joint venture or partner agreement, so as to commercialize dronabinol for the treatment of OSA in Australia, New Zealand and Southeast Asia. Discussions are in progress.

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 (see below with respect to dronabinol) 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.

On September 4, 2018, RespireRx entered into a dronabinol Development and Supply Agreement with Noramco Inc., one of the world's major dronabinol manufacturers. Under the terms of the Agreement, Noramco agreed to (i) provide all of the active pharmaceutical ingredient ("API") estimated to be needed for the clinical development process for both the first- and second-generation products (each a "Product" and collectively, the "Products"), three validation batches for New Drug Application ("NDA") filing(s) and adequate supply for the initial inventory stocking for the wholesale and retail channels, subject to certain limitations, (ii) maintain or file valid drug master files ("DMFs") with the FDA or any other regulatory authority and provide the Company with access or a right of reference letter entitling the Company to make continuing reference to the DMFs during the term of the agreement in connection with any regulatory filings made with the FDA by the Company, (iii) participate on a development committee, and (iv) make available its regulatory consultants, collaborate with any regulatory consulting firms engaged by the Company and participate in

all FDA or Drug Enforcement Agency ("DEA") meetings as appropriate and as related to the API.

In consideration for these supplies and services, the Company has agreed to purchase exclusively from Noramco during the commercialization phase all API for its Products (as defined in the Development and Supply Agreement) at a pre-determined price subject to certain producer price adjustments and agreed to Noramco's participation in the economic success of the commercialized Product or Products up to the earlier of the achievement of a maximum dollar amount or the expiration of a period of time.

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, 2018 and as of the date of filing of this Annual Report on Form 10-K, the Company employed three people (all officers), two of whom were full time. The Company also engages certain contractors who provide substantial services to the Company. Effective September 30, 2018, one employee (officer), resigned as President and Chief Executive Officer, and his responsibilities were assigned to one of the remaining officers on an interim basis. 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

In August 2012, RespireRx acquired Pier Pharmaceuticals, Inc. (“Pier”), which is now its wholly-owned subsidiary.

Through the merger, RespireRx gained access to an Exclusive License Agreement (as amended, the “Old License Agreement”) that Pier had entered into with the University of Illinois Chicago (“UIC”) on October 10, 2007. The Old License Agreement covered certain patents and patent applications in the United States and other countries claiming

the use of certain compounds referred to as cannabinoids, of which dronabinol is a specific example, for the treatment of sleep-related breathing disorders (including sleep apnea). Pier's business plan was to determine whether dronabinol would significantly improve subjective and objective clinical measures in patients with OSA.

The Old License Agreement was terminated effective March 21, 2013 and the Company entered into a new license agreement (the "2014 License Agreement") with the UIC on June 27, 2014, the material terms of which were substantially similar to the Old License Agreement. The 2014 License Agreement grants the Company, among other provisions, exclusive rights: (i) to practice certain patents in the United States, Germany and the United Kingdom, as defined in the 2014 License Agreement, that are held by the UIC; (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 UIC a license fee, royalties, patent costs and certain milestone payments.

University of Alberta License Agreement and Research Agreement

By letter dated May 18, 2018, the Company received notice from counsel claiming to represent TEC Edmonton and The Governors of the University of Alberta, which purported to terminate, effective December 12, 2017, the license agreement dated May 9, 2007 between the Company and The Governors of the University of Alberta. The Company, through its counsel, disputed any grounds for termination and notified the representative that it invoked Section 13 of that license agreement, which mandates a meeting to be attended by individuals with decision-making authority to attempt in good faith to negotiate a resolution to the dispute. In February 2019, the Company and TEC Edmonton tentatively agreed to terms acceptable to all parties to establish a new license agreement and the form of a new license agreement. However, the parties have not signed the draft new license agreement pending the Company's payment of the agreed amount of historical unreimbursed patent fees of approximately CAD$23,000 (approximately US$17,000 as of December 31, 2018). No assurance can be provided that the Company will or will not be able to remit the historical license fees or that the draft new license agreement will be executed and become effective. If we do not remit the historical fees and the new license agreement does not become effective, we cannot estimate the possible adverse impact on the Company's operations or business prospects.

On May 9, 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. This is the license agreement that has been the subject of purported license termination and negotiation of a new draft license agreement in the paragraph above.

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.

Research and Development Expenses

The Company invested $688,286 and $1,499,940 in research and development in 2018 and 2017, respectively. Of those amounts, $495,638 and $1,132,604 were incurred with related parties in 2018 and 2017 respectively. See our consolidated financial statements for the years ended December 31, 2018 and 2017 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, 2018 and 2017 and our statements of operations, stockholders' equity (deficiency), and cash flows for the years ended December 31, 2018 and 2017, 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, 2018, we have generated only minimal operating revenues. For the fiscal year ended December 31, 2018, our net loss was $2,591,790 and as of December 31, 2018, we had an accumulated deficit of $164,394,052. For the 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. 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 require additional cash resources for basic operations and 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, 2018, we estimated that our existing cash resources will not be sufficient to meet our requirements for 2019. 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:

Our ability to raise equity or debt capital, or our ability to obtain in-kind services
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 or in-kind services 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 9, 2007, the Company entered into a license agreement with The Governors of the University of Alberta, as subsequently amended, granting he Company exclusive rights to practice patents held by the University of Alberta claiming the use of ampakines for the treatment of various respiratory disorders. By letter dated May 18, 2018, the Company received notice from counsel claiming to represent TEC Edmonton and The Governors of the University of Alberta, which purports to terminate, effective December 12, 2017, the license agreement dated May 9, 2007 between the Company and The Governors of the University of Alberta. The Company, through its counsel, disputed any grounds for termination and notified the representative that it invoked Section 13 of that license agreement, which mandates a meeting to be attended by individuals with decision-making authority to attempt in good faith to negotiate a resolution to the dispute. In February 2019, the Company and TEC Edmonton, in February 2019, tentatively agreed to terms acceptable to all parties to establish a new license agreement and the form of a new license agreement. However, the parties have not signed the draft new license agreement pending the Company's payment of the agreed amount of historical unreimbursed patent fees, of approximately CAD$23,000 (approximately US$17,000 as of December 31, 2018). No assurance can be provided that the Company will or will not be able to remit the historical license fees or that the draft new license agreement will be executed and become effective. If we do not remit the historical fees and the new license agreement does not become effective, we cannot estimate the possible adverse impact on the Company's operations or business prospects.

We may not be able to successfully develop and commercialize our proposed 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 to mid-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. In a recent study (in the journal BioStatistics, Volume 20, Issue 2, April 2019, pp 273-286) covering approximately 16 years of clinical trial data (both company sponsored clinical trials and non-company sponsored trials), the authors showed transitional success rates from Phase 1 to Phase 2 of 66.4% (failure rate of 33.6%), from Phase 2 to Phase 3 of 58.3% (failure rate of 41.7%) and from Phase 3 to approval of 59.0% (failure rate of 41%). Other studies have shown lower success and higher failure rates. 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 and other strategic 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 or in-kind services in exchange for exclusive or non-exclusive license or other rights to the technologies and products that we are currently developing. Competition between biopharmaceutical companies for these types of arrangements is intense. We cannot give any assurance that our discussions with candidate companies will result in an agreement or agreements in a timely manner, or at all. Additionally, we cannot assure you that any resulting agreement will generate sufficient revenues to offset our operating expenses and longer-term funding requirements.

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

There are a limited number of manufacturers that operate under the FDA's and European Union's good manufacturing practices regulations and are capable of manufacturing products like those we are developing. Third-party manufacturers may encounter difficulties in achieving quality control and quality assurance and may experience shortages of qualified personnel. A failure of third-party manufacturers to follow current good manufacturing practices or other regulatory requirements and to document their adherence to such practices may lead to significant

delays in the availability of products for commercial use or clinical study, the termination of, or hold on, a clinical study, or may delay or prevent filing or approval of marketing applications for our products. In addition, we could be subject to sanctions, including fines, injunctions and civil penalties. Changing manufacturers may require additional clinical trials and the revalidation of the manufacturing process and procedures in accordance with FDA mandated current good manufacturing practices and would require FDA approval. This revalidation may be costly and time consuming. If we are unable to arrange for third-party manufacturing of our products, or to do so on commercially reasonable terms, we may not be able to complete development or marketing of our products.

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

Generally, a change of more than 50% in the ownership of a Company's stock, by value, over a three-year period constitutes an ownership change for U.S. federal income tax purposes. An ownership change may limit our ability to use our net operating loss carry forwards attributable to the period prior to such change. We have sold or otherwise issued shares of our common stock in various transactions sufficient to constitute an ownership change, including the issuance of the Series G 1.5% Convertible Preferred Stock (as defined below), the issuance of qualified and non-qualified stock options 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 limited experience in conducting and managing later-stage clinical testing or in preparing applications necessary to obtain regulatory approvals. Although we have engaged regulatory consultants and contract research organizations to assist us in such endeavors, it is possible that our competitors may succeed in developing products, or may obtain FDA approvals for their products faster than we can and/or such competitors may develop products that are safer or more effective than those that we are developing. 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 Interim Chief Executive Officer, Interim President, Chief Scientific Officer and Executive Chairman, James Sapirstein, our Executive Vice Chairman, Jeff E. Margolis, our Senior Vice President, Chief Financial Officer, 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.

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, 2018 and 2017, as quoted on the OTC QB, was $0.40 to $2.90 and $0.80 to $4.20, respectively. The following factors, in addition to factors that affect that market generally, could significantly affect our business, and the market price of our common stock could decline:

competitors announcing technological innovations or new commercial products;
competitors' publicity regarding actual or potential products under development;
regulatory developments in the United States and foreign countries;
legal developments regarding cannabinoids and cannabis products 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 shares 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, 2018, we had 3,872,076 shares of our common stock outstanding.

If all warrants and options outstanding as of December 31, 2018 are exercised prior to their expiration, up to 6,128,223 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.

As of December 31, 2018, there were remaining outstanding convertible notes totaling $239,666 inclusive of accrued interest. Of that amount, $187,233 was convertible into 16,319 shares of common stock and the remainder into an indeterminate number of shares of common stock as such notes may convert, at the option of each note holder, acting separately and independently of the other note holders, into the next exempt private securities offering of equity securities. 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 to issue, as of December 31, 2018, 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, 2018, 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, 2018 and December 31, 2017, including accrued interest at 4.5% annually from February 26, 2018, the date of the judgment, through December 31, 2018, totaling $7,470.

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, 2018 and 2017—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". 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, 2018 and 2017. 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.

As of December 31, 2018, there were 107 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 28, 2018, as quoted on the OTC QB market, were $0.65 and $0.65, respectively, the last date of the fiscal year on which the common stock traded (390 shares of common stock). No shares of common stock traded on December 31, 2018, therefore the OTC QB market reflected a high and low stock price on that date of $0.65.

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, 2018, we did not repurchase any of our securities.

Item 6. Selected Financial Data

Not applicable to smaller reporting companies.

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

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

Overview

The mission of RespireRx Pharmaceuticals Inc. ("RespireRx" or the "Company" or "we" or "our") is to develop innovative and revolutionary treatments to combat diseases caused by disruption of neuronal signaling. We are developing treatment options that address conditions that affect millions of people, but for which there are few or poor treatment options, including obstructive sleep apnea ("OSA"), attention deficit hyperactivity disorder ("ADHD") and recovery from spinal cord injury ("SCI"), as well as certain neurological orphan diseases such as Fragile X Syndrome. RespireRx is developing a pipeline of new drug products based on our broad patent portfolios for two drug platforms: ampakines, proprietary compounds that positively modulate AMPA-type glutamate receptors to promote neuronal function and cannabinoids, including dronabinol ("Δ9-THC").

Ampakines

Since its formation in 1987, RespireRx Pharmaceuticals Inc. (formerly known as Cortex Pharmaceuticals, Inc.) has been engaged in the research and clinical development of 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. We currently are developing two lead clinical compounds, CX717 and CX1739, and one pre-clinical compound, CX1942. These compounds belong to a new class of ampakines that do not display the electrophysiological and biochemical effects that lead to undesirable side effects, namely convulsive activities, previously reported in animal models of earlier generations.

The Company owns patents and patent applications, or the rights thereto, for certain families of chemical compounds, including ampakines, which 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 patent applications claiming the use of ampakines in the treatment of certain neurological and neuropsychiatric disorders, such as Attention Deficit Hyperactivity Disorder ("ADHD") have been or are expected to be filed in the near future.

In 2007, we determined that expansion of our strategic development into the areas of central respiratory dysfunction, including drug-induced respiratory dysfunction represented cost-effective opportunities for potentially rapid development and commercialization of RespireRx's compounds. On May 9, 2007, RespireRx entered into a license agreement, as subsequently amended, with the University of Alberta granting RespireRx exclusive rights to method of treatment patents held by the University of Alberta claiming the use of ampakines for the treatment of various respiratory disorders. These patents, along with RespireRx's own patents claiming chemical structures, comprise RespireRx's principal intellectual property supporting RespireRx's research and clinical development program in the use of ampakines for the treatment of central and drug-induced respiratory disorders.

On May 18, 2018, the Company received a letter from counsel claiming to represent TEC Edmonton and The Governors of the University of Alberta, which purported to terminate, effective December 12, 2017, the license agreement dated May 9, 2007 (as subsequently amended) between the Company and The Governors of the University of Alberta. The Company, through its counsel, disputed any grounds for termination and notified the representative that it invoked Section 13 of that license agreement, which mandates a meeting to be attended by individuals with decision-making authority to attempt in good faith to negotiate a resolution to the dispute. In February 2019, the Company and TEC Edmonton tentatively agreed to terms acceptable to all parties to establish a new license agreement and the form of a new license agreement. However, the parties have not signed the draft new license agreement pending the Company's payment of the agreed amount of historical unreimbursed patent fees of approximately CAD$23,000 (approximately US$17,000 as of December 31, 2018). No assurance can be provided that the Company will or will not be able to remit the historical license fees or that the draft new license agreement will be executed and become effective. If we do not remit the historical fees and the new license agreement does not become effective, we cannot estimate the possible adverse impact on the Company's operations or business prospects.

Through an extensive translational research effort from the cellular level through Phase 2 clinical trials, the Company has developed a family of novel, low impact ampakines, including CX717, CX1739 and CX1942 that have clinical application in the treatment of neurobehavioral disorders, CNS-driven respiratory disorders, spinal cord injury, neurological diseases, and orphan indications. We have been addressing CNS-driven respiratory disorders that affect millions of people, but for which there are few treatment options and limited drug therapies, including opioid induced respiratory disorders, such as apnea (transient cessation of breathing) or hypopnea (transient reduction in breathing). When these symptoms become severe, as in opioid overdose, they are the primary cause of opioid lethality.

RespireRx has completed pre-clinical studies indicating that several of its ampakines, including CX717, CX1739 and CX1942, were efficacious in treating drug induced respiratory depression caused by opioids or certain anesthetics without altering the analgesic effects of the opioids or the anesthetic effects of the anesthetics. The results of our preclinical research studies have been replicated in three separate Phase 2A human clinical trials with two ampakines, CX717 and CX1739, confirming the translational mechanism and target site engagement and demonstrating proof of principle that ampakines act as positive allosteric modulators of AMPA receptors in humans and can be used in humans for the prevention of opioid induced apnea. In addition, RespireRx has conducted a Phase 2A clinical study in which patients with sleep apnea were administered CX1739, RespireRx's lead clinical compound. The results suggested that CX1739 might have use as a treatment for central sleep apnea ("CSA") and mixed sleep apnea, but not OSA.

RespireRx is committed to advancing the ampakines through the clinical and regulatory path to approval and commercialization. Until recently, RespireRx has focused on the ampakines' ability to antagonize opioid induced respiratory depression both as a translational tool to verify target engagement, as well as an eventual commercial indication. We believe the loss of over 70,000 lives in our country last year alone demands that new solutions for opioid induced deaths be developed to ensure the public health.

To this end, the Company has conducted preclinical and clinical research with CX1739, CX717 and CX1942 in the prevention, treatment, and management of opioid induced apnea, the primary cause of overdose deaths. In particular, we have conducted several Phase 2 clinical trials demonstrating that both CX717 and CX1739 significantly reduced opioid induced respiratory depression (“OIRD”) without altering analgesia. Since one of the primary risk factors for opioid overdose is CSA, it is significant that a Phase 2A clinical study with CX1739 produced data suggesting a possible reduction in central sleep apnea.

As there are neither drugs nor devices approved to treat CSA, Company management believes there is the potential for a rapid path to commercialization. Unfortunately, rather than support novel approaches for opioid treatment, the recent public and governmental discourses regarding the “opioid epidemic” has focused almost entirely on the distribution of naloxone, an opioid antagonist used for acute emergency situations, so-called “non-abuseable” opioid formulations, as well as on means of reducing opioid consumption by limiting production of opioids and access to legal opioid prescriptions. It remains to be seen whether these approaches will have an impact on the situation. Nevertheless, as a result, we believe that there is an ongoing industry-wide pullback from opioids, as evidenced by a reduction in opioid prescriptions and a major reduction in manufacturing by two of the largest opioid manufactures in the United States.

These factors have made it difficult to raise capital or find strategic partners for the development of ampakines for the treatment of opioid induced respiratory depression and we are assessing whether to continue with this program. In addition, as noted above, we have been notified by the University of Alberta ("TEC Edmonton") that they consider our license agreement to be terminated and we are in discussions with them to determine whether and under what conditions a resolution to the dispute can be achieved. At the present time, we are suspending the development of this program until we reach an understanding with the University of Alberta, the political climate is clarified and we are able to either raise funding or enter into a strategic relationship for this purpose. Nevertheless, the valuable data derived from these translational studies have established antagonism of OIRD as a biomarker for demonstrating proof of principle and target engagement in support of continued ampakine development for other indications.

In addition, the Company is pursuing potentially promising clinical development programs in neuro-behavioral and cognitive disorders, with translational and clinical research programs focused on the use of ampakines for the treatment of ADHD and, together with our academic collaborators, motor impairment resulting from SCI and for Fragile X Autism.

ADHD is one of the most common neurobehavioral disorders, with 6.1% of American children taking medication for treatment, and ADHD is estimated to affect 7.8% of U.S. children aged 4 to 17, which is approximately 4.5 million children, according to the U.S. Centers for Disease Control and Prevention ("CDC"). The principal characteristics of ADHD are inattention, hyperactivity and impulsivity. ADHD symptoms are known to persist into adulthood. In a study published in *Psychiatry Res in May 2010,* up to 78% of children affected by this disorder showed at least one of the major symptoms of ADHD when followed up 10 years later. According to the CDC, approximately 4% of the US adult population has ADHD, which can negatively impair many aspects of daily life, including home, school, work and interpersonal relationships.

Currently available treatments for ADHD include amphetamine-type stimulants and non-stimulant agents targeting the monoaminergic receptor systems in the brain. However, these receptors are not restricted to the brain and are widely found throughout the body. Thus, while these agents can be effective in ameliorating ADHD symptoms, they also can produce adverse cardiovascular effects, such as increased heart rate and blood pressure. Existing treatments also affect eating habits and can reduce weight gain and growth in children and have been associated with suicidal ideation in adolescents and adults. In addition, approved stimulant treatments are DEA classified as controlled substances and present logistical issues for distribution and protection from diversion. Approved non-stimulant treatments, such as atomoxetine, can take four to eight weeks to become effective and undesirable side effects have been observed.

Various investigators have generated data supporting the concept that alterations in AMPA receptor function might underlie the production of some of the symptoms of ADHD. In rodent and primate models of cognition, ampakines have been demonstrated to reduce inattention and impulsivity, two of the cardinal symptoms of ADHD. Furthermore, ampakines do not stimulate spontaneous locomotor activity in either mice or rats, unlike the stimulants presently used for the treatment of ADHD, nor do they increase the stimulation produced by amphetamine or cocaine. These preclinical considerations prompted us to conduct a randomized, double-blind, placebo controlled, two period crossover study to assess the efficacy and safety of CX717 in adults with ADHD.

In a repeated measures analysis, a statistically significant treatment effect on ADHD Rating Scale (ADHD-RS), the primary outcome measure, was observed after a three-week administration of CX717, 800 mg BID. Differences between this dose of CX717 and placebo were seen as early as week one of treatment and continued throughout the remainder of the study. The low dose of CX717, 200 mg BID, did not differ from placebo. In general, results from both the ADHD-RS hyperactivity and inattentiveness subscales, which were secondary efficacy variables, paralleled the results of the total score. CX717 was considered safe and well tolerated.

Based on these clinical results, ampakines such as CX717 might represent a breakthrough opportunity to develop a non-stimulating therapeutic for ADHD with the rapidity of onset normally seen with stimulants. Subject to raising sufficient financing (of which no assurance can be provided), we are planning to continue this program with a Phase 2B clinical trial in patients with adult ADHD.

Ampakines also may have potential utility in the treatment and management of SCI to enhance motor functions and improve the quality of life for SCI patients. An estimated 17,000 new cases of SCI occur each year in the United States, most a result of automobile accidents. Currently, there are roughly 282,000 people living with spinal cord injuries, which often produce impaired motor function.

SCI can profoundly impair neural plasticity leading to significant morbidity and mortality in human accident victims. Plasticity is a fundamental property of the nervous system that enables continuous alteration of neural pathways and synapses in response to experience or injury. One frequently studied model of plasticity is long-term facilitation of motor nerve output ("LTF"). A large body of literature exists regarding the ability of ampakines to stimulate neural plasticity, possibly due to an enhanced synthesis and secretion of various growth factors.

Recently, studies of acute intermittent hypoxia ("AIH") in patients with SCI demonstrate that neural plasticity can be induced to improve motor function. This LTF is based on physiological mechanisms associated with the ability of spinal circuitry to learn how to adjust spinal and brainstem synaptic strength following repeated hypoxic bouts. Because AIH induces spinal plasticity, the potential exists to harness repetitive AIH as a means of inducing functional recovery of motor function following SCI.

RespireRx has been working with Dr. David Fuller, at the University of Florida with funding from the National Institutes of Health, to evaluate the use of ampakines for the treatment of compromised motor function in SCI. Using mice that have received spinal hemisections, CX717 was observed to increase motor nerve activity bilaterally. The effect on the hemisected side was greater than that measured on the intact side, with the recovery approximating that seen on the intact side prior to administration of ampakine. In addition, CX717 was observed to produce a dramatic and long-lasting effect on LTF produced by AIH. The doses of ampakines active in SCI were comparable to those demonstrating antagonism of OIRD, indicating target engagement of the AMPA receptors.

These animal models of motor nerve function following SCI support proof of concept for a new treatment paradigm using ampakines to improve motor functions in patients with SCI. With additional funding recently granted by NIH to Dr. Fuller, RespireRx is continuing its collaborative preclinical research with Dr. Fuller while it is planning a clinical trial program focused on developing ampakines for the restoration of certain motor functions in patients with SCI. The Company is working with our Clinical Advisory Panel and with researchers at highly regarded clinical sites to finalize a Phase 2 clinical trial protocol. Subject to raising sufficient financing (of which no assurance can be provided), we believe that a clinical study could be initiated as early as 2019.

According to the Autism Society, more than 3.5 million Americans live with an Autism Spectrum Disorder ("ASD"), a complex neurodevelopmental disorder. Fragile X Syndrome ("FXS") is the most common identifiable single-gene cause of autism, affecting approximately 1.4 in every 10,000 males and 0.9 in every 10,000 females, according to the CDC. Individuals with FXS and ASD exhibit a range of abnormal behaviors comprising hyperactivity and attention problems, executive function deficits, hyper-reactivity to stimuli, anxiety and mood instability. Also, according the Autism Society, the prevalence rate of ASD has risen from 1 in 150 children in 2000 to 1 in 68 children in 2010, with current estimates indicating a significant rise in ASD diagnosis to 1 in 59 births, placing a significant emotional and economic burden on families and educational systems. The Autism Society estimates the economic cost to U.S. citizens of autism services to be between $236 and $262 billion annually.

Since “autistic disturbances” were first identified in children in 1943, extensive research efforts have attempted to identify the genetic, molecular, environmental, and clinical causes of ASD, but until recently the underlying etiology of the disorder remained elusive. Today, there are no medications that can treat ASD or its core symptoms, and only two anti-psychotic drugs, aripiprazole and risperidone, are approved by the United States Food and Drug Administration (“FDA”) for the treatment of irritability associated with ASD.

Thanks to wide ranging translational research efforts, FXS and ASD are currently recognized as disorders of the synapse with alterations in different forms of synaptic communication and neuronal network connectivity. Focusing on the proteins and subunits of the AMPA receptor complex, autism researchers at the University of San Diego (“UCSD”) have proposed that AMPA receptor malfunction and disrupted glutamate signal transmission may play an etiologic role in the behavioral, emotional and neurocognitive phenotypes that remain the standard for ASD diagnosis. For example, Stargazin, also known as CACNG2 (Ca^{2+} channel 2 subunit), is one of four closely related proteins recently categorized as transmembrane AMPA receptor regulating proteins (“TARPs”).

Researchers at the UCSD have been studying genetic mutations in the AMPA receptor complex that lead to cognitive and functional deficiencies along the autism spectrum. They work with patients and their families to conduct detailed genetic analyses in order to better understand the underlying mechanisms of autism. In one case, they have been working with a teenage patient who has an autism diagnosis, with a phenotype that is characterized by subtle Tourette-like behaviors, extreme aggression, and verbal and physical outbursts with disordered thought. Despite the behaviors, his language is normal. Using next generation sequencing and genome editing technologies, the researchers identified a specific mutation in stargazin, a transmembrane AMPA receptor regulatory protein that alters the configuration and kinetics of the AMPA receptor. When the aberrant sequence was introduced into C57bL6 mice using CRISPR (Clustered Regulatory Interspaced Short Palindromic Repeats), the heterozygous allele had a dominant negative effect on the trafficking of post-synaptic AMPA receptors and produced behaviors consistent with a glutamatergic deficit and similar to what has been observed in the teenage patient.

With funding from the National Institutes of Health to UCSD, RespireRx is working with UCSD to explore the use of ampakines for the amelioration of the cognitive and other deficits associated with AMPA receptor gene mutations. Because CX1739 has an open IND, subject to securing sufficient outside funding (of which no assurance can be provided), we are considering a Phase 2A clinical trial sometime in 2019.

Cannabinoids

OSA is a sleep-related breathing disorder that afflicts an estimated 29 million people in the United States according to the American Academy of Sleep Medicine (“AASM”), and an additional 26 million in Germany and 8 million in the United Kingdom, as presented at the European Respiratory Society’s (“ERS”) annual Congress in Paris, France in September 2018. OSA involves a decrease or complete halt in airflow despite an ongoing effort to breathe during sleep. When the muscles relax during sleep, soft tissue in the back of the throat collapses and obstructs the upper airway. OSA remains significantly under-recognized, as only 20% of cases in the United States according to the AASM and 20% of cases globally have been properly diagnosed. About 24 percent of adult men and 9 percent of adult women have the breathing symptoms of OSA with or without daytime sleepiness. OSA significantly impacts the lives of sufferers who do not get enough sleep; their quality of sleep is deteriorated such that daily function is compromised and limited. OSA is associated with decreased quality of life, significant functional impairment, and increased risk of road traffic accidents, especially in professions like transportation and shipping.

Research has established links between OSA and several important co-morbidities, including hypertension, type II diabetes, obesity, stroke, congestive heart failure, coronary artery disease, cardiac arrhythmias, and even early mortality. The consequences of undiagnosed and untreated OSA are medically serious and economically costly. According to the AASM, the estimated economic burden of OSA in the United States is approximately $162 billion annually. We believe that a new drug therapy that is effective in reducing the medical and economic burden of OSA would have significant advantages for optimal pricing in this costly disease indication.

Continuous Positive Airway Pressure (“CPAP”) is the most common treatment for OSA. CPAP devices work by blowing pressurized air into the nose (or mouth and nose), which keeps the pharyngeal airway open. CPAP is not curative, and patients must use the mask whenever they sleep. Reduction of the apnea/hypopnea index (“AHI”) is the standard objective measure of therapeutic response in OSA. Apnea is the cessation of breathing for 10 seconds or more and hyponea is a reduction in breathing. AHI is the sum of apnea and hypopnea events per hour. In the sleep laboratory, CPAP is highly effective at reducing the AHI. However, the device is cumbersome and difficult for many patients to tolerate. Most studies describe that 25-50% of patients refuse to initiate or completely discontinue CPAP use within the first several months and that most patients who continue to use the device do so only intermittently.

Oral devices may be an option for patients who cannot tolerate CPAP. Several dental devices are available including the Mandibular Advancement Device (“MAD”) and the Tongue Retaining Device (“TRD”). The MAD is the most widely used dental device for sleep apnea and is similar in appearance to a sports mouth guard. It forces the lower jaw forward and down slightly which keeps the airway more open. The TRD is a splint that holds the tongue in place to keep the airway as open as possible. Like CPAP, oral devices are not curative for patients with OSA. The cost of these devices tends to be high and side effects associated with them include night time pain, dry lips, tooth discomfort, and excessive salivation.

Patients with clinically significant OSA who cannot be treated adequately with CPAP or oral devices can elect to undergo surgery. The most common surgery is uvulopalatopharyngoplasty which involves the removal of excess tissue in the throat to make the airway wider. Other possible surgeries include tracheostomies, rebuilding of the lower jaw, and nose surgery. Patients who undergo surgery for the treatment of OSA risk complications, including infection, changes in voice frequency, and impaired sense of smell. Surgery is often unsuccessful and, at present, no method exists to reliably predict therapeutic outcome from these forms of OSA surgery.

Recently, another surgical option has become available based on upper airway stimulation. It is a combination of an implantable nerve stimulator and an external remote controlled by the patient. The hypoglossal nerve is a motor nerve that controls the tongue. The implanted device stimulates the nerve with every attempted breath, regardless of whether such stimulation is needed for that breath, to increase muscle tone to prevent the tongue and other soft tissues from collapsing. The surgically implanted device is turned on at night and off in the morning by the patient with the remote.

The poor tolerance and long-term adherence to CPAP, as well as the limitations of mechanical devices and surgery, make discovery of therapeutic alternatives clinically relevant and important. RespireRx's translational research results demonstrate that dronabinol, a synthetic cannabinoid, has the potential to become the first drug treatment for this large and underserved market.

In order to expand RespireRx's respiratory disorders program and develop cannabinoids for the treatment of OSA, RespireRx 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 had been 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.

Through the merger, RespireRx gained access to an Exclusive License Agreement (as amended, the "Old License Agreement") that Pier had entered into with the University of Illinois Chicago (the "UIC") on October 10, 2007. The Old License Agreement covered certain patents and patent applications in the United States and other countries claiming the use of certain compounds referred to as cannabinoids, of which dronabinol is a specific example, for the treatment of sleep-related breathing disorders (including sleep apnea). Pier's business plan was to determine whether dronabinol would significantly improve subjective and objective clinical measures in patients with OSA.

The Old License Agreement was terminated effective March 21, 2013 and the Company entered into a new license agreement (the "2014 License Agreement") with the UIC on June 27, 2014, the material terms of which were substantially similar to the Old License Agreement. The 2014 License Agreement grants the Company, among other provisions, exclusive rights: (i) to practice certain patents in the United States, Germany and the United Kingdom, as defined in the 2014 License Agreement, that are held by the UIC; (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 UIC a license fee, royalties, patent costs and certain milestone payments.

Dronabinol is a synthetic derivative of Δ9-THC, one of the pharmacologically active substances naturally occurring in the cannabis plant. Dronabinol is a Schedule III, controlled generic drug that has been approved by the FDA for the treatment of AIDS-related anorexia and chemotherapy-induced nausea and vomiting. Dronabinol is available in the United States as the branded prescription drug product Marinol® capsules. Marinol®, together with numerous generic

formulations, is available in 2.5, 5, and 10 mg capsules, with a maximum labelled dosage of 20 mg/day for the AIDS indication, or 15 mg/m^2 per dose for chemotherapy-induced nausea and vomiting.

The Company conducted a 21 day, randomized, double-blind, placebo-controlled, dose escalation Phase 2A clinical study in 22 patients with OSA, in which dronabinol produced a statistically significant reduction in AHI, the primary therapeutic end-point, and was observed to be safe and well tolerated, with the frequency of side effects no different from placebo (Prasad *et al, Frontiers in Psychiatry*, 2013).

With approximately $5 million in funding from the National Heart, Lung and Blood Institute of National Institutes of Health ("NIH"), Dr. David Carley of UIC, along with his colleagues at UIC and Northwestern University, recently completed a Phase 2B multi-center, double-blind, placebo-controlled clinical trial of dronabinol in patients with OSA. Entitled Pharmacotherapy of Apnea with Cannabimimetic Enhancement ("PACE"), this study replicated the earlier Phase 2A study. The authors reported (Carley *et al*, *Sleep*, 2018) that, in a dose dependent fashion, treatment with 2.5mg and 10mg of dronabinol once a day at night, significantly reduced, compared to placebo, the AHI during sleep in 56 evaluable patients with moderate to severe OSA who completed the study. Additionally, treatment with 10mg of dronabinol significantly improved daytime sleepiness as measured by the Epworth Sleepiness Scale and achieved the greatest overall patient satisfaction. As in the previous study, dronabinol was observed to be safe and well tolerated, with the frequency of side effects no different from placebo. The Company did not manage or fund this clinical trial which was funded by the National Heart, Lung and Blood Institute of NIH.

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 allow us or a development partner to submit a 505(b)(2) New Drug Application ("NDA") to the FDA for approval of a new dronabinol label, as opposed to the submission and approval of a full 505(b)(1) NDA. The 505(b)(2) NDA was created by the Hatch-Waxman Amendments to the Federal Food, Drug and Cosmetic Act, in part, to help avoid unnecessary duplication of studies already performed on a previously approved drug; the section gives the FDA express permission to rely on data not developed by the NDA applicant. A 505(b)(2) NDA contains full safety and effectiveness reports but allows at least some of the information required for NDA approval, such as safety and efficacy information on the active ingredient, to come from studies not conducted by or for the applicant. This can result in a less expensive and faster route to approval, compared with a traditional development path, such as 505(b)(1), while creating new, differentiated products. This regulatory path offers market protections under Hatch-Waxman provisions for market exclusivity at the FDA. Other regulatory routes are available to pursue proprietary formulations of dronabinol that will provide further market protections. In Europe, a regulatory approval route similar to the 505(b)(2) pathway is the hybrid procedure based on Article 10 of Directive 2001/83/EC.

In conjunction with its management and consultants, RespireRx has developed a regulatory strategy in which we intend to file a new NDA under Section 505(b)(2) claiming the efficacy of dronabinol in the treatment of OSA and, in the process, create a new branded product. We have engaged Camargo Pharmaceutical Services, LLC to act as regulatory consultants and assist with FDA filings and regulatory strategy.

Unlike a standard 505(b)(1) NDA, the 505(b)(2) Abbreviated New Drug Application ("ANDA") process begins with a pre-IND meeting with the FDA, then moves to formulation development (and nonclinical studies, if necessary) and then to the IND (investigational new drug) filing. Since we intend to utilize an already approved or equivalent dronabinol product from manufacturers that have approved Drug Master Files, we believe that the pre-IND meeting will forego discussions of CMC (chemistry, manufacturing and controls), formulation and safety, as well as Phase 1 and 2 studies. Instead, we believe that the focus will be on the Phase 3 clinical development program. When a Phase 3 study is required for a 505(b)(2), usually only one study with fewer patients is necessary versus the two, large scale, confirmatory studies generally required for 505(b)(1). While no assurance can be provided, with an extensive safety database tracking chronic, long-term use of Marinol® and generics, we believe that FDA should not have major safety concerns with dronabinol in the treatment of OSA.

We anticipate requesting a pre-IND meeting with the FDA possibly during the second quarter of 2019, which would functionally serve as the equivalent of an end-of-Phase 2 meeting. The FDA responses to this meeting will be incorporated into an IND, which we believe we could be in a position to submit within 60 days of receiving their communication.

RespireRx has worked with the PACE investigators and staff, as well as with our Clinical Advisory Panel to design a Phase 3 protocol that, based on the experience and results from the Phase 2A and Phase 2B trials, we believe will provide sufficient data for FDA approval of a RespireRx dronabinol branded capsule for OSA. Subject to raising sufficient financing (of which no assurance can be provided). RespireRx intends to submit the Phase 3 protocol to the FDA. The current version of the protocol is designed as a 90-day randomized, blinded, placebo controlled study of dronabinol in the treatment of OSA. Depending on feedback from the FDA, RespireRx estimates that the Phase 3 trial would require between 120 and 300 patients at 15 to 20 sites, and take 18 to 24 months to complete, at a cost of between $10 million and $14 million.

Subject to raising sufficient financing (of which no assurance can be provided), RespireRx intends to hire Clinilabs Drug Development Corporation, a full-service CRO, to consult and potentially provide clinical site management, monitoring, data management, and centralized sleep monitoring services for the Phase 3 OSA trial. Dr. Gary Zammitt, CEO of Clinilabs, serves on the RespireRx Clinical Advisory Panel, and his management team has provided guidance on study design and CNS drug development that will be relevant for the Phase 3 program. For example, Clinilabs offers specialized clinical trial services for CNS drug development through an alliance with Neuroclinics, including clinical trials examining the effects of drugs on driving, cognitive effects of food and (medicinal) drugs, and sleep and sleep disordered breathing.

On September 4, 2018, RespireRx entered into a dronabinol Development and Supply Agreement with Noramco Inc., one of the world's major dronabinol manufacturers. Under the terms of the Agreement, Noramco agreed to (i) provide all of the active pharmaceutical ingredient ("API") estimated to be needed for the clinical development process for both the first- and second-generation products (each a "Product" and collectively, the "Products"), three validation batches for NDA filing(s) and adequate supply for the initial inventory stocking for the wholesale and retail channels, subject to certain limitations, (ii) maintain or file valid drug master files ("DMFs") with the FDA or any other regulatory authority and provide the Company with access or a right of reference letter entitling the Company to make continuing reference to the DMFs during the term of the agreement in connection with any regulatory filings made with the FDA by the Company, (iii) participate on a development committee, and (iv) make available its regulatory consultants, collaborate with any regulatory consulting firms engaged by the Company and participate in all FDA or Drug Enforcement Agency ("DEA") meetings as appropriate and as related to the API.

In consideration for these supplies and services, the Company has agreed (i) to purchase exclusively from Noramco, during the commercialization phase, all API for its Products (as defined in the Development and Supply Agreement) at a pre-determined price subject to certain producer price adjustments and (ii) Noramco's participation in the economic success of the commercialized Product or Products up to the earlier of the achievement of a maximum dollar amount or the expiration of a period of time.

We plan to establish strategic relationships with appropriate companies to complete formulation and packaging. RespireRx has identified several candidates to perform the encapsulation. Some of these already supply finished product to generic pharmaceutical companies marketing dronabinol for its current non-OSA indications. In addition, as described below, RespireRx has been in discussions with several companies that have considerable expertise in developing novel formulations for dronabinol and have expressed interest in helping us develop a proprietary controlled release formulation. No assurance can be provided that encapsulation or formulation agreements will be consummated on terms acceptable to us; the failure to consummate these agreements would materially adversely affect the Company.

After considerable research and discussions with consultants, we believe the most direct route to commercialization is to proceed directly to a Phase 3 pivotal clinical trial using the currently available dronabinol formulation (2.5, 5 and 10 mg gel caps) and to commercialize a RespireRx branded dronabinol capsule ("RBDC") with an NDA. To that end, RespireRx plans to complete the Phase 3 trial and submit a 505(b)(2) application to FDA for approval of a new, branded, once per day dronabinol gel capsule for the treatment of OSA estimated to occur in 2020. Under the provisions of the Hatch-Waxman Act, the RBDC would have 3-year market exclusivity, as well as further protection from generic substitution through 2025 due to our patents and an anticipated listing in the ***Approved Drug Products with Therapeutic Equivalence Evaluations*** publication (the "Orange Book"), which identifies drug products approved on the basis of safety and effectiveness by the FDA and related patent and exclusivity information.

In addition, management believes there are numerous opportunities for reformulation of dronabinol to produce a proprietary, branded product for the treatment of OSA. Therefore, simultaneous with the development of the RBDC, RespireRx plans to develop a proprietary dronabinol formulation to optimize the dose and duration of action for

treating OSA. An analysis of the time-related efficacy results provides potential guidance on development. We have identified several formulation companies with existing dronabinol formulations, expertise, and licensure to develop a proprietary formulation of dronabinol for RespireRx based on RespireRx's pending patents for low-dose and extended release dronabinol, which we expect would enable brand extensions and market protections through 2036.

Since RBDC is expected, if approved, to be approved under a 505(b)(2) NDA, it would be considered a new, proprietary, branded dronabinol product, with a specific label for OSA. It would be non-identical to any other dronabinol product and there would be no generic equivalents or AB substitutions. There are many examples of branded products that might ordinarily have applied for an ANDA as a branded generic, but which have successfully utilized this 505(b)(2) NDA approach to grant them new product status and protect them from generic substitution.

Because the 505(b)(2) NDA requires clinical data for approval of a new indication, we anticipate that our RBDC would be eligible for market protection under the Hatch-Waxman Amendment clause for “other significant changes” and we expect would therefore be eligible for 3-years of market exclusivity. At the end of these 3 years, if a generic company wished to challenge our issued patents, they would have to file an ANDA with bioequivalence data to our RBDC and, if our patents were listed in the Orange Book, they would have to simultaneously file a Paragraph 4 certification stating that they are challenging our patent. At that point, we would receive a 30-months stay of the patent challenge.

We believe the 5.5 years of market exclusivity expected to result from the Hatch-Waxman Act and the Orange Book listing will provide adequate time for the development and approval of a novel, proprietary formulation of dronabinol, optimized for all-night treatment of OSA, with patent protections through 2036. If the new formulation is approved, we plan to rescind the 505(b)(2) NDA for RBDC and replace the branded product with the new and improved formulation on the market, with the intention of preventing ANDA competition and protecting market share.

With guidance based on the product launch experience of Dr. MacFarland, a member of our Board of Directors, and Richard Purcell, our senior vice-president of research and development, and the managed markets experience of our consultant, Commercialization Consulting, LLC, we have prepared an approach to marketing and commercialization of both the RBDC and the proprietary dronabinol formulation. Based upon an extensive analysis conducted by Commercialization Consulting, LLC we believe that if we were to execute our strategy, we should not experience a loss of more than approximately 15% of sales due to off-label generic dronabinol sales.

Recent Developments

Resignation of James S. Manuso, President and Chief Executive Officer, Vice Chairman and Member of the Board of Directors and Appointment of Arnold S. Lippa as lnterim President and Interim Chief Executive Officer

The resignation of Dr. James S. Manuso as the Company’s President and Chief Executive Officer, Vice Chairman and Member of the Board of Directors became effective on September 30, 2018, the end of the term of his employment agreement. Dr. Manuso did not resign because of any disagreement with the Company relating to the Company’s operations, policies or practices.

On October 12, 2018, Arnold S. Lippa, Ph.D. was named Interim President and Interim Chief Executive Officer. Dr. Lippa continues to serve as the Company’s Chief Scientific Officer and Chairman of the Board of Directors.

University of Alberta (TEC Edmonton)

On May 9, 2007, the Company entered into a license agreement with The Governors of the University of Alberta, as subsequently amended, 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. On May 18, 2018, the Company received a letter from counsel claiming to represent TEC Edmonton and The Governors of the University of Alberta, which purported to terminate, effective December 12, 2017, the license agreement dated May 9, 2007 (as subsequently amended) between the Company and The Governors of the University of Alberta. The Company, through its counsel, disputed any grounds for termination and notified the representative that it invoked Section 13 of that license agreement, which mandates a meeting to be attended by individuals with decision-making authority to attempt in good faith to negotiate a resolution to the dispute. In February 2019, the Company and TEC Edmonton tentatively agreed to terms acceptable to all parties to establish a new license agreement and the form of a new license agreement. However, the parties have not signed the draft new license agreement pending the Company's payment of the agreed amount of historical unreimbursed patent fees of approximately CAD$23,000 (approximately US$17,000 as of December 31, 2018). No assurance can be provided that the Company will or will not be able to remit the historical license fees or that the draft new license agreement will be executed and become effective. If we do not remit the historical fees and the new license agreement does not become effective, we cannot estimate the possible adverse impact on the Company's operations or business prospects.

Dronabinol Development and Supply Agreement

On September 4, 2018, RespireRx entered into a dronabinol Development and Supply Agreement with Noramco Inc., one of the world's major dronabinol manufacturers. Under the terms of the Agreement, Noramco agreed to (i) provide all of the active pharmaceutical ingredient ("API") estimated to be needed for the clinical development process for both the first- and second-generation products (each a "Product" and collectively, the "Products"), three validation batches for NDA filing(s) and adequate supply for the initial inventory stocking for the wholesale and retail channels, subject to certain limitations, (ii) maintain or file valid drug master files ("DMFs") with the FDA or any other regulatory authority and provide the Company with access or a right of reference letter entitling the Company to make continuing reference to the DMFs during the term of the agreement in connection with any regulatory filings made with the FDA by the Company, (iii) participate on a development committee, and (iv) make available its regulatory consultants, collaborate with any regulatory consulting firms engaged by the Company and participate in all FDA or Drug Enforcement Agency ("DEA") meetings as appropriate and as related to the API.

In consideration for these supplies and services, the Company has agreed to purchase exclusively from Noramco during the commercialization phase all API for its Products (as defined in the Development and Supply Agreement) at a pre-determined price subject to certain producer price adjustments and agreed to Noramco's participation in the economic success of the commercialized Product or Products up to the earlier of the achievement of a maximum dollar amount or the expiration of a period of time.

2018 Unit Offering

On September 12, 2018, the Company consummated an initial closing on an offering ("2018 Unit Offering") of Units comprised of one share of the Company's common stock and one common stock purchase warrant. The 2018 Unit Offering was for up to $1.5 million and had a final termination date of October 15, 2018. The initial closing was for $250,750 of which $200,750 was the gross cash proceeds. The additional $50,000 was represented by the conversion or exchange into the 2018 Unit Offering of the principal amount of the Arnold S. Lippa, Demand Promissory Note described below. With the exchange of Dr. Lippa's Demand Promissory Note into the 2018 Unit Offering, 47,620 warrants exercisable at $150% of the unit price ($1.575) per share of common stock and expiring on April 30, 2023 were issued with a value of $49,975 which amount was considered a loss on the extinguishment of that officer note and which amount was credited to additional paid-in capital. Units were sold for $1.05 per unit and the warrants issued in connection with the units are exercisable through April 30, 2023 at a fixed price of 150% of the unit purchase price. 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 $3.00 or more for any five (5) consecutive trading days. In total, 238,814 shares of the Company's common stock and 238,814 common stock purchase warrants were purchased. Other than Arnold S. Lippa, the investors in the offering were not affiliates of the Company. Investors also received an unlimited number of piggy-back registration rights in respect to the shares of common stock and the shares of common stock underlying the common stock purchase warrants, unless such common stock is eligible to be

sold with volume limits under an exemption from registration under any rule or regulation of the SEC that permits the holder to sell securities of the Company to the public without registration and without volume limits (assuming the holder is not an affiliate).

The shares of common stock and common stock purchase warrants 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 common stock purchase warrants, the Common Stock issuable upon exercise of the common stock purchase warrants or any warrants issued to a qualified referral source (of which there were none in the initial closing) 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.

Prior to the initial closing of the 2018 Unit Offering, the Company issued to Arnold S. Lippa, Ph.D, the Company's Interim President, Interim Chief Executive Officer, Executive Chairman and Chief Scientific Officer and James S. Manuso, Ph.D., the Company's then Vice Chairman and then Chief Executive Officer, $100,000 aggregate principal amount ($50,000 each) of demand promissory notes bearing interest at 10% (the "Demand Promissory Notes"). The Demand Promissory Note issued to Dr. Lippa, exclusive of any interest accrued, was exchanged or converted into the 2018 Unit Offering simultaneously with its initial closing. The principal amount of, but not the interest on, the Demand Promissory Note was taken into consideration when determining if the Company had achieved the minimum amount necessary to effect the initial closing of the 2018 Unit Offering. With the exchange of Dr. Lippa's Demand Promissory Note into the 2018 Unit Offering, 47,620 warrants exercisable at $150% of the unit price ($1.575) per share of common stock and expiring on April 30, 2023 were issued with a value of $49,975 which amount was considered a loss on the extinguishment of that officer note and which amount was credited to additional paid-in capital. The Demand Promissory Note issued to Dr. Manuso was not exchanged or converted in connection with the 2018 Unit Offering.

In addition, as set forth in the Purchase Agreements, each Purchaser had an unlimited number of exchange rights, which were options and not obligations, to exchange such Purchaser's entire investment, as defined, (but 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 within stockholders' equity, and excluding any form of debt or convertible debt or preferred stock redeemable at the discretion of the holder (each such financing a "Subsequent Equity Financing"). These exchange rights were effective until the earlier of: (i) the completion of any number of Subsequent Equity Financings that aggregate at least $15 million of gross proceeds, or (ii) December 30, 2018. The exchange rights expired on December 30, 2018.

The 2018 Unit Offering was terminated on October 15, 2018 without any additional closings.

Impression Healthcare Limited

On February 13, 2019, the Company entered into a non- binding memorandum of understanding ("MOU") and exclusivity agreement with Impression Healthcare Limited (ASX: IHL,"Impression") for the purpose of negotiating terms by which the parties would enter in an arrangement, such as a license, joint venture or partnership agreement, so as to commercialize dronabinol for the treatment of OSA in Australia, New Zealand and Southeast Asia. Discussions are in progress.

Recent Accounting Pronouncements

For a description of recent accounting pronouncements, see Note 3 to the Company's consolidated financial statements for the fiscal years ended December 31, 2018 and 2017.

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 in respect to which, the Company is engaged in a dispute resolution process with TEC Edmonton on behalf of The Governors of the University of Alberta, the Company maintains that it 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 9, 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 with respect to the subject matter of this disputed license, no maintenance payments are currently due and payable to the University of Alberta. The University of Alberta claims a prospective payment of approximately $3,600 is currently due and payable.

By letter dated May 18, 2018, the Company received notice from counsel claiming to represent TEC Edmonton and The Governors of the University of Alberta, which purports to terminate, effective December 12, 2017, the license agreement dated May 9, 2007 between the Company and The Governors of the University of Alberta. The Company, through its counsel, disputed any grounds for termination and notified the representative that it invoked Section 13 of that license agreement, which mandates a meeting to be attended by individuals with decision-making authority to attempt in good faith to negotiate a resolution to the dispute. In February 2019, the Company and TEC Edmonton tentatively agreed to terms acceptable to all parties to establish a new license agreement and the form of a new license agreement. However, the parties have not signed the draft new license agreement pending the Company’s payment of the agreed amount of historical unreimbursed patent fees, of approximately CAD$23,000 (approximately US$17,000 as of December 31, 2018). No assurance can be provided that the Company will or will not be able to remit the historical license fees or that the draft new license agreement will be executed and become effective. If we do not remit the historical fees and the new license agreement does not become effective, we cannot estimate the possible adverse impact on the Company’s operations or business prospects.

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

As of December 31, 2018, the Company received an extension of time to make a $100,000 payment that would have due on such date. An additional extension was granted until February 28, 2019 (See Subsequent Events) on which date the Company made the required payment.

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.

Stock-Based Compensation and Awards

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 consolidated 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 sometimes subject to time-based vesting, 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 outside consultants and other vendors are valued on the grant date. At each reporting period, the common stock options are re-valued and the Company recognizes this expense over the period in which the services are provided.

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 uses 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.

Note Exchange Agreements

See Note 4 to our consolidated financial statements for information on our “Note Exchange Agreements” during the years ended December 31, 2018 and 2017.

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) 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 and, in accordance with SEC accounting rules, are charged to general and administrative expenses.

Results of Operations

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

	Years Ended December 31,	
	2018	2017
Operating expenses:		
General and administrative	1,488,238	2,747,471
Research and development	688,286	1,499,940
Total operating expenses	2,176,524	4,247,411
Loss from operations	(2,176,524)	(4,247,411)
Loss on extinguishment of debt and other liabilities in exchange for equity	(166,382)	-
Interest expense	(136,243)	(102,225)
Foreign currency transaction (loss) gain	(112,641)	58,153

Net loss	$(2,591,790)	$(4,291,483)
Net loss per common share - basic and diluted	$(0.77)	$(1.77)
Weighted average common shares outstanding - basic and diluted	3,351,105	2,418,271

Years Ended December 31, 2018 and 2017

Revenues. During the year ended December 31, 2018 and 2017, the Company had no revenues.

General and Administrative. For the year ended December 31, 2018, general and administrative expenses were $1,488,238, a decrease of $1,259,233, as compared to $2,747,471 for the year ended December 31, 2017.

Stock-based compensation costs and fees included in general and administrative expenses were $14,248 for the December 31, 2018, as compared to $1,164,537 for the year ended December 31, 2017, reflecting a decrease of $1,150,289. The decrease is the result of the fact that no stock-based compensation was granted to general and administrative employees of the Company during the year ended December 31, 2018. Salaries and employee benefits included in general and administrative expenses were $685,884 for the year ended December 31, 2018 as compared to $696,445 for the year ended December 31, 2017, a decrease of $10,561. The decrease is the net effect of an increase in base salary of one executive officer in July 2017, reflecting a partial year in 2017, but a full year in 2018, offset by the elimination of the salary and employee benefits of the former Chief Executive Officer and President as of September 30, 2018. Legal fees for general corporate purposes were $278,373 for the year ended December 31, 2018 as compared to $290,290 for the year ended December 31, 2017, a decrease of $11,917. Legal fees for patents and other patent expenses included in general and administrative expenses were $199,363 for the year ended December 31, 2018, a decrease of 32,272 as compared to $231,635. The decreases in both general legal fees and legal fees associated with patents and other patent costs is a result of a reduction in utilization of professional resources as part of the Company's cost control efforts.

The remaining decrease in general and administrative expenses is due to a number of smaller decreases, partially offset by increases in a number of other expense categories.

Research and Development. For the year ended December 31, 2018, research and development expenses were $688,286, a decrease of $811,654, as compared to $1,499,940 for the year ended December 31, 2017, primarily due to a decrease in share-based compensation expenses of $747,741, a reduction in research contracts of $136,779, partially offset by an increase in consulting fees of $63,702 and other expenses.

Loss on Extinguishment of Debt and other Liabilities in Exchange for Equity. Loss on extinguishment of debt or other liabilities during the year ended December 31, 2018 was $166,382. There was no such loss for the year ended December 31, 2017.

Interest Expense. During the year ended December 31, 2018, interest expense was $136,243 (including $42,821 to related parties of which $17,682 is to a single vendor that is also a related party representing interest on invoices subject to delayed payment), an increase of $34,018, as compared to $102,225 (including $15,519 to related parties) for the year ended December 31, 2017. The increase in interest expense resulted primarily from interest on two new promissory notes issued to officers totaling $100,000 of principal amount in 2018, one of which converted or exchanged into the 2018 Unit Offering, net of the reduction in interest associated with the exchange of four convertible notes to non-affiliates and the addition of interest with respect to the Salamandra legal settlement as well as from a single vendor associated with the delay of cash remittances to that vendor.

Foreign Currency Transaction Loss or Gain. The foreign currency transaction loss was $112,641 for the year ended December 31, 2018, as compared to a foreign currency transaction gain of $58,153 for the year ended December 31,

2017. The foreign currency transaction loss or 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, 2018, the Company incurred a net loss of $2,591,790, as compared to a net loss of $4,291,484 for the year ended December 31, 2017.

Liquidity and Capital Resources – December 31, 2018

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 $2,591,790 for the fiscal year ended December 31, 2018 and $4,291,483 for the fiscal year ended December 31, 2017, and negative operating cash flows of $427,368 and $697,009 for the fiscal years ended December 31, 2018 and 2017 respectively. The Company had a stockholders' deficiency of $5,733,255 at December 31, 2018, 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. In addition, the Company's independent registered public accounting firm, in its report on the Company's consolidated financial statements for the year ended December 31, 2018, has expressed substantial doubt about the Company's ability to continue as a going concern (see "Going Concern" below).

At December 31, 2018, the Company had a working capital deficit of $5,736,369, as compared to a working capital deficit of $4,373,443 at December 31, 2017, reflecting an increase in the working capital deficit of $1,362,926 for the fiscal year ended December 31, 2018. The increase in the working capital deficit during the fiscal year ended December 31, 2018 is comprised of an increase in total current liabilities of $1,307,291, and a decrease in current assets of $55,635. The increase in total current liabilities consists of a net increase in accounts payable and accrued expenses of $381,107, an increase in accrued compensation and related expenses of $825,134 (in December 2017, the Company was able to reduce a substantial amount of accrued compensation and related expenses and issued options related thereto), a decrease in convertible notes payable of $134,890, an increase in the note payable to SY Corporation of $160,614, an increase in notes payable to officers of $75,139 and an increase in other short-term notes payable of $277.

At December 31, 2018, the Company had cash aggregating $33,284 as compared to $84,902 at December 31, 2017, reflecting a decrease in cash of $51,618 during the fiscal year ended December 31, 2018.

At December 31, 2018, the Company had $125,000 principal amount of the original 10% convertible notes payable outstanding (plus accrued interest of $62,233), which matured and become due and payable in full on September 15, 2016. Certain of the note holders have notified the Company that the convertible notes are in default. As of the date of such notification, the interest rate on such defaulted convertible notes was increased to 12%. The Company is continuing efforts to extend and/or satisfy these convertible notes payable through the issuance of the Company’s securities, although there can be no assurances that the Company will be successful in this regard.

In December, 2018, the Company issued new 10% convertible notes, due on February 28, 2019 with a face amount of $80,000. Common stock purchase warrants were issued in connection with the issuance of such notes. The Company valued the warrants and recorded an original issue discount associated with the new 10% convertible notes which was then amortized, in part, resulting is amount of unamortized original issue discount of $27,969 as of December 31, 2018.

Operating Activities. For the fiscal year ended December 31, 2018, operating activities utilized cash of $427,368 as compared to utilizing cash of $427,368 for the fiscal year ended December 31, 2017, to support the Company’s ongoing operations and research and development activities.

Financing Activities. For the fiscal year ended December 31, 2018, financing activities consisted of three financings and the payment of vendor liabilities with restricted stock. The Company received $100,000 from the proceeds of two notes issued to executive officers. The 2018 Unit Offering generated cash of $195,750 in net proceeds which was a closing of $250,750, of which $50,000 resulted from an exchange of the principal amount of one officer note and $5,000 represented costs associated with the offering. In addition, the New 10% Convertible Note Financing generated cash of $80,000 in December 2018. 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, which was

partially offset by principal paid on short-term notes of $64,629.

On April 9, 2018, Dr. Arnold S. Lippa and Dr. James S. Manuso, the Company's Chief Scientific Officer and Chairman of the Board of Directors and the Company's then Chief Executive Officer and then Vice Chairman of the Board of Directors, advanced $50,000 each, for a total of $100,000, to the Company for working capital purposes. Each note was payable on demand after June 30, 2018. Each note was subject to a mandatory exchange provision that provided that the principal amount of the note would be mandatorily exchanged into a board approved offering of the Company's securities, if such offering held its first closing on or before June 30, 2018 and the amount of proceeds from such first closing was at least $150,000, not including the principal amounts of the notes that would be exchanged, or $250,000 including the principal amounts of such notes. Upon such exchange, the notes would be deemed repaid and terminated. Any accrued but unpaid interest outstanding at the time of such exchange will be (i) repaid to the note holder or (ii) invested in the offering, at the note holder's election. A first closing did not occur on or before June 30, 2018. Dr. Arnold S. Lippa agreed to exchange his note into the board approved offering that had its initial closing on September 12, 2018 (See Note 9). Accrued interest on Dr. Lippa's note did not exchange. Dr. Manuso's note has not been exchanged and remains outstanding as of December 31, 2018.

On September 12, 2018, the Company consummated an initial closing on an offering ("2018 Unit Offering") of Units comprised of one share of the Company's common stock and one common stock purchase warrant. The 2018 Unit Offering was for up to $1.5 million and had a final termination date of October 15, 2018. The initial closing was for $250,750 of which $200,750 was the gross cash proceeds. The additional $50,000 was represented by the conversion or exchange into the 2018 Unit Offering of the principal amount of the Arnold S. Lippa Demand Promissory Note described below. Units were sold for $1.05 per unit and the warrants issued in connection with the units are exercisable through April 30, 2023 at a fixed price of 150% of the unit purchase price. 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 $3.00 or more for any five (5) consecutive trading days. In total, 238,814 shares of the Company's common stock and 238,814 common stock purchase warrants were purchased. Other than Arnold S. Lippa, the investors in the offering were not affiliates of the Company. Investors also received an unlimited number of piggy-back registration rights in respect to the shares of common stock and the shares of common stock underlying the common stock purchase warrants, unless such common stock is eligible to be sold with volume limits under an exemption from registration under any rule or regulation of the SEC that permits the holder to sell securities of the Company to the public without registration and without volume limits (assuming the holder is not an affiliate).

The shares of common stock and common stock purchase warrants 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 common stock purchase warrants, the Common Stock issuable upon exercise of the common stock purchase warrants or any warrants issued to a qualified referral source (of which there were none in the initial closing) 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.

Prior to the initial closing of the 2018 Unit Offering, the Company issued to Arnold S. Lippa, Ph.D, the Company's Interim President, Interim Chief Executive Officer, Executive Chairman and Chief Scientific Officer and James S. Manuso, Ph.D., the Company's then Vice Chairman and then Chief Executive Officer, respectively, $100,000 aggregate principal amount ($50,000 each) of demand promissory notes bearing interest at 10% (the "Demand Promissory Notes"). The Demand Promissory Note issued to Dr. Lippa, exclusive of any interest accrued, was exchanged into the 2018 Unit Offering simultaneously with its initial closing. With the exchange of Dr. Lippa's Demand Promissory Note into the 2018 Unit Offering, 47,620 warrants exercisable at $150% of the unit price ($1.575) per share of common stock and expiring on April 30, 2023 were issued with a value of $49,975 which amount was considered a loss on the extinguishment of that officer note and which amount was credited to additional paid-in capital. The principal amount of, but not the interest on, the Demand Promissory Note was taken into consideration when determining if the Company had achieved the minimum amount necessary to effect the initial closing of the 2018 Unit Offering. The Demand Promissory Note issued to Dr. Manuso was not exchanged or converted in connection with the closing of the 2018 Unit Offering.

In addition, as set forth in the Purchase Agreements, each Purchaser had an unlimited number of exchange rights, which were options and not obligations, to exchange such Purchaser's entire investment as defined (but 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 within stockholders' equity, and excluding any form of debt or convertible debt or preferred stock redeemable at the discretion of the holder (each such financing a "Subsequent Equity Financing"). These exchange rights were effective until the earlier of: (i) the completion of any number of Subsequent Equity Financings that aggregate at least $15 million of gross proceeds, or (ii) December 30, 2018. For clarity, a Purchaser's entire investment was the entire amount invested ("Investment Amount") (for purposes of the multiple described below) and all of the Common Stock and Warrants purchased (for purposes of the exchange) pursuant to the Purchase Agreement of such Purchaser, however, if the Warrants had been exercised in part or in whole on a cashless basis, then the Investment Amount (for purposes of the multiple described below) would have been the Investment Amount (for purposes of the multiple described below) and all of the Common Stock initially purchased pursuant to the Purchase Agreement of such Purchaser plus any shares of Common Stock issued pursuant to a cashless exercise and any Warrants remaining after such cashless exercise (for purposes of the exchange), or, if the Warrants had been exercised for cash, then the entire investment would have been the Investment Amount plus the amount of cash paid upon cash exercise (for purposes of the multiple described below) and all of the Common Stock initially purchased pursuant to the Purchase Agreement of such Purchaser plus any shares of Common Stock issued pursuant to the cash exercise and any Warrants remaining after such cash exercise (for purposes of the exchange). 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. There were no additional closings of the 2018 Unit Offering. The exchange rights expired on December 30, 2018.

On November 21, 2018, the Company issued common stock in payment of $198,550 of liabilities to one vendor the Company granted non-qualified stock options with a value of $15,000 in payment of a liability to another vendor.

On December 6, 2018, December 7, 2018 and December 31, 2018, the company received an aggregate of $80,000 from the proceeds of the sale to three unaffiliated investors of 10% convertible promissory notes due, inclusive of accrued interest, on February 28, 2019 and associated common stock purchase warrants. The warrants are exercisable at $1.50 per share of common stock and expire on December 30, 2023. The warrants have cashless exercise, call, blocker and other provisions similar to those described above for the warrants in the 2018 Unit Offering.

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 $2,591,790 for the fiscal year ended December 31, 2018 and $4,291,483 for the fiscal year ended December 31, 2017, and negative operating cash flows of $427,368 and $697,009 for the fiscal years ended December 31, 2018 and 2017, respectively. The Company had a stockholders' deficiency of $5,733,255 at December 31, 2018 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, 2018, 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 sustainable revenue. Management is continuing to address various aspects of the Company's operations and obligations, including, without limitation, debt obligations, financing requirements, intellectual property, licensing agreements, legal and patent matters and regulatory compliance, and has continued to raise new debt and equity capital to fund the Company's business activities from both related and unrelated parties.

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 the pursuit of the Company's planned research and development activities. The Company regularly evaluates various measures to satisfy the Company's liquidity needs, including development and other agreements with collaborative partners and, when necessary, seeking to exchange or restructure the Company's outstanding securities. The Company is evaluating certain changes to its operations and structure to facilitating raising capital from sources that may be interested in financing only discrete aspects of the Company's development programs. Such changes could include a significant reorganization, which may include the formation of one or more subsidiaries into which one or more programs may be contributed. 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.

Principal Commitments

Employment Agreements

On August 18, 2015, the Company entered into an employment agreement with Dr. James S. Manuso, Ph.D., to be its new President and Chief Executive Officer. Dr. Manuso resigned as President and Chief Executive Officer effective September 30, 2018 and therefore Dr. Manuso's employment agreement was not automatically extended as described below. Pursuant to the agreement, which was for an initial term through September 30, 2018 (and which would have been deemed to be automatically extended, upon the same terms and conditions, for successive periods of one year, except that Dr. Manuso resigned effective September 30, 2018), Dr. Manuso received an annual base salary of $375,000. Dr. Manuso was, through September 30, 2018, also eligible to earn a performance-based annual bonus award of up to 50% of his base salary, based upon the achievement of annual performance goals established by the Board of Directors in consultation with the executive prior to the start of such fiscal year, or any amount at the discretion of the Board of Directors. No such bonuses were earned or granted during the fiscal years ended December 31, 2018 and December 31, 2017. Additionally, Dr. Manuso was granted stock options to acquire 261,789 shares of common stock of the Company and was eligible to receive additional awards under the Company's Plans in the discretion of the Board of Directors. No such awards were granted to Dr. Manuso during the fiscal year ended December 31, 2018. During the fiscal year ended December 31, 2017, Dr. Manuso was granted, from the Company's 2015 Stock and Stock Option Plan (the "2015 Plan"), non-qualified stock options to acquire 125,000 shares of common stock. Dr. Manuso was also entitled to receive, until such time as the Company established a group health plan for its employees, $1,200 per month, on a tax-equalized basis, as additional compensation to cover the cost of health coverage and up to $1,000 per month, on a tax-equalized basis, as additional compensation for a term life insurance policy and disability insurance policy. Such amounts were accrued during fiscal year ended December 31, 2018 for the nine-month periods ended September 30, 2018, the effective date of Dr. Manuso's termination and for the twelve months during fiscal year ended December 31, 2017. Dr. Manuso was also entitled to be reimbursed for business expenses. The Company has accrued all submitted and approved business expenses as of September 30, 2018, the effective date of Dr. Manuso's termination and December 30, 2017. Additional information with respect to the stock options granted to Dr. Manuso is provided at Note 6 to the Company's consolidated financial statements for the fiscal year ended December 31, 2018 and 2017. Cash compensation inclusive of employee benefits accrued pursuant to this agreement totaled $310,950 during fiscal year ended December 31, 2018 for each of the nine months ended September 30, 2018, and $414,600 for the fiscal year ended December 31, 2017, respectively. Such amounts were included in accrued compensation and related expenses in the Company's consolidated balance sheet at December 31, 2018 and 2017, respectively, and in general and administrative expenses in the Company's consolidated statement of operations for the fiscal years ended December 31, 2018 and 2017, as appropriate. On December 9, 2017, Dr. Manuso forgave $878,360 of accrued compensation and related expenses which was the amount owed by the Company as of September 30, 2017, as described in more detail below. On the same date, Dr. Manuso received options to purchase 608,704 shares of common stock, as described in more detail below. Dr. Manuso did not receive any additional compensation for serving as Vice Chairman or a member of on the Board of Directors. Amounts accruing after September 30, 2017 have not been paid to Dr. Manuso. Effective on September 30, 2018, Dr. Manuso also resigned as Vice Chairman and as a member of the Board of Directors.

On August 18, 2015, concurrently with the hiring of Dr. James S. Manuso as the Company's then new President and Chief Executive Officer, Dr. Arnold S. Lippa resigned as the Company's President and Chief Executive Officer. On October 12, 2018, Dr. Lippa was named Interim President and Interim Chief Executive Officer (see Note 9 to the Company's consolidated financial statements for the fiscal years ended December 31, 2018 and 2017) to replace Dr. Manuso who resigned effective September 30, 2018. Dr. Lippa continues to serve as the Company's Executive Chairman and as a member of the Board of Directors. Also on August 18, 2015, Dr. Lippa was named Chief Scientific Officer of the Company, and the Company entered into an employment agreement with Dr. Lippa in that capacity. Pursuant to the agreement, which was for an initial term through September 30, 2018 (and which automatically extended on September 30, 2018 and will automatically extend annually, upon the same terms and conditions, for successive periods of one year, unless either party provides written notice of its intention not to extend the term of the agreement at least 90 days prior to the applicable renewal date), Dr. Lippa received an annual base salary of $300,000. Dr. Lippa is also eligible to earn a performance-based annual bonus award of up to 50% of his base salary, based upon the achievement of annual performance goals established by the Board of Directors in consultation with the executive prior to the start of such fiscal year, or any amount at the discretion of the Board of Directors. Additionally, Dr. Lippa was granted stock options to acquire 30,769 shares of common stock of the Company and is eligible to receive additional awards under the Company's Plans at the discretion of the Board of Directors. Dr. Lippa did not receive any option to purchase shares of common stock during fiscal year ended December 31, 2018. Dr. Lippa received from the 2015 Plan, non-qualified stock options to purchase 50,000 shares of common stock on January 17, 2017 and non-qualified stock options to purchase an additional 50,000 shares of common stock on June 30, 2017. Dr. Lippa is also entitled to receive, until such time as the Company establishes a group health plan for its employees, $1,200 per month, on a tax-equalized basis, as additional compensation to cover the cost of health coverage and up to $1,000 per month, on a tax-equalized basis, as reimbursement for a term life insurance policy and disability insurance policy. Dr. Lippa is also entitled to be reimbursed for business expenses. Additional information with respect to the stock options granted to Dr. Lippa is provided at Note 6 to the Company's consolidated financial statements for the fiscal years ended December 31, 2018 and 2017. Cash compensation inclusive of employee benefits accrued pursuant to this agreement totaled $339,600 for each of the fiscal years ended December 31, 2017 and 2018, respectively, which amounts are included in accrued compensation and related expenses in the Company's consolidated balance sheet at December 31, 2017 and 2018, and in research and development expenses in the Company's consolidated statement of operations for the fiscal years ended December 31, 2018 and 2017. Dr. Lippa does not receive any additional compensation for serving as Executive Chairman and on the Board of Directors. On December 9, 2017, Dr. Lippa forgave $807,497 of accrued compensation and related expenses which was the amount owed by the Company as of September 30, 2017. On the same date, Dr. Lippa received options to purchase 559,595 shares of common stock, as described in more detail below.

On August 18, 2015, the Company also entered into an employment agreement with Jeff E. Margolis, in his role at that time as Vice President, Secretary and Treasurer. Pursuant to the agreement, which was for an initial term through September 30, 2016 (and which automatically extended on September 30, 2016 and will automatically extend annually, upon the same terms and conditions for successive periods of one year, unless either party provides written notice of its intention not to extend the term of the agreement at least 90 days prior to the applicable renewal date), Mr. Margolis received, at that time, an annual base salary of $195,000, and was eligible to receive performance-based annual bonus awards ranging from $65,000 to $125,000, based upon the achievement of annual performance goals established by the Board of Directors in consultation with the executive prior to the start of such fiscal year, or any amount at the discretion of the Board of Directors. Additionally, Mr. Margolis was granted stock options to acquire 30,769 shares of common stock of the Company and is eligible to receive additional awards under the Company's Plans at the discretion of the Board of Directors. Mr. Margolis received from the 2015 Plan, non-qualified stock option to acquire 50,000 shares of common stock on each of January 17, 2017 and June 30, 2017. Mr. Margolis is also entitled to receive, until such time as the Company establishes a group health plan for its employees, $1,200 per month, on a tax-equalized basis, as additional compensation to cover the cost of health coverage and up to $1,000 per month, on a tax-equalized basis, as reimbursement for a term life insurance policy and disability insurance policy. Mr. Margolis is also entitled to be reimbursed for business expenses. Additional information with respect to the stock options granted to Mr. Margolis is provided at Note 6 to the Company's consolidated financial statements for fiscal years ended December 31, 2018 and 2017. Mr. Margolis' employment agreement was amended effective July 1, 2017. 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 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. Recurring cash compensation accrued pursuant to this amended agreement totaled $321,600 for the fiscal year ended December 31, 2018 and totalled $269,100 pro-rated between the pre-amendment and post-amendment terms of Mr. Margolis' employment contract for fiscal year ended December 31, 2017 which amounts are included in accrued compensation and related expenses in the Company's consolidated balance sheet December 31, 2017 and, 2018, and in general and administrative expenses in the Company's consolidated statement of operations.

The employment agreements between the Company and each of Dr. Manuso, Dr. Lippa, and Mr. Margolis (prior to the 2017 amendment), respectively, provided that the payment obligations associated with the first year base salary were to accrue, but no payments were to be made, until at least $2,000,000 of net proceeds from any offering or financing of debt or equity, or a combination thereof, was received by the Company, at which time scheduled payments were to commence. Dr. Lippa, and Mr. Margolis (who are each also directors of the Company), (and prior to his resignation, Dr. James S. Manuso) have each agreed, effective as of August 11, 2016, to continue to defer the payment of such amounts indefinitely, until such time as 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.

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 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, 38114, 38,114, and 138,842, respectively, for options exercisable into a total of 1,772,055 shares of common stock with a total value of $2,475,561.

On April 5, 2018, the Company accepted an offer from Robert N. Weingarten, (former Chief Financial Officer), pursuant to which Mr. Weingarten would forgive accrued compensation and related accrued expenses as of that date in the amount of $200,350. On the same date, the Company granted Mr. Weingarten, from the 2015 Plan, non-qualified stock options exercisable for 10 years with an exercise price of $1.12 per share of common stock, among other terms and features and with a total value of $200,404.

University of Alberta License Agreement

On May 9, 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 in the near term, no maintenance payments to the University of Alberta are currently due and payable, nor are any maintenance payments expected to be due in the near future in connection with the license agreement.

By letter dated May 18, 2018, the Company received notice from counsel claiming to represent TEC Edmonton and The Governors of the University of Alberta, which purports to terminate, effective December 12, 2017, the license agreement dated May 9, 2007 between the Company and The Governors of the University of Alberta. The Company, through its counsel, disputed any grounds for termination and notified the representative that it invoked Section 13 of that license agreement, which mandates a meeting to be attended by individuals with decision-making authority to attempt in good faith to negotiate a resolution to the dispute. In February 2019, the Company and TEC Edmonton tentatively agreed to terms acceptable to all parties to establish a new license agreement and the form of a new license agreement. However, the parties have not signed the draft new license agreement pending the Company's payment of the agreed amount of historical unreimbursed patent fees, of approximately CAD$23,000 (approximately US$17,000 as of December 31, 2018). No assurance can be provided that the Company will or will not be able to remit the historical license fees or that the draft new license agreement will be executed and become effective. If we do not remit the historical fees and the new license agreement does not become effective, we cannot estimate the possible adverse impact on the Company's operations or business prospects.

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 a 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 obligation of $100,000 due on December 31, 2018, was extended to February 28, 2019 when such payment obligation was paid by the Company. The minimum annual royalty obligation was paid as scheduled in December 2017. One-time milestone payments may become due based upon the achievement of certain development milestones. $350,000 will be due within five days after the dosing of the first patient is a Phase III human clinical trial anywhere in the world. $500,000 will be due within five days after the first NDA filing with FDA or a foreign equivalent. $1,000,000 will be due within twelve months of the first commercial sale. One-time royalty payments may also become due and payable. Annual royalty payments may also become due. In the year after the first application for market approval is submitted to the FDA or a foreign equivalent 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 or a foreign equivalent 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. During the fiscal years ended December 31, 2018 and 2017, the Company recorded a charge to operations of $100,000 with respect to its minimum annual royalty obligation, which is included in research and development expenses in the Company's consolidated statements of operations for the fiscal years ended December 31, 2018 and 2017.

Noramco Inc. - Dronabinol Development and Supply Agreement

On September 4, 2018, RespireRx entered into a dronabinol Development and Supply Agreement with Noramco Inc., one of the world's major dronabinol manufacturers. Under the terms of the Agreement, Noramco agreed to (i) provide all of the active pharmaceutical ingredient ("API") estimated to be needed for the clinical development process for both the first- and second-generation products (each a "Product" and collectively, the "Products"), three validation batches for New Drug Application ("NDA") filing(s) and adequate supply for the initial inventory stocking for the wholesale and retail channels, subject to certain limitations, (ii) maintain or file valid drug master files ("DMFs") with the FDA or any other regulatory authority and provide the Company with access or a right of reference letter entitling the Company to make continuing reference to the DMFs during the term of the agreement in connection with any regulatory filings made with the FDA by the Company, (iii) participate on a development committee, and (iv) make available its regulatory consultants, collaborate with any regulatory consulting firms engaged by the Company and participate in all FDA or Drug Enforcement Agency ("DEA") meetings as appropriate and as related to the API.

In consideration for these supplies and services, the Company has agreed to purchase exclusively from Noramco during the commercialization phase all API for its Products as defined in the Development and Supply Agreement at a pre-determined price subject to certain producer price adjustments and agreed to Noramco's participation in the economic success of the commercialized Product or Products up to the earlier of the achievement of a maximum dollar amount or the expiration of a period of time.

National Institute of Drug Abuse Agreement

As a result of agreements entered into on October 19, 2015 and January 19, 2016, the Medications Development Program of the National Institute of Drug Abuse ("NIDA") funded and conducted research on the Company's ampakine compounds CX717 and CX1739 to determine their potential usefulness for the treatment of cocaine and methamphetamine addiction and abuse. The Company retains all intellectual property resulting from this research, as well as proprietary and commercialization rights to these compounds.

In general, the ampakines did not produce behavioral effects in rats and mice that are commonly associated with administration of stimulants such as cocaine or amphetamines. Instead, the ampakines reduced the stimulation produced by both of these drugs. In addition, the ampakines were not recognized as cocaine- or amphetamine-like when administered to rats that had been trained to recognize whether they had been administered these drugs. The absence of stimulant properties on the part of the ampakines may confirm their value as potential non-stimulant treatments for ADHD.

Transactions with Biovail Laboratories International SRL

In March 2010, the Company entered into an asset purchase agreement with Biovail Laboratories International SRL ("Biovail"). Pursuant to the asset purchase agreement, Biovail acquired the Company's interests in CX717, CX1763, CX1942 and the injectable dosage form of CX1739, as well as certain of its other ampakine compounds and related intellectual property for use in the field of respiratory depression or vaso-occlusive crises associated with sickle cell disease. The agreement provided the Company with the right to receive milestone payments in an aggregate amount of up to $15,000,000 plus the reimbursement of certain related expenses, conditioned upon the occurrence of particular events relating to the clinical development of certain assets that Biovail acquired. None of these events occurred.

As part of the transaction, Biovail licensed back to the Company certain exclusive and irrevocable rights to some acquired ampakine compounds, other than CX717, an injectable dosage form of CX1739, CX1763 and CX1942, for use outside of the field of respiratory depression or vaso-occlusive crises associated with sickle cell disease. Accordingly, following the transaction with Biovail, the Company retained its rights to develop and commercialize the non-acquired ampakine compounds as a potential treatment for neurological diseases and psychiatric disorders. Additionally, the Company retained its rights to develop and commercialize the ampakine compounds as a potential treatment for sleep apnea disorders, including an oral dosage form of ampakine CX1739.

In September 2010, Biovail's parent corporation, Biovail Corporation, combined with Valeant Pharmaceuticals International in a merger transaction and the combined company was renamed "Valeant Pharmaceuticals International, Inc." ("Valeant"). Following the merger, Valeant and Biovail conducted a strategic and financial review of their product pipeline and, as a result, in November 2010, Biovail announced its intent to exit from the respiratory depression project acquired from the Company in March 2010.

Following that announcement, the Company entered into discussions with Biovail regarding the future of the respiratory depression project. In March 2011, the Company entered into a new agreement with Biovail to reacquire the ampakine compounds, patents and rights that Biovail had acquired from the Company in March 2010. The new agreement provided for potential future payments of up to $15,150,000 by the Company based upon the achievement of certain developments, including new drug application submissions and approval milestones pertaining to an intravenous dosage form of the ampakine compounds for respiratory depression. Biovail is also eligible to receive additional payments of up to $15,000,000 from the Company based upon the Company's net sales of an intravenous dosage form of the compounds for respiratory depression.

At any time following the completion of Phase 1 clinical studies and prior to the end of Phase 2A clinical studies, Biovail retains an option to co-develop and co-market intravenous dosage forms of an ampakine compound as a treatment for respiratory depression and vaso-occlusive crises associated with sickle cell disease. In such an event, the Company would be reimbursed for certain development expenses to date and Biovail would share in all such future development costs with the Company. If Biovail makes the co-marketing election, the Company would owe no further milestone payments to Biovail and the Company would be eligible to receive a royalty on net sales of the compound by Biovail or its affiliates and licensees.

Duke University Clinical Trial Agreement

On January 27, 2015, the Company entered into a Clinical Study and Research Agreement with Duke University (as amended, the "Duke Agreement") to develop and conduct a protocol for a program of clinical study and research which was amended on October 30, 2015 and further amended on July 28, 2016, which agreement, as amended, resulted in a total amount payable under the Agreement to $678,327. During the fiscal years ended December 31, 2018 and 2017, the Company charged $0 to research and development expenses with respect to work conducted pursuant to the Duke Agreement. The clinical trial completed in October 2016 and the Company announced the study results on December 15, 2016. Amounts still owing under this agreement are in the Company's balance sheets at December 31, 2018 and 2017.

Sharp Clinical Services, Inc. Agreement

The Company has various agreements with Sharp Clinical Services, Inc. to provide packaging, labeling, distribution and analytical services.

Covance Laboratories Inc. Agreement

On October 26, 2016, the Company entered into a twelve-month agreement with Covance Laboratories Inc. to provide compound testing and storage services with respect to CX1739, CX1866 and CX1929 at a total budgeted cost of $35,958. This agreement was renewed in October 2018.

Summary of Principal Cash 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, 2018, aggregating $995,900.

		Payments Due By Year				
	Total	2019	2020	2021	2022	2023
License agreements	$500,000	$100,000	$100,000	$100,000	$100,000	$100,000
Employment agreements (1)	495,900	495,900		-	-	-
Total	$995,900	$595,900	$100,000	$100,000	$100,000	$100,000

(1) The payment of such amounts has been deferred indefinitely, as described above at "Employment Agreements". 2019 obligations include nine months of employment agreement obligations for Dr. Lippa and Mr. Margolis as their employment contracts renewed on September 30, 2018.

Off-Balance Sheet Arrangements

At December 31, 2018, the Company did not have any transactions, obligations or relationships that could be considered off-balance sheet arrangements.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Not applicable for smaller reporting companies.

Item 8. Financial Statements and Supplementary Data

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

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

Not applicable.

Item 9A. Controls and Procedures

Disclosure Controls and Procedures

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

disclosures.

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

The Company failed to complete and file various periodic reports in 2012, 2013 and 2014 in a timely manner because the Company's accounting and financial staff had resigned by October 26, 2012 and its financial and accounting systems had been shut-down at December 31, 2012. Current management, two of whom joined the Company in March 2013, has been focusing on developing replacement controls and procedures that are adequate to ensure that information required to be disclosed in reports filed under the Exchange Act is recorded, processed, summarized and reported within the required time periods and is accumulated and communicated to the Company's management to allow timely decisions regarding required disclosure. Current management has instituted a program to reestablish the Company's accounting and financial staff and install new accounting and internal control systems, and has retained accounting personnel, established accounting and internal control systems, addressed the preparation of delinquent financial statements, and worked diligently to bring current delinquent SEC filings as promptly as reasonably possible under the circumstances. The Company is current in its SEC periodic reporting obligations, but as of the date of the filing of this Annual Report on Form 10-K, the Company had not yet completed the process to establish adequate internal controls over financial reporting. In February 2017, the Company's Chief Financial Officer resigned and one of the existing officers was appointed Interim Chief Financial Officer and subsequently, Chief Financial Officer. The Company has not completed its search for a permanent replacement.

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

Management's Annual Report on Internal Control over Financial Reporting

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

Our management, consisting of our Interim Chief Executive Officer and our Chief Financial Officer, has evaluated our internal control over financial reporting as of December 31, 2018 based on the 2013 Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations ("COSO") of the Treadway Commission. Based on this assessment, and taking into account the operating structure of the Company as it has existed from October 2012 through December 2018, as well as the various factors discussed herein, our management has concluded that material weaknesses in the Company's internal control over financial reporting existed as of December 31, 2018, as a result of which our internal control over financial reporting was not effective at December 31, 2018.

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

Within the constraints of the Company's limited financial resources, new management has retained accounting personnel, established accounting and internal control systems, addressed the preparation of delinquent SEC financial filings, and filed all delinquent SEC filings. As of the date of the filing of this Annual Report on Form 10-K, the

Company has not yet completed this process of reestablishing adequate internal controls over financial reporting.

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

Changes in Internal Control over Financial Reporting

The Company's management, consisting of its principal executive officer and principal financial officer, has determined that no change in the Company's internal control over financial reporting (as that term is defined in Rules 13(a)-15(f) and 15(d)-15(f) of the Securities Exchange Act of 1934) occurred during or subsequent to the fourth quarter of the year ended December 31, 2018 that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting. The Company's management has made this determination as of December 31, 2018 and 2017.

Item 9B. Other Information

Arnold S. Lippa, the Company's Interim Chief Executive Officer, Interim President and Chief Scientific Officer has extended credit to the Company on April 15, 2019 for operating expenses by making a payment of $25,000 to the Company's auditors which amount has been accounted for by the Company as an advance by Dr. Lippa payable on demand. The balance of the amount payable to the auditors has been paid directly by the Company.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

Directors

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

Name	Age	Director Since	Principal Occupation
Arnold S Lippa, Ph.D.	72	2013	Interim Chief Executive Officer, Interim President, Chief Scientific Officer and Chairman of the Board of the Company
Jeff E. Margolis	63	2013	Senior Vice President, Chief Financial Officer, Treasurer and Secretary of the Company and President of Aurora Capital LLC, an investment banking and securities brokerage firm
James Sapirstein, RPh. M.B.A.	57	2014	Director and since December 28, 2018, Executive Vice Chairman of the Board of the Company
Kathryn MacFarlane, PharmD	53	2014	Owner and Managing Partner of SmartPharma LLC, a consulting firm

Arnold S. Lippa, Ph.D.: Dr. Lippa is a Senior Managing Director and founder of T Morgen Capital LLC through which he administers his family's assets. T Morgen Capital LLC is a significant equity owner and managing member of Aurora Capital LLC ("Aurora"), a boutique investment bank and securities firm of which Mr. Margolis is the president and founder, which has served as a placement agent with respect to certain of the Company's prior financings. Dr. Lippa and Mr. Margolis jointly manage, since 2004, Atypical BioCapital Management LLC and Atypical BioVentures Fund LLC, a life sciences fund management company and venture fund, respectively. Since 2006, Dr. Lippa has also been the Executive Chairman of the board of Xintria Pharmaceutical Corporation, a Delaware corporation, as well as a member of its board of directors. Dr. Lippa is a member of the Board of Directors of ContraVir Pharmaceuticals, Inc. since December 2015 where he is a member of the audit committee, the compensation committee and the Corporate Governance/Nominating Committee. Dr. Lippa was co-founder of DOV Pharmaceutical, Inc., where he served as Chairman of the Board and Chief Executive Officer from its inception in 1995 through 2005. Dr. Lippa stepped down as a director of DOV Pharmaceuticals, Inc. in 2006.

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

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

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

James Sapirstein, RPh. M.B.A.: Mr. Sapirstein was the Chief Executive Officer and director of ContraVir Pharmaceuticals, Inc., a public reporting company, from March 20, 2014 until October 2018. Prior to joining Contravir, Mr. Sapirstein served as the Chief Executive Officer of Alliqua Biomedical, Inc., a public reporting company. He is considered a start-up and turnaround specialist, with 30 years of pharmaceutical and biotechnology industry experience. He was a founder and Chief Executive Officer and President of Tobira Therapeutics, Inc. from October 2006 to April, 2011, a company that was acquired by Allergan plc in November 2016. At Tobira Therapeutics, Inc. Mr. Sapirstein led an experienced biotechnology development team. He has launched several HIV/AIDS agents worldwide during his career in the biotechnology and pharmaceutical industry. Mr. Sapirstein was with Bristol-Myers Squibb from 1996-2000. While at Bristol-Myers Squibb he served as the Head of the International HIV business as well as working in its Infectious Disease marketing teams. In 2002, he accepted the position of Executive Vice President for Serono Laboratories, where he led a team of over 100 professionals in the HIV and pediatric growth hormone business. He had held positions at Gilead Sciences (where he was responsible for the product Viread®), Bristol-Myers Squibb, Hoffmann-LaRoche Ltd. and Eli Lilly and Company. He serves as a member of the Advisory Board at MusclePharm Corp., a public reporting company and a member of the Board of Directors of Clinical Supplies Management, Inc., a private company. He currently serves as an Advisory Board Director at the Fairleigh Dickinson School of Pharmacy. Mr. Sapirstein previously served as a Director of ContraVir Pharmaceuticals, Inc, Tobira Therapeutics, Inc. as well as Alliqua, Inc. He is also Chairman of BioNJ and a Board director for BIO, where he Board sits on both the Health Section Governing Board and Emerging Companies Section Governing Board. Mr. Sapirstein received his Pharmacy degree from the Ernest Mario School of Pharmacy at the Rutgers University, and his Masters of Business Administration degree from Farleigh Dickinson University.

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

Kathryn MacFarlane, PharmD: Kathryn MacFarlane is the co-founder and Managing Partner of SmartPharma, LLC, where she has contracted to serve as the Chief Commercial Officer of Agile Therapeutics and the Sr. Vice President of Commercial Development for Napo Pharmaceuticals. SmartPharma performs market assessments and develops forecasts and commercial plans for pharmaceutical products. Ms. MacFarlane has provided advice to over 75 companies and investors on financing, licensing, and acquisition of drug products and technologies. She is an experienced pharmaceutical executive with over 25 years in the industry, including senior level roles in drug development, marketing, and sales management at Parke-Davis, Pfizer, and Warner Chilcott, where she was the Vice

President of Sales, Marketing, and New Product Planning. Ms. MacFarlane played a key role in the launch of several leading brands, most notably Lipitor®, Celexa®, and Loestrin® 24. Ms. MacFarlane earned a B.S. and PharmD from Purdue University and completed a Postdoctoral Fellowship with Rutgers University and Hoffmann-LaRoche. She was named a Distinguished Alumna and was awarded the Eaton Entrepreneur of the Year by the Purdue University School of Pharmacy, where she currently is an Affiliate Faculty member. Ms. MacFarlane is Chairwoman on the Finance Committee for the Board of Directors of INMED Partnerships for Children, and a member of the Executive Committee of the Woodley Park Community Association.

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

Executive Officers

Each executive officer of the Company serves at the discretion of the Board of Directors. The names of the Company's executive officers are set forth below. At December 31, 2018, each of our executive officers except Richard Purcell was also a member of our board of directors, and the biographical information of those officers appears above in the immediately prior section.

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

Richard Purcell: In addition to his role at the Company, Richard Purcell (Age: 58), manages a consulting firm, DNA Healthlink, Inc. through which he is contracted as a Senior Vice President of Research & Drug Development at Generex Biotechnology. In this role, he oversees the research and development activities of the company's subsidiaries, and provides strategic guidance on mergers and acquisitions, including implementation and integration of a management service organization (MSO) through the company's subsidiary, NuGenerex Distribution Solutions. Mr. Purcell has over 30 years of experience in consulting and advising emerging biopharmaceutical and technology companies on new business strategy, operations management, clinical development of novel compounds, data solutions for clinical and medical applications, patient engagement and communication, medical education for professionals and consumers, and data analytics for outcomes research. He is a biopharmaceutical development specialist, with extensive experience in providing consulting services to financial, venture capital, and start-up companies to concentrate on new business strategy and clinical development of novel compounds.

Previously, Mr. Purcell was president of ClinPro, Inc., a mid-sized clinical research organization ("CRO"), where he led this full-service, technology driven CRO specializing in Phase I, II, and III clinical trial management. His work included the design and implementation of a number of early stage clinical development programs. Prior to joining ClinPro, Mr. Purcell worked for SCP Communications, a medical communications company, where he served as Corporate Vice President and General Manager of the Clinical Programs Division. Mr. Purcell previously headed the Life Sciences Consulting Group for Kline and Company. Mr. Purcell started his career as a molecular biologist, where he developed and patented a second generation TPA (tissue plasminogen activator) with increased half-life. He has also conducted primary research and published manuscripts on the topics of AIDS and immunomodulators. Mr. Purcell graduated with a degree in Biochemical Sciences from Princeton University, and attended Rutgers Graduate School of Management focusing in marketing and finance. He is also an Adjunct Professor of Biology at Monmouth University where he developed and teaches The Business of Biotechnology.

BOARD COMMITTEES

The board of directors does not maintain any separate standing board committees. Instead, the functions of each of the Audit Committee, the Compensation Committee and the Governance and Nomination Committee have been and are currently being addressed by the full board of directors. This arrangement was initially implemented in 2013 when current management was put in place. At that time there were no independent directors. Since that time, the Company has added two independent directors, both in 2014, however, because of the small size of the Board generally and because the Board includes only two independent directors, the Company has not appointed standing committees.

***Audit Committee*.** The board of directors meets with the Company's independent registered public accountants and management to prepare for and to review the results of the annual audit and to discuss the annual and quarterly financial statements, earnings releases and related matters. The board of directors, among other things, (i) selects and retains the independent registered public accountants, (ii) reviews with the independent registered public accountants the scope and anticipated cost of their audit, and their independence and performance, (iii) reviews accounting practices, financial structure and financial reporting, (iv) receives and considers the independent registered public accountants' comments as to controls, adequacy of staff and management performance and procedures in connection with audit and financial controls, (v) reviews and pre-approves all audit and non-audit services provided to the Company by the independent registered public accountants, and (vi) reviews and pre-approves all related-party transactions. The board of directors does not itself prepare financial statements or perform audits, and its members are not auditors or certifiers of the Company's financial statements.

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

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

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

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

considered.

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

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires the Company's executive officers and directors and persons who beneficially own more than 10% of the Company's outstanding common stock, whom the Company refers to collectively as the "reporting persons," to file reports of ownership and changes in ownership with the SEC, and to furnish the Company with copies of these reports.

Based solely on the Company's review of the copies of these reports received by it and written representations received from certain of the reporting persons with respect to the filing of reports on Forms 3, 4 and 5, the Company believes that all such filings required to be made by the reporting persons for the fiscal year ended December 31, 2018 were made on a timely basis, except for any Form 3 or Form 4 that may be required for any of the beneficial holders, other than officers and directors, listed in Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

Code of Ethics

The Company previously adopted a Code of Business Conduct and Ethics, which covered all of our directors and employees, including our principal executive and financial officers. That Code of Business Conduct and Ethics has never been formally ratified or approved by the current Board of Directors after a change in management occurred in March 2013. When practicable, Board of Directors intends to adopt an Amended and Restated Code of Business Conduct and Ethics, and that document, and any further amendment to, or waiver from, any applicable provision (related to elements listed under Item 406(b) of Regulation S-K) of our Code of Business Conduct and Ethics that applies to our directors or executive officers will be posted on our website at www.respirerx.com or in a report filed with the SEC on a Current Report on Form 8-K.

Item 11. Executive Compensation

Summary Compensation Table for 2018

The table below summarizes the total compensation paid or earned by each of the named executive officers for the fiscal years ended December 31, 2018, 2017 and 2016. The information contained under the heading "Stock Awards" for all named executive officers includes the estimated value of equity awards using the Black-Scholes option-pricing model and does not reflect actual cash payments or actual dollars awarded.

Name and Principal Position	Year	Salary ($)(1)	Bonus ($)	Stock Awards ($)(1)	All Other Compensation ($)(2)	Total ($)
Arnold S Lippa, Ph.D. Executive Chairman	2018	339,600	-	-	-	339,600
and Chief Scientific Officer	2017	339,600	-	274,106	-	613,706
Jeff E. Margolis Senior Vice President,	2018	321,600	-	-	-	321,600
Chief Financial Officer, Treasurer and Secretary	2017	269,100	-	301,034	(17,881)	552,253
James S. J. Manuso, Ph.D President,	2018	310,950	-	-	-	310,950
Chief Executive Officer and Vice Chairman	2017	414,600	-	366,782	(28,001)	753,381
Richard Purcell, Senior Vice President of Research and Development	2018	150,000	-	-	17,682	$167,682

(1) The 2018 salary amounts in the table above reflect contractual salary amounts plus employee benefits. James S. J. Manuso terminated employment as of September 30, 2018 and therefore, amounts for Dr. Manuso reflect such amounts for the period from January 1, 2018 through September 30, 2018. There were no bonuses, stock or stock option awards or other compensation during the year ended December 31, 2018.

Mr. Purcell has been the Senior Vice President of Research and Development for the Company since October 15, 2014 and provides services to the Company on a month-to-month basis through DNA Healthlink, Inc. at the rate of $12,500 per month.

The 2017 salary amounts in the table above do not include the net benefit associated with the forgiveness of accrued compensation on December 9, 2017, offset by the expense incurred on that same date associated with option awards. The 2017 salary amounts are shown in the table above before the benefit associated with the forgiveness that is reflected in the “All Other Compensation” column in the table above. On January 17, 2017, the Board of Directors awarded from the 2015 Plan, non-qualified stock options with respect to 225,000 shares of common stock to the named executive officers who were also directors of the Company at the time and options with respect to 40,000 shares of common stock to an additional officer and options with respect to 50,000 shares of common stock, in the aggregate to the two independent directors. On July 26, 2017, the Board of Directors awarded non-qualified stock options with respect to 25,000 shares of common stock to Jeff E. Margolis and the Company recorded an expense of $27,225 for this award. On December 9, 2017, the Board of Directors awarded non-qualified stock options from the 2015 Plan with respect to 1,695,827 shares of common stock to the four named executive officers, three of whom were directors at the time, options with respect to 100,000 shares of common stock to an additional officer and options with respect to 76,228 shares of common stock in the aggregate, to the two independent directors.

On June 30, 2017, the Board of Directors awarded from the 2015 Plan, non-qualified stock options with respect to 150,000 shares of common stock to the named executive officers who were also directors of the Company at the time and options with respect to 40,000 shares of common stock to an additional officer and options with respect to 50,000 shares of common stock, in the aggregate to the two independent directors.

On March 31, 2016, the Board of Directors of the Company awarded non-qualified stock option with respect to a total 523,085 shares of common stock, of which 303,080 the four named executive officers who were also directors of the Company at the time, and options for 61,539 for an additional officer and 30,770 to each of the two independent directors, as well as 30,770 to the Chairman of the Scientific Advisory Board. The remaining 66,156 were granted to advisors. These awards were made with an exercise price of $7.3775, as compared to the closing market price of the Company's common stock on such date of $7.3669 reflecting an exercise price premium per share of $0.0106 or 0.14%. These awards were made to those individuals on that date as partial compensation for services rendered through December 31, 2016. During the year ended December 31, 2016, the Company recorded an aggregate charge to operations of $2,186,700 with respect to these stock options awarded to named executive officers, reflecting the grant date fair value of the stock options calculated pursuant to the Black-Scholes option-pricing model.

(2) In accordance with Securities and Exchange Commission rules, "Other Annual Compensation" in the form of perquisites and other personal benefits has been omitted where the aggregate amount of such perquisites and other personal benefits was less than $10,000. This column also reflects the amount of the benefit resulting from the forgiveness of accrued compensation and related costs. The amount reflected for Richard Purcell is the amount of interest charged by DNA Healthlink, Inc. for delayed payment of invoices.

Narrative to Summary Compensation Table

In 2018 and 2017, no cash bonuses, performance or otherwise were awarded.

In 2018, no stock or option awards were granted.

The options that were awarded to our named executive officers in January 2017, vested 25% on January 17, 2017 (at issuance), 25% on March 31, 2017 and 50% on June 30, 2017, thus all options awarded on that date vested before December 31, 2017. The options that were awarded to our named executive officers on December 9, 2017, all vested immediately upon award, thus all options awarded on that date were vested before December 31, 2017. All awards were made under the Company's 2015 Stock and Stock Option Plan. The options will provide a return to the named executive officer only if the market price of the Company's common stock appreciates over the option term.

In connection with the recent changes to our board membership and taking into account the Company's current operating structure and business plans, management is currently reevaluating the compensation policies of the

Company and, as a result of that reassessment, and in light of the Company's current financial circumstances, has made departures from the Company's historic compensation policies and will likely make substantial adjustments to such policies, including the termination of such policies, in the future.

Outstanding Equity Awards at Fiscal Year End

The following table shows information concerning outstanding equity awards at December 31, 2018, made by The Company to its named executive officers.

	Option Awards				
Name	Number of Securities Underlying Unexercised Options Exercisable (#)	Number of Securities Underlying Unexercised Options Unexercisable (#)	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price ($)	Option Expiration Date
Arnold S. Lippa	46,154	0	0	8.125	6/30/22
	30,769	0	0	6.396	8/18/22
	73,847	0	0	7.3775	3/31/21
	15,385	0	0	16.25	7/17/19
	50,000	0	0	3.90	1/17/22
	50,000	0	0	2.00	6/30/22
	559,595	0	0	1.45	12/9/27
Jeff E. Margolis	46,154	0	0	8.125	6/30/22
	30,769	0	0	6.396	8/18/22
	73,847	0	0	7.3775	3/31/21
	15,385	0	0	16.25	7/17/19
	50,000	0	0	3.90	1/17/22
	50,000	0	0	2.00	6/30/22
	25,000	0	0	2.00	7/26/22
	388,687	0	0	1.45	12/9/27
James S. D. Manuso	261,789	0	0	6.396	8/18/25
	81,539	0	0	7.3775	3/31/21
	75,000	0	0	3.90	1/17/22
	50,000	0	0	2.00	6/30/22
	608,704	0	0	1.45	12/9/27
Richard Purcell	6,154	0	0	8.125	6/30/22
	9,231	0	0	6.396	8/18/22
	61,539	0	0	7.3775	3/31/21
	40,000	0	0	3.90	1/17/22
	40,000	0	0	2.00	6/30/22
	100,000	0	0	1.45	12/9/27

At December 31, 2018, there were 2,833,548 options outstanding to named executive officers all of which had vested.

OPTION EXERCISES AND STOCK VESTED FOR 2018

None of the Company's named executive officers exercised any options to purchase shares of the Company's common stock during the year ended December 31, 2018. There were no unvested option awards as of December 31, 2018 and 2017. As of December 31, 2018, collectively, the named executive officers, held options to purchase 2,582,624 shares of the Company's common stock, all of which had vested, at an exercise prices ranging from $1.45 – $16.25 per share.

Employment Agreements – Termination or Change in Control

Three of the Company's named executive officers, James S. Manuso, Ph.D., Arnold S. Lippa, Ph.D. and Jeff E. Margolis (each an "Executive"), entered into employment agreements with the Company on August 18, 2015. Upon entering into such agreements, the Company disclosed these agreements and filed them as exhibits on a Current Report on Form 8-K filed August 19, 2015. That 8-K was subsequently amended by an 8-K/A filing dated November 2, 2016, to correct an aspect of Dr. Manuso's (who was then a named executive officer) compensation (see below). James S. Manuso, a former named executive, resigned September 30, 2018, thus terminating his employment agreement. The employment agreements that would have terminated on September 30, 2018 for the other two named executive officers above, were automatically extended for a period of one year pursuant to the terms of such agreements on September 30, 2018. Following is a summary of the arrangements that provide for payment to a named executive officer at, following or in connection with any termination, including resignation, retirement or other termination, or in connection with a change of control or a change in the named executive officer's responsibilities following a change in control. Robert N. Weingarten, a former named executive officer, resigned in February 2017, thus terminating his employment agreement.

Each of the Executive employment agreements provide that if the Executive is terminated by the Company for cause, or by the Executive without good reason, or as a result of death or disability, Executive (or his estate) would be entitled to receive (i) any base salary earned but not paid through the date of such termination, paid on the next regularly scheduled payroll date following such termination and (ii) all other benefits, if any, due Executive, as determined in accordance with the plans, policies and practices of the Company. There are currently no plans policies or practices of the Company under clause (ii) of the prior sentence that would provide any additional benefits.

Each of the Executive employment agreements provide that if the Executive is terminated by the Company without cause, or by the Executive for good reason, the Executive Officer would be entitled to (i) a lump sum payment equal to twelve months of the Executive's then current base salary and (ii) full acceleration of the vesting of any then unvested stock options or other equity compensation awards held by the Executive (with any unvested performance-based awards accelerated at 100% of target performance levels).

If the Executive were to breach any of section of the employment agreement related to confidentiality, inventions or restrictive covenants, or the Company determines that Executive engaged in an act or omission that, if discovered during Executive's employment, would have entitled the Company to terminate Executive's employment hereunder for Cause, the Executive would forfeit the right to any unpaid severance and any unexercised options.

As used in the employment agreements, "cause" means (i) any act of personal dishonesty taken by the Executive in connection with his employment hereunder, (ii) the Executive's conviction or plea of *nolo contendere* to a felony, (iii) any act by the Executive that constitutes material misconduct and is injurious to the Company, (iv) continued violations by the Executive of the Executive's obligations to the Company, (v) material breach of the employment agreement, (vi) commission of any act of serious moral turpitude, or (vii) material failure to comply with the lawful direction of the Board. As used in the employment agreements, "for good reason" means without Executive's express written consent (i) a material diminution of Executive's duties, position or responsibilities relative to Executive's duties, position or responsibilities in effect immediately prior to such reduction; (ii) a material diminution by the Company of Executive's base salary as in effect immediately prior to such reduction, other than a general reduction in base salary that affects all of the Company's executive officers; (iii) any material breach by the Company of the employment agreement; or (iv) the relocation of Executive to a facility or a location more than fifty (50) miles from the current location of the Executive's principal office, which the Company and Executive agree would constitute a material change in the geographic location at which Executive must perform services to the Company.

In the event of a change in control of the company prior to the vesting of any of the options granted to the Executive in connection with entering into the employment agreement, all such unvested options would vest and become exercisable and would be exercised by cashless or net exercise, subject to any limitations set forth in the applicable option plans, option agreements and applicable law. As used in the employment agreements, "Change in Control" means the occurrence of any of the following events: (i) any "person" (as such term is used in Sections 13(d) and 14(d) of the Exchange Act) becomes the "beneficial owner" (as defined in Rule 13d-3 of the Exchange Act), directly or indirectly, of securities of the Company representing more than fifty percent (50%) of the total voting power represented by the Company's then outstanding voting securities; (ii) the consummation of the sale or disposition by the Company of all

or substantially all of the Company's assets; or (iii) the consummation of a merger or consolidation of the Company with any other corporation, other than a merger consolidation which would result in the voting securities of the Company outstanding immediately prior thereto continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity or its parent) more than fifty percent (50%) of the total voting power represented by the voting securities of the Company or such surviving entity or its parent outstanding immediately after such merger or consolidation; provided, however, that notwithstanding the foregoing, the following shall not constitute a Change in Control: (A) any acquisition directly from the Company, (B) any acquisition by the Company, (C) any acquisition by any employee benefit plan (or related trust) sponsored or maintained by the Company or one of its affiliates, (D) any joint venture, (E) any royalty agreement, or (F) any license agreement.

The Company entered into an agreement with DNA Healthlink, Inc. effective on October 15, 2014 pursuant to which, among other things, the fourth named executive officer, Richard Purcell was to serve as the Company's Senior Vice President of Research and Development on a month-to-month basis at the rate of $12,500 per month.

Director Compensation

The Compensation Committee historically had used a combination of cash and stock-based incentive compensation to attract and retain qualified candidates to serve on the Board of Directors. In setting director compensation, the Compensation Committee considers the significant amount of time that directors expend in fulfilling their duties to the Company, as well as the skill-level required by the Company of members of the Board of Directors.

On January 17, 2017, each of James Sapirstein and Kathryn MacFarlane received options to purchase 25,000 shares of common stock of the Company at an exercise price of $3.90 per share which vested 25% on January 17, 2017 (date of the award), 25% on March 31, 2017, and 50% on June 30, 2017. The stock options were awarded as compensation for 2017. During the year ended December 31, 2017, the Company recorded an aggregate charge to operations of $92,678 with respect to these stock options, or $46,339 per individual.

On June 30, 2017, each of James Sapirstein and Kathryn MacFarlane received options to purchase 25,000 shares of common stock of the Company at an exercise price of $2.00 per share which vested immediately upon award. The stock options were awarded as compensation for 2017. During the year ended December 31, 2017, the Company recorded an aggregate charge to operations of $92,678 with respect to these stock options, or $46,339 per individual.

On December 9, 2017, each of James Sapirstein and Kathryn MacFarlane forgave $55,000 of accrued directors fees which represented accrued and unpaid directors fees through September 30, 2017 and which in the aggregate totaled $110,000. On December 9, 2017, each of James Sapirstein and Kathryn MacFarlane received options to purchase 38,114 shares of common stock of the Company at an exercise price of $1.45 which vested immediately. During the year ended December 31, 2017, the Company recorded an aggregate charge to operations of $106,490 with respect to these options or $53,245 per individual.

There were no option grants to either James Sapirstein or Kathryn MacFarlane in 2018. During 2018, they each earned $26,667 in cash compensation. Such amounts have not yet been paid.

Director Summary Compensation Table

The following table shows the compensation received by the non-employee members of our board of directors for the year ended December 31, 2018. Directors who are also employees/officers of the Company did not receive any additional compensation for services as a director.

Name	Fees Earned or Paid in Cash ($)(2)	Stock Awards ($)	Option Awards ($)(1)	Total ($)
James Sapirstein	26,667			26,667
Kathryn MacFarlane	26,667			26,667

(1) No options were granted in 2018.
(2) $26,667 per individual was earned in 2018.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

Beneficial Ownership of Common Stock

The following table sets forth certain information regarding the beneficial ownership of the Company's common stock as of December 31, 2018, by (i) each person known by the Company to be the beneficial owner of more than 5% of the outstanding common stock, (ii) each of the Company's directors, (iii) each of the Company's named executive officers, and (iv) all of the Company's executive officers and directors as a group. Except as indicated in the footnotes to this table, the Company believes that the persons named in this table have sole voting and investment power with respect to the shares of common stock indicated. In computing the number and percentage ownership of shares beneficially owned by a person, shares of common stock that a person has a right to acquire within sixty (60) days of December 31, 2018 pursuant to options, warrants or other rights are considered as outstanding, while these shares are not considered as outstanding for computing the percentage ownership of any other person or group.

Directors, Officers and 5% Stockholders[1]	Number of Shares of Beneficial Ownership of Common Stock	Percent of Class
Arnold Lippa Family Trust of 2007[2]	1,156,466	24.6 %
James S. J. Manuso, PhD[3]		
2 Fifth Avenue	1,199,857	24.0 %
New York, NY 10011		
Robert N. Weingarten[4]	586,538	13.3 %
John Safranek MD[5]		
3508 Poppleton Avenue	258,415	6.3 %
Omaha, NE 68105		
Big Rock LLC[6]		
34 Page Street	240,000	6.2 %
San Francisco, CA 94102		
Kingfish Ventures LLC[7]		
23335 Dorre Don Way SE	231,501	5.9 %
Maple Valley, WA 98038		
Dariusz Naziek[8]		
55 Hardwick Lane	212,764	5.4 %
Wayne, NJ 07470		
DIRECTORS AND OFFICERS		
Jeff E. Margolis[9]	731,252	16.0 %
Arnold S. Lippa, Ph.D.[10]	16,880	0.4 %

James Sapirstein[11]	140,421	3.5	%
Kathryn MacFarlane[12]	140,421	3.5	%
Richard Purcell[13]	263,077	6.4	%
All directors and officers as a group	1,292,051	27.2	%

(1) Except as otherwise indicated, the address of such beneficial owner is c/o RespireRx Pharmaceuticals Inc., 126 Valley Road, Suite C, Glen Rock, New Jersey 07452.

(2) All of these holdings were acquired by Dr. Arnold Lippa and subsequently transferred to the Trust, or are held by an entity owned by the Trust. Dr. Lippa is neither the trustee nor the beneficiary of the Trust. Linda Lippa, his wife, is a beneficiary of the Trust.

(3) Dr. Manuso's holdings include: 73,155 shares of common stock acquired in August 2015 and by exchange of warrants pursuant to an Exchange Agreement in respect to the 2015 Unit Offering as well as 1,077,032 options to acquire common stock and warrants to acquire 49,670 shares of common stock.

(4) Mr. Weingarten's holdings include: (i) 46,153 shares of common stock, and (ii) options to acquire an additional 540,385 shares of common stock. Mr. Weingarten holds these shares and options indirectly through Resource One Group LLC, an entity he controls as well as individually.

(5) Dr. Safranek's holdings include 216,138 shares of common stock acquired in various private placement unit offerings, some of which shares of common stock are held jointly with his spouse. Also included in Dr. Safranek's holdings are warrants to purchase 42,277 shares of common stock, also acquired in various private placement unit offerings. Excluded from Dr. Safranek's holdings are warrants to purchase 240,000 shares of common stock due to certain blocker provisions prohibiting exercise of such warrant in part or in whole if such exercise were to increase the investor's holding above 4.99%.

(6) Big Rock LLC's holdings include 240,000 shares of common stock, ultimately acquired after exchanging into the 2nd 2017 Unit Offering after initially participating in the 1st 2017 Unit Offering. Excluded from Big Rock LLC's holding are warrants to purchase 240,000 shares of common stock due to certain blocker provisions prohibiting exercise of such warrant in part or in whole if such exercise were to increase the investor's holding above 4.99%.

(7) Kingfish Ventures LLC's holdings include (i) 212,270 shares of common stock, and (ii) options to acquire an additional 19,231 shares of common stock.

(8) Dr. Nasiek's holdings include 168,697 shares acquired by the conversion of Series G Convertible Preferred Stock or by exchange of his Convertible Note and the related Warrant and Extension Warrant and by exchange in respect to the 2015 unit offering. Dr. Nasiek also holds 44,067 warrants. Some of Dr. Nasiek's holdings are owned jointly with his spouse.

(9) Mr. Margolis's holdings other than his 6,993 incentive stock options and 25,000 non-qualified stock options were transferred to six trusts of which Mr. Margolis is the trustee of three of those trusts and Mr. Margolis' spouse is the trustee of the other three trusts. In the aggregate, the holdings of the trusts include: (i) 46,565 shares of common stock, (ii) options to acquire an additional 679,842 shares of common stock, and (iii) the 4,845 warrants to purchase shares of common received as an owner of Aurora Capital LLC from the warrants Aurora received as a placement agent in the sale of the Company's Common Stock and Warrant Financing.

(10) Dr. Lippa's holdings include: (i) 598 shares of common stock, and (ii) 16,282 warrants to purchase shares of common stock. In addition, Dr. Lippa no longer beneficially owns many of the shares of the Company that were initially awarded to him because he has transferred these shares into family trusts, of which he is neither the trustee nor the beneficiary, including the Arnold Lippa Family Trust of 2007 as noted in footnote 2 above. In addition, Dr. Lippa has been awarded options to acquire an additional 15,385 shares of common stock which have been assigned to another family trust for the benefit of other family members. Dr. Lippa is neither the trustee nor the beneficiary of that trust.

(11) Dr. Sapirstein's holdings include: (i) 6,153 shares of common stock, and (ii) options to purchase 134,268 shares of common stock.

(12) Dr. MacFarlane's holdings include: (i) 6,153 shares of common stock, and (ii) options to purchase 134,268 shares of common stock.

(13) Mr. Purcell's holdings include: (i) 6,153 shares of common stock, and (ii) options to purchase 256,924 shares of common stock.

The Company is not aware of any arrangements that may at a subsequent date result in a change of control of the Company.

EQUITY COMPENSATION PLAN INFORMATION

The following table sets forth information regarding outstanding options, warrants and rights and shares reserved for future issuance under our existing equity compensation plans as of December 31, 2018. In March 2014, the Company's stockholders approved, by written consent, the Cortex Pharmaceuticals, Inc. 2014 Equity, Equity-Linked and Equity Derivative Incentive Plan, filed as exhibit 10.2 to the Company's Current Report on Form 8-K filed March 24, 2014, which provides for the issuance of equity and equity derivative securities such as options. On June 30, 2015, the Board of Directors adopted the 2015 Stock and Stock Option Plan, filed as exhibit 10.1 to the Company's Current Report on Form 8-K filed July 8, 2015, which similarly provides for the issuance of equity and equity derivative securities such as options. The Company amended the 2015 Stock and Stock Option Plan on March 31, 2016 and January 17, 2017, December 9, 2017, and December 28, 2018 and filed descriptions of such amendments on the Company Current Report on Form 8-K on April 6, 2016, January 23, 2017, December 14, 2017, and January 4, 2019, respectively. The amendments discussed above primarily increased the number of shares available under the 2015 Plan as approved by the board of directors, with the latest amendment expanding the plan to 8,985,260 shares. The Company has not presented, nor does it intend to present, the 2015 Stock and Stock Option Plan to shareholders for approval.

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)		Weighted average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	61,792	(1)(4)	$ 13.76	63,245
Equity compensation plans not approved by security holders (including non-plan options)	4,284,205	(2)(3)(4)(5)(6)	$ 3.39	4,427,342
Total	4,344,997		$ 3.541	4,490,587

(1)

On July 17, 2014, the Board of Directors of the Company awarded stock options to purchase a total of 46,155 shares of common stock of the Company, consisting of options for 15,385 shares to each of the Company's three executive officers, Dr. Arnold S. Lippa, Jeff E. Margolis and Robert N. Weingarten, who were also all of the directors of the Company at that time. The stock options were awarded as compensation for those individuals through December 31, 2014. The stock options vested in three equal installments on July 17, 2014 (at issuance), September 30, 2014, and December 31, 2014, and expire on July 17, 2019. The exercise price of the stock options was established on the grant date at $16.25 per share, as compared to the closing market price of the Company's common stock on such date of $14.30 per share, reflecting an exercise price premium of $1.95 per share or 13.6%. These awards were made under the Company's 2014 Equity, Equity-Linked and Equity Derivative Incentive Plan.

(2) On June 30, 2015, the Company issued fully-vested stock options to purchase 87,913 shares of common stock exercisable at $5.6875 per share for a period of five years in partial payment of an obligation to its current law firm. This issuance was made under the Company's 2015 Stock and Stock Option Plan.

(3) On June 30, 2015, the Board of Directors of the Company awarded stock options to purchase a total of 169,232 shares of common stock, consisting of options for 46,154 shares to each of the Company's then three executive officers, Dr. Arnold S. Lippa, Jeff E. Margolis and Robert N. Weingarten, and options for 6,154 shares to each of five other individuals who are members of management, the Company's Scientific Advisory Board, or independent members of the Board of Directors. The stock options were awarded as partial compensation for those individuals through December 31, 2015. The stock options vested 50% on June 30, 2015 (at issuance), 25% on September 30, 2015 and 25% on December 31, 2015, and will expire on June 30, 2022. The exercise price of the stock options was established on the grant date at $8.125 per share, as compared to the closing market price of the Company's common stock on such date of $5.6875 per share, reflecting an exercise price premium of $2.4375 per share or 42.9%. These awards were made under the Company's 2015 Stock and Stock Option Plan.

(4) 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 Mr. 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 Stock and Stock Option Plan and options for 15,635 shares were granted pursuant to the Company's 2014 Equity, Equity-Linked and Equity Derivative Incentive 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 $6.396 per share, which is equal to the simple average of the most recent four full trading weeks, weekly Volume Weighted Average Prices ("VWAPs") of the Company's common stock price immediately preceding the date of grant as reported by OTC IQ, as compared to the closing market price of the Company's common stock on August 18, 2015 of $6.6883 per share.

(5) On August 18, 2015, the Company 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 30,770 shares of common stock pursuant to the Company's 2015 Stock and Stock Option 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 $6.396 per share, which is equal to the simple average of the most recent four full trading weeks, weekly VWAPs of the Company's common stock price immediately preceding the date of grant as reported by OTC IQ, as compared to the closing market price of the Company's common stock on August 18, 2015 of $6.6883 per share.

On August 18, 2015, the Board of Directors of the Company awarded stock options for 9,231 shares of common stock to each of seven other 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 Stock and Stock Option Plan, representing stock options for a total of 64,617 shares of common stock. 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, 2020 as to stock options for 27,693 shares of common stock and August 18, 2022 as to stock options for 36,924 shares of common stock. The exercise price of the stock options was established on the grant date at $6.396 per share, which is equal to the simple average of the most recent four full trading weeks, weekly VWAPs of the Company's common stock price immediately preceding the date of grant as reported by OTC IQ, as compared to the closing market price of the Company's common stock on

August 18, 2015 of $6.6883 per share.

On December 11, 2015, the Company entered into a consulting agreement for the provision of investor relations services. The fee for such services was paid through the granting of non-qualified stock options to purchase a total of 8,792 shares of common stock pursuant to the Company's 2015 Stock and Stock Option Plan. The stock options will vested in equal installments on the last day of each month during the term of the consulting agreement, December 11, 2015 through March 31, 2016, and will expire on December 11, 2020. The exercise price of the stock options was established on the grant date at $6.825 per share, which was the closing market price of the Company's common stock on the date of grant.

On March 31, 2016, the Board of Directors of the Company awarded stock options for 81,539 shares of common stock to Dr. James S. Manuso, President and Chief Executive Officer and 73,847 to each of Arnold S. Lippa, Robert N. Weingarten and Jeff E. Margolis, all executive officers as described above. All four individuals are also members of the Board of Directors. The stock options were awarded as compensation for the year 2016. In addition, on that date, Board of Directors of the Company awarded stock options for 30,770 shares of common stock to the two independent members of the Board of Directors, stock options for 61,539 to a service provider who is an executive officer of the Company, but not a member of the Board of Directors as compensation for services for the year 2016, and additional stock options were awarded for 96,298 shares of common stock to other service providers. These stock options were awarded as partial or full payment for services. All stock options that were awarded on March 31, 2016 vested 25% upon issuance and 25% on each of June 30, 2016, September 30, 2016 and December 31, 2016. All stock options awarded on March 31, 2016 have an exercise price of $7.3775 per share of common stock and expire on March 31, 2021. The exercise price of $7.3775 as compared to the closing market price of the Company's common stock on March 31, 2016 of $7.3669 represents a premium of 0.14%. All of these options were awarded pursuant to the Company's 2015 Stock and Stock Option Plan.

On September 2, 2016 and September 12, 2016, pursuant to the Company's 2015 Stock and Stock Option Plan, stock options for 9,830 shares of common stock were awarded to two service providers and vested immediately upon issuance. Stock options for 7,222 shares of common stock have an exercise price of $4.50 per share and stock options for 2,608 shares have an exercise price of $5.75.

On January 17, 2017, pursuant to the Company's 2015 Stock and Stock Option Plan, stock options for 395,000 shares of common stock were awarded to four executive officers, two independent directors, one additional officer, and ten service providers, all of which vested 25% upon award on January 17, 2017, 25% on March 31, 2017 and 50% on June 30, 2017. The stock options for all 395,000 shares of common stock had an exercise price of $3.90 per share.

On June 30, 2017, pursuant to the Company's 2015 Stock and Stock Option Plan, stock options for 285,000 shares of common stock were awarded to three executive officers, two independent directors, one additional officer, and three service providers, all of which vested upon award on June 30, 2017. The stock options for all 285,000 shares of common stock had an exercise price of $2.00 per share.

On July 26, 2017, pursuant to the Company's 2015 Stock and Stock Option Plan, a stock option for 25,000 shares was awarded to Jeff E. Margolis, the Company's Senior Vice President, Chief Financial Officer, Treasurer and Secretary and a director, which vested 25% upon award on July 26, 2017, 25% on September 30, 2017 and 50% on December 31, 2017. The stock option for the 25,000 shares of common stock had an exercise price of $2.00 per share.

On July 28, 2017, pursuant to the Company's 2015 Stock and Stock Option Plan, stock options for 34,000 shares were awarded to two service providers. Options with respect to 9,000 shares of common stock vested one-third upon award on July 28, 2017, one-third on August 31, 2017 and one-third on September 30, 2017. Options with respect to 25,000 shares of common stock vested 20% on each of August 31, 2017, September 30, 2017, October 31, 2017, November 30, 2017 and December 31, 2017. The stock options on all 34,000 shares of common stock had an exercise price of $1.35 per share.

On December 9, 2017, pursuant to the Company's 2015 Stock and Stock Option Plan, stock options for 1,949,418 shares were awarded to four executive officers, one former executive officer, two independent directors, one additional officer, and two service providers, all of which vested immediately upon award. The stock options for 1,849,418 shares of common stock were issued to individuals and one entity that had, on the same date, forgiven $2,668,718 of accrued compensation and related costs and other accounts payable. The stock option for 100,000 shares was a bonus to the additional officer. All stock options for 1,949,418 shares of common stock had an exercise

price of $1.45 per share.

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On December 7, 2017, pursuant to the Company's 2015 Stock and Stock Option Plan, stock options for 16,762 shares were awarded to two individuals associated with a service provider which vested as to 6,286 shares on January 31, 2018, as to 5,238 shares on each of March 31, 2018 and May 31, 2018. All stock options for 16,762 shares of common stock had an exercise price of $1.25 per share.

On April 5, 2018, pursuant to the Company's 2015 Stock and Stock Option Plan, a stock option for 185,388 shares was awarded to Robert N. Weingarten, a former named executive officer of the Company, all of which vested immediately upon award. The stock option for 185,388 shares of common stock was issued to Mr. Weingarten who, on the same date, forgave $200,350 of accrued compensation and related costs. The stock option for 185,388 shares of stock had an exercise price of $1.12 per share.

On April 5, 2018, pursuant to the Company's 2015 Stock and Stock Option Plan, a stock option for 125,000 shares was awarded to a vendor in satisfaction of certain liabilities due to such vendor. The entire stock option vested immediately upon award. The stock option for 125,000 shares of common stock was issued to the vendor which, on the same date, agreed to the extinguishment of $124,025 of liabilities. The stock option for 125,000 shares of stock had an exercise price of $1.12 per share.

On November 21, 2018 pursuant to the Company's 2015 Stock and Stock Option Plan, a stock option for 21,677 shares was awarded to a vendor in satisfaction of certain liabilities due to such vendor. The entire stock option vested immediately upon award. The stock option for 21,677 shares of common stock was issued to thevendor which, on the same date, agreed to the extinguishment of $15,000 of liabilities. The stock option for 21,677 shares of stock had an exercise price of $0.70 per share.

Non-plan options are exercisable into 44,042 shares of the Company's common stock and were issued in July and August 2012, February, March and April 2014 and January, April and June 2015 to eight former employees, consultants and vendors. The stock options are all fully vested and have exercise prices ranging from $5.6875 to $19.50 and expiration dates ranging from March 13, 2019 to February 29, 2024.

Item 13. Certain Relationships and Related Transactions, and Director Independence

Director Independence

As of December 31, 2018, James Sapirstein, RPh., M.B.A. and Kathryn MacFarlane, PharmD. were "independent directors", as that term is defined under Section 803 of the NYSE Amex Company Guide. As noted above, as of December 31, 2018, all of the functions of the Audit, Compensation and Governance and Nominations Committees were being performed by the full board of directors.

Transactions with Related Persons

In 2017, the Company engaged in certain transactions with Arnold S. Lippa, our Chairman, Interim President, Interim Chief Executive Officer and our Chief Scientific Officer, and certain of his affiliates, and James S. Manuso, our then Chief Executive Officer. These transactions have been previously disclosed and are discussed in and Note 1 to our consolidated financial statements for the years ended December 31, 2018 and 2017—Organization and Business Operations—*Going Concern* and Note 4 to our consolidated financial statements for the years ended December 31, 2018 and 2017—Notes Payable—*Advances and Notes Payable to Officers.* Dr. Lippa has extended credit to the Company on April 15, 2019 for operating expenses by making a payment of $25,000 to the Company's auditors which amount has been accounted for by the Company as an advance by Dr. Lippa payable on demand. The balance of the amount payable to the auditors has been paid directly by the Company.

In connection with the 1st 2017 Unit Offering, Aurora Capital LLC ("Aurora") served as a placement agent and earned $20,000 fees and 8,000 placement agent common stock warrants. The 1st 2017 Unit Offering is discussed in greater retail in Management's Discussion and Analysis of Financial Condition and Results of Operations—Recent Developments—*Common Stock and Warrant Financings*. The fees were unpaid as of December 31, 2018 and have been accrued in accounts payable and accrued expenses and charged against Additional paid-in capital as of March 31, 2018, June 30, 2018 and September 30, 2018 and December 31, 2018. 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, 2018.

Item 14. Principal Accountant Fees and Services

Haskell & White LLP, acted as our independent registered public accounting firm for the fiscal years ended December 31, 2017 and 2018 and for the interim periods in such fiscal years. The following table shows the approximate fees that were incurred by us for audit and other services provided by Haskell & White LLP in fiscal 2017 and 2018.

	2018	2017
Audit Fees[1]	$99,000	$81,070
Audit-Related Fees[2]	—	2,250
Tax Fees[3]	—	—
All Other Fees[4]	—	—
Total	$99,000	$83,320

(1) Audit fees represent fees for professional services provided in connection with the audit of our annual financial statements and the review of our financial statements included in our Quarterly Reports on Form 10-Q and services that are normally provided in connection with statutory or regulatory filings.

(2) Audit-related fees, if any, represent fees for assurance and related services that are reasonably related to the performance of the audit or review of our financial statements and not reported above under “Audit Fees.”

(3) Tax fees, if any, represent fees for professional services related to tax compliance, tax advice and tax planning.

(4) All other fees, if any, represent fees for products and services rendered by our independent registered accounting firm other than those listed above.

All audit related services and other services rendered by Haskell & White LLP were pre-approved by our Board of Directors. The Board of Directors has adopted a pre-approval policy that provides for the pre-approval of all services performed for us by our independent registered public accounting firm. Tax services are not provided by Haskell & White LLP.

PART IV

Item 15. Exhibits and Financial Statement Schedules

(a) List of documents filed as part of this report:

(1) Financial Statements

Reference is made to the Index to Financial Statements on page F-1, where these documents are listed.

(2) Financial Statement Schedules

The financial statement schedules have been omitted because the required information is not applicable, or not present in amounts sufficient to require submission of the schedules, or because the information is included in the financial statements or notes thereto.

(3) Exhibits

A list of exhibits required to be filed as a part of this Annual Report on Form 10-K is set forth in the Exhibit Index, which is presented elsewhere in this document and incorporated herein by reference.

Item 16. Form 10-K Summary

Not applicable

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RESPIRERX PHARMACEUTICALS INC.

AND SUBSIDIARY

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

(INCLUDING REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM)

Years Ended December 31, 2018 and 2017

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and Board of Directors

RespireRx Pharmaceuticals Inc. and Subsidiary

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of RespireRx Pharmaceuticals Inc. and Subsidiary (the "Company") as of December 31, 2018 and 2017, the related consolidated statements of operations, stockholders' equity (deficiency), and cash flows for each of the years then ended, and the related notes (collectively, the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2018 and 2017, and the consolidated results of its operations and its cash flows for each of the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the consolidated financial statements, the Company has experienced recurring losses, negative cash flows from operations, has limited capital resources, and a net stockholders' deficiency. These matters raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ HASKELL & WHITE LLP

We have served as the Company's auditor since 2004.

Irvine, California

April 16, 2019

RESPIRERX PHARMACEUTICALS INC.

AND SUBSIDIARY

CONSOLIDATED BALANCE SHEETS

	December 31, 2018	2017
ASSETS		
Current assets:		
Cash and cash equivalents	$33,284	$84,902
Advance payment on research contract	48,912	48,912
Prepaid expenses, including current portion of long-term prepaid insurance of $14,945 at December 31, 2018 and 2017	38,880	42,897
Total current assets	121,076	176,711
Long-term prepaid insurance, net of current portion of $14,945 at December 31, 2018 and 2017	3,114	18,059
Total assets	$124,190	$194,770
LIABILITIES AND STOCKHOLDERS' DEFICIENCY		
Current liabilities:		
Accounts payable and accrued expenses, including $400,229 and $228,939 payable to related parties at December 31, 2018 and 2017, respectively	$3,303,120	$2,922,013
Accrued compensation and related expenses	1,304,434	479,300
Convertible notes payable, currently due and payable on demand, including accrued interest of $62,635 and $98,646 at December 31, 2018 and 2017, respectively, (of which $38,292, including accrued interest of $13,292, was deemed to be in default at December 31, 2018) (Note 4)	239,666	374,646
Note payable to SY Corporation, including accrued interest of $315,307 and $267,335 at December 31, 2018 and 2017, respectively (payment obligation currently in default – Note 4)	744,441	583,827
Notes payable to officers, including accrued interest of $51,677 and $26,538 at December 31, 2018 and 2017, respectively (Note 4)	256,877	181,738
Other short-term notes payable	8,907	8,630
Total current liabilities	5,857,445	4,550,154
Commitments and contingencies (Note 9)		
Stockholders' deficiency: (Note 6)		
	21,703	21,703

Series B convertible preferred stock, $0.001 par value; $0.6667 per share liquidation preference; aggregate liquidation preference $25,001; shares authorized: 37,500; shares issued and outstanding: 37,500; common shares issuable upon conversion at 0.00030 common shares per Series B share: 11		
Common stock, $0.001 par value; shares authorized: 65,000,000; shares issued and outstanding: 3,872,076 and 3,065,261 at December 31, 2018 and 2017, respectively	3,872	3,065
Additional paid-in capital	158,635,222	157,422,110
Accumulated deficit	(164,394,052)	(161,802,262)
Total stockholders' deficiency	(5,733,255)	(4,355,384)
Total liabilities and stockholders' deficiency	$124,190	$194,770

See accompanying notes to consolidated financial statements and report of independent registered public accounting firm.

RESPIRERX PHARMACEUTICALS INC.

AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF OPERATIONS

	Years Ended December 31,	
	2018	2017
Operating expenses:		
General and administrative, including $740,975 and $1,846,947 to related parties for the years ended December 31, 2018 and 2017, respectively	$1,488,238	$2,747,471
Research and development, including $495,638 and $1,132,604 to related parties for the years ended December 31, 2018 and 2017, respectively	688,286	1,499,940
Total operating costs and expenses	2,176,524	4,247,411
Loss from operations	(2,176,524)	(4,247,411)
Loss on extinguishment of debt and other liabilities in exchange for equity	(166,382)	-
Interest expense, including $42,821 and $15,519 to related parties for the years ended December 31, 2018 and 2017, respectively	(136,243)	(102,225)
Foreign currency transaction (loss) gain	(112,641)	58,153
Net loss	$(2,591,790)	$(4,291,483)
Net loss per common share - basic and diluted	$(0.77)	$(1.77)
Weighted average common shares outstanding - basic and diluted	3,351,105	2,418,271

See accompanying notes to consolidated financial statements and

report of independent registered public accounting firm.

RESPIRERX PHARMACEUTICALS INC.

AND SUBSIDIARY

CONSOLIDATED STATEMENT OF STOCKHOLDERS' DEFICIENCY

Years Ended December 31, 2018 and 2017

	Series B Convertible Preferred Stock		Common Stock		Additional		Total
	Shares	Amount	Shares	Par Value	Paid-in Capital	Accumulated Deficit	Stockholders' Deficiency
Balance, December 31, 2016	37,500	$21,703	2,149,045	$2,149	$151,993,550	$(157,510,779)	$(5,493,377)
Sale of common stock units in private placement, net of placement agent fees of $20,000			544,500	$544	$733, 956		734,500
Common stock issued in connection with unit exchanges			371,716	$372	$(372)		-
Fair value of common stock options issued for compensation					$1,927,278		$1,927,278
Fair value of common stock options issued in exchange for accrued compensation					$2,582,698		$2,582,698
Reclassification of non-permanent equity					$185,000		$185,000
Net loss						$(4,291,483)	$(4,291,483)
Balance at December 31, 2017	37,500	$21,703	3,065,261	$3,065	$157,422,110	$(161,802,262)	$(4,355,384)
Fair value of common stock options issued for services	-	-	-	-	29,248		29,248
Fair value of common stock options issued in exchange for accrued compensation and accounts payable					335,529		335,529
Common stock issued related to extinguishment of	-	-	284,358	284	318,236		318,520

convertible notes							
Sale of common stock units in private placement, net of escrow fees of $5,000	-	-	191,194	191	195,559		195,750
Issuance of common stock units in exchange for note payable to officer	-	-	47,620	48	49,952		50,000
Fair value of warrants issued in connection issuance of units in exchange for note payable to officer					49,975		49,975
Issuance of common stock to patent counsel			283,643	284	198,266		198,550
Fair value of original issue discount associated with warrants issued with convertible notes					36,347		36,347
Net Loss						$(2,591,790)	$(2,591,790)
Balance at December 31, 2018	37,500	$21,703	3,872,076	$3,872	$158,635,222	$(164,394,052)	$(5,733,255)

See accompanying notes to consolidated financial statements and

report of independent registered public accounting firm.

RESPIRERX PHARMACEUTICALS INC.

AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years Ended December 31,	
	2018	2017
Cash flows from operating activities:		
Net loss	$(2,591,790)	$(4,291,483)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	-	5,167
Amortization of debt discounts related to convertible notes payable	8,378	-
Loss on extinguishment of debt	105,254	-
Loss on extinguishment of other liabilities	11,154	-
Loss on exchange of officer note	49,974	-
Stock-based compensation and fees included in -		
General and administrative expenses	14,248	1,164,537
Research and development expenses	15,000	762,741
Foreign currency transaction loss (gain)	112,641	(58,153)
Changes in operating assets and liabilities:		
(Increase) decrease in -		
Prepaid expenses	18,962	26,772
Increase (decrease) in -		
Accounts payable and accrued expenses	703,682	476,449
Accrued compensation and related expenses	1,025,484	1,117,439
Accrued interest payable	99,645	99,522
Net cash used in operating activities	(427,368)	(697,009)
Cash flows from financing activities:		
Proceeds from sale of common stock units and issuance of restricted stock, net of fees	195,750	754,500
Proceeds from officer notes	100,000	-
Proceeds from issuance of notes payable	80,000	-
Principal paid on other short-term notes payable	-	(64,629)
Net cash provided by financing activities	375,750	689,871
Cash and cash equivalents:		
Net decrease	(51,618)	(7,138)
Balance at beginning of period	84,902	92,040
Balance at end of period	$33,284	$84,902

(Continued)

RESPIRERX PHARMACEUTICALS INC.

AND SUBSIDIARY

CONSOLIDATED STATEMENTS OF CASH FLOWS

(Continued)

	Years Ended December 31,	
	2018	2017
Supplemental disclosures of cash flow information:		
Cash paid for -		
Interest	$3,345	$2,608
Non-cash financing activities:		
10% convertible notes payable, including accrued interest of $62,267 exchanged for common stock	$213,266	$-
Accounts payable and accrued expenses extinguished with common stock options	$138,273	$-
Accrued compensation extinguished with option to purchase common stock options	$200,350	-
Officer note payable, exchanged for common stock and warrants	$50,000	-
Short-term note payable issued in connection with financing of directors and officers insurance policy	$63,750	$59,857
Short-term note payable issued in connection with financing of clinical trial and other office insurance policies	$9,322	$9,307
Fair value of common stock issued to service provider	$198,550	$-
Accrual of fees payable to placement agent in connection with the sale common stock units	$-	$20,000
Fair value of common stock warrants issued to placement agent in connection with the sale of common stock units	$-	$27,648
Reclassification of non-permanent equity	$-	$185,000

See accompanying notes to consolidated financial statements and

report of independent registered public accounting firm.

RESPIRERX PHARMACEUTICALS INC.

AND SUBSIDIARY

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Years Ended December 31, 2018 and 2017

1. Organization and Basis of Presentation

Organization

RespireRx Pharmaceuticals Inc. ("RespireRx") was formed in 1987 under the name Cortex Pharmaceuticals, Inc. to engage in the discovery, development and commercialization of innovative pharmaceuticals for the treatment of neurological and psychiatric disorders. On December 16, 2015, RespireRx filed a Certificate of Amendment to its Second Restated Certificate of Incorporation with the Secretary of State of the State of Delaware to amend its Second Restated Certificate of Incorporation to change its name from Cortex Pharmaceuticals, Inc. to RespireRx Pharmaceuticals Inc. While developing potential applications for respiratory disorders, RespireRx has retained and expanded its ampakine intellectual property and data with respect to neurological and psychiatric disorders and is considering developing certain potential products in this platform, pending additional financing and/or strategic relationships.

In August 2012, RespireRx acquired Pier Pharmaceuticals, Inc. ("Pier"), which is now its wholly-owned subsidiary.

Basis of Presentation

The consolidated financial statements are of RespireRx and its wholly-owned subsidiary, Pier (collectively referred to herein as the "Company" or "we" or "our" unless the context indicates otherwise) as of December 31, 2018 and for each of the years ended December 31, 2018 and 2017.

2. Business

The mission of the Company is to develop innovative and revolutionary treatments to combat diseases caused by disruption of neuronal signaling. We are developing treatment options that address conditions that affect millions of people, but for which there are few or poor treatment options, including obstructive sleep apnea ("OSA"), attention deficit hyperactivity disorder ("ADHD") and recovery from spinal cord injury ("SCI"), as well as certain neurological orphan diseases such as Fragile X Syndrome. RespireRx is developing a pipeline of new drug products based on our broad patent portfolios for two drug platforms: cannabinoids, including dronabinol ("Δ9-THC"), and the ampakines, proprietary compounds that positively modulate AMPA-type glutamate receptors to promote neuronal function.

RespireRx is developing a number of potential products. From the cannabinoid platform, two Phase 2 clinical trials have been completed demonstrating the ability of dronabinol to significantly reduce the symptoms of OSA, which management believes is potentially a multi-billion-dollar market. Subject to raising sufficient financing, we believe that we have put most of the necessary pieces into place to rapidly initiate a Phase 3 clinical trial program. By way of definition, when a new drug is allowed by the United States Food and Drug Administration ("FDA") to be tested in humans, Phase 1 clinical trials are conducted in healthy people to determine safety and pharmacokinetics. If successful, Phase 2 clinical trials are conducted in patients to determine safety and preliminary efficacy. Phase 3 trials, large scale studies to determine efficacy and safety, are the final step prior to seeking FDA approval to market a drug.

From our ampakine platform, our lead clinical compounds, CX717 and CX1739, have successfully completed multiple Phase 1 safety trials. Both compounds have also completed Phase 2 efficacy trials demonstrating target engagement, by antagonizing the ability of opioids to induce respiratory depression. CX717 has completed a Phase 2 trial demonstrating the ability to significantly reduce the symptoms of adult ADHD. In an early Phase 2 study, CX1739 improved breathing in patients with central sleep apnea. Preclinical studies have highlighted the potential ability of these ampakines to improve motor function in animals with spinal injury. Subject to raising sufficient financing (of which no assurance can be provided), we believe that we will be able to rapidly initiate a human Phase 2 study with CX1739 and/or CX717 in patients with spinal cord injury and a human Phase 2B study in patients with ADHD with either CX717 or CX1739.

RespireRx is considering an internal restructuring plan that contemplates spinning out the cannabinoid platform into what would initially be a wholly-owned subsidiary that the Company currently intends would ultimately have its own management team and board of directors. This spin-out company would be tasked with raising financing in order to develop and commercialize the dronabinol platform for the treatment of OSA.

As previously disclosed on June 19, 2018, James S. Manuso, Ph.D., the Company's former President and Chief Executive Officer, resigned as an officer and as Vice Chairman and a member of the Company's Board of Directors, effective as of the end of the term of his employment agreement, September 30, 2018. On October 12, 2018, Arnold S. Lippa, Ph.D. was named Interim President and Interim Chief Executive Officer. Dr. Lippa continues to serve as the Company's Chief Scientific Officer and Chairman of the Board of Directors.

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 $2,591,790 and $4,291,483 for the fiscal years ended December 31, 2018 and 2017, respectively, and negative operating cash flows of $427,368 and $697,009 for the fiscal years ended December 31, 2018 and 2017, respectively. The Company also had a stockholders' deficiency of $5,733,255 at December 31, 2018 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, 2018, 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 extremely limited cash resources and current assets and has no ongoing source of sustainable revenue. 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 taken steps to continue to raise new debt and equity capital to fund the Company's business activities from both related and unrelated parties.

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 the pursuit of the Company's planned research and development activities. The Company regularly evaluates various measures to satisfy the Company's liquidity needs, including development and other agreements with collaborative partners and, when necessary, seeking to exchange or restructure the Company's outstanding securities. The Company is evaluating certain changes to its operations and structure to facilitate raising capital from sources that may be interested in financing only discrete aspects of the Company's development programs. Such changes could include a significant reorganization, which may include the

formation of one or more subsidiaries into which one or more programs may be contributed. 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.

3. Summary of Significant Accounting Policies

Principles of Consolidation

The accompanying consolidated financial statements are prepared in accordance with United States generally accepted accounting principles ("GAAP") and include the financial statements of RespireRx and its wholly-owned subsidiary, Pier. Intercompany balances and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions. These estimates and assumptions affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Significant estimates include, among other things, accounting for potential liabilities, and the assumptions used in valuing stock-based compensation issued for services. Actual amounts may differ from those estimates.

Concentrations of Credit 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 quality financial institutions. The Company's cash balances may periodically exceed federally insured limits. The Company has not experienced a loss in such accounts to date.

Cash Equivalents

The Company considers all highly liquid short-term investments with maturities of less than three months when acquired to be cash equivalents.

Fair Value of Financial Instruments

The authoritative guidance with respect to fair value of financial instruments established a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value into three levels and requires that assets and liabilities carried at fair value be classified and disclosed in one of three categories, as presented below. Disclosure as to transfers into and out of Levels 1 and 2, and activity in Level 3 fair value measurements, is also required.

Level 1. Observable inputs such as quoted prices in active markets for an identical asset or liability that the Company has the ability to access as of the measurement date. Financial assets and liabilities utilizing Level 1 inputs include active-exchange traded securities and exchange-based derivatives.

Level 2. Inputs, other than quoted prices included within Level 1, which are directly observable for the asset or liability or indirectly observable through corroboration with observable market data. Financial assets and liabilities utilizing Level 2 inputs include fixed income securities, non-exchange-based derivatives, mutual funds, and fair-value hedges.

Level 3. Unobservable inputs in which there is little or no market data for the asset or liability which requires the reporting entity to develop its own assumptions. Financial assets and liabilities utilizing Level 3 inputs include infrequently-traded, non-exchange-based derivatives and commingled investment funds, and are measured using present value pricing models.

The Company determines the level in the fair value hierarchy within which each fair value measurement falls in its entirety, based on the lowest level input that is significant to the fair value measurement in its entirety. In determining the appropriate levels, the Company performs an analysis of the assets and liabilities at each reporting period end.

The carrying amounts of financial instruments (consisting of cash, cash equivalents, advances on research grants and accounts payable and accrued expenses) are considered by the Company to be representative of the respective fair values of these instruments due to the short-term nature of those instruments. With respect to the note payable to SY Corporation and the convertible notes payable, management does not believe that the credit markets have materially changed for these types of borrowings since the original borrowing date. The Company considers the carrying amounts of the notes payable to officers, inclusive of accrued interest, to be representative of the respective fair values of such instruments due to the short-term nature of those instruments and their terms.

Deferred Financing Costs

Costs incurred in connection with ongoing debt and equity financings, including legal fees, are deferred until the related financing is either completed or abandoned.

Costs related to abandoned debt or equity financings are charged to operations in the period of abandonment. Costs related to completed debt financings are presented as a direct deduction from the carrying amount of the related debt liability (see “Capitalized Financing Costs” below). Costs related to completed equity financings are charged directly to additional paid-in capital.

Capitalized Financing Costs

The Company presents debt issuance costs related to debt liability in its consolidated balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with the presentation for debt discounts.

Convertible Notes Payable

Convertible notes are evaluated to determine if they should be recorded at amortized cost. To the extent that there are associated warrants or a beneficial conversion feature, the convertible notes and warrants are evaluated to determine if there are embedded derivatives to be identified, bifurcated and valued at fair value in connection with and at the time of such financing.

Note Exchanges

In cases where debt or other liabilities are exchanged for equity, the Company compares the carrying value of debt, inclusive of accrued interest, if applicable, being exchanged, to the fair value of the equity issued and records any loss or gain as a result of such exchange. See Note 4.

Extinguishment of Debt

The Company accounts for the extinguishment of debt in accordance with GAAP by comparing the carrying value of the debt to the fair value of consideration paid or assets given up and recognizing a loss or gain in the consolidated statement of operations in the amount of the difference in the period in which such transaction occurs.

Equipment

Equipment is recorded at cost and depreciated on a straight-line basis over their estimated useful lives, which range from three to five years. All equipment was fully depreciated as of December 31, 2018.

Prepaid Insurance

Prepaid insurance represents the premium paid in March 2017 for directors' and officers' insurance tail coverage, which is being amortized on a straight-line basis over the policy period of six years. The amount amortizable in the ensuing twelve-month period is recorded as prepaid insurance in the Company's consolidated balance sheet at each reporting date, with the remaining amount recorded as long-term prepaid insurance.

Impairment of Long-Lived Assets

The Company reviews its long-lived assets, including long-term prepaid insurance, for impairment whenever events or changes in circumstances indicate that the total amount of an asset may not be recoverable, but at least annually. An impairment loss is recognized when estimated future cash flows expected to result from the use of the asset and its eventual disposition is less than the asset's carrying amount. The Company has not deemed any long-lived assets as impaired at December 31, 2018.

Stock-Based Awards

The Company periodically issues common stock and stock options to officers, directors, Scientific Advisory Board members, consultants and other vendors 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 consolidated financial statements over the vesting period of the awards.

Stock grants, which are sometimes subject to time-based vesting, 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 outside consultants and other vendors are valued on the grant date. As the stock options vest, the Company recognizes this expense over the period in which the services are provided.

The fair value of stock options granted as stock-based compensation 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 stock option 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 market 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 uses 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.

During fiscal year ended December 31, 2018, there were stock grants totaling 283,643 shares of common stock to designees of one vendor with a value on the date of the grant of $198,550 which amount paid $198,550 of account

payable to that vendor. There was no gain or loss on such stock grant.

For stock options requiring an assessment of value during the fiscal years ended December 31, 2018 and 2017, the fair value of each stock option award was estimated using the Black-Scholes option-pricing model using the following assumptions:

	2018		**2017**	
Risk-free interest rate	2.64-2.89	%	1.89% to 2.2	%
Expected dividend yield	0	%	0	%
Expected volatility	186.07-222.64	%	132.87% to 184.92	%
Expected life at date of issuance	5 years		4.55-5 years	

The expected life is estimated to be equal to the term of the common stock options issued in 2018. For certain common stock options issued in 2017, the simple method was used to estimate the expected life.

The Company recognizes the fair value of stock-based awards 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 and warrant exercises. There were no stock options exercised during the fiscal years ended December 31, 2018. and 2017.

There were no warrants issued as compensation or for services during the fiscal year ended December 31, 2018 requiring such assessment.

Income Taxes

The Company accounts for income taxes under an asset and liability approach for financial accounting and reporting for income taxes. Accordingly, the Company recognizes deferred tax assets and liabilities for the expected impact of differences between the financial statements and the tax basis of assets and liabilities.

The Company records a valuation allowance to reduce its deferred tax assets to the amount that is more likely than not to be realized. In the event the Company was to determine that it would be able to realize its deferred tax assets in the future in excess of its recorded amount, an adjustment to the deferred tax assets would be credited to operations in the period such determination was made. Likewise, should the Company determine that it would not be able to realize all or part of its deferred tax assets in the future, an adjustment to the deferred tax assets would be charged to operations in the period such determination was made.

Pursuant to Internal Revenue Code Sections 382 and 383, use of the Company's net operating loss and credit carryforwards may be limited if a cumulative change in ownership of more than 50% occurs within any three-year period since the last ownership change. The Company may have had a change in control under these Sections. However, the Company does not anticipate performing a complete analysis of the limitation on the annual use of the net operating loss and tax credit carryforwards until the time that it anticipates it will be able to utilize these tax attributes.

As of December 31, 2018, the Company did not have any unrecognized tax benefits related to various federal and state income tax matters and does not anticipate any material amount of unrecognized tax benefits within the next 12 months.

The Company is subject to U.S. federal income taxes and income taxes of various state tax jurisdictions. As the Company's net operating losses have yet to be utilized, all previous tax years remain open to examination by Federal

authorities and other jurisdictions in which the Company currently operates or has operated in the past.

The Company accounts for uncertainties in income tax law under a comprehensive model for the financial statement recognition, measurement, presentation and disclosure of uncertain tax positions taken or expected to be taken in income tax returns as prescribed by GAAP. The tax effects of a position are recognized only if it is "more-likely-than-not" to be sustained by the taxing authority as of the reporting date. If the tax position is not considered "more-likely-than-not" to be sustained, then no benefits of the position are recognized. As of December 31, 2018, the Company had not recorded any liability for uncertain tax positions. In subsequent periods, any interest and penalties related to uncertain tax positions will be recognized as a component of income tax expense.

Foreign Currency Transactions

The note payable to SY Corporation, which is denominated in a foreign currency (the South Korean Won), is translated into the Company's functional currency (the United States Dollar) at the exchange rate on the balance sheet date. The foreign currency exchange gain or loss resulting from translation is recognized in the related consolidated statements of operations.

Research and Development

Research and development costs include compensation paid to management directing the Company's research and development activities, and fees paid to consultants and outside service providers and organizations (including research institutes at universities), and other expenses relating to the acquisition, design, development and clinical testing of the Company's treatments and product candidates.

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

On May 6, 2016, the Company made an advance payment to Duke University with respect to the Phase 2A clinical trial of CX1739. At December 31, 2018 and 2017, an asset balance of $48,912 remained from the advance payment.

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 and are charged to general and administrative expenses.

Earnings per Share

The Company's computation of earnings per share ("EPS") includes basic and diluted EPS. Basic EPS is measured as the income (loss) attributable to common stockholders divided by the weighted average common shares outstanding for the period. Diluted EPS is similar to basic EPS but presents the dilutive effect on a per share basis of potential common shares (e.g., warrants and options) as if they had been converted at the beginning of the periods presented, or issuance date, if later. Potential common shares that have an anti-dilutive effect (i.e., those that increase income per share or decrease loss per share) are excluded from the calculation of diluted EPS.

Net income (loss) attributable to common stockholders consists of net income or loss, as adjusted for actual and deemed preferred stock dividends declared, amortized or accumulated.

Loss per common share is computed by dividing net loss by the weighted average number of shares of common stock outstanding during the respective periods. Basic and diluted loss per common share is the same for all periods presented because all warrants and stock options outstanding are anti-dilutive.

At December 31, 2018 and 2017, the Company excluded the outstanding securities summarized below, which entitle the holders thereof to acquire shares of common stock, from its calculation of earnings per share, as their effect would have been anti-dilutive.

	December 31,	
	2018	2017
Series B convertible preferred stock	11	11
Convertible notes payable	16,319	32,941
Common stock warrants	1,783,229	1,464,415
Common stock options	4,344,994	3,996,167
Total	6,144,553	5,493,534

Reclassifications

Certain comparative figures in 2017 have been reclassified to conform to the current year's presentation. These reclassifications were immaterial, both individually and in the aggregate.

Recent Accounting Pronouncements

In June 2018, the FASB issued Accounting Standards Update No. 2018-07 (ASU 2018-07), Compensation-Stock Compensation (Topic 718)—Improvements to Nonemployee Share-Based Payment Accounting. ASU 2018-07 are amendments to Topic 718 that become effective for public entities like the Company for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. This update applies to nonemployee share-based awards within the scope of Topic 718. Consistent with the accounting requirement for employee share-based payment awards, nonemployee share-based payment awards are measured at grant-date fair value of the equity instruments that an entity is obligated to issue when the good has been delivered or the service has been rendered and any other conditions necessary to earn the right to benefit from the instruments have been satisfied. Equity-classified nonemployee share- based payment awards are measured at the grant date. The definition of the term grant date has been amended to generally state the date at which a grantor and a grantee reach a mutual understanding of the key terms and conditions of a share- based payment award. An entity considers the probability of satisfying performance conditions when nonemployee share-based payment awards contain such conditions. This is consistent with the treatment for employee-based awards. Generally, the classification of equity- classified nonemployee share-based payment awards will continue to be subject to the requirements of Topic 718 unless modified after the good has been delivered, the service has been rendered, any other conditions necessary to earn the right to benefit from the instruments have been satisfied, and the nonemployee is no longer providing goods or services. This eliminates the requirement to reassess classification of such awards upon vesting. This standard will change the valuation of applicable awards granted in subsequent periods.

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 Topic 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.

4. Notes Payable

Convertible Notes Payable

During December 2018, convertible notes (“2018 Convertible Notes”) bearing interest at 10% per year and maturing on February 28, 2019 and warrants were sold to investors with an aggregate face amount of $80,000. Investors also received 80,000 common stock purchase warrants. The warrants were valued using the Black Scholes option pricing model calculated on the date of each grant and had an aggregate value of $68,025. Total value received by the investors was $148,025, the sum of the face value of the convertible note and the value of the warrant. Therefore, the Company recorded an initial original issue discount of $36,347 and an initial value of the note of $43,653 using the relative fair value method. $8,379 of the original issue discount was amortized to interest expense through December 31, 2018. An additional $401 of interest expense was recorded based upon the 10% annual rate. The 2018 Convertible Notes matured on February 28, 2019 and were not paid and remain outstanding and continue to accrue interest. Although the 2018 Convertible Notes are in default, the Company has not received any notices of default from any of the note holders. The 2018 Convertible Notes have no reset rights or other protections based on subsequent equity transactions, equity-linked transactions or other events other than the right, but not the obligation for each investor to convert or exchange his or her 2018 Convertible Note, but not the warrant, into the next equity or equity-linked offering (not convertible into any debt offering), which offering has not occurred as of December 31, 2018 or as of the date of the issuance of these financial statements. Therefore, the number of shares of common stock (or preferred stock) into which the 2018 Convertible Notes may convert is not determinable and the Company has not accounted for any beneficial conversion feature. The warrants to purchase 80,000 shares of common stock issued in connection with the sale of the 2018 Convertible Notes are exercisable at a fixed price of $1.50 per share of common stock, provide no right to receive a cash payment, and included no reset rights or other protections based on subsequent equity transactions, equity-linked transactions or other events. The Company determined that there were no embedded derivatives to be identified, bifurcated and valued in connection with this financing.

The 2018 Convertible Notes consist of the following at December 31, 2018 and December 31, 2017:

	December 31, 2018	December 31, 2017

Principal amount of notes payable	$ 80,000	$ -
Original issue discount net of amortization of $8,379	(27,968)	-
Add accrued interest payable	401	-
	$ 52,433	$ -

The convertible notes sold to investors in 2014 and 2015 (“Original Convertible Notes), which aggregated a total of $579,500, had a fixed interest rate of 10% per annum and those that remain outstanding are convertible into common stock at a fixed price of $11.3750 per share. The Original Convertible Notes have no reset rights or other protections based on subsequent equity transactions, equity-linked transactions or other events. The warrants to purchase 50,945 shares of common stock issued in connection with the sale of the convertible notes were exercisable at a fixed price of $11.3750 per share. All such warrants have either been exchanged as part of April and May 2016 note and warrant exchange agreements or expired on September 15, 2016.

The maturity date of the Original Convertible Notes was extended to September 15, 2016 and included the issuance of 27,936 additional warrants to purchase common stock, exercisable at $11.375 per share of common stock, which expired on September 15, 2016.

The Original Convertible Notes (including those for which default notices have been received) consist of the following at December 31, 2018 and December 31, 2017:

	December 31, 2018	December 31, 2017
Principal amount of notes payable	$125,000	$276,000
Add accrued interest payable	62,233	98,646
	$187,233	$374,646

Between October 3, 2016 and October 25, 2016, the Company received several notices of default from holders of Original Convertible Notes. The effect of such notices of default was to increase the annual interest rate from 10% to 12% with respect to the Original Convertible Notes to which such notices applied. On February 28, 2018, two of such Original Convertible Notes were exchanged for common stock of the Company and were extinguished. The Company measured the fair value of the shares of common stock issued to the holder in respect to the extinguishment of the two convertible notes as compared to the aggregate of principal and interest on such notes and recorded a loss of $66,782 which is the amount of the excess fair value paid as compared to the aggregate principal and interest extinguished. The total amount of principal and accrued interest that was due and payable was $43,552. The Original Convertible Notes were exchanged for 58,071 shares of the Company’s common stock. The effective exchange rate was $0.75 per share of the Company’s common stock. The closing price of the Company’s common stock on February 28, 2018, was $1.90 as reported by the OTC Markets.

On February 28, 2018, the Board of Directors authorized the offering of a similar exchange arrangement at the same effective exchange rate of $0.75 per share of the Company’s common stock to all remaining holders of Original Convertible Notes (some of which Original Convertible Notes were the subject of notices of default and therefore accruing annual interest at 12%).

On May 31, 2018, the Company entered into exchange agreements with four holders of Original Convertible Notes who agreed to exchange their Original Convertible Notes for the Company’s common stock at an exchange rate of $0.75 per share. The note holders, in the aggregate, agreed to exchange $169,715 of principal and accrued interest for 226,287 shares of the Company’s common stock. The closing price of the Company’s common stock on May 31, 2018 was $0.92 per share. As a result of the exchange, $169,715 of convertible notes, inclusive of accrued interest, were cancelled and $208,185 of common stock was issued, resulting in a loss on extinguishment of debt of $38,470.

As of December 31, 2018, principal and accrued interest on the one remaining outstanding Original Convertible Note subject to a default notice totaled $38,292, of which $13,292 was accrued interest. As of December 31, 2017, principal and accrued interest on convertible notes subject to default notices totaled $91,028 of which $25,028 was accrued interest.

As of December 31, 2018, the remaining total outstanding Original Convertible Notes, inclusive of accrued interest, were convertible into 16,460 shares of the Company's common stock, including 5,471 shares attributable to accrued interest of $62,233 payable as of such date. As of December 31, 2017, the outstanding Original Convertible Notes were convertible into 32,941 shares of the Company's common stock, including 8,677 shares attributable to accrued interest of $98,646 payable as of such date. Such Original Convertible Notes will continue to accrue interest until exchanged, paid or otherwise discharged. There can be no assurance that any of the additional holders of the remaining Original Convertible Notes will exchange their notes.

Note Payable to SY Corporation Co., Ltd.

On June 25, 2012, the Company borrowed 465,000,000 Won (the currency of South Korea, equivalent to approximately $400,000 United States Dollars) from and executed a secured note payable to SY Corporation Co., Ltd., formerly known as Samyang Optics Co. Ltd. ("SY Corporation"), an approximately 20% common stockholder of the Company at that time. SY Corporation was a significant stockholder and a related party at the time of the transaction, but has not been a significant stockholder or related party of the Company subsequent to December 31, 2014. The note accrues simple interest at the rate of 12% per annum and had a maturity date of June 25, 2013. The Company has not made any payments on the promissory note. At June 30, 2013 and subsequently, the promissory note was outstanding and in default, although SY Corporation has not issued a notice of default or a demand for repayment. The Company believes that SY Corporation is in default of its obligations under its January 2012 license agreement, as amended, with the Company, but the Company has not yet issued a notice of default. The Company is continuing efforts towards a comprehensive resolution of the aforementioned matters involving SY Corporation.

The promissory note is secured by collateral that represents a lien on certain patents owned by the Company, including composition of matter patents for certain of the Company's high impact ampakine compounds and the low impact ampakine compounds CX2007 and CX2076, and other related compounds. The security interest does not extend to the Company's patents for its ampakine compounds CX1739 and CX1942, or to the patent for the use of ampakine compounds for the treatment of respiratory depression.

Note payable to SY Corporation consists of the following at December 31, 2018 and 2017:

	December 31, 2018	December 31, 2017
Principal amount of note payable	$399,774	$399,774
Accrued interest payable	315,307	267,335
Foreign currency transaction adjustment	29,360	(83,282)
	$744,441	$583,827

Interest expense with respect to this promissory note was $47,973 for years ended December 31, 2018 and 2017, respectively.

Advances and Notes Payable to Officers

On January 29, 2016, Dr. Arnold S. Lippa, the Company's Interim President, Interim Chief Executive Officer, Chief Scientific Officer and Chairman of the Board of Directors, advanced $52,600 to the Company for working capital purposes under a demand promissory note with interest at 10% per annum. On September 23, 2016, Dr. Lippa advanced $25,000 to the Company for working capital purposes under a second demand promissory note with interest at 10% per annum. The notes are secured by the assets of the Company. Additionally, on April 9, 2018, Dr. Lippa advanced another $50,000 to the Company as discussed in more detail below. In connection with the loans, Dr. Lippa was issued fully vested warrants to purchase 15,464 shares of the Company's common stock, 10,309 of which have an exercise price of $5.1025 per share and 5,155 of which have an exercise price of $4.85 which were the closing prices of the Company's common stock on the respective dates of grant. The warrants expire on January 29, 2019 and September 23, 2019 respectively and may be exercised on a cashless basis.

On February 2, 2016, Dr. James S. Manuso, the Company's then Chief Executive Officer and Vice Chairman of the Board of Directors, advanced $52,600 to the Company for working capital purposes under a demand promissory note with interest at 10% per annum. On September 22, 2016, Dr. Manuso, advanced $25,000 to the Company for working capital purposes under a demand promissory note with interest at 10% per annum. The notes are secured by the assets of the Company. Additionally, on April 9, 2018, Dr. Manuso advanced another $50,000 to the Company as discussed in more detail below. In connection with the loans, Dr. Manuso was issued fully vested warrants to purchase 13,092 shares of the Company's common stock, 8,092 of which have an exercise price of $6.50 per share and 5,000 of which have an exercise price of $5.00, which were the closing market prices of the Company's common stock on the respective dates of grant. The warrants expire on February 2, 2019 and September 22, 2019, respectively, and may be exercised on a cashless basis.

On April 9, 2018, Dr. Arnold S. Lippa, the Company's Interim President, Interim Chief Executive Officer, Chief Scientific Officer and Chairman of the Board of Directors and Dr. James S. Manuso, the Company's then Chief Executive Officer and Vice Chairman of the Board of Directors, advanced $50,000 each, for a total of $100,000, to the Company for working capital purposes. Each note is payable on demand after June 30, 2018. Each note was subject to a mandatory exchange provision that provided that the principal amount of the note would be mandatorily exchanged into a board approved offering of the Company's securities, if such offering held its first closing on or before June 30, 2018 and the amount of proceeds from such first closing was at least $150,000, not including the principal amounts of the notes that would be exchanged, or $250,000 including the principal amounts of such notes. Upon such exchange, the notes would be deemed repaid and terminated. Any accrued but unpaid interest outstanding at the time of such exchange will be (i) repaid to the note holder or (ii) invested in the offering, at the note holder's election. A first closing did not occur on or before June 30, 2018. Dr. Arnold S. Lippa agreed to exchange his note into the board approved offering that had its initial closing on September 12, 2018. Accrued interest on Dr. Lippa's note was not exchanged. As of December 31, 2018, Dr. James S. Manuso had not exchanged his note.

For the fiscal years ended December 31, 2018 and 2017, $11,268 and $7,760 was charged to interest expense with respect to Dr. Lippa's notes, respectively.

For the fiscal years ended December 31, 2018 and 2017, $12,769 and $7,760 was charged to interest expense with respect to Dr. James S. Manuso's notes, respectively.

As of September 30, 2018, Dr. James S. Manuso resigned his executive officer positions and as a member of the Board of Directors of the Company. Of the $12,769 of interest expense noted above, $3,564 was incurred while Dr. Manuso was no longer an officer.

Other Short-Term Notes Payable

Other short-term notes payable at December 31, 2018 and December 31, 2017 consisted of premium financing agreements with respect to various insurance policies. At December 31, 2018, a premium financing agreement was payable in the initial amount of $63,750, with interest at 8.930% per annum, in ten monthly installments of $6,639, and another premium financing arrangement was payable in the initial amount of $9,322 payable in equal quarterly installments. At December 31, 2018 and 2017, the aggregate amount of the short-term notes payable was $8,907 and $8,630 respectively.

5. Settlement and Payment Agreements

On April 5, 2018, the Company issued 185,388 common stock purchase options to Robert N. Weingarten, the Company's former Chief Financial Officer and 125,000 common stock purchase options to Pharmaland Executive Consulting Services LLC ("Pharmaland") exercisable until April 5, 2023 at $1.12 per share of common stock, which was the closing price of the common stock as quoted on the OTC QB on that date. All of these common stock purchase options vested immediately. Each of the common stock purchase options were valued on the issuance date based upon a Black-Scholes valuation method at $1.081. Mr. Weingarten simultaneously with the issuance of the common stock purchase options, agreed to forgive $200,350 of accrued compensation owed to him. The value of the options granted to Mr. Weingarten was $200,404. The resulting loss on extinguishment of the accrued liability was $54. The common stock purchase options issued to Pharmaland was in partial payment of accounts payable owed. The common stock purchase options issued to Pharmaland had a value of $135,125 and the accounts payable extinguished was $124,025. The loss on extinguishment of this accounts payable was $11,100.

On November 21, 2018, the Company issued 283,643 shares of common stock with a value of $198,550 to designees of one of its intellectual property law firms as partial settlement of accounts payable due to the law firm. There was no gain or loss on the settlement of this accounts payable.

On November 21, 2018, the Company granted a non-qualified stock option ("NQSO") to purchase 21,677 shares of common stock to a vendor to settle $15,000 of accounts payable due to that vendor. The NQSO vested immediately with respect to 14,452 shares of common stock and on November 30, 2018 with respect to an additional 7,225 shares of common stock. As of December 31, 2018, the NQSO has vested with respect to all shares. The NQSO has a term of 5 years and have an exercise price of $0.70 per share, which was the closing price on the trading day of the grant date. The NQSO was valued using the Black-Scholes option pricing model resulting value was $0.692 per NQSO. There was no gain or loss on the extinguishment of the accounts payable.

On December 9, 2017, the Company accepted offers from certain executive officers, a former executive officer, the independent members of the Board of Directors and two consultants ("Offerees") pursuant to which such Offerees offered to forgive all, or in one case, a portion of their accrued compensation and compensation related amounts owed to them and vendor accounts payable as of September 30, 2017. Also, on December 9, 2017, the Company granted NQSOs to the Offerees. The NQSOs immediately vested, have a term of 10 years and have an exercise price of $1.45 per share, which was the closing price on the last trading day before the grant date (Friday, December 8, 2017). The NQSOs were valued using the Black-Scholes option pricing model. The resulting value was $1.396 per NQSO.

The table below summarizes the result of the forgiveness and NQSO grant transactions on December 9, 2017:

	Dollar amount forgiven	Number of NQSOs granted	Value of NQSOs granted	Gain
Executive Officers, former executive officer, independent members of the Board of Directors	$2,557,083	1,772,056	$2,475,561	$81,522
Consultants	$111,635	77,362	$108,076	$3,559
Total	$2,668,718	1,849,418	$2,583,637	$85,081

The Company continues to explore ways to reduce its obligations and indebtedness, and might in the future enter into additional settlement and payment agreements.

6. Stockholders' Deficiency

Preferred Stock

The Company has authorized a total of 5,000,000 shares of preferred stock, par value $0.001 per share. As of December 31, 2018 and 2017, 1,250,000 shares were designated as 9% Cumulative Convertible Preferred Stock (non-voting, "9% Preferred Stock"); 37,500 shares were designated as Series B Convertible Preferred Stock (non-voting, "Series B Preferred Stock"); 205,000 shares were designated as Series A Junior Participating Preferred Stock (non-voting, "Series A Junior Participating Preferred Stock"); and 1,700 shares were designated as Series G 1.5% Convertible Preferred Stock. Accordingly, as of December 31, 2018, 3,505,800 shares of preferred stock were undesignated and may be issued with such rights and powers as the Board of Directors may designate.

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There were no shares of 9% Preferred Stock or Series A Junior Participating Preferred Stock or Series G 1.5% Convertible Preferred Stock outstanding as of December 31, 2018 and 2017.

Series B Preferred Stock outstanding as of December 31, 2018 and 2017 consisted of 37,500 shares issued in a May 1991 private placement. Each share of Series B Preferred Stock is convertible into approximately 0.00030 shares of common stock at an effective conversion price of $2,208.375 per share of common stock, which is subject to adjustment under certain circumstances. As of December 31, 2018 and 2017, the shares of Series B Preferred Stock outstanding are convertible into 11 shares of common stock. The Company may redeem the Series B Preferred Stock for $25,001, equivalent to $0.6667 per share, an amount equal to its liquidation preference, at any time upon 30 days prior notice.

Common Stock

There are 3,872,076 shares of the Company's Common Stock outstanding as of December 31, 2018. After reserving for conversions of convertible debt as well as common stock purchase options and warrants exercises, there are 50,486,154 shares of the Company's Common Stock available for future issuances.

2018 Unit Offering

On September 12, 2018, the Company consummated an initial closing on an offering ("2018 Unit Offering") of Units comprised of one share of the Company's common stock and one common stock purchase warrant. The 2018 Unit Offering was for up to $1.5 million and had a final termination date of October 15, 2018. The initial closing was for $250,750 of which $200,750 was the gross cash proceeds. The additional $50,000 was represented by the conversion into the 2018 Unit Offering of the principal amount of the Arnold S. Lippa, Demand Promissory Note described below. With the exchange of Dr. Lippa's Demand Promissory Note into the 2018 Unit Offering, 47,620 warrants exercisable at 150% of the unit price ($1.575) per share of common stock and expiring on April 30, 2023 were issued with a value of $49,975 which amount was considered a loss on the extinguishment of that officer note and which amount was credited to additional paid-in capital. Units were sold for $1.05 per unit and the warrants issued in connection with the units are exercisable through April 30, 2023 at a fixed price of 150% of the unit purchase price. 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 $3.00 or more for any five (5) consecutive trading days. In total, 238,814 shares of the Company's common stock and 238,814 common stock purchase warrants were purchased. Other than Arnold S. Lippa, the investors in the offering were not affiliates of the Company. Investors also received an unlimited number of piggy-back registration rights in respect to the shares of common stock and the shares of common stock underlying the common stock purchase warrants, unless such common stock is eligible to be sold with volume limits under an exemption from registration under any rule or regulation of the SEC that permits the holder to

sell securities of the Company to the public without registration and without volume limits (assuming the holder is not an affiliate).

The shares of common stock and common stock purchase warrants 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 common stock purchase warrants, the Common Stock issuable upon exercise of the common stock purchase warrants or any warrants issued to a qualified referral source (of which there were none in the initial closing) 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.

In addition, as set forth in the Purchase Agreements, each Purchaser had an unlimited number of exchange rights, which were options and not obligations, to exchange such Purchaser's entire investment as defined (but 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 within stockholders' equity, and excluding any form of debt or convertible debt or preferred stock redeemable at the discretion of the holder (each such financing a "Subsequent Equity Financing"). These exchange rights were effective until the earlier of: (i) the completion of any number of Subsequent Equity Financings that aggregate at least $15 million of gross proceeds, or (ii) December 30, 2018. For clarity, a Purchaser's entire investment was the entire amount invested ("Investment Amount") (for purposes of the multiple described below) and all of the Common Stock and Warrants purchased (for purposes of the exchange) pursuant to the Purchase Agreement of such Purchaser, however, if the Warrants had been exercised in part or in whole on a cashless basis, then the Investment Amount (for purposes of the multiple described below) would have been the Investment Amount (for purposes of the multiple described below) and all of the Common Stock initially purchased pursuant to the Purchase Agreement of such Purchaser plus any shares of Common Stock issued pursuant to a cashless exercise and any Warrants remaining after such cashless exercise (for purposes of the exchange), or, if the Warrants had been exercised for cash, then the entire investment would have been the Investment Amount plus the amount of cash paid upon cash exercise (for purposes of the multiple described below) and all of the Common Stock initially purchased pursuant to the Purchase Agreement of such Purchaser plus any shares of Common Stock issued pursuant to the cash exercise and any Warrants remaining after such cash exercise (for purposes of the exchange). The exchange rights expired on December 31, 2018.

1st 2017 Unit Offering

On March 10, 2017 and March 28, 2017, the Company sold units to investors 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 (the "2017 Unit Offering"). 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. Investors were not affiliates of the Company. The investors 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 would be 1.2 times the amount of the original investment. Under certain circumstances, the ratio might have been 1.4 instead of 1.2. 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, 2018 and have been accrued in accounts payable and accrued expenses and charged against Additional paid-in capital as of December 31, 2017 and December 31, 2018. The placement agent common stock warrants were valued at $27,648 and were accounted for in Additional paid-in capital as of December 31, 2017 and remain valued at that amount as of December 31, 2018.

On July 26, 2017, the Company's Board approved an offering of securities conducted via private placement (the "2nd 2017 Unit Offering" described below) that, because of the terms of the 2nd 2017 Unit Offering as compared to the terms of the 1st2017 Unit Offering, resulted in an exchange of all of the units from the 1st 2017 Unit Offering into equity securities of the Company in the 2nd 2017 Unit Offering by 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 in the 2nd 2017 Unit Offering to investors 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 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 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