

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

FORM 10-K

ANNUAL REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended June 30, 2019

TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission file number: 000-55347

Relmada Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Nevada

(State or other jurisdiction of
incorporation or organization)

45-5401931

(I.R.S. Employer
Identification No.)

880 Third Avenue, 12th Floor

New York, NY 10022

(Address of principal executive offices)(Zip Code)

(646) 876 3459

(Registrant's telephone number, including area code)

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

Securities registered pursuant to Section 12(g) of the Act:

Title of each class

Common Stock (\$.001 par value)

Name of Market Where Traded

OTCQB

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes No

Indicate by checkmark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 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 No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes 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 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, 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

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 Rule 12b-2 of the Exchange Act). Yes No

State the aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, or the average bid and asked price of such common equity, as of the last business day of the registrant's most recently completed second fiscal quarter.

As of December 31, 2018, the aggregate market value of the registrant's common stock held by non-affiliates of the registrant was \$9,408,840 based on the closing price as reported on the OTCQB.

As of September 24, 2019, there are 39,578,986 shares of common stock, \$0.001 par value per share outstanding.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K (this Report) contains forward looking statements that involve risks and uncertainties, principally in the sections entitled “Description of Business,” “Risk Factors,” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations.” All statements other than statements of historical fact contained in this Annual Report, including statements regarding future events, our future financial performance, business strategy and plans and objectives of management for future operations, are forward-looking statements. We have attempted to identify forward-looking statements by terminology including “anticipates,” “believes,” “can,” “continue,” “could,” “estimates,” “expects,” “intends,” “may,” “plans,” “potential,” “predicts,” “should,” or “will” or the negative of these terms or other comparable terminology. Although we do not make forward-looking statements unless we believe we have a reasonable basis for doing so, we cannot guarantee their accuracy. These statements are only predictions and involve known and unknown risks, uncertainties and other factors, including the risks outlined under “Risk Factors” or elsewhere in this Annual Report, which may cause our or our industry’s actual results, levels of activity, performance or achievements expressed or implied by these forward-looking statements. Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time and it is not possible for us to predict all risk factors, nor can we address the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause our actual results to differ materially from those contained in any forward-looking statements. All forward-looking statements included in this document are based on information available to us on the date hereof, and we assume no obligation to update any such forward-looking statements.

You should not place undue reliance on any forward-looking statement, each of which applies only as of the date of this Annual Report on Form-10-K. Before you invest in our securities, you should be aware that the occurrence of the events described in the section entitled “Risk Factors” and elsewhere in this Annual Report could negatively affect our business, operating results, financial condition and stock price. Except as required by law, we undertake no obligation to update or revise publicly any of the forward-looking statements after the date of this Annual Report on Form-10-K to conform our statements to actual results or changed expectations.

PART I

All brand names or trademarks appearing in this report are the property of their respective holders. Unless the context requires otherwise, references in this report to "Relmada," the "Company," "we," "us," and "our" refer to Relmada Therapeutics, Inc., a Nevada corporation.

ITEM 1. BUSINESS

Business Overview

Relmada is a clinical-stage, publicly traded biotechnology company focused on the development of d-methadone (dextromethadone, REL-1017), an N-methyl-D-aspartate (NMDA) receptor antagonist. d-methadone is a new chemical entity that potentially addresses areas of high unmet medical need in the treatment of central nervous system (CNS) diseases and other disorders.

Our lead product candidate, d-methadone, is a New Chemical Entity (NCE) being developed as a rapidly acting, oral agent for the treatment of depression and other potential indications. We have completed Phase 1 single and multiple ascending dose studies. A Phase 2 study in major depressive disorder is ongoing, with first patient dosed in June 2018 and last patient-last dose completed in July 2019. We expect to have top line results in the second half of 2019.

NMDA receptors are present in many parts of the central nervous system and play important roles in regulating neuronal activity. We believe that dextromethadone acting as a NMDA receptor antagonist can have potential applications in a number of disease indications which mitigates risk and offers significant upside.

In addition, the Company has a portfolio of three 505b2 product candidates at various stages of development. These products are: LevoCap ER (REL-1015), an abuse resistant, sustained release dosage form of the opioid analgesic levorphanol; BuTab (oral buprenorphine, REL-1028), an oral dosage form of the opioid analgesic buprenorphine; and MepiGel (topical mepivacaine, REL-1021), an orphan drug designated topical formulation of the local anesthetic mepivacaine.

Our four development projects are briefly described below:

d-Methadone (dextromethadone, REL-1017) and Treatment-Resistant Depression (TRD)

Background

In 2014, the National Institute of Mental Health (NIMH) estimated that 15.7 million adults aged 18 or older in the United States had at least one major depressive episode in the past year. According to data from nationally representative surveys supported by NIMH, only about half of Americans diagnosed with major depression in a given year receive treatment. Of those receiving treatment with as many as four different standard antidepressants, 33% of drug-treated depression patients do not achieve adequate therapeutic benefits according to the Sequenced Treatment Alternatives to Relieve Depression (STAR*D) trial published in the American Journal of Psychiatry. Accordingly, we believe that approximately 3 million patients with such treatment-resistant depression are in need of new treatment options.

In addition to the high failure rate, none of the marketed products for depression can demonstrate rapid antidepressant effects and most of the products take up to a month to show effectiveness. The urgent need for improved, faster acting antidepressant treatments is underscored by the fact that severe depression can be life-threatening, due to heightened risk of suicide.

Recent studies have shown that ketamine, a drug known previously as an anesthetic, can lift depression in many patients within hours. Like d-methadone, ketamine is an NMDA receptor antagonist. However, it is unlikely that ketamine itself will become a practical treatment for most cases of depression. It must be administered through intravenous infusion or intranasally, requiring a hospital setting, and more importantly can potentially trigger adverse side effects including psychedelic symptoms (hallucinations, memory defects, panic attacks), nausea/vomiting, somnolence, cardiovascular stimulation and, in a minority of patients, hepatotoxicity. Ketamine also hasn't been thoroughly studied for long-term safety and effectiveness, and the FDA hasn't approved it to treat depression.

d-Methadone Overview and Mechanism of Action

d-Methadone's mechanism of action, as a non-competitive NMDA channel blocker or antagonist, is fundamentally differentiated from all currently FDA-approved antidepressants, as well as all atypical antipsychotics used adjunctively with standard, FDA-approved antidepressants. Working through the same brain mechanisms as ketamine but potentially lacking its adverse side effects, Relmada's d-methadone is being developed as a rapidly acting, oral agent for the treatment of depression and/or other potential CNS pathological conditions.

In chemistry an enantiomer, also known as an optical isomer, is one of two stereoisomers that are mirror images of each other that are non-superposable (not identical), much as one's left and right hands are the same except for being reversed along one axis. A racemic compound, or racemate, is one that has equal amounts of left- and right-handed enantiomers of a chiral molecule. For racemic drugs, often only one of a drug's enantiomers is responsible for the desired physiologic effects, while the other enantiomer is less active or inactive.

Racemic methadone has been used since the 1950s as a treatment for opioid addiction and has remained the primary therapy for this condition for more than 40 years. Methadone is a highly lipophilic molecule that is suitable for a variety of administration routes, with oral bioavailability close to 80%.

As a single isomer of racemic methadone, d-methadone has been shown to possess NMDA antagonist properties with virtually no traditional opioid or ketamine-like adverse events at the expected therapeutic doses. In contrast, racemic methadone is associated with common opioid side effects that include anxiety, nervousness, restlessness, sleep problems (insomnia), nausea, vomiting, constipation, diarrhea, drowsiness, and others. It has been shown that the left (levo) isomer, l-methadone, is largely responsible for methadone's opioid activity, while the right (dextro) isomer, d-methadone, is much less active as an opioid while maintaining affinity for the NMDA receptor.

NMDA receptors are present in many parts of the central nervous system and play important roles in regulating neuronal activity and promoting synaptic plasticity in brain areas important for cognitive functions such as executive function, learning and memory. Based on these premises, d-methadone could show benefits in several different CNS indications.

d-Methadone Phase 1 Clinical Safety Studies

The safety data from two Company-funded d-methadone Phase 1 clinical safety studies and a third study conducted by researchers at Memorial Sloan-Kettering Cancer Center indicate that d-methadone was safe and well tolerated in both healthy subjects and cancer patients at all projected therapeutic doses tested.

In November 2014, Health Canada approved a Clinical Trial Application (CTA) to conduct the first Phase 1 study with d-methadone. This was a Single Ascending Dose (SAD) study and was followed by a Multiple Ascending Dose (MAD) study, both in healthy volunteers. The two studies were designed to assess the safety, tolerability and pharmacokinetics of d-methadone in healthy, opioid-naïve subjects. The SAD study included single escalating oral doses of d-methadone to determine the maximum tolerated dose, defined as the highest dose devoid of unacceptable adverse events. In the MAD study, healthy subjects received daily oral doses of d-methadone for several days to assess its safety, pharmacokinetics and tolerability. In March 2015, we reported that d-methadone demonstrated an acceptable safety profile with no dose limiting side effects after four cohorts were exposed to increasing higher doses. In April 2015, the Company received clearance from Health Canada to continue with dose escalation and explore even higher single doses of d-methadone. In June 2015, the Company successfully completed the SAD study identifying the maximum tolerated dose and subsequently received a No Objection Letter (NOL) from Health Canada to conduct the MAD clinical study in August 2015. The MAD study was completed in January 2016 and the results successfully demonstrated a potential therapeutic dosing regimen for d-methadone with a favorable side effect and tolerability profile. The data from these studies was used to design a Phase 2a study in patients with depression.

d-Methadone In Vivo Study for Depression

In May 2016, we announced the results of an in vivo study showing that administration of d-methadone results in antidepressant-like effects in a well-validated animal model of depression, known as the forced swim test (FST), providing preclinical support for its potential as a novel treatment of depression.

According to the Journal of Visualized Experiments, the FST is based on the assumption that when placing an animal in a container filled with water, it will first make efforts to escape by swimming or climbing, but eventually will exhibit “immobility” that may be considered to reflect a measure of behavioral despair. This test has been extensively used because it involves the exposure of the animals to stress, which was shown to have a role in the tendency for major depression. Additionally, the FST has been shown to be influenced by some of the factors that are altered by or worsen depression in humans, including changes in food consumption and sleep abnormalities. The main advantages of this procedure are that it is relatively easy to perform and that its results are easily and quickly analyzed. Importantly, the FST’s sensitivity to a broad range of antidepressant drugs makes it a suitable screening test and is one of the most important features leading to its high predictive validity.

In the Company’s FST study, male Sprague Dawley rats were administered single doses of placebo, ketamine, or d-methadone on day one (after habituation; 24 hours prior to forced swim testing). At all doses tested, d-methadone significantly decreased immobility of the rats compared to the placebo, suggesting antidepressant-like activity. In addition, the effect of d-methadone on immobility at the two highest doses tested was larger than the effect seen with ketamine. Moreover, the effects of d-methadone in the forced swim test were not caused by a stimulant effect on spontaneous locomotor activity of the rats. Locomotor activity of lab animals is often monitored to assess the behavioral effects of drugs.

In September 2017 we completed two additional in vivo studies to confirm and support the antidepressant-like effect of dextromethadone in validated animal models, the Novelty Suppressed Feeding Test (NSFT) and the Female Urine-Sniffing test (FUST) test. The studies were performed by Professor Ronald S. Duman, Ph.D. at Yale University School of Medicine.

For FUST, rats are first exposed to a cotton tip dipped in tap water and later exposed to another cotton tip infused with fresh female urine. Male behavior was video recorded and total time spent sniffing the cotton-tipped applicator is determined. For NSFT, rats were food deprived for 24 hr and then placed in an open field with food pellets in the center; latency to eat is recorded in seconds. As a control, food consumption in the home cage is quantified. Rats were administered vehicle, ketamine or d-methadone.

The results of the FUST demonstrate that administration of ketamine significantly increases the time male rats spent engaged in sniffing female urine compared to vehicle group. Similarly, a single dose of d-methadone significantly increased the time spent sniffing female urine compared to vehicle. In contrast, ketamine or d-methadone had no effect on time sniffing water, demonstrating that the effect of drug treatment was specific to the rewarding effects of female urine. The results of the NSFT demonstrate that a single dose of ketamine significantly decreases the latency to eat in a novel open field. Similarly, a single dose of d-methadone also significantly decreased the latency to enter and eat in the novel feed. In contrast, neither ketamine nor methadone influenced latency to feed in the home cage.

These findings demonstrate that ketamine and d-methadone produce rapid antidepressant actions in the FUST and NSFT, effects that are only observed after chronic administration of an SSRI antidepressant.

A separate in vitro electrophysiology study of d-methadone was conducted using 2 subtypes of cloned human NMDA receptors.

The results of this study demonstrated functional antagonist activity with d-methadone comparable to that of both racemic ketamine and the isomer [S]-ketamine.

Phase 2 Program for d-Methadone in Depression

Combined with the results of our Phase 1 studies, the encouraging results of in vivo and in vitro studies strongly support further evaluation of d-methadone in a Phase 2 study as a rapidly acting, oral agent for the treatment of major depressive disorder. Relmada filed an Investigational New Drug (IND) application for the Phase 2 study with the FDA, which was accepted on January 25, 2017.

On April 13, 2017, we announced that the FDA granted Fast Track designation for d-methadone (REL-1017 dextromethadone) for the adjunctive treatment of major depressive disorder. Fast Track designation is a process designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need. The purpose, according to the FDA, is to get important new drugs to the patient earlier. Drugs that receive Fast Track designation may be eligible for more frequent meetings and written communications with the FDA, accelerated review and priority approval, and rolling New Drug Application (NDA) review.

On January 17, 2018, we announced that Relmada had acquired the global rights to develop and market dextromethadone for the treatment of neurological conditions including certain rare diseases with symptoms affecting the CNS.

In February 2018, Relmada initiated its Phase 2 study of d-methadone in patients with major depressive disorder.

In July 2019, Relmada announced the completion of dosing of the last patient in its Phase 2 study of d-methadone in patients with major depressive disorder.

d-Methadone (dextromethadone, REL-1017) in other indications

In addition to developing dextromethadone in major depression, Relmada is initiating work in additional indications. In particular, we have initiated a preclinical program to test the potential efficacy of dextromethadone in Rett syndrome. Rett syndrome is an X-linked neurodevelopmental disorder with high unmet need caused by Mecp2 gene mutation. Loss of Mecp2 disrupts synaptic function and structure and neuronal networks. Rett syndrome is an Orphan Disease affecting ~15,000 in U.S., primarily girls, with no approved therapy. The disease begins with a short period of developmental stagnation, then rapid regression in language and motor skills, followed by long-term stability.

Studies of ketamine, an NMDAR antagonist with mechanistic similarities with dextromethadone, in Rett Syndrome mouse models show that low-dose ketamine acutely reverses multiple disease manifestations and chronic administration of ketamine improves Rett Syndrome progression, providing a solid rationale to pursue this indication with dextromethadone.

Other indications that Relmada may explore in the future, potentially includes restless leg syndrome, and other glutamatergic system activation related diseases.

In January 2018, we entered into an Intellectual Property Assignment Agreement (the Assignment Agreement) and License Agreement (the "License Agreement" and together with the Assignment Agreement, the Agreements) with Dr. Charles E. Inturrisi and Dr. Paolo Manfredi (collectively, the Licensor). Pursuant to the Agreements, Relmada assigned its existing rights, including patents and patent applications, to d-methadone in the context of psychiatric use (the Existing Invention) to Licensor. Licensor then granted Relmada under the License Agreement a perpetual, worldwide, and exclusive license to commercialize the Existing Invention and certain further inventions regarding d-methadone in the context of other indications such as those contemplated above.

LevoCap ER (REL-1015)

LevoCap ER (REL-1015) is a novel version of a proven drug product. LevoCap ER -is an extended release, abuse deterrent, and proprietary formulation of levorphanol (levo-3-hydroxy-N-methyl-morphinan), a unique, broad spectrum opioid with additional "non-opioid" mechanisms of action. In particular, levorphanol binds to all three opioid receptor subtypes involved in analgesia (mu, kappa, and delta), the NMDA receptor, and the norepinephrine and serotonin reuptake pumps, whereas morphine, oxycodone, hydrocodone, and other opioids are highly selective for the mu receptor subtype. Due to its multi-modal mechanism of action, levorphanol could achieve analgesia in patients resistant to other strong opioids. In clinical studies, levorphanol has demonstrated a remarkably broad spectrum of analgesic activity against many different types of pain including neuropathic pain, post-surgical pain, and chronic pain in patients refractory to other opioids.

Levorphanol is a potent opioid analgesic first introduced in the U.S. around 1953 for the treatment of moderate to severe pain where an opioid analgesic is appropriate. Extended-release (long-acting opioid) agents may be preferable to immediate release formulations due to better patient adherence, less dose-watching, and result in improved sleep. Both immediate- and extended-release opioids can potentially be crushed to produce concentrated drug with greater appeal to abusers. Intentional crushing or extracting the active ingredient from the extended-release dosage form by addicts and recreational drug users can destroy the timed-release mechanism and result in a rapid surge of drug into the bloodstream for the purpose of achieving a high or euphoric feeling. Serious side effects and death have been reported from such misuse.

LevoCap ER is the first product candidate utilizing SECUREL™, Relmada's proprietary abuse deterrent extended release technology for opioid drugs. SECUREL dosage forms cannot be easily crushed for inhalation or to obtain rapid euphoria from high blood levels when swallowed. It is also exceedingly difficult for intravenous abusers to extract the active drug from the dosage form using common solvents, including alcohol.

LevoCap ER can be developed under the 505(b)(2) regulatory pathway. Following an exchange of correspondence and meeting with the FDA in January 2017, we have defined a path forward for the Phase 3 clinical study for LevoCap ER and a new drug application (NDA) filing. In light of the promising data generated by Relmada's d-methadone research program, and Relmada's focus on the d-methadone program, Relmada is currently limiting the investments in LevoCap ER.

BuTab (REL-1028)

BuTab (REL-1028) represents a novel formulation of oral, modified release buprenorphine as a potential therapeutic for both chronic pain and opioid dependence. Buprenorphine has been widely used by the sublingual and transdermal routes of administration, but was believed to be ineffective by the oral route because of poor oral bioavailability. We have completed a preclinical program to better define the pharmacokinetic profile of BuTab and to assess the time course of systemic absorption of buprenorphine using several different oral modified release formulations of buprenorphine in dogs, compared to an intravenous administration. Based on the results of this work, we obtained approval from Health Canada and initiated a Phase 1 pharmacokinetic study in healthy volunteers in the second quarter of 2015. This trial was completed in the fourth quarter of 2015. The absolute bioavailability of BuTab relative to intravenous (IV) administration exceeded published data with non-modified buprenorphine when administered orally and compares favorably with a currently marketed transdermal patch. There were no safety or tolerability issues. The data generated by this study will guide formulation optimization and inform the design of subsequent clinical pharmacology studies. BuTab can be developed under the 505(b)(2) regulatory pathway. In light of the promising data generated by Relmada's d-methadone research program, and Relmada's focus on the d-methadone program, Relmada is currently limiting the investments in BuTab.

MepiGel (REL-1021)

MepiGel (REL-1021), is a proprietary topical dosage form of the local anesthetic mepivacaine for the treatment of painful peripheral neuropathies, such as painful diabetic neuropathy, postherpetic neuralgia and painful HIV-associated neuropathy. Mepivacaine is an anesthetic (numbing medicine) that blocks the nerve impulses that send pain signals to the brain. It is chemically related to bupivacaine but pharmacologically related to lidocaine. Mepivacaine is currently indicated for infiltration, nerve block and epidural anesthesia. Relmada has received two FDA Orphan Drug Designations for mepivacaine, one each for "the treatment of painful HIV-associated neuropathy" and for "the management of postherpetic neuralgia," or PHN. We have selected the formulations to be advanced into clinical studies for MepiGel after the evaluation of results from in vitro and ex vivo studies comparing various topical prototypes of mepivacaine that were conducted by MedPharm Ltd, a specialist formulation development company recognized internationally for its expertise in topical and transdermal products. Multiple toxicology studies were successfully conducted and completed in 2015. MepiGel can be developed under the 505(b)(2) regulatory pathway. In light of the promising data generated by Relmada's d-methadone research program, and Relmada's focus on the d-methadone program, Relmada is currently limiting the investments in MepiGel.

Overview of the 505(b)(2) Pathway

Part of our strategy is the utilization of FDA's 505(b)(2) NDA for approval. The 505(b)(2) NDA is one of three FDA drug approval pathways and represents an appealing regulatory strategy for many companies. The pathway was created by the Hatch-Waxman Amendments of 1984, with 505(b)(2) referring to a section of the Federal Food, Drug, and Cosmetic Act. The provisions of 505(b)(2) were created, in part, to help avoid unnecessary duplication of studies already performed on a previously approved (reference or listed) 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 much less expensive and much faster route to approval, compared with a traditional development path [such as 505(b)(1)], while creating new, differentiated products with tremendous commercial value.

Overview of Orphan Drug Status

In accordance with laws and regulations pertaining to the Regulatory Agencies, a sponsor may request that the Regulatory Agencies designate a drug intended to treat a "Rare Disease or Condition" as an "Orphan Drug." For example, in the United States, a "Rare Disease or Condition" is defined as one which affects less than 200,000 people in the United States, or which affects more than 200,000 people but for which the cost of developing and making available the product is not expected to be recovered from sales of the product in the United States. Upon the approval of the first NDA or BLA for a drug designated as an orphan drug for a specified indication, the sponsor of that NDA or BLA is entitled to 7 years of exclusive marketing rights in the United States unless the sponsor cannot assure the availability of sufficient quantities to meet the needs of persons with the disease. In Europe, this exclusivity is 10 years, and in Australia it is 5 years. However, orphan drug status is particular to the approved indication and does not prevent another company from seeking approval of an off-patent drug that has other labeled indications that are not under orphan or other exclusivities. Orphan drugs may also be eligible for federal income tax credits for costs associated with such as the disease state, the strength and complexity of the data presented, the novelty of the target or compound, risk-management approval and whether multiple rounds of review are required for the agency to evaluate the submission. There is no guarantee that a potential treatment will receive marketing approval or that decisions on marketing approvals or treatment indications will be consistent across geographic areas.

Our Corporate History and Background

We are a clinical-stage, publicly traded biotechnology company developing NCEs together with novel versions of proven drug products that potentially address areas of high unmet medical need in the treatment of depression and other CNS diseases.

Currently, none of our drugs have been approved for sale in the United States or elsewhere. We have no commercial products nor do we have a sales or marketing infrastructure. In order to market and sell our products we must conduct clinical trials on patients and obtain regulatory approvals from appropriate regulatory agencies, like the FDA in the United States, and similar organizations elsewhere in the world.

We have not generated revenues and do not anticipate generating revenues for the foreseeable future. We had net loss of approximately \$17,318,000 and \$8,961,000 for the years ended June 30, 2019 and June 30, 2018, respectively. At June 30, 2019, we have an accumulated deficit of approximately \$111,662,000.

Business Strategy

Our strategy is to leverage our considerable industry experience, understanding of CNS markets and development expertise to identify, develop and commercialize product candidates with significant market potential that can fulfill unmet medical needs in the treatment of depression. We have assembled a management team along with both scientific and business advisors, including recognized experts in the fields of depression, with significant industry and regulatory experience to lead and execute the development and commercialization of d-methadone.

We plan to further develop d-methadone as the priority program for the Company. As the drug d-methadone is a NCE, the regulatory pathway to approval will consist of conducting a full clinical development program. Depending on the resources available to us, we may also develop REI-1028, REI-1015, REL-1021 via the 505(b)(2) development pathway and also to gain exclusivity under the Hatch-Waxman Act for new indications and also orphan drug designation in certain indications. We plan to also generate intellectual property (IP) that will further protect our products from competition. We will continue to prioritize our product development activities after taking into account the resources we have available, market dynamics and potential for adding value. We will continue to outsource development of our products, while retaining scientific, operational and financial oversight and control.

We intend to seek and execute licensing and/or co-development agreements with companies capable of supporting the final stage development of the Company's products and their subsequent commercialization in the U.S. and international markets.

We may in-license late-stage or approved drugs to accelerate the pathway to become a fully integrated biopharmaceutical company with commercial capability. Alternatively, we might consider a trade sale of our products or the entire company if we deem that it is in the best interests of our shareholders.

Market Opportunity

We believe that the market for addressing areas of high unmet medical need in the treatment of CNS diseases will continue to be large for the foreseeable future and that it will represent a sizable revenue opportunity for Relmada. For example, the World Health Organization (WHO) has estimated that CNS diseases affect nearly 2 billion people globally, making up approximately 40% of total disease burden (based on disability adjusted life years), compared with 13% for cancer and 12% for cardiovascular disease. We also believe that each of our product candidates is designed to have value added features that will provide product related competitive advantages versus the existing drugs available on the market.

The depression treatment market is segmented on the basis of antidepressants drugs, devices, and therapies. Antidepressants are the largest and most popular market segment. According to Research and Markets, every year more than 5 billion antidepressant prescriptions are written globally. The antidepressants segment consists of large pharmaceutical and generic companies, such as Eli Lilly, Pfizer, GlaxoSmithKline, Allergan, Sage Therapeutics and Johnson & Johnson. Some of the popular drugs produced by these companies are Cymbalta® (Eli Lilly), Effexor® (Pfizer), Pristiq® (Pfizer), Zulusso (Sage) and Spravato (Johnson & Johnson).

Intellectual Property Portfolio and Market Exclusivity

We have secured three Orphan Drug Designations from the FDA: 1) d-methadone for “the treatment of postherpetic neuralgia”; 2) MepiGel for “the treatment of painful HIV-associated neuropathy”; and MepiGel for “the management of postherpetic neuralgia.” Each would, upon NDA approval, carry 7-year FDA Orphan Drug marketing exclusivity. In the European Union, some of our products may be eligible up to 10 years of market exclusivity, which includes 8 years data exclusivity and 2 years market exclusivity. In addition to any granted patents, our products will be eligible for market exclusivity to run concurrently with the term of the patent for 3 years in the U.S. (Hatch Waxman plus pediatric exclusivity) and up to 10 years of in the E.U. We believe an extensive intellectual property estate of several patents will protect our technology and products once our patent applications for our products are approved.

The following is a summary of our patents and patent applications:

Levorphanol: These patents and patent applications cover the Levorphanol product.

US Patent No. 9,125,833, filed 4/28/08, granted on 9/8/15. Multimodal Abuse Resistant and Extended Release Opioid Formulations. Owned by Relmada. Estimated expiry in 2030. This patent covers the SECUREL technology platform and Relmada’s lead product candidate, LevoCap ER (REL-1015, levorphanol extended-release, abuse deterrent capsules) as well as providing additional coverage for multiple opioid molecules that are prone to abuse.

EU patent No. 2,448,406, filed 2/26/10, granted on 4/20/16. Extended Release Oral Pharmaceutical Compositions of 3-Hydroxy-N-Methylmorphinan and Method of Use. Owned by Relmada. Estimated expiry in 2030.

Patent application 12/223,327 filed 1/29/07, Abuse Resistant and Extended Release Formulations and Method of Use Thereof. Cover US. Owned by Relmada. Currently pending.

Patent application 13/320,989 filed 2/26/10 Extended Release Oral Pharmaceutical Compositions of 3-Hydroxy-N-Methylmorphinan and Method of Use. Owned by Relmada. Currently pending.

d-Methadone: These patents and patent application cover the d-methadone product.

U.S. Patent No. 9,468,611 issued on 10/18/2016 (filed 3/14/2013), “d-Methadone for the Treatment of Psychiatric Symptoms.” Owned by Relmada. Estimated expiry in 2032.

U.S. Patent No. 9,855,226 issued on 1/2/2018 (filed 7/7/2016), “d-Methadone for the Treatment of Psychiatric Symptoms.” Owned by Relmada. Estimated expiry in 2032.

U.S. Patent Application No. 15/884,915 (filed 1/31/2018), “Compounds for the treatment or prevention of disorders of the Nervous system and symptoms and manifestations thereof, and for cyto-protection against diseases and aging of cells and symptoms and manifestations thereof.”

Australian Patent No. 2013323645 issued on 2/15/2018 (filed 9/25/2013), “d-Methadone for the Treatment of Psychiatric Symptoms.” Owned by Relmada. Estimated expiry in 2032.

European Patent No. 2,906,209 granted on 6/20/2018 (filed 9/25/2013), “d-Methadone for the Treatment of Psychiatric Symptoms.” Owned by Relmada. Estimated expiry in 2032.

Australian Patent Application No. 2017276189 (filed 9/25/2013), “d-Methadone for the Treatment of Psychiatric Symptoms.” Owned by Relmada.

Canadian Patent Application No. 2,893,238 (filed 9/25/2013), “d-Methadone for the Treatment of Psychiatric Symptoms.” Owned by Relmada.

Chinese Patent Application No. 201380061197.3 (filed 9/25/2013), “d-Methadone for the Treatment of Psychiatric Symptoms.” Owned by Relmada. Currently allowed and awaiting issuance.

Hong Kong Patent Application No. 16101841.1 (filed 9/25/2013), “d-Methadone for the Treatment of Psychiatric Symptoms.” Owned by Relmada. Currently allowed and awaiting issuance.

Indian Patent Application No. 3481/DELNP/2015 (filed 9/25/2013), “d-Methadone for the Treatment of Psychiatric Symptoms.” Owned by Relmada.

South Korean Patent Application No. 2017-7036888 (filed 9/25/2013), “d-Methadone for the Treatment of Psychiatric Symptoms.” Owned by Relmada.

International (PCT) Patent Application No. PCT/US2018/16159 (filed 1/31/2018), “Compounds for the treatment or prevention of disorders of the Nervous system and symptoms and manifestations thereof, and for cyto-protection against diseases and aging of cells and symptoms and manifestations thereof.”

Taiwanese Patent Application No. 107108987 (filed 3/16/2018), “Compounds for the treatment or prevention of disorders of the Nervous system and symptoms and manifestations thereof, and for cyto-protection against diseases and aging of cells and symptoms and manifestations thereof.”

Buprenorphine: This patent application covers the buprenorphine product.

Patent application 12/989,209 filed 3/9/09, Oral Pharmaceutical Compositions of Buprenorphine and Method of Use cover US. EP 9719755.2 covers EU. Owned by Relmada. Both are currently pending.

Mepivacaine: These patents and patent applications cover the Mepivacaine product.

Canadian Patent No. 2,796,575 issued on 5/15/2018 (filed 4/13/2011), “Dermal Pharmaceutical Compositions of 1-Methyl-2,6-Pipecoloxylidide and Method of Use.” Owned by Relmada. Estimated expiry in 2030.

Chinese Patent No. 103491778 issued on 5/31/2017 (filed 4/13/2011), “Dermal Pharmaceutical Compositions of 1-Methyl-2,6-Pipecoloxylidide and Method of Use.” Owned by Relmada. Estimated expiry in 2030.

Japanese Patent No. 5927506 issued on 5/13/2016 (filed 4/13/2011), “Dermal Pharmaceutical Compositions of 1-Methyl-2,6-Pipecoloxylidide and Method of Use.” Owned by Relmada. Estimated expiry in 2030.

U.S. Patent Application No. 13/641,240 (filed 4/13/2011), "Dermal Pharmaceutical Compositions of 1-Methyl-2,6-Pipecoloxylidide and Method of Use." Owned by Relmada.

Australian Patent Application No. 2016259348 (filed 4/13/2011), "Dermal Pharmaceutical Compositions of 1-Methyl-2,6-Pipecoloxylidide and Method of Use." Owned by Relmada.

European Patent Application No. 11769549.4 (filed 4/13/2011), "Dermal Pharmaceutical Compositions of 1-Methyl-2,6-Pipecoloxylidide and Method of Use." Owned by Relmada.

Indian Patent Application No. 9424/CHENP/2012 (filed 4/13/2011), "Dermal Pharmaceutical Compositions of 1-Methyl-2,6-Pipecoloxylidide and Method of Use." Owned by Relmada.

South Korean Patent Application No. 2015-7006794 (filed 4/13/2011), "Dermal Pharmaceutical Compositions of 1-Methyl-2,6-Pipecoloxylidide and Method of Use." Owned by Relmada.

Key Strengths

We believe that the key elements for our market success include:

- Highly-compelling lead product opportunity, dextromethadone currently in Phase 2 trial for treatment of Major Depressive Disorder (MDD)
- De-risked program following successful extensive Phase 1 safety studies and strong efficacy signal in depression established in three independent animal models
- Significant potential in additional multiple indications in underserved markets with large patient population and rare diseases such as Restless Rett Syndrome and Rett Syndrome.
- Scientific support of leading experts: Our scientific advisors include clinicians and scientists who are affiliated with a number of highly regarded medical institutions such as Harvard, Cornell, Yale, Penn and John Hopkins Universities
- Substantial IP portfolio and market protection: approved and filed patent applications provide protection beyond 2030. In addition, some of our drugs, including dextromethadone have also been designated as Orphan Drugs by the FDA, thereby providing seven years of market exclusivity at launch.

Competition Overview

The pharmaceutical and biotechnology industry is characterized by intense competition, rapid product development and technological change. Competition is intense among manufacturers of prescription pharmaceuticals and other product areas where we may develop and market products in the future. Most of our competitors are large, well-established pharmaceutical or healthcare companies with considerably greater financial, marketing, sales and technical resources than are available to us. Additionally, many of our competitors have research and development capabilities that may allow such competitors to develop new or improved products that may compete with our products. Our products could be rendered obsolete or made uneconomical by the development of new products.

Regarding our competitive position in the industry, none of our products have been approved for sale.

Currently, there are no oral FDA-approved therapies for TRD with the mechanism of action of d-methadone. Johnson & Johnson's Spravato (esketamine nasal spray) has been recently approved for the treatment of TRD however it needs to be taken under the supervision of a healthcare provider in a healthcare setting. Products approved for other indications, for example, low doses of the anesthetic ketamine, are being or may be increasingly used off-label for treating depression, as well as other CNS indications for which d-methadone may have therapeutic potential. Additionally, other treatment options, such psychotherapy and electroconvulsive therapy, are sometimes used instead of and before antidepressant medications to treat patients with TRD.

In the field of new generation antidepressants focused on specifically blocking the NMDA receptor channel, our principal competitor is intranasal esketamine, an isomer of ketamine, developed by Johnson & Johnson subsidiary Janssen Pharmaceuticals and approved in the United States in March 2019. Other potential competitors focused on modulation of the NMDA receptor at its glycine co-agonist site include VistaGen Therapeutics, Inc. that is developing AV-101, an orally available prodrug candidate that gains access to the CNS after systemic administration and is rapidly converted in the brain into its active metabolite, 7-chlorokynurenic acid (7-Cl-KYNA), a well-characterized, potent and highly selective antagonist of the NMDA receptor at the glycine co-agonist site. Vistagen is currently conducting a multicenter Phase 2 study for the adjunctive use of oral AV-101 for MDD in patients with an inadequate response to standard antidepressant therapy.

Government Regulation

Governmental authorities in the United States and other countries extensively regulate, among other things, the research, development, testing, manufacture, labeling, promotion, advertising, distribution and marketing of active pharmaceutical ingredients, excipients, controlled substances and finished pharmaceutical products such as those being developed by Relmada.

In the United States, the FDA regulates such products under the FDCA, as amended and regulations pursuant to the FDCA.

The U.S. Drug Enforcement Agency (DEA), a division of the Department of Justice, administers the federal Controlled Substances Act (CSA) of 1970, as amended. The CSA imposes various registration, record-keeping and reporting requirements, procurement and manufacturing quotas, import and export controls, labeling and packaging requirements, security controls, and a restriction on prescription refills on certain pharmaceutical products.

To meet its responsibilities, the DEA conducts periodic inspections of registered establishments that handle controlled substances. Failure of companies to maintain compliance, particularly as manifested in loss or diversion, can result in regulatory action including civil and criminal penalties, refusal to renew necessary registrations, or initiating proceedings to revoke those registrations. If a manufacturer or distributor has its registration revoked, it can no longer lawfully possess or distribute controlled substances meaning effectively that the operations of such an organization must cease with respect to controlled substances. In certain circumstances, violations also can lead to criminal proceedings.

Most states impose similar controls over controlled substances under state law as regulated by the Board of Pharmacy or other state regulatory authorities.

The U.S. Federal Trade Commission (FTC) and the Office of the Inspector General of the U.S. Department of Health and Human Services (HHS) also regulate certain pharmaceutical marketing practices. Thus, reimbursement practices of the HHS covering medicine and medical services are important to the success of our products.

We are also subject to United States regulation under the CSA. DEA regulations require Scheduled II controlled substances to be manufactured in the United States if the products are to be marketed in the United States. Our only products that contain Schedule II controlled substances are LevoCap ER and d-methadone. We are in the process of transferring all third party manufacturing of these products to the United States, and we intend to comply with this CSA requirement.

We are also subject to numerous federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control, and disposal of hazardous or potentially hazardous substances.

Failure to comply with applicable FDA, DEA, FTC, HHS and other federal and state regulations and requirements, both before and after drug approval may subject us to administrative and judicial sanctions, such as a delay in approving or refusal by the FDA to approve pending applications, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines and/or criminal prosecution.

Please see “Company Overview” above for a status of our drug development.

U.S. Food and Drug Administration Regulation

Our research, development and clinical programs, as well as our manufacturing and marketing operations, are subject to extensive regulation in the United States and other countries. Most notably, all of our products sold in the United States are subject to the FDCA as implemented and enforced by the FDA. Certain of our product candidates in the United States require FDA pre-marketing approval of an NDA pursuant to 21 C.F.R. § 314. Foreign countries may require similar or more onerous approvals to manufacture or market these products.

Failure by us or by our suppliers to comply with applicable regulatory requirements can result in enforcement action by the FDA, the DEA or other regulatory authorities, which may result in sanctions including, but not limited to: untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties; customer notifications or repair, replacement, refunds, recall, detention or seizure of our products; operating restrictions or partial suspension or total shutdown of production; refusing or delaying our requests for NDA premarket approval of new products or modified products; withdrawing NDA approvals that have already been granted; refusal to grant export approval for our products; or criminal prosecution.

Corporate Information

Our principal executive offices are located at 880 Third Avenue, 12th Floor, New York, New York 10022 and our telephone number is (646) 876 3459. Our website address is www.relmada.com. The information contained in, or that can be accessed through, our website is not part of, and is not incorporated in, this Annual Report. The information contained therein or connected thereto shall not be deemed to be incorporated into this 10-K which it forms a part.

Employees

As of June 30, 2019, we have four (4) full-time employees and no part-time employees. None of these employees are covered by a collective bargaining agreement, and we believe our relationship with our employees is good. We also engage consultants on an as-needed basis to supplement existing staff.

Available Information

Reports we file with the Securities and Exchange Commission (SEC) pursuant to the Exchange Act of 1934, as amended (the Exchange Act), including annual and quarterly reports, and other reports we file, can be inspected and copied at the public reference facilities maintained by the SEC at 100 F Street NE, Washington, D.C. 20549.

ITEM 1A. RISK FACTORS

An investment in our common stock involves a high degree of risk. You should carefully consider the risks described below, together with all of the other information included in this report, before making an investment decision. If any of the following risks actually occurs, our business, financial condition or results of operations could suffer. In that case, the trading price of our shares of common stock could decline, and you may lose all or part of your investment. You should read the section entitled "Forward-Looking Statements" above for a discussion of what types of statements are forward-looking statements, as well as the significance of such statements in the context of this Annual Report.

Risk Related to Our Business

Our product candidates are in early stages of clinical testing.

Our product candidates are still in the early stages of clinical testing. None has gone beyond the Phase 1/Phase 2a stage and FDA approval requires that a drug candidate complete a Phase 3 study program, to test the safety and efficacy of the drug candidate on a large sample of patients. The timeline between a Phase 1 study and a Phase 3 study and subsequent filing of a NDA can be several years. We will need to commit substantial time and additional resources to conducting further nonclinical studies and clinical trials before we can submit an NDA with respect to any of these product candidates. We cannot predict with any certainty if or when we might submit an NDA for regulatory approval of any of our product candidates.

We have generated no revenue from commercial sales to date and our future profitability is uncertain.

We have a limited operating history and our business is subject to all of the risks inherent in the establishment of a new business enterprise. Our likelihood of success must be considered in light of the problems, expenses, difficulties, complications and delays frequently encountered in connection with this. Since we began our business, we have focused on research, development and clinical trials of product candidates, and have incurred significant losses since inception and generated no product revenues. If we continue to incur operating losses and fail to become a profitable company, we may be unable to continue our operations. We expect to continue to operate at a net loss for at least the next several years as we continue our research and development efforts, continue to conduct clinical trials and develop manufacturing, sales, marketing and distribution capabilities. There can be no assurance that the products under development by us will be approved for sales in the US or elsewhere. Furthermore, there can be no assurance that if such products are approved they will be successfully commercialized, and the extent of our future losses and the timing of our profitability are highly uncertain.

International commercialization of our product candidates faces significant obstacles.

We may plan to commercialize some of our products internationally through collaborative relationships with foreign partners. We have limited foreign regulatory, clinical and commercial resources. Future partners are critical to our international success. We may not be able to enter into collaboration agreements with appropriate partners for important foreign markets on acceptable terms, or at all. Future collaborations with foreign partners may not be effective or profitable for us. We will need to obtain approvals from the appropriate regulatory, pricing and reimbursement authorities to market any of our proposed products internationally, and we may be unable to obtain foreign regulatory approvals. Pursuing foreign regulatory approvals will be time-consuming and expensive. The regulations can vary among countries and foreign regulatory authorities may require different or additional clinical trials than we conducted to obtain FDA approval for our product candidates. In addition, adverse clinical trial results, such as death or injury due to side effects, could jeopardize not only regulatory approval, but if approval is granted, may also lead to marketing restrictions. Our product candidates may also face foreign regulatory requirements applicable to controlled substances.

We need to raise additional capital to operate our business.

We are a company focused on product development and have not generated any product revenues to date. Until, and if, we receive approval from the FDA and other regulatory authorities for our product candidates, we cannot sell our drugs and will not have product revenues. Therefore, for the foreseeable future, we will have to fund all of our operations and capital expenditures from the net proceeds of future offerings and grants. Our actual capital requirements will depend on many factors. If we experience unanticipated cash requirements, we may need to seek additional sources of financing, which may not be available on favorable terms, if at all. If we do not succeed in raising additional funds on acceptable terms, we may be unable to complete planned nonclinical studies and clinical trials or obtain approval of our product candidates from the FDA and other regulatory authorities. In addition, we could be forced to discontinue product development, reduce or forego sales and marketing efforts and attractive business opportunities, or discontinue operations.

We have a history of losses and we may never achieve or sustain profitability.

We have incurred substantial losses since our inception, and we may not achieve profitability for the foreseeable future, if at all. Since inception, we have an accumulated deficit of approximately \$111.7 million at June 30, 2019. The Company has cash and cash equivalents of approximately \$9.2 million at June 30, 2019. Even if we succeed in developing and commercializing one or more of our product candidates, we expect to incur substantial net losses and negative cash flows for the foreseeable future due in part to increasing research and development expenses, including clinical trials, and increasing expenses from leasing additional facilities and hiring additional personnel. As a result, we will need to generate significant revenues in order to achieve and maintain profitability. We may not be able to generate these revenues or achieve profitability in the future. Even if we do achieve profitability, we may not be able to sustain or increase profitability.

We have a limited operating history upon which to base an investment decision.

Our limited operating history may limit your ability to evaluate our prospects due to our limited historical financial data and our unproven potential to generate profits. You should evaluate the likelihood of financial and operational success in light of the risks, uncertainties, expenses and difficulties associated with an early-stage business, many of which may be beyond our control, including:

- our potential inability to continue to undertake preclinical studies, pharmaceutical development and clinical trials,
- our potential inability to obtain regulatory approvals, and
- our potential inability to manufacture, sell and market our products.

Our operations have been limited to organizing and staffing, on a limited basis, our company, acquiring, developing and securing our proprietary technology and undertaking preclinical studies and early stage clinical trials of our principal product candidates. These operations provide a limited basis for you to assess our ability to commercialize our product candidates and the advisability of investing in our common stock.

If we fail to obtain the capital necessary to fund our operations, we will be unable to continue or complete our product development and you will likely lose your entire investment.

The Company has cash and cash equivalents of approximately \$9.2 million at June 30, 2019, which will not be sufficient to capitalize the development and commercialization of d-methadone and we will need to continue to seek capital from time to time to continue the development and to acquire and develop other product candidates. Our first product is not expected to be commercialized until at least 2023 and the revenues it will generate may not be sufficient to fund our ongoing operations. Accordingly, we believe that we will need to raise substantial additional capital to fund our continuing operations and the development and commercialization of our product candidates in or before the end of calendar year 2020. Our business or operations may change in a manner that would consume available funds more rapidly than anticipated and substantial additional funding may be required to maintain operations, fund expansion, develop new or enhanced products, acquire complementary products, business or technologies or otherwise respond to competitive pressures and opportunities, such as a change in the regulatory environment or a change in preferred depression treatment modalities. In addition, we may need to accelerate the growth of our sales capabilities and distribution beyond what is currently envisioned and this would require additional capital. However, we may not be able to secure funding when we need it or on favorable terms. If we cannot raise adequate funds to satisfy our capital requirements, we will have to delay, scale-back or eliminate our research and development activities, clinical studies or future operations. We may also be required to obtain funds through arrangements with collaborators, which arrangements may require us to relinquish rights to certain technologies or products that we otherwise would not consider relinquishing, including rights to future product candidates or certain major geographic markets. We may further have to license our technology to others. This could result in sharing revenues which we might otherwise retain for ourselves. Any of these actions may harm our business, financial condition and results of operations.

The amount of capital we may need depends on many factors, including the progress, timing and scope of our product development programs; the progress, timing and scope of our nonclinical studies and clinical trials; the time and cost necessary to obtain regulatory approvals; the time and cost necessary to further develop manufacturing processes and arrange for contract manufacturing; our ability to enter into and maintain collaborative, licensing and other commercial relationships; and our partners' commitment of time and resource to the development and commercialization of our products.

We have limited access to the capital markets and even if we can raise additional funding, we may be required to do so on terms that are dilutive to you.

We have limited access to the capital markets to raise capital. The capital markets have been unpredictable in the recent past for unprofitable companies such as ours. In addition, it is generally difficult for companies to raise capital under current market conditions. The amount of capital that a company such as ours is able to raise often depends on variables that are beyond our control. As a result, we may not be able to secure financing on terms attractive to us, or at all. If we are able to consummate a financing arrangement, the amount raised may not be sufficient to meet our future needs. If adequate funds are not available on acceptable terms, or at all, our business, results of operations, financial condition and our continued viability will be materially adversely affected.

Our license agreement for our product dextromethadone could terminate under certain circumstances.

In January 2018, we entered into an Intellectual Property Assignment Agreement (the “Assignment Agreement”) and License Agreement (the “License Agreement” and together with the Assignment Agreement, the “Agreements”) with Dr. Charles E. Inturrisi and Dr. Paolo Manfredi (collectively, the “Licensor”). Pursuant to the Agreements, Relmada assigned its existing rights, including patents and patent applications, to d-methadone in the context of psychiatric use (the “Existing Invention”) to Licensor. Licensor then granted Relmada under the License Agreement a perpetual, worldwide, and exclusive license to commercialize the Existing Invention and certain further inventions regarding d-methadone in the context of neurological and other uses. In consideration of the rights granted to Relmada under the License Agreement, Relmada will pay Licensor an upfront, non-refundable license fee of \$180,000. Additionally, Relmada will pay Licensor \$45,000 every three months until the earliest to occur of the following events: (i) the first commercial sale of a licensed product anywhere in the world, (ii) the expiration or invalidation of the last to expire or be invalidated of the patent rights anywhere in the world, or (iii) the termination of the License Agreement. Relmada will also pay Licensor tiered royalties with a maximum rate of 2%, decreasing to 1.75%, and 1.5% in certain circumstances, on net sales of licensed products covered under the License Agreement. Relmada will also pay Licensor tiered payments up to a maximum of 20%, and decreasing to 17.5%, and 15% in certain circumstances, of all consideration received by Relmada for sublicenses granted under the License Agreement. The License Agreement may terminate under certain circumstances, including bankruptcy, failure to perform certain covenants (including, but not limited, to payment obligations and certain key man provisions regarding our CEO), and invalidation or unenforceability of patent rights.

Risks Related to Clinical and Regulatory Matters

If we or our potential collaborators fail to obtain the necessary regulatory approvals, or if such approvals are limited, we and our potential collaborators will not be allowed to commercialize our drug candidates, and we will not generate product revenues.

Satisfaction of all regulatory requirements for commercialization of a drug candidate typically takes many years, is dependent upon the type, complexity and novelty of the drug candidate, and requires the expenditure of substantial resources for research and development. Our research and clinical approaches may not lead to drugs that the FDA considers safe for humans and effective for indicated uses we are studying. The FDA may require additional studies, in which case we or our collaborators would have to expend additional time and resources and would likely delay the date of potentially receiving regulatory approval. The approval process may also be delayed by changes in government regulation, future legislation or administrative action or changes in FDA policy that occur prior to or during our regulatory review. Delays in obtaining regulatory approvals would:

- delay commercialization of, and product revenues from, our drug candidates; and
- diminish the competitive advantages that we may have otherwise enjoyed, which would have an adverse effect on our operating results and financial condition.

Even if we or our collaborators comply with all FDA regulatory requirements, our drug candidates may never obtain regulatory approval. If we or our collaborators fail to obtain regulatory approval for any of our drug candidates we will have fewer commercial products, if any, and corresponding lower product revenues, if any. Even if our drug candidates receive regulatory approval, such approval may involve limitations on the indications and conditions of use or marketing claims for our products. Further, later discovery of previously unknown problems or adverse events could result in additional regulatory restrictions, including withdrawal of products. The FDA may also require us or our collaborators to commit to perform lengthy Phase 4 post-approval clinical efficacy or safety studies. Our expending additional resources on such trials would have an adverse effect on our operating results and financial condition.

In jurisdictions outside the United States, we or our collaborators must receive marketing authorizations from the appropriate regulatory authorities before commercializing our drugs. Regulatory approval processes outside the United States generally include all of the aforementioned requirements and risks associated with FDA approval.

If we or our collaborators are unable to design, conduct and complete clinical trials successfully, our drug candidates will not be able to receive regulatory approval.

In order to obtain FDA approval for any of our drug candidates, we or our collaborators must submit to the FDA an NDA that demonstrates with substantive evidence that the drug candidate is both safe and effective in humans for its intended use. This demonstration requires significant research and animal tests, which are referred to as preclinical studies, as well as human tests, which are referred to as clinical trials.

Results from Phase 1 clinical programs may not support moving a drug candidate to Phase 2 or Phase 3 clinical trials. Phase 3 clinical trials may not demonstrate the safety or efficacy of our drug candidates. Success in preclinical studies and early clinical trials does not ensure that later clinical trials will be successful. Results of later clinical trials may not replicate the results of prior clinical trials and preclinical studies. Even if the results of Phase 3 clinical trials are positive, we or our collaborators may have to commit substantial time and additional resources to conducting further preclinical studies and clinical trials before obtaining FDA approval for any of our drug candidates.

Clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous requirements. The clinical trial process also consumes a significant amount of time. Furthermore, if participating patients in clinical trials suffer drug-related adverse reactions during the course of such clinical trials, or if we, our collaborators or the FDA believe that participating patients are being exposed to unacceptable health risks, such clinical trials will have to be suspended or terminated. Failure can occur at any stage of the clinical trials, and we or our collaborators could encounter problems that cause abandonment or repetition of clinical trials.

Our clinical trials and our future clinical trials for dextromethadone measure clinical symptoms, such as depression that are not biologically measurable. The success in clinical trials depends on reaching statistically significant changes in patients' symptoms based on clinician-rated scales. Due in part to a lack of consensus on standardized processes for assessing clinical outcomes, these scores may or may not be reliable, useful or acceptable to regulatory agencies.

We have no history of developing drug candidates. We do not know whether any of our planned clinical trials will result in marketable drugs.

In addition, completion of clinical trials can be delayed by numerous factors, including:

- delays in identifying and agreeing on acceptable terms with prospective clinical trial sites;
- slower than expected rates of patient recruitment and enrollment;
- unanticipated patient dropout rates;
- increases in time required to complete monitoring of patients during or after participation in a clinical trial; and

Any of these delays could significantly impact the timing, approval and commercialization of our drug candidates and could significantly increase our overall costs of drug development.

Even if clinical trials are completed as planned, their results may not support expectations or intended marketing claims. The clinical trials process may fail to demonstrate that our drug candidates are safe and effective for indicated uses. Such failure would cause us to abandon a drug candidate and could delay development of other drug candidates.

With respect to the Phase 2a clinical trial, these discussions are not binding obligations on the part of regulatory authorities.

Regulatory authorities may revise previous guidance or decide to ignore previous guidance at any time during the course of our clinical activities or after the completion of our clinical trials. Even with successful clinical safety and efficacy data, including such data from a clinical trial conducted pursuant to an SPA, we or our collaborators may be required to conduct additional, expensive clinical trials to obtain regulatory approval.

We may not receive royalty or milestone revenue under our collaboration and license agreements for several years, or at all.

Certain of our license agreements provide for payments on achievement of development or commercialization milestones and for royalties on product sales. However, because none of our drug candidates has been approved for commercial sale, many of our drug candidates are at early stages of development and drug development entails a high risk of failure, we may never realize much of the milestone revenue provided for in our collaboration and license agreements and we do not expect to receive any royalty revenue for several years, if at all. Similarly, drugs we select to commercialize ourselves or partner for later stage co-development and commercialization may not generate revenue for several years, or at all.

Developments by competitors may establish standards of care that affect our ability to conduct our clinical trials as planned.

Changes in standards related to clinical trial design could affect our ability to design and conduct clinical trials as planned. For example, regulatory authorities may not allow us to compare our drug candidates to placebo in a particular clinical indication where approved products are available. In that case, both the cost and the amount of time required to conduct a clinical trial could increase.

The DEA limits the availability of the active ingredients in certain of our current drug candidates and, as a result, quotas for these ingredients may not be sufficient to complete clinical trials, or to meet commercial demand or may result in clinical delays.

The U.S. Drug Enforcement Administration, or DEA, regulates chemical compounds as Schedule I, II, III, IV or V substances, with Schedule I substances considered to present the highest risk of substance abuse and Schedule V substances the lowest risk. Certain active ingredients in our current drug candidates, such as oxycodone, are listed by the DEA as Schedule II under the Controlled Substances Act of 1970. Consequently, their manufacture, research, shipment, storage, sale and use are subject to a high degree of oversight and regulation. For example, all Schedule II drug prescriptions must be signed by a physician, physically presented to a pharmacist and may not be refilled without a new prescription. Furthermore, the amount of Schedule II substances that can be obtained for clinical trials and commercial distribution is limited by the DEA and quotas for these substances may not be sufficient to complete clinical trials or meet commercial demand. There is a risk that DEA regulations may interfere with the supply of the drugs used in clinical trials for our product candidates, and, in the future, the ability to produce and distribute our products in the volume needed to meet commercial demand.

Conducting clinical trials of our drug candidates or commercial sales of a drug candidate may expose us to expensive product liability claims and we may not be able to maintain product liability insurance on reasonable terms or at all.

The risk of product liability is inherent in the testing of pharmaceutical products. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit or terminate testing of one or more of our drug candidates. Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against product liability claims could prevent or inhibit the commercialization of our drug candidates. We currently carry clinical trial insurance but do not carry product liability insurance. If we successfully commercialize one or more of our drug candidates, we may face product liability claims, regardless of FDA approval for commercial manufacturing and sale. We may not be able to obtain such insurance at a reasonable cost, if at all. Even if our agreements with any current or future corporate collaborators entitle us to indemnification against product liability losses, such indemnification may not be available or adequate should any claim arise.

If our drug candidates receive regulatory approval, we and our collaborators will also be subject to ongoing FDA obligations and continued regulatory review, such as continued safety reporting requirements, and we and our collaborators may also be subject to additional FDA post-marketing obligations or new regulations, all of which may result in significant expense and limit our and our collaborators' ability to commercialize our drugs.

Any regulatory approvals that our drug candidates receive may also be subject to limitations on the indicated uses for which the drug may be marketed or contain requirements for costly post-marketing follow-up studies. In addition, if the FDA approves any of our drug candidates, the labeling, packaging, adverse event reporting, storage, advertising, promotion and record keeping for the drug will be subject to extensive regulatory requirements. The subsequent discovery of previously unknown problems with the drug, including but not limited to adverse events of unanticipated severity or frequency, or the discovery that adverse events previously observed in preclinical research or clinical trials that were believed to be minor actually constitute much more serious problems, may result in restrictions on the marketing of the drug, and could include withdrawal of the drug from the market.

The FDA's policies may change and additional government regulations may be enacted that could prevent or delay regulatory approval of our drug candidates. For example, on July 9, 2012, the FDA approved a risk management program, known as a Risk Evaluation and Mitigation Strategy, or REMS, for extended-release and long-acting opioid analgesics, or ER/LA opioid analgesics. This REMS will require companies affected by the REMS to make available training for health care professionals who prescribe ER/LA opioid analgesics on proper prescribing practices and also to distribute educational materials to prescribers and patients on the safe use of ER/LA opioid analgesics.

We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are not able to maintain regulatory compliance, we may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution. Any of these events could prevent us from marketing our drugs and our business could suffer. If time and resources devoted are limited or there is a failure to fund the continued development of our drug candidates or there is otherwise a failure to perform as we expect to do, we may not achieve clinical and regulatory milestones and regulatory submissions and related product introductions may be delayed or prevented, and revenues that we would receive from these activities will be less than expected.

We may depend on independent investigators and collaborators, such as universities and medical institutions, to conduct our preclinical and clinical trials under agreements with us. These investigators and collaborators are not our employees and we cannot control the amount or timing of resources that they devote to our programs. They may not assign as great a priority to our programs or pursue them as diligently as we would if we were undertaking such activities ourselves. If these investigators or collaborators fail to devote sufficient time and resources to our drug development programs, or if their performance is substandard, the approval of our regulatory submissions and our introductions of new drugs will be delayed or prevented.

Our potential collaborators may also have relationships with other commercial entities, some of which may compete with us. If outside collaborators assist our competitors to our detriment, the approval of our regulatory submissions will be delayed and the sales from our products, if any are commercialized, will be less than expected.

We may not succeed at in-licensing drug candidates or technologies to expand our product pipeline.

We may not successfully in-license drug candidates or technologies to expand our product pipeline. The number of such candidates and technologies is limited. Competition among large pharmaceutical companies and biopharmaceutical companies for promising drug candidates and technologies is intense because such companies generally desire to expand their product pipelines through in-licensing. If we fail to carry out such in-licensing and expand our product pipeline, our potential future revenues may suffer.

If we fail to obtain or maintain necessary U.S. Food and Drug Administration clearances for our products, or if such clearances are delayed, we will be unable to commercially distribute and market our products.

Our products are subject to rigorous regulation by the FDA and numerous other federal, state and foreign governmental authorities. The process of seeking regulatory clearance or approval to market a depression product is expensive and time consuming and, notwithstanding the effort and expense incurred, clearance or approval is never guaranteed. If we are not successful in obtaining timely clearance or approval of our products from the FDA, we may never be able to generate significant revenue and may be forced to cease operations. In particular, the FDA permits commercial distribution of a new depression therapy product only after the product has received approval of a NDA filed with the FDA pursuant to 21 C.F.R. § 314, seeking permission to market the product in interstate commerce in the United States. The NDA process is costly, lengthy and uncertain. Any NDA application filed by the Company will have to be supported by extensive data, including, but not limited to, technical, nonclinical, clinical trial, manufacturing and labeling data, to demonstrate to the FDA's satisfaction the safety and efficacy of the product for its intended use.

Obtaining clearances or approvals from the FDA and from the regulatory agencies in other countries could result in unexpected and significant costs for us and consume management's time and other resources. The FDA and other agencies could ask us to supplement our submissions, collect non-clinical data, conduct additional clinical trials or engage in other time-consuming actions, or they could simply deny our applications. In addition, even if we obtain an NDA approval or pre-market approvals in other countries, the approval could be revoked or other restrictions imposed if post-market data demonstrates safety issues or lack of effectiveness. We cannot predict with certainty how, or when, the FDA will act. If we are unable to obtain the necessary regulatory approvals, our financial condition and cash flow may be adversely affected, and our ability to grow domestically and internationally may be limited. Additionally, even if cleared or approved, the Company's products may not be approved for the specific indications that are most necessary or desirable for successful commercialization or profitability.

Our clinical trials may fail to demonstrate adequately the safety and efficacy of our product candidates, which could prevent or delay regulatory approval and commercialization.

Before obtaining regulatory approvals for the commercial sale of any of our product candidates, we must demonstrate through lengthy, complex and expensive nonclinical testing and clinical trials that the product is both safe and effective for use in each target indication. Clinical trial results from the study of depression, chronic pain (e.g., osteoarthritis and chronic low back pain) and neuropathic pain (e.g., painful diabetic neuropathy, postherpetic neuralgia and painful HIV-associated neuropathy) are inherently difficult to predict. The primary measure of depression is subjective and can be influenced by factors outside of our control, and can vary widely from day to day for a particular patient, and from patient to patient and site to site within a clinical study. The results we have obtained in completed animal studies or we have observed in published clinical trials conducted by third parties of other dosage forms of the same drug (e.g., sublingual, immediate release oral, parenteral) may not be predictive of results from our future clinical trials. Additionally, we may suffer significant setbacks in advanced clinical trials, even after promising results in earlier studies.

We cannot predict whether regulatory agencies will determine that the data from our clinical trials support marketing approval.

The FDA's and other regulatory agencies' decision to approve our depression product candidates will depend on our ability to demonstrate with substantial clinical evidence through well-controlled clinical trials, that the product candidates are effective, as measured statistically by comparing the overall improvement in depression in actively-treated patients against improvement in depression in the control group (usually a placebo control). However, there is a possibility that our data may fail to show a statistically significant difference from the placebo-control or the active control. Alternatively, there is a possibility that our data may be statistically significant, but that the actual clinical benefit of the product candidates may not be considered to be clinically significant, clinically relevant or clinically meaningful. Consequently, we believe that the FDA may consider additional data, such as a "responder" analysis, secondary efficacy endpoints and even safety when evaluating whether our product can be approved. We cannot predict whether the regulatory agencies will find that our clinical trial results provide compelling "responder" or other secondary endpoint data. Even if we believe that the data from our trials will support marketing approval in the United States or in Europe, we cannot predict whether the agencies will agree with our analysis and approve our applications.

We may need to focus our future efforts in new therapeutic areas where we have little or no experience.

Although our primary strategic interest is in the areas of depression, dextromethadone has potential benefits in other therapeutic areas. If our drug development efforts in depression fails, or if the competitive landscape or investment climate for antidepressant drug development is less attractive, we may need to change the company's strategic focus to include development of our product candidates, or of newly acquired product candidates, for therapeutic areas other than depression. We have very limited drug development experience in other therapeutic areas and we may be unsuccessful in making this change from a depression company to a company with a focus in areas other than depression or a company with a focus in multiple therapeutic areas including depression.

Our product candidates contain controlled substances, the supply of which may be limited by U.S. government policy and the use of which may generate public controversy.

The active ingredients in our current product candidates, including levorphanol, buprenorphine and d-methadone are listed by the DEA, as "Controlled Substances" or schedule substances, under the Controlled Substance Act of 1970. The DEA regulates chemical compounds as Schedule I, II, III, IV or V substances, with Schedule I substances considered to present the highest risk of substance abuse and Schedule V substances the lowest risk. These product candidates are subject to DEA regulations relating to manufacturing, storage, distribution and physician prescription procedures. For example, all regular Schedule II drug prescriptions must be signed by a physician and may not be refilled.

Some of our drug products (e.g., buprenorphine, REL-1041) have a less restrictive controlled substance schedule (i.e., within the Schedule III to V range) than Schedule II drugs. According to the DEA, Schedule V drugs have lower abuse potential than Schedule II, III and IV drugs, Schedule IV drugs have lower abuse potential than Schedule II and III drugs and Schedule III drugs have lower abuse potential than Schedule II. However, despite the foregoing reduced risk of abuse from Schedule III, IV and V drugs, when compared to Schedule II drugs, there is no assurance that such reduced risk can be demonstrated in well controlled non-clinical and/or clinical studies in models of physical dependence, psychic dependence, addiction or precipitated withdrawal, or in studies of addiction or abuse liability in opioid addicts, opioid ex-addicts or recreational drug users. In the event that a reduced risk of abuse from Schedule III, IV and V drugs, when compared to Schedule II drugs is demonstrated in well controlled non-clinical and/or clinical studies, there is no assurance that the FDA will agree to incorporation of such favorable language in the products prescribing information.

Our LevoCap ER is a Schedule II drug in an abuse resistant, abuse deterrent or tamper resistant dosage form. Although the dosage form is referred to as abuse resistant, abuse deterrent or tamper resistant, a determined or persistent abuser can defeat, wholly or partially, the tamper resistance within the dosage form. In addition, opioid addicts and recreational opioid users can over time find new methods to defeat the tamper resistance mechanism within the dosage form.

Although our LevoCap ER is a tamper resistant dosage form, we may elect to not seek specific language in the prescribing information to describe this feature in order to reduce the amount of data required for our NDA, the time required to file the NDA and/or the probability of a protracted review process. The absence of such language in the prescribing information may reduce the commercial value of the product. Even if we do seek specific language in the prescribing information to describe the tamper resistance feature, there is no assurance that FDA will agree to any such language.

Products containing controlled substances may generate public controversy. Opponents of these products may seek restrictions on marketing and withdrawal of any regulatory approvals. In addition, these opponents may seek to generate negative publicity in an effort to persuade the medical community to reject these products. Political pressures and adverse publicity could lead to delays in, and increased expenses for, and limit or restrict the introduction and marketing of our product candidates.

Failure to comply with the Drug Enforcement Administration regulations, or the cost of compliance with these regulations, may adversely affect our business.

A number of our products are opioids and subject to extensive regulation by the DEA, due to their status as controlled substances or scheduled drugs. Although d-methadone is substantially devoid of opioid activity, the DEA may elect to designate it as a controlled substance falling under a Schedule, up to the Schedule II [C-II]. Any level of DEA scheduling for d-methadone, particularly Schedule II, III or IV, would substantially reduce commercial interest in d-methadone. Additionally, d-Methadone is produced by separation from racemic methadone, a scheduled drug subject to extensive regulation by the DEA.

The manufacture, shipment, storage, sale and use of controlled substances are subject to a high degree of regulation, including security, record-keeping and reporting obligations enforced by the DEA. For example, all Schedule II drug prescriptions must be signed by a physician, physically presented to a pharmacist and may not be refilled. This high degree of regulation can result in significant costs in order to comply with the required regulations, which may have an adverse effect on the development and commercialization of our product candidates.

The DEA limits the availability and production of all scheduled substances, including dextromethadone, through a quota system. The DEA requires substantial evidence and documentation of expected legitimate medical and scientific needs before assigning quotas to manufacturers. In future years, we may need greater amounts of controlled substances to sustain our Phase 3 development program, and we will need significantly greater amounts to implement our commercialization plans if the FDA approves our proposed formulations. Any delay or refusal by the DEA in establishing the procurement quota or a reduction in our quota for scheduled controlled substances or a failure to increase it over time as we anticipate could delay or stop the clinical development or commercial sale of some of our products or product candidates. This could have a material adverse effect on our business, results of operations, financial condition and prospects.

Some of our products for clinical trials are manufactured outside the United States including Schedule II controlled substances.

Drug Enforcement Administration regulations require Scheduled II controlled substances to be manufactured in the United States if the products are to be marketed in the United States. There is no guarantee that we will secure a commercial supply agreement with a manufacturer based in the United States. Switching or adding commercial manufacturing capability can involve substantial cost and require extensive management time and focus, as well as additional regulatory filings. In addition, there is a natural transition period when a new manufacturing facility commences work. As a result, delays may occur, which can materially impact our ability to meet our desired commercial timelines, thereby increasing our costs and reducing our ability to generate revenue.

The facilities of any of our future manufacturers of controlled substances must be approved by the FDA after we submit our NDA and before approval. We are dependent on the continued adherence of third party manufacturers to GMP manufacturing and acceptable changes to their process. If our manufacturers cannot successfully produce material that conforms to our specifications and the FDA's strict regulatory requirements, they will not be able to secure FDA approval for their manufacturing facilities. If the FDA does not approve these facilities for the commercial manufacture, we will need to find alternative suppliers, which would result in significant delays in obtaining FDA approvals. These challenges may have a material adverse impact on our business, results of operations, financial condition and prospects.

We manufacture some products outside the United States for development and to conduct human clinical studies either in the US or outside the US. These products are for development purposes only, and not for commercial manufacturing.

If the supplier of active pharmaceutical ingredient (API) or pharmaceutical excipient fails to provide us sufficient quantities, we may not be able to obtain an alternative supply on a timely or acceptable basis.

We currently rely on a single source for our supply of levorphanol. There are presently no alternative sources of pharmaceutical grade levorphanol. We may also not be able to find alternative suppliers in a timely manner that would provide levorphanol at acceptable quantities and prices. Any interruption in the supply of levorphanol would disrupt our ability to manufacture LevoCap ER and could have a material adverse effect on our business. Currently this single source supplies the API for research and development purposes only. There is no material agreement for commercial supply at this time.

Our pharmaceutical excipients and other API's are multisource, although not all sources have an active Drug Master File (DMF) with the FDA. (A DMF is a submission to the FDA used to provide confidential detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of drugs to support a drug development and approval). In addition, some of the countries for our multisource APIs are not the same as our drug manufacturing locations. Thus, any disruption in supply from our preferred vendor could result in significant delays with our pharmaceutical development, clinical trials, NDA filing, NDA approval or commercial sale of the finished product due to contract delays, the need to manufacture a new batch of API, out of specification API, the need for import and export permits, and the failure of the newly sourced API to perform to the standards of the previously sourced API.

Our pain product candidates are in the early stages of development and we have not demonstrated that any of our products can actually treat pain.

Adverse or inconclusive results from pre-clinical testing or clinical trials of product candidates may substantially delay, or halt entirely, any further development of one or more of our products. The projected timetables for continued development of the technologies and related product candidates by us may otherwise be subject to delay or suspension.

Modifications to our products may require new NDA approvals.

Once a particular company product receives FDA approval or clearance, expanded uses or uses in new indications of our products may require additional human clinical trials and new regulatory approvals or clearances, including additional IND and NDA submissions and premarket approvals before we can begin clinical development, and/or prior to marketing and sales. If the FDA requires new clearances or approvals for a particular use or indication, we may be required to conduct additional clinical studies, which would require additional expenditures and harm our operating results. If the products are already being used for these new indications, we may also be subject to significant enforcement actions.

Conducting clinical trials and obtaining clearances and approvals can be a time consuming process, and delays in obtaining required future clearances or approvals could adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth.

There is no guarantee that the FDA will grant NDA approval of our future products and failure to obtain necessary clearances or approvals for our future products would adversely affect our ability to grow our business.

We are currently conducting a Phase 2a clinical trial for d-methadone and in the future expect to submit an NDA to the FDA for approval of d-methadone for the treatment of depression. The FDA may not approve or clear d-methadone or other product candidates for the indications that are necessary or desirable for successful commercialization. Indeed, the FDA may refuse our requests for NDA market approval of new products, new intended uses or indications to existing or future products. Failure to receive approval for our new products would have an adverse effect on our ability to expand our business.

Delays in the commencement or completion of pharmaceutical development, manufacturing or clinical efficacy and safety testing could result in increased costs to us and delay our ability to generate revenues.

We do not know whether our pharmaceutical development, manufacturing or clinical efficacy and safety testing will begin on time or be completed on schedule, if at all. For example, we may encounter delays during the manufacture of pilot scale batches including delays with our contract development or manufacturing organization, sourcing satisfactory quantities of active pharmaceutical ingredient, narcotic import and export permits, sourcing of excipients, contract disputes with our third party vendors and manufacturers, or failure of the product to meet specification. Similar delays may occur during our GMP manufacture of the product.

The commencement and completion of clinical trials can be disrupted for a variety of reasons, including difficulties in:

- recruiting and enrolling patients to participate in a clinical trial;
- obtaining regulatory approval to commence a clinical trial;
- reaching agreement on acceptable terms with prospective clinical research organizations and trial sites;
- manufacturing sufficient quantities of a product candidate;
- investigator fraud, including data fabrication by clinical trial personnel;
- diversion of controlled substances by clinical trial personnel; and

A clinical trial may also be suspended or terminated by us, the FDA or other regulatory authorities due to a number of factors, including:

- failure to conduct the clinical trial in accordance with regulatory requirements or in accordance with our clinical protocols;
- inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;
- unforeseen safety issues; or
- inadequate patient enrollment or lack of adequate funding to continue the clinical trial.

In addition, changes in regulatory requirements and guidance may occur and we may need to amend clinical trial protocols to reflect these changes, which could impact the cost, timing or successful completion of a clinical trial. If we experience delays in the commencement or completion of our clinical trials, the commercial prospects for our product candidates will be harmed, and our ability to generate product revenues will be delayed. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also lead to the denial of regulatory approval of a product candidate.

Clinical trials necessary to support NDA approval of our future products will be time consuming and expensive. Delays or failures in our clinical trials will prevent us from commercializing our products and will adversely affect our business, operating results and prospects and could cause us to cease operations.

Initiating and completing clinical trials necessary to support NDA approval of a new formulation of an existing product or a new product, will be time consuming and expensive and the outcome uncertain. Moreover, the results of early clinical trials are not necessarily predictive of future results, and any product we advance into clinical trials may not have favorable results in later clinical trials.

Some of the trials we undertake are not designed to support final NDA approval of the product and additional trials will have to be conducted in the future before we file an NDA. In addition, there can be no assurance that the data generated during the trials will meet our chosen safety and effectiveness endpoints or otherwise produce results that will eventually support the filing or approval of an NDA.

Conducting successful clinical studies may require the enrollment of large numbers of patients, and suitable patients may be difficult to identify and recruit.

Patient enrollment in clinical trials and completion of patient participation and follow-up depends on many factors, including the size of the patient population; the nature of the trial protocol; the attractiveness of, or the discomforts and risks associated with, the treatments received by enrolled subjects; the availability of appropriate clinical trial investigators; support staff; the number of ongoing clinical trials in the same indication that compete for the same patients; and proximity of patients to clinical sites and ability to comply with the eligibility and exclusion criteria for participation in the clinical trial and patient compliance. For example, patients may be discouraged from enrolling in our clinical trials if the trial protocol requires them to undergo extensive post-treatment procedures or follow-up to assess the safety and effectiveness of our products or if they determine that the treatments received under the trial protocols are not attractive or involve unacceptable risks or discomforts. Patients may also not participate in our clinical trials if they choose to participate in contemporaneous clinical trials of competitive products.

Development of sufficient and appropriate clinical protocols to demonstrate safety and efficacy are required and we may not adequately develop such protocols to support clearance and approval.

The FDA may require us to submit data on a greater number of patients than we originally anticipated and/or for a longer follow-up period or change the data collection requirements or data analysis applicable to our clinical trials. They may also require additional data on certain categories of patients, should it emerge during the conduct of our clinical trials that certain categories of patients are likely to be affected in different and/or additional manner than most of the patients. In addition to FDA requirements, our clinical trial requires the approval of the institutional review board (IRB), at each site selected for participation in our clinical trial.

Additional delays to the completion of clinical studies may result from modifications being made to the protocol during the clinical trial, if such modifications are warranted and/or required by the occurrences in the given trial.

Each of such modifications has to be submitted to the FDA. This could result in the delay or halt of a clinical trial while the modification is evaluated. In addition, depending on the magnitude and nature of the changes made, FDA could take the position that the data generated by the clinical trial cannot be pooled because the same protocol was not used throughout the trial. This might require the enrollment of additional subjects, which could result in the extension of the clinical trial and the FDA delaying clearance or approval of a product.

There can be no assurance that the data generated using modified protocols will be acceptable to FDA.

There can be no assurance that the data generated using modified protocols will be acceptable to FDA or that if future modifications during the trial are necessary, any such modifications will be acceptable to FDA. If FDA believes that its prior approval is required for a particular modification, it can delay or halt a clinical trial while it evaluates additional information regarding the change.

Serious injury or death resulting from a failure of one of our drug candidates during current or future clinical trials could also result in the FDA delaying our clinical trials or denying or delaying clearance or approval of a product.

Even though an adverse event may not be the result of the failure of our drug candidate, FDA or an IRB could delay or halt a clinical trial for an indefinite period of time while an adverse event is reviewed, and likely would do so in the event of multiple such events.

Any delay or termination of our current or future clinical trials as a result of the risks summarized above, including delays in obtaining or maintaining required approvals from IRBs, delays in patient enrollment, the failure of patients to continue to participate in a clinical trial, and delays or termination of clinical trials as a result of protocol modifications or adverse events during the trials, may cause an increase in costs and delays in the filing of any product submissions with the FDA, delay the approval and commercialization of our products or result in the failure of the clinical trial, which could adversely affect our business, operating results and prospects. Lengthy delays in the completion of clinical trials of our products would adversely affect our business and prospects and could cause us to cease operations.

On November 29, 2006, the FDA imposed a bold warning on the label of racemic methadone, a parent compound to our d-methadone related to cardiac death. Although the decision was based on case reports and not on a controlled clinical trial, as part of the development of d-methadone we will likely have to conduct a specific study to evaluate the effects of d-methadone on QTc interval prolongation. QT interval is a measure of the time between the start of the Q wave and the end of the T wave in the heart's electrical cycle. Drugs that prolong the corrected QT interval (QTc) are associated with an increased risk of serious disturbances in heart rhythm, potentially leading to sudden death. QT interval studies can be costly and there is no assurance that we will have funds to undertake such a study. In addition, even if we do a QT interval prolongation study in accordance with regulatory guidelines, there is no assurance that the results of the study will demonstrate an absence of QT interval prolongation with d-methadone. An adverse safety outcome from such study could result in a similar bolded warning on the label of d-methadone or in a decision not to approve d-methadone, either one of which could have serious consequences for our continued operation.

The future results of our current or future clinical trials may not support our product candidate claims or may result in the discovery of unexpected adverse side effects.

Even if our clinical trials are completed as planned, we cannot be certain that their results will support our drug candidate claims or that the FDA or foreign authorities will agree with our conclusions regarding them. Success in pre-clinical studies and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the later trials will replicate the results of prior trials and pre-clinical studies. The clinical trial process may fail to demonstrate that our drug candidates are safe and effective for the proposed indicated uses. If FDA concludes that the clinical trials for any of our products for which we might seek clearance, have failed to demonstrate safety and effectiveness, we would not receive FDA clearance to market that product in the United States for the indications sought. In addition, such an outcome could cause us to abandon the product candidate and might delay development of others. Any delay or termination of our clinical trials will delay the filing of any product submissions with the FDA and, ultimately, our ability to commercialize our product candidates and generate revenues. It is also possible that patients enrolled in clinical trials will experience adverse side effects that are not currently part of the product candidate's profile. In addition, our clinical trials performed until now involve a relatively small patient population. Because of the small sample size, their results may not be indicative of future results.

Future products may never achieve market acceptance.

Future products that we may develop may never gain market acceptance among physicians, patients and the medical community. The degree of market acceptance of any of our products will depend on a number of factors, including the actual and perceived effectiveness and reliability of our products; the results of any long-term clinical trials relating to use of our products; the availability, relative cost and perceived advantages and disadvantages of alternative technologies; the degree to which treatments using our products are approved for reimbursement by public and private insurers; the strength of our marketing and distribution infrastructure; and the level of education and awareness among physicians and hospitals concerning our products. Failure of any of our products to significantly penetrate current or new markets would negatively impact our business, financial condition and results of operations.

To be commercially successful, physicians must be persuaded that using our products for treatment of depression are effective alternatives to existing therapies and treatments.

We believe that doctors and other physicians will not widely adopt our products unless they determine, based on experience, clinical data, and published peer reviewed journal articles, that the use of our products provides an effective alternative to other means of treating depression. Patient studies or clinical experience may indicate that treatment with our products does not provide patients with sufficient benefits in depression relief and/or quality of life. We believe that recommendations and support for the use of our products from influential physicians will be essential for widespread market acceptance. Our products are still in the development stage and it is premature to attempt to gain support from physicians at this time. We can provide no assurance that such support will ever be obtained. If our products do not receive such support from these physicians and from long-term data, physicians may not use or continue to use, and hospitals may not purchase or continue to purchase, our products.

Even if our products are approved by regulatory authorities, if we or our suppliers fail to comply with ongoing FDA regulation or if we experience unanticipated problems with our products, these products could be subject to restrictions or withdrawal from the market.

Any product for which we obtain clearance or approval, and the manufacturing processes, reporting requirements, post-approval clinical data and promotional activities for such product, will be subject to continued regulatory review, oversight and periodic inspections by the FDA. In particular, we and our suppliers are required to comply with FDA's Quality System Regulations, or QSR, and International Standards Organization, or ISO, regulations for the manufacture of our products and other regulations which cover the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of any product for which we obtain clearance or approval. Regulatory bodies, such as the FDA, enforce these regulations through periodic inspections. The failure by us or one of our suppliers to comply with applicable statutes and regulations administered by the FDA and other regulatory bodies, or the failure to timely and adequately respond to any adverse inspectional observations or product safety issues could result in, among other things, enforcement actions by the FDA.

If any of these actions were to occur it would harm our reputation and cause our product sales and profitability to suffer and may prevent us from generating revenue. Furthermore, our key component suppliers may not currently be or may not continue to be in compliance with all applicable regulatory requirements which could result in our failure to produce our products on a timely basis and in the required quantities, if at all.

Even if regulatory clearance or approval of a product is granted, such clearance or approval may be subject to limitations on the intended uses for which the product may be marketed and reduce the potential to successfully commercialize the product and generate revenue from the product. If the FDA determines that the product promotional materials, labeling, training or other marketing or educational activities constitute promotion of an unapproved use, it could request that we or our commercialization partners cease or modify our training or promotional materials or subject us to regulatory enforcement actions. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider such training or other promotional materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement.

In addition, we may be required to conduct costly post-market testing and surveillance to monitor the safety or effectiveness of our products, and we must comply with adverse event and pharmacovigilance reporting requirements, including the reporting of adverse events which occur in connection with, and whether or not directly related to, our products. Later discovery of previously unknown problems with our products, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems, or failure to comply with regulatory requirements, may result in changes to labeling, restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recalls, a requirement to recall, replace or refund the cost of any product we manufacture or distribute, fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties which would adversely affect our business, operating results and prospects.

Some of our other product candidates will require Risk Evaluation and Mitigation Strategies (REMS).

The FDA Amendments Act of 2007 implemented safety-related changes to product labeling and requires the adoption of REMS. Some of our product candidates, the controlled substance-based and maybe others, will require REMS. The REMS may include requirements for special labeling or medication guides for patients, special communication plans to health care professionals and restrictions on distribution and use. We cannot predict the specific REMS to be required as part of the FDA's approval of any of our products. Depending on the extent of the REMS requirements, our costs to commercialize our products may increase significantly. Furthermore, controlled substances risks that are not adequately addressed through proposed REMS for our product candidates may also prevent or delay their approval for commercialization.

Our revenue stream will depend upon third party reimbursement.

The commercial success of our products in both domestic and international markets will be substantially dependent on whether third-party coverage and reimbursement is available for patients that use our products. However, the availability of insurance coverage and reimbursement for newly approved drugs to treat depression is uncertain, and therefore, third-party coverage may be particularly difficult to obtain even if our products are approved by the FDA as safe and efficacious. Many patients using existing approved therapies are generally reimbursed all or part of the product cost by Medicare or other third-party payors. Medicare, Medicaid, health maintenance organizations and other third-party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement of new drugs, and, as a result, they may not cover or provide adequate payment for these products. Submission of applications for reimbursement approval generally does not occur prior to the filing of an NDA for that product and may not be granted for as long as many months after NDA approval. In order to obtain reimbursement arrangements for these products, we or our commercialization partners may have to agree to a net sales price lower than the net sales price we might charge in other sales channels. The continuing efforts of government and third-party payors to contain or reduce the costs of healthcare may limit our revenue. Initial dependence on the commercial success of our products may make our revenues particularly susceptible to any cost containment or reduction efforts.

We may have conflicts with our partners that could delay or prevent the development or commercialization of our product candidates.

We may have conflicts with our partners, such as conflicts concerning the interpretation of nonclinical or clinical data, the achievement of milestones, the interpretation of contractual obligations, payments for services, development obligations or the ownership of intellectual property developed during our collaboration. If any conflicts arise with any of our partners, such partner may act in a manner that is adverse to our best interests. Any such disagreement could result in one or more of the following, each of which could delay or prevent the development or commercialization of our product candidates, and in turn prevent us from generating revenues: unwillingness on the part of a partner to pay us milestone payments or royalties we believe are due to us under a collaboration; uncertainty regarding ownership of intellectual property rights arising from our collaborative activities, which could prevent us from entering into additional collaborations; unwillingness by the partner to cooperate in the development or manufacture of the product, including providing us with product data or materials; unwillingness on the part of a partner to keep us informed regarding the progress of its development and commercialization activities or to permit public disclosure of the results of those activities; initiating of litigation or alternative dispute resolution options by either party to resolve the dispute; or attempts by either party to terminate the agreement.

Our products will face significant competition in the markets for such products, and if they are unable to compete successfully, our business will suffer.

Our products candidates face, and will continue to face, intense competition from large pharmaceutical companies, specialty pharmaceutical and biotechnology companies as well as academic and research institutions. We compete in an industry that is characterized by: (i) rapid technological change, (ii) evolving industry standards, (iii) emerging competition and (iv) new product introductions. Our competitors have existing products and technologies that will compete with our products and technologies and may develop and commercialize additional products and technologies that will compete with our products and technologies. Because several competing companies and institutions have greater financial resources than us, they may be able to: (i) provide broader services and product lines, (ii) make greater investments in research and development, (R&D), and (iii) carry on larger R&D initiatives. Our competitors also have greater development capabilities than we do and have substantially greater experience in undertaking nonclinical and clinical testing of products, obtaining regulatory approvals, and manufacturing and marketing pharmaceutical products. They also have greater name recognition and better access to customers than us. Our chief competitors include companies such as Johnson and Johnson, Allergan, Pfizer, Eli Lilly, Sage Therapeutics, Vistagen among others.

We are faced with intense competition and rapid technological change, which may make it more difficult for us to achieve significant market penetration. If we cannot compete successfully for market share against other drug companies, we may not achieve sufficient product revenues and our business will suffer.

The market for our product candidates is characterized by intense competition and rapid technological advances. If our product candidates receive FDA approval, they will compete with a number of existing and future drugs and therapies developed, manufactured and marketed by others. If our competitors' existing products or new products are more effective than or considered superior to our future products, the commercial opportunity for our product candidates will be reduced or eliminated. Existing or future competing products may provide greater therapeutic convenience or clinical or other benefits for a specific indication than our products, or may offer comparable performance at a lower cost. We face competition from fully integrated pharmaceutical companies and smaller companies that are collaborating with larger pharmaceutical companies, academic institutions, government agencies and other public and private research organizations. If we are successful in penetrating the relevant markets for pain treatment with our product candidates, other companies may be attracted to the market. Many of our competitors have products already approved or in development. In addition, many of these competitors, either alone or together with their collaborative partners, are larger than we are and have substantially greater financial, technical, research, marketing, sales, distribution and other resources than we do. Our competitors may develop or market products that are more effective or commercially attractive than any that we are developing or marketing. Our competitors may obtain regulatory approvals, and introduce and commercialize products before we do. These developments could have a significant negative effect on our financial condition. Even if we are able to compete successfully, we may not be able to do so in a profitable manner.

Adverse events involving our products may lead the FDA to delay or deny clearance for our products or result in product recalls that could harm our reputation, business and financial results.

Once a product receives FDA clearance or approval, the agency has the authority to require the recall of commercialized products in the event of adverse side effects, material deficiencies or defects in design or manufacture. The authority to require a recall must be based on an FDA finding that there is a reasonable probability that the device would cause serious injury or death. Manufacturers may, under their own initiative, recall a product if any material deficiency in a product is found. A government-mandated or voluntary recall by us or one of our distributors could occur as a result of adverse side effects, impurities or other product contamination, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of any of our products would divert managerial and financial resources and have an adverse effect on our financial condition and results of operations. The FDA requires that certain classifications of recalls be reported to FDA within 10 working days after the recall is initiated. Companies are required to maintain certain records of recalls, even if they are not reportable to the FDA. We may initiate voluntary recalls involving our products in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, they could require us to report those actions as recalls. A future recall announcement could harm our reputation with customers and negatively affect our sales. In addition, the FDA could take enforcement action for failing to report the recalls when they were conducted.

We may be exposed to liability claims associated with the use of hazardous materials and chemicals.

Our research and development activities involve the controlled use of hazardous materials and chemicals. Although we believe that our safety procedures for using, storing, handling and disposing of these materials comply with federal, state and local laws and regulations, we cannot completely eliminate the risk of accidental injury or contamination from these materials. In the event of such an accident, we could be held liable for any resulting damages and any liability could materially adversely affect our business, financial condition and results of operations. In addition, the federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous or radioactive materials and waste products may require us to incur substantial compliance costs that could materially adversely affect our business and financial condition.

We may incur substantial liabilities and may be required to limit commercialization of our products in response to product liability lawsuits.

The testing and marketing of medical products entail an inherent risk of product liability. We may be held liable if serious adverse reactions from the use of our product candidates occur. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of pharmaceutical products we develop, alone or with corporate collaborators. We currently do not carry product liability insurance. We, or any corporate collaborators, may not be able to obtain insurance at a reasonable cost, if at all. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate if any claim arises.

Our business depends upon securing and protecting critical intellectual property.

Our commercial success will depend in part on our obtaining and maintaining patent, trade secret, copyright and trademark protection of our technologies in the United States and other jurisdictions as well as successfully enforcing this intellectual property and defending this intellectual property against third-party challenges. We will only be able to protect our technologies from unauthorized use by third parties to the extent that valid and enforceable intellectual property protection, such as patents or trade secrets, cover them. In particular, we place considerable emphasis on obtaining patent and trade secret protection for significant new technologies, products and processes. Furthermore, the degree of future protection of our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. Moreover, the degree of future protection of our proprietary rights is uncertain for products that are currently in the early stages of development because we cannot predict which of these products will ultimately reach the commercial market or whether the commercial versions of these products will incorporate proprietary technologies.

Our patent position is highly uncertain and involves complex legal and factual questions.

Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents. For example, we or our licensors might not have been the first to make the inventions covered by each of our pending patent applications and issued patents; we or our licensors might not have been the first to file patent applications for these inventions; others may independently develop similar or alternative technologies or duplicate any of our technologies; it is possible that none of our pending patent applications or the pending patent applications of our licensors will result in issued patents; our issued patents and issued patents of our licensors may not provide a basis for commercially viable technologies, or may not provide us with any competitive advantages, or may be challenged and invalidated by third parties; and, we may not develop additional proprietary technologies that are patentable.

As a result, our owned and licensed patents may not be valid and we may not be able to obtain and enforce patents and to maintain trade secret protection for the full commercial extent of our technology. The extent to which we are unable to do so could materially harm our business.

We or our licensors have applied for and will continue to apply for patents for certain products. Such applications may not result in the issuance of any patents, and any patents now held or that may be issued may not provide us with adequate protection from competition. Furthermore, it is possible that patents issued or licensed to us may be challenged successfully. In that event, if we have a preferred competitive position because of such patents, any preferred position held by us would be lost. If we are unable to secure or to continue to maintain a preferred position, we could become subject to competition from the sale of generic products. Failure to receive, inability to protect, or expiration of our patents would adversely affect our business and operations.

Patents issued or licensed to us may be infringed by the products or processes of others. The cost of enforcing our patent rights against infringers, if such enforcement is required, could be significant, and the Company does not currently have the financial resources to fund such litigation. Further, such litigation can go on for years and the time demands could interfere with our normal operations. There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical industry. We may become a party to patent litigation and other proceedings. The cost to us of any patent litigation, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the costs of such litigation more effectively than we can because of their substantially greater financial resources. Litigation may also absorb significant management time.

Unpatented trade secrets, improvements, confidential know-how and continuing technological innovation are important to our scientific and commercial success. Although we attempt to and will continue to attempt to protect our proprietary information through reliance on trade secret laws and the use of confidentiality agreements with our corporate partners, collaborators, employees and consultants and other appropriate means, these measures may not effectively prevent disclosure of our proprietary information, and, in any event, others may develop independently, or obtain access to, the same or similar information.

Certain of our patent rights are licensed to us by third parties. If we fail to comply with the terms of these license agreements, our rights to those patents may be terminated, and we will be unable to conduct our business.

If we are found to be infringing on patents or trade secrets owned by others, we may be forced to cease or alter our product development efforts, obtain a license to continue the development or sale of our products, and/or pay damages.

Our manufacturing processes and potential products may violate proprietary rights of patents that have been or may be granted to competitors, universities or others, or the trade secrets of those persons and entities. As the pharmaceutical industry expands and more patents are issued, the risk increases that our processes and potential products may give rise to claims that they infringe the patents or trade secrets of others. These other persons could bring legal actions against us claiming damages and seeking to enjoin clinical testing, manufacturing and marketing of the affected product or process. If any of these actions are successful, in addition to any potential liability for damages, we could be required to obtain a license in order to continue to conduct clinical tests, manufacture or market the affected product or use the affected process. Required licenses may not be available on acceptable terms, if at all, and the results of litigation are uncertain. If we become involved in litigation or other proceedings, it could consume a substantial portion of our financial resources and the efforts of our personnel.

Our ability to protect and enforce our patents does not guaranty that we will secure the right to commercialize our patents.

A patent is a limited monopoly right conferred upon an inventor, and his successors in title, in return for the making and disclosing of a new and non-obvious invention. This monopoly is of limited duration but, while in force, allows the patent holder to prevent others from making and/or using his invention. While a patent gives the holder this right to exclude others, it is not a license to commercialize the invention, where other permissions may be required for permissible commercialization to occur. For example, a drug cannot be marketed without the appropriate authorization from the FDA, regardless of the existence of a patent covering the product. Further, the invention, even if patented itself, cannot be commercialized if it infringes the valid patent rights of another party.

We rely on confidentiality agreements to protect our trade secrets. If these agreements are breached by our employees or other parties, our trade secrets may become known to our competitors.

We rely on trade secrets that we seek to protect through confidentiality agreements with our employees and other parties. If these agreements are breached, our competitors may obtain and use our trade secrets to gain a competitive advantage over us. We may not have any remedies against our competitors and any remedies that may be available to us may not be adequate to protect our business or compensate us for the damaging disclosure. In addition, we may have to expend resources to protect our interests from possible infringement by others.

If we are unable to obtain the statutory patent extension related to the review time in the United States, we may need to rely on the 3-year Hatch-Waxman Act marketing exclusivity, the six month pediatric exclusivity, any approved 7- year Orphan Drug exclusivities, potential future formulation patents and up to ten years of data exclusivity in Europe.

We may not be able to obtain or maintain orphan drug exclusivity for our products.

The FDA Office of Orphan Products (OOPD) has granted orphan drug designation for mepivacaine to which we have secured rights. The orphan designations cover postherpetic neuralgia (PHN) and painful HIV neuropathy. We have also received orphan designation covering d-methadone for PHN. If a product that has orphan drug designation subsequently receives FDA approval for the indication for which it has such designation, the product is entitled to orphan exclusivity, i.e., for seven years, the FDA may not approve any other applications to market the same drug for the same indication, except in very limited circumstances. We may be unable to obtain orphan drug designations for any additional product candidates or orphan exclusivity for any of our product candidates, or our potential competitors may obtain orphan drug exclusivity for d-methadone or mepivacaine-based products competitive with our product candidates before we do, in which case we may be excluded from that market for the exclusivity period. Even if we obtain orphan drug exclusivity for any of our product candidates, we may not be able to maintain it if a competitive product is shown to be clinically superior to our product. Although obtaining FDA approval to market a product with orphan exclusivity can be advantageous, there can be no assurance that it would provide us with a significant commercial advantage.

We may not be able to obtain Hatch-Waxman Act marketing exclusivity or equivalent regulatory data exclusivity protection in other jurisdictions for our products.

We intend to rely, in part, on Hatch-Waxman exclusivity for the commercialization of our products in the United States. The Hatch-Waxman Act provides marketing exclusivity to the first applicant to gain approval of an NDA under specific provisions of the Food, Drug and Cosmetic Act for a product using an active ingredient that the FDA has not previously approved (five years) or for a new dosage form, route or indication (three years). This market exclusivity will not prevent the FDA from approving a competitor's NDA if the competitor's NDA is based on studies it has performed and not on our studies.

There can be no assurance that European authorities will grant data exclusivity for our products, because it does not contain a new active molecule. Even if European data exclusivity is granted for our products, that may not protect us from direct competition. Given the well-established use of our product candidates as pain relievers, a competitor with a generic version of our products may be able to obtain approval of their product during our product's period of data exclusivity, by submitting a marketing authorization application (MAA) with a less than full package of nonclinical and clinical data.

We may undertake international operations, which will subject us to risks inherent with operations outside of the United States.

Although we do not have any foreign operations at this time, we intend to seek to obtain market clearances in foreign markets that we deem to generate significant opportunities. However, even with the cooperating of a commercialization partner, conducting drug development in foreign countries involves inherent risks, including, but not limited to: difficulties in staffing, funding and managing foreign operations; unexpected changes in regulatory requirements; export restrictions; tariffs and other trade barriers; difficulties in protecting, acquiring, enforcing and litigating intellectual property rights; fluctuations in currency exchange rates; and potentially adverse tax consequences.

If we were to experience any of the difficulties listed above, or any other difficulties, any international development activities and our overall financial condition may suffer and cause us to reduce or discontinue our international development and registration efforts.

We may not be successful in hiring and retaining key employees.

Our future operations and successes depend in large part upon the continued service of key members of our senior management team whom we are highly dependent upon to manage our business, specifically Dr. Sergio Traversa, our Chief Executive Officer. If he terminates employment with us, such a departure would have a material adverse effect on our business.

Our future success also depends on our ability to identify, attract, hire or engage, retain and motivate other well-qualified managerial, technical, clinical and regulatory personnel. We will need to hire additional qualified personnel with expertise in nonclinical pharmacology and toxicology, pharmaceutical development, clinical research, regulatory affairs, manufacturing, sales and marketing. We compete for qualified individuals with numerous biopharmaceutical companies, universities and other research institutions. Competition for such individuals, particularly in the United States, is intense, and we may not be able to hire sufficient personnel to support our efforts. There can be no assurance that these professionals will be available in the market, or that we will be able to retain existing professionals or to meet or to continue to meet their compensation requirements. Furthermore, the cost base in relation to such compensation, which may include equity compensation, may increase significantly, which could have a material adverse effect on us. Failure to establish and maintain an effective management team and work force could adversely affect our ability to operate, grow and manage our business.

Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to:

- comply with FDA regulations or similar regulations of comparable foreign regulatory authorities; provide accurate information to the FDA or comparable foreign regulatory authorities;
- comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable foreign regulatory authorities;
- report financial information or data accurately; or
- disclose unauthorized activities to us.

In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a Code of Ethics, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions.

Our relationships with customers and payors will be subject to applicable anti-kickback, fraud and abuse, transparency, and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens, and diminished profits and future earnings.

Healthcare providers, physicians and payors play a primary role in the recommendation and prescription of any product candidates for which we may obtain marketing approval. Our arrangements with payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute any product candidates for which we may obtain marketing approval. Restrictions under applicable federal, state and foreign healthcare laws and regulations may affect our ability to operate, including:

- the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid;
- the federal False Claims Act, which imposes criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- state and foreign anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental payors, including private insurers;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 and its implementing regulations, which also imposes obligations on certain covered entity healthcare providers, health plans, and healthcare clearinghouses as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- laws which require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restricting payments that may be made to healthcare providers; and
- federal laws requiring drug manufacturers to report information related to payments and other transfers of value made to physicians and other healthcare providers, as well as ownership or investment interests held by physicians and their immediate family members, including under the federal Open Payments program, as well as other state and foreign laws regulating marketing activities.

Managing our growth as we expand operations may strain our resources.

We expect to need to grow rapidly in order to support additional, larger, and potentially international, pivotal clinical trials of our drug candidates, which will place a significant strain on our financial, managerial and operational resources. In order to achieve and manage growth effectively, we must continue to improve and expand our operational and financial management capabilities. Moreover, we will need to increase staffing and to train, motivate and manage our employees. All of these activities will increase our expenses and may require us to raise additional capital sooner than expected. Failure to manage growth effectively could harm our business, financial condition or results of operations.

We may not successfully manage our growth.

Our success will depend upon the expansion of our operations and the effective management of our growth. We expect to experience significant growth in the scope of our operations and the number of our employees. If we grow significantly, such growth will place a significant strain on our management and on our administrative, operational and financial resources. To manage this growth, we must expand our facilities, augment our operational, financial and management systems, internal controls and infrastructure and hire and train additional qualified personnel. Our future success is heavily dependent upon growth and acceptance of our future products. If we are unable to scale our business appropriately or otherwise adapt to anticipated growth and new product introduction, our business and financial condition will be harmed.

We may expand our business through the acquisition of rights to new drug candidates that could disrupt our business, harm our financial condition and may also dilute current stockholders' ownership interests in our company.

Our business strategy includes expanding our products and capabilities, and we may seek acquisitions of drug candidates or technologies to do so. Acquisitions involve numerous risks, including substantial cash expenditures; potentially dilutive issuance of equity securities; incurrence of debt and contingent liabilities, some of which may be difficult or impossible to identify at the time of acquisition; difficulties in assimilating the acquired technologies or the operations of the acquired companies; diverting our management's attention away from other business concerns; risks of entering markets in which we have limited or no direct experience; and the potential loss of our key employees or key employees of the acquired companies.

We cannot assure you that any acquisition will result in short-term or long-term benefits to us. We may incorrectly judge the value or worth of an acquired product, company or business. In addition, our future success would depend in part on our ability to manage the rapid growth associated with some of these acquisitions. We cannot assure you that we will be able to make the combination of our business with that of acquired products, businesses or companies work or be successful. Furthermore, the development or expansion of our business or any acquired products, business or companies may require a substantial capital investment by us. We may not have these necessary funds or they might not be available to us on acceptable terms or at all. We may also seek to raise funds by selling shares of our preferred or common stock, which could dilute each current stockholder's ownership interest in the Company.

If we cannot compete successfully for market share against other drug companies, we may not achieve sufficient product revenues and our business will suffer.

The market for our drug candidates is characterized by intense competition and rapid technological advances. If our drug candidates receive FDA approval, they will compete with a number of existing and future drugs and therapies developed, manufactured and marketed by others. Existing or future competing products may provide greater therapeutic convenience or clinical or other benefits for a specific indication than our products, or may offer comparable performance at a lower cost. If our products are unable to capture and maintain market share, we may not achieve sufficient product revenues and our business will suffer.

We and our collaborators will compete for market share against fully integrated pharmaceutical companies or other companies that are collaborating with larger pharmaceutical companies, academic institutions, government agencies and other public and private research organizations. Many of these competitors have drugs already approved or drug candidates in development that will or may compete against our approved drug candidates. In addition, many of these competitors, either alone or together with their collaborative partners, operate larger research and development programs and have substantially greater financial resources than we do, as well as significantly greater experience in:

- developing drugs;
- conducting preclinical testing and human clinical trials;
- obtaining FDA and other regulatory approvals of drugs;
- formulating and manufacturing drugs; and
- launching, marketing, distributing and selling drugs.

Government agencies, professional and medical societies, and other groups may establish usage guidelines that apply to our Law enforcement concerns over diversion of opioids and social issues around abuse of opioids may make the regulatory approval process and commercialization of our drug candidates very difficult.

Media stories regarding the diversion of opioids and other controlled substances are commonplace. Law enforcement agencies or regulatory agencies may apply policies that seek to limit the availability of opioids. Such efforts may adversely affect the regulatory approval and commercialization of our drug candidates.

Developments by competitors may render our products or technologies obsolete or non-competitive.

Alternative technologies and products are being developed to improve or replace the use of opioids for pain management, several of which are in clinical trials or are awaiting approval from the FDA. In addition, the active ingredients in nearly all opioid drugs are available in generic form. Drug companies that sell generic opioid drugs represent substantial competition. Many of these organizations competing with us have substantially greater capital resources, larger research and development staffs and facilities, greater experience in drug development and in obtaining regulatory approvals and greater manufacturing and marketing capabilities than we do. Our competitors may market less expensive or more effective drugs that would compete with our drug candidates or reach market with competing drugs before we are able to reach market with our drug candidates. These organizations also compete with us to attract qualified personnel and partners for acquisitions, joint ventures or other collaborations.

Business interruptions could limit our ability to operate our business.

Our operations as well as those of our collaborators on which we depend are vulnerable to damage or interruption from computer viruses, human error, natural disasters, electrical and telecommunication failures, international acts of terror and similar events. We have not established a formal disaster recovery plan and our back-up operations and our business interruption insurance may not be adequate to compensate us for losses we may suffer. A significant business interruption could result in losses or damages incurred by us and require us to cease or curtail our operations.

Unfavorable media coverage of opioid pharmaceuticals could negatively affect our business.

Opioid drug abuse receives a high degree of media coverage. Unfavorable publicity regarding, for example, the use or misuse of oxycodone or other opioid drugs, the limitations of abuse-resistant formulations, public inquiries and investigations into prescription drug abuse, litigation or regulatory activity, or the independent actions regarding the sales, marketing, distribution or storage of our drug products, could adversely affect our reputation. Such negative publicity could have an adverse effect on the potential size of the market for our drug candidates and decrease revenues and royalties, which would adversely affect our business and financial results.

Risks Related to Our Reliance on Third Parties

We have no manufacturing capabilities and depend on other parties for our manufacturing operations. If these manufacturers fail to meet our requirements and strict regulatory requirements, our product development and commercialization efforts may be materially harmed.

We currently depend on contract manufacturers. We plan to enter into long-term commercial supply agreements for our product candidates. If any manufacturer is unable to produce required quantities on a timely basis or at all, our operations would be delayed and our business harmed. Our reliance on contract manufacturers exposes us to additional risks, including:

- failure of our future manufacturers to comply with strictly-enforced regulatory requirements;
- failure to manufacture to our specifications, or to deliver sufficient quantities in a timely manner;
- the possibility that we may terminate a contract manufacturer and need to engage a replacement;
- the possibility that our future manufacturers may not be able to manufacture our product candidates and products without infringing the intellectual property rights of others;
- the possibility that our future manufacturers may not have adequate intellectual property rights to provide for exclusivity and prevent competition; and
- insufficiency of intellectual property rights to any improvements in the manufacturing processes or new manufacturing processes for our products.

Any of these factors could result in significant delay or suspension of our clinical trials, regulatory submissions, receipt of required approvals or commercialization of our products and harm our business.

We intend to rely on third parties to conduct our clinical trials. If these third parties do not perform as contractually required or otherwise expected, we may not be able to obtain regulatory approval for our product candidates.

We are currently conducting a Phase 2a clinical trial for dextromethadone. We do not currently intend to conduct clinical trials on our own, and instead will rely on third parties, such as contract research organizations, medical institutions, clinical investigators and contract laboratories, to assist us with our clinical trials. We are also required to comply with regulations and standards, commonly referred to as good clinical practices, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the trial participants are adequately protected. If these third parties do not successfully carry out their duties to us or regulatory obligations or meet expected deadlines, if the third parties need to be replaced, or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our nonclinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for our product candidates.

If the third parties on which we rely to conduct our clinical trials and to assist us with pre-clinical development do not perform as contractually required or expected, we may not be able to obtain regulatory approval for or commercialize our products.

We do not have the ability to independently conduct all the pre-clinical and clinical trials for our products and we must rely on third parties, such as contract research organizations, medical institutions, clinical investigators and contract laboratories to conduct such trials. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if these third parties need to be replaced, or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our pre-clinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize, our products on a timely basis, if at all, and our business, operating results and prospects may be adversely affected. Furthermore, our third-party clinical trial investigators may be delayed in conducting our clinical trials for reasons outside of their control.

We are dependent on third parties for manufacturing and marketing of our proposed proprietary products. If we are not able to secure favorable arrangements with such third parties, our business and financial condition could be harmed.

We are not planning to manufacture any of our proposed proprietary products for commercial sale nor do we have the resources necessary to do so. In addition, we currently do not have the capability to market our drug products ourselves. We intend to contract with specialized manufacturing companies to manufacture our proposed proprietary products and partner with larger pharmaceutical companies for commercialization of our products, retaining the marketing and promotion rights for specialty medical areas. In connection with our efforts to commercialize our proposed proprietary products, we will seek to secure favorable arrangements with third parties to distribute, promote, market and sell our proposed proprietary products. If we are not able to secure favorable commercial terms or arrangements with third parties for distribution, marketing, promotion and sales of our proposed proprietary products, we may have to retain promotional and marketing rights and seek to develop the commercial resources necessary to promote or co-promote or co-market certain or all of our proprietary drug candidates to the appropriate channels of distribution in order to reach the specific medical market that we are targeting. We may not be able to enter into any partnering arrangements on this or any other basis. If we are not able to secure favorable partnering arrangements, or are unable to develop the appropriate resources necessary for the commercialization of our proposed proprietary products, our business and financial condition could be harmed. In addition, we will have to hire additional employees or consultants, since our current employees have limited experience in these areas. Sufficient employees with relevant skills may not be available to us. Any increase in the number of our employees would increase our expense level, and could have an adverse effect on our financial position.

In addition, we, or our potential commercial partners, may not successfully introduce our proposed proprietary products or our proposed proprietary products may not achieve acceptance by patients, health care providers and insurance companies. Further, it is possible that we may not be able to secure arrangements to manufacture, market, distribute, promote and sell our proposed proprietary products on favorable commercial terms that would permit us to make a profit. To the extent that corporate partners conduct clinical trials, we may not be able to control the design and conduct of these clinical trials.

We must enter into an agreement, including an existing agreement with a large shareholder, with, and depend upon, one or more partners to assist us in commercializing our product candidates.

Because of our limited financial and other resources, we must actively seek and enter into a collaboration with one or more partners to assist us in our product launch, if marketing approval is granted. Any collaboration agreement we enter into may contain unfavorable terms, for example, with respect to product candidates covered, control over decisions and responsibilities, termination rights, payment, and other significant terms. Our ability to receive any significant revenue from our product candidates covered by the collaboration agreement will be dependent on the efforts of our collaboration partner and may result in lower levels of income to us than if we marketed our product candidates entirely on our own. The collaboration partner may not fulfill its obligations or commercialize our product candidates as quickly as we would like. We could also become involved in disputes with our partner, which could lead to delays in or termination of our commercialization programs and time-consuming and expensive litigation or arbitration. If a collaboration partner terminates or breaches its agreement with us, or otherwise fails to complete its obligations in a timely manner, the chances of successfully developing or commercializing our product candidates would be materially and adversely affected.

We also currently have an existing agreement with our largest shareholder where they have a right of first refusal to commercialize certain of our products in Asia, including d-methadone. If the parties do not agree to the terms of such a license then they could force binding arbitration to protect their rights to commercialize in Asia. Accordingly, the terms of such a license could be on unfavorable terms to us.

Additionally, depending upon the collaboration partner that we choose, other companies that might otherwise be interested in developing products with us could be less inclined to do so because of our relationship with the collaboration partner. If our ability to work with present or future strategic partners or collaborators is adversely affected as a result of our collaboration agreement, our business prospects may be limited and our financial condition may be adversely affected.

Upon commercialization of our products, we may be dependent on third parties to market, distribute and sell our products.

Our ability to receive revenues may be dependent upon the sales and marketing efforts of any future co-marketing partners and third-party distributors. At this time, we have not entered into an agreement with any commercialization partner and only plan to do so after the successful completion of Phase 2 clinical trials and prior to commercialization. If we fail to reach an agreement with any commercialization partner or upon reaching such an agreement that partner fails to sell a large volume of our products, it may have a negative impact on our business, financial condition and results of operations.

We are unable to develop our own sales, marketing and distribution capabilities, or if we are not successful in contracting with third parties for these services on favorable terms, or at all, our product revenues could be disappointing.

We currently have no sales, marketing or distribution capabilities. In order to commercialize our products, if any are approved by the FDA, we will either have to develop such capabilities internally or collaborate with third parties who can perform these services for us. If we decide to commercialize any of our drugs ourselves, we may not be able to hire the necessary experienced personnel and build sales, marketing and distribution operations which are capable of successfully launching new drugs and generating sufficient product revenues. In addition, establishing such operations will take time and involve significant expense.

If we decide to enter into new co-promotion or other licensing arrangements with third parties, we may be unable to locate acceptable collaborators because the number of potential collaborators is limited and because of competition from others for similar alliances with potential collaborators. Even if we are able to identify one or more acceptable new collaborators, we may not be able to enter into any collaborative arrangements on favorable terms, or at all.

In addition, any revenues we receive would depend upon our collaborators' efforts which may not be adequate due to lack of attention or resource commitments, management turnover, change of strategic focus, business combinations or other factors outside of our control. Depending upon the terms of our collaboration, the remedies we have against an under-performing collaborator may be limited. If we were to terminate the relationship, it may be difficult or impossible to find a replacement collaborator on acceptable terms, or at all.

We have no experience selling, marketing or distributing products and no internal capability to do so.

We currently have no sales, marketing or distribution capabilities. In order to commercialize our products, if any are approved, we may develop internal sales, marketing and distribution capabilities to target particular markets for our products, as well as make arrangements with third parties to perform these services for us with respect to other markets for our products. We may not be able to establish these capabilities internally or hire marketing and sales personnel with appropriate expertise to market and sell our products, if approved. In addition, even if we are able to identify one or more acceptable collaborators to perform these services for us, we may not be able to enter into any collaborative arrangements on favorable terms, or at all. If we enter into any collaborative arrangements for the marketing or sale of our products, our product revenues are likely to be lower than if we marketed and sold our products ourselves. In addition, any revenues we receive would depend upon the efforts of our collaborators, which may not be adequate due to lack of attention or resource commitments, management turnover, change of strategic focus, business combinations, and their inability to comply with regulatory requirements or other factors outside of our control. Depending upon the terms of our collaboration, the remedies we have against an under-performing collaborator may be limited. If we were to terminate a relationship, it may be difficult or impossible to find a replacement collaborator on acceptable terms, if at all.

Risks Related to Ownership of Our Common Stock

There is a limited market for our common stock that may make it more difficult to dispose of your stock.

Our common stock is currently quoted on the OTCQB under the symbol "RLMD". There is a limited trading market for our common stock. Accordingly, there can be no assurance as to the liquidity of any markets that may develop for our common stock, the ability of holders of our common stock to sell shares of our common stock, or the prices at which holders may be able to sell their common stock.

A sale of a substantial number of shares of our common stock may cause the price of the common stock to decline.

If our stockholders sell substantial amounts of our common stock in the public market, the market price of our common stock could fall. These sales also may make it more difficult for us to sell equity or equity-related securities in the future at a time and price that we deem reasonable or appropriate. Stockholders who have held their shares for at least six months are be able to sell their shares pursuant to Rule 144 under the Securities Act of 1933.

We are subject to the reporting requirements of federal securities laws, which can be expensive and may divert resources from other projects, thus impairing our ability grow.

We are a public reporting company and, accordingly, subject to the information and reporting requirements of the Exchange Act and other federal securities laws, including compliance with the Sarbanes-Oxley Act of 2002 (the Sarbanes-Oxley Act). The costs of preparing and filing annual and quarterly reports, proxy statements and other information with the SEC and furnishing audited reports to stockholders would cause our expenses to be higher than they would be if we remained privately held and did not consummate the Reverse Merger.

It may be time consuming, difficult and costly for us to develop and implement the internal controls and reporting procedures required by the Sarbanes-Oxley Act. We may need to hire additional financial reporting, internal controls and other finance personnel in order to develop and implement appropriate internal controls and reporting procedures. If we are unable to comply with the internal controls requirements of the Sarbanes-Oxley Act, then we may not be able to obtain the independent accountant certifications required by such act, which may preclude us from keeping our filings with the SEC current.

If we fail to establish and maintain an effective system of internal control, we may not be able to report our financial results accurately or to prevent fraud. Any inability to report and file our financial results accurately and timely could harm our reputation and adversely impact the trading price of our Common Stock.

Effective internal control is necessary for us to provide reliable financial reports and prevent fraud. If we cannot provide reliable financial reports or prevent fraud, we may not be able to manage our business as effectively as we would if an effective control environment existed, and our business and reputation with investors may be harmed. As a result, our small size and any current internal control deficiencies may adversely affect our financial condition, results of operation and access to capital. We have not performed an in-depth analysis to determine if historical un-discovered failures of internal controls exist, and may in the future discover areas of our internal control that need improvement.

Public company compliance may make it more difficult to attract and retain officers and directors.

The Sarbanes-Oxley Act and new rules subsequently implemented by the SEC have required changes in corporate governance practices of public companies. As a public company these new rules and regulations to increase our compliance costs and make certain activities more time consuming and costly. As a public company, these new rules and regulations may make it more difficult and expensive for us to obtain director and officer liability insurance in the future and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified persons to serve on our board of directors or as executive officers.

Our stock price may be volatile.

The market price of our Common Stock is likely to be highly volatile and could fluctuate widely in price in response to various factors, many of which are beyond our control, including the following:

- changes in our industry;
- competitive pricing pressures;
- our ability to obtain working capital financing;
- additions or departures of key personnel;
- limited “public float” in the hands of a small number of persons whose sales or lack of sales could result in positive or negative pricing pressure on the market price for our common stock;
- sales of our common stock;
- our ability to execute our business plan;
- operating results that fall below expectations;
- loss of any strategic relationship;
- regulatory developments;
- economic and other external factors;
- period-to-period fluctuations in our financial results; and
- inability to develop or acquire new or needed technology or products.

In addition, the securities markets have from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. These market fluctuations may also materially and adversely affect the market price of our Common Stock.

Our Common Stock may be deemed a “penny stock,” which would make it more difficult for our investors to sell their shares.

Our common stock may be subject to the “penny stock” rules adopted under Section 15(g) of the Exchange Act. The penny stock rules generally apply to companies whose common stock is not listed on The NASDAQ Stock Market or other national securities exchange and trades at less than \$5.00 per share, other than companies that have had average revenue of at least \$6,000,000 for the last three years or that have tangible net worth of at least \$5,000,000 (\$2,000,000 if the company has been operating for three or more years). These rules require, among other things, that brokers who trade penny stock to persons other than “established customers” complete certain documentation, make suitability inquiries of investors and provide investors with certain information concerning trading in the security, including a risk disclosure document and quote information under certain circumstances. Many brokers have decided not to trade penny stocks because of the requirements of the penny stock rules and, as a result, the number of broker-dealers willing to act as market makers in such securities is limited. If we remain subject to the penny stock rules for any significant period, it could have an adverse effect on the market, if any, for our securities. If our securities are subject to the penny stock rules, investors will find it more difficult to dispose of our securities.

You may have difficulty trading and obtaining quotations for our Common Stock.

Our securities are not actively traded, and the bid and asked prices for our Common Stock on the Over-the-Counter Bulletin Board may fluctuate widely. As a result, investors may find it difficult to dispose of, or to obtain accurate quotations of the price of, our securities. This severely limits the liquidity of the Common Stock, and would likely reduce the market price of our Common Stock and hamper our ability to raise additional capital. There is a limited market for our securities. Accordingly, investors may therefore bear the economic risk of an investment in the Securities thereof, for an indefinite period of time. Even if an active market develops for the common stock, Rule 144 promulgated under the Securities Act (Rule 144), which provides for an exemption from the registration requirements under the Securities Act under certain conditions, requires, among other conditions, a one-year holding period prior to the resale (in limited amounts) of securities acquired in a non-public offering without having to satisfy the registration requirements under the Securities Act. There can be no assurance that we will fulfill any reporting requirements in the future under the Securities Exchange Act of 1934, as amended, or disseminate to the public any current financial or other information concerning the Company, as is required by Rule 144 as part of the conditions of its availability. Our securities have not been registered under the Securities Act.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable

ITEM 2. PROPERTIES

We do not own any property.

On January 1, 2019, the Company changed its corporate headquarters to 880 Third Avenue, 12th Floor, New York, New York 10022.

Pursuant to a Lease Agreement, dated January 1, 2019, between the Company and 880 Third Avenue Tenant, LLC, the Company occupies a portion of the 12th Floor at 880 Third Avenue, New York, NY 10022. The rental fee for the Premises is \$7,513 per month. The lease agreement expires on December 31, 2019.

Effective January 1, 2019, the Company terminated its prior lease agreement, dated May 2, 2017, with Regus Management Group, LLC for space at 750 Third Avenue, 9th Floor, New York, NY 10017.

On June 8, 2017, the Company entered into an Amended and Restated License Agreement (the License) with Actinium for office space located at 275 Madison Avenue, 7th Floor, New York, New York 10016, our former corporate headquarters. This agreement amends and restates the license agreement entered into between the parties on March 10, 2016. Pursuant to the terms of the License, Actinium will continue to license the furniture, fixtures, equipment and tenant improvements located in the Premises (the FFE). Actinium will pay to the Company a license fee of \$7,529 per month. Actinium shall have at any time during the term of this Agreement the right to purchase the FFE. The term of the License is contemporaneous with the Lease Agreement.

ITEM 3. LEGAL PROCEEDINGS

From time to time, the Company may become involved in lawsuits and other legal proceedings that arise in the course of business. Litigation is subject to inherent uncertainties, and it is not possible to predict the outcome of litigation with total confidence. Except as disclosed below, the Company is currently not aware of any legal proceedings or potential claims against it whose outcome would be likely, individually or in the aggregate, to have a material adverse effect on the Company's business, financial condition, operating results, or cash flows.

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

Market Information

Our common stock is listed on OTCQB, under the symbol "RLMD".

The following table shows, for the years ended June 30, 2019 and 2018, the high and low closing prices per share of our common stock as reported by the OTCQB quotation service. These closing prices represent prices quoted by broker-dealers on the OTCQB quotation service. The quotations reflect inter-dealer prices, without retail mark-up, mark-down or commissions, and may not represent actual transactions.

For the Year Ended June 30, 2019	High	Low
Three months ended June 30, 2019	\$ 2.74	\$ 1.45
Three months ended March 31, 2019	\$ 1.97	\$ 1.15
Three months ended December 31, 2018	\$ 1.24	\$ 1.01
Three months ended September 30, 2018	\$ 1.30	\$ 0.86
For the Year Ended June 30, 2018	High	Low
Three months ended June 30, 2018	\$ 1.74	\$ 0.89
Three months ended March 31, 2018	\$ 0.89	\$ 0.68
Three months ended December 31, 2017	\$ 1.00	\$ 0.69
Three months ended September 30, 2017	\$ 1.00	\$ 0.71

Lack of a Public Market for Common Stock

There is no assurance that our shares will continue to be traded on the bulletin board, or if traded, that a public market will materialize.

The SEC has adopted rules that regulate broker-dealer practices in connection with transactions in penny stocks. Penny stocks are generally equity securities with a price of less than \$5.00, other than securities registered on certain national securities exchanges or quoted on the NASDAQ system, provided that current price and volume information with respect to transactions in such securities is provided by the exchange or system. The penny stock rules require a broker-dealer, prior to a transaction in a penny stock, to deliver a standardized risk disclosure document prepared by the SEC, that: (a) contains a description of the nature and level of risk in the market for penny stocks in both public offerings and secondary trading;(b) contains a description of the broker's or dealer's duties to the customer and of the rights and remedies available to the customer with respect to a violation to such duties or other requirements of Securities' laws; (c) contains a brief, clear, narrative description of a dealer market, including bid and ask prices for penny stocks and the significance of the spread between the bid and ask price;(d) contains a toll-free telephone number for inquiries on disciplinary actions;(e) defines significant terms in the disclosure document or in the conduct of trading in penny stocks; and;(f) contains such other information and is in such form, including language, type, size and format, as the SEC shall require by rule or regulation.

The broker-dealer also must provide, prior to effecting any transaction in a penny stock, the customer with; (a) bid and offer quotations for the penny stock; (b) the compensation of the broker-dealer and its salesperson in the transaction; (c) the number of shares to which such bid and ask prices apply, or other comparable information relating to the depth and liquidity of the market for such stock; and (d) a monthly account statements showing the market value of each penny stock held in the customer's account.

In addition, the penny stock rules require that prior to a transaction in a penny stock not otherwise exempt from those rules; the broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive the purchaser's written acknowledgment of the receipt of a risk disclosure statement, a written agreement to transactions involving penny stocks, and a signed and dated copy of a written suitability statement.

These disclosure requirements may have the effect of reducing the trading activity in the secondary market for our stock if it becomes subject to these penny stock rules. Therefore, because our common stock is subject to the penny stock rules, stockholders may have difficulty selling those securities.

Holders

As of June 30, 2019, 38,978,555 shares of common stock were issued and outstanding, which were held by 331 holders of record. These stockholders held their stock either individually or in nominee or "street" names through various brokerage firms. There are no shares of Class A convertible preferred stock outstanding. Our transfer agent is:

Empire Stock Transfer
1859 Whitney Mesa Drive
Henderson, NV 89014
Telephone (702) 818-5898
www.empirestock.com

Inquiries regarding stock transfers, lost certificates or address changes should be directed to the above address.

Registration Rights

As required by the Unit Purchase Agreements, the investors also became parties to Registration Rights Agreements dated as of October 12, 2018, October 18, 2018, November 2, 2018, December 5, 2018, and February 12, 2019 pursuant to which the Company was required to register with the Securities and Exchange Commission such common shares and the shares of common stock underlying the warrants. The Registration Statement was declared effective by the SEC on March 1, 2019.

As required by the Unit Purchase Agreements, the investors also became parties to Registration Rights Agreements dated as of May 14, 2019, June 14, 2019, June 20, 2019, and June 28, 2019 pursuant to which the Company will be required to register with the Securities and Exchange Commission such common shares and the shares of common stock underlying the warrants. If the registration statement is not filed or declared effective within the timeframe set forth in the Registration Rights Agreements, the Company is obligated to pay the investors an amount equal to 1% of the total purchase price of the securities per month (up to a maximum of 6% in the aggregate) until such failure is cured. A Form S-1 registration statement was filed with the SEC on August 12, 2019, but has not been declared effective by the SEC.

Dividends

We plan to retain any earnings for the foreseeable future for our operations. We have never paid any cash dividends on our stock and do not anticipate paying any cash dividends in the foreseeable future. Any future determination to pay cash dividends will be at the discretion of our Board of Directors and will depend on our financial condition, operating results, capital requirements and such other factors as our Board of Directors deems relevant.

Securities Authorized for Issuance under Equity Compensation Plans

Relmada has a 2014 Option and Equity Incentive Plan, as amended (the Plan) in which its directors, officers, employees and consultants shall be eligible to participate. The Plan allows for the granting of common stock awards, stock appreciation rights, and incentive and nonqualified stock options to purchase shares of the Company. As of June 30, 2019, the Company has 4,668,153 awards available to be issued.

The following table summarizes our equity compensation plan information as of June 30, 2019.

Equity Compensation Plan Information

Plan Category	Number of securities to be issued upon exercise of outstanding options and stock appreciation rights (a)	Weighted-average exercise price of outstanding options and stock appreciation rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	5,893,240	\$ 1.29	4,668,153
Equity compensation plans not approved by security holders	-	-	-
Total	5,890,240	\$ 1.29	4,668,153

ITEM 6. SELECTED FINANCIAL DATA

Smaller reporting companies are not required to provide the information required by this item.

ITEM 7. MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The information and financial data discussed below is derived from the consolidated financial statements of Relmada for the year ended June 30, 2019 and for the year ended June 30, 2018. The consolidated financial statements of Relmada were prepared and presented in accordance with generally accepted accounting principles in the United States. The information and financial data discussed below is only a summary and should be read in conjunction with the historical financial statements and related notes of Relmada contained elsewhere in this Report. The consolidated financial statements contained elsewhere in this Report fully represent Relmada’s financial condition and operations; however, they are not indicative of the Company’s future performance. See “Cautionary Note Regarding Forward Looking Statements” above for a discussion of forward-looking statements and the significance of such statements in the context of this Annual Report.

This discussion contains forward-looking statements reflecting our current expectations that involve risks and uncertainties. Actual results may differ materially from those discussed in these forward-looking statements due to a number of factors, including those set forth in the section entitled “**Risk Factors**” and elsewhere herein. The information and financial data discussed below is only a summary and should be read in conjunction with the historical financial statements and related notes of Relmada Therapeutics, Inc. contained elsewhere in this document. Relmada’s current consolidated financial position and consolidated results of operations; are not necessarily indicative of the Company’s future performance. See “Cautionary Note Regarding Forward Looking Statements” above for a discussion of forward-looking statements and the significance of such statements in the context of this document.

Our Corporate History and Background

Relmada Therapeutics is a clinical-stage, publicly traded biotechnology company developing NCEs together with novel versions of proven drug products that potentially address areas of high unmet medical need in the treatment of CNS diseases - primarily depression. The Company has a diversified portfolio of four products at various stages of development, including d-methadone (dextromethadone, REL-1017), a NMDA receptor antagonist for treating depression and neuropathic pain; LevoCap ER (REL-1015), an abuse resistant, sustained release dosage form of the opioid analgesic levorphanol; BuTab (oral buprenorphine, REL-1028), an oral dosage form of the opioid analgesic buprenorphine; and MepiGel (topical mepivacaine, REL-1021), an orphan drug designated topical formulation of the local anesthetic mepivacaine.

Following a pipeline prioritization and strategic review of our business, we emerged with clear priorities as a refocused research and clinical development company. We identified d-methadone as the most promising clinical program on which we will focus the majority of our development efforts going forward. We believe this refined strategy will drive Relmada's long-term success.

As we continue the development of d-methadone, we are seeking strategic partnerships with established healthcare companies to pursue further development, regulatory approval and commercialization of our remaining pipeline programs. We do not expect to manufacture finished products in-house, nor conduct direct or indirect sales of products which may allow the Company to avoid significant capital investment in production facilities and sales and marketing teams. It is difficult to predict whether we will be able to enter into beneficial commercial partner relationships with recognized healthcare companies.

Our lead product candidate, d-methadone, is a NCE being developed as a rapidly acting, oral agent for the treatment of depression, neuropathic pain, and/or other potential conditions. We have completed Phase 1 single and multiple ascending dose studies and have confirmed safety, tolerability, and dose range for a planned Phase 2 study in TRD. A Phase 2 study in major depressive disorder is ongoing, with first patient dosed in June 2018 and last patient dosed in July 2019. We expect to have top line results in the second half of 2019.

We have not generated revenues and do not anticipate generating revenues for the foreseeable future. We had net loss of approximately \$17,318,100 and \$8,961,000 for the years ended June 30, 2019 and 2018, respectively. At June 30, 2019, we have an accumulated deficit of approximately \$111,662,400.

Results of Operations

For the year ended June 30, 2019 versus June 30, 2018

Research and Development Expense

Total research and development spending for the year ended June 30, 2019 was approximately \$7,024,800, as compared to \$2,942,600 for the same period of 2018, an increase of \$4,082,200. The increase in research and development expenses was primarily due to:

- Increase in study costs of \$4,334,200 associated with the execution of our Phase 2a study;
- Increase in manufacturing and drug storage costs of \$186,200
- Increase in pre-clinical and toxicology expenses of \$297,300
- Increase in stock based compensation expense of research and development staff of \$153,500.
- Decrease in research expenses of \$913,700

General and Administrative Expense

Total general and administrative expenses were approximately \$5,703,200 for the year ended June 30, 2019, as compared to \$3,974,900 for the prior year, an increase of \$1,728,300. The increase in general and administrative expenses was primarily due to:

- Increase in legal and settlement expenses from the resolution of the “Babul” litigation of \$1,249,900;
- Increase in stock-based compensation of \$542,400;
- Increase in other G&A of \$121,100
- Decreased non-litigation professional fees of \$185,100;

Change in Fair Value of Derivative Liabilities

The change in the fair value of derivative liabilities was an unrealized loss of approximately \$54,600 for the year ended June 30, 2019, as compared to the prior year unrealized loss of \$708,900.

For the year ended June 30, 2019, the Company elected to early adopt ASU 2017-11 and reversed the derivative liability into equity effective July 1, 2018. During the year ended June 30, 2019, the Company had warrants resulting from equity offerings in May 2014 and June 2014 that do not have fixed settlement provisions because their exercise prices may be lowered if the Company issues securities at lower prices in the future, the Company concluded that the instruments are not indexed to the Company’s stock. These warrants expired unexercised in the quarter ended June 30, 2019.

For the year ended June 30, 2018, derivative liabilities included warrants issued with the May 2014 and June 2014 offerings. The derivative liability would decrease when warrants were exercised, expire or when the anti-dilution feature was eliminated. The anti-dilution feature will be eliminated when the Company is up-listed to a National Exchange (NYSE or NASDAQ). The derivative liabilities were affected by factors that are subject to significant fluctuations and are not under the Company’s control. Therefore, the resulting effect upon our net income or loss was subject to significant fluctuations. The accounting guidance applicable to these warrants required the Company (assuming all other inputs to the pricing model remain constant) to record a non-cash loss when the Company’s stock price was rising and to record non-cash income when the Company’s stock price was decreasing.

Interest Income and Expense, Net

Net interest expense for the year ended June 30, 2019 was approximately \$761,000 as compared to net interest expense of \$1,336,800 for the year ended June 30, 2018. The difference primarily consisted of decreased interest expense resulting from the extinguishment of the two-year convertible promissory notes on October 18, 2018.

Other Income

On March 10, 2016 and effective as of January 1, 2016, Relmada entered into an Office Space License Agreement (the License) with Actinium Pharmaceuticals, Inc. (Actinium), for office space located at 275 Madison Avenue, 7th Floor, New York, New York 10016. The term of the License was for three years from the effective date, with an automatic renewal provision. The cost of the License is approximately \$16,600 per month for Actinium, subject to customary escalations and adjustments. The Company recorded the license fees as other income in the consolidated statements of operations. On June 6, 2017, the landlord and Relmada agreed to assign the lease for all of the office space at 275 Madison Avenue to Actinium. As of such date all rights, titles, and interest to the lease, including related duties, liabilities, and obligations, were transferred from the Company to Actinium. Pursuant to the assignment of the lease, the Company derecognized its deferred rent liability and recorded gain on assignment of office lease.

On June 8, 2017, the Company entered into an Amended and Restated License Agreement with Actinium. Pursuant to the terms of the agreement, Actinium will continue to license the furniture, fixtures, equipment and tenant improvements located in the office (FFE) for a license fee of \$7,529 per month until December 8, 2022. Actinium shall have at any time during the term of this agreement the right to purchase the FFE for \$496,909, less any previously paid license fees. The license of FFE qualifies as a sales-type lease. At inception, the Company derecognized the underlying assets, recognized a discounted lease payments receivable using the discount rate of 8.38% and recognized a loss on the lease of fixed assets.

Income Taxes

The Company did not provide for income taxes for the years ended June 30, 2019 and 2018 since there were losses for both years and a full valuation allowance against all deferred tax assets.

Loss per Common Share

The Company recorded a net loss of approximately \$17,318,100 and \$8,960,900 or \$0.69 and \$0.71 per common share, basic and diluted, for the years ended June 30, 2019 and 2018, respectively, based on the factors described above.

Liquidity

As shown in the accompanying financial statements, the Company incurred negative operating cash flows of \$10,497,854 for the year ended June 30, 2019 and has an accumulated deficit of \$111,662,367 from inception through June 30, 2019. During the year ended June 30, 2019, the Company incurred non-recurring expenses of approximately \$1,600,000 related to the settlement with Najib Babul (see Note 12) and related legal fees.

Relmada has funded its past operations through equity raises and most recently in the year ended June 30, 2019 Relmada raised net proceeds from the sale of common stock and warrants of \$17,760,635. Further, the Company was able to reduce its debt obligations by converting \$8,030,365 of promissory notes and accrued interest into common stock.

In Note 2 of the notes to the Company's audited consolidated financial statements as of and for the year ended June 30, 2018, and subsequently in each of the Company's quarterly unaudited condensed consolidated financial statements, management stated that the Company had incurred significant losses, negative operating cash flows and as of those dates needed to raise additional funds to meet its obligations and sustain its operations. As a result, the Company concluded that there was substantial doubt as to the Company's ability to continue as a going concern.

Management believes that due to the following it has obtained sufficient funding to alleviate the probability of substantial doubt about the Company's ability to continue as a going concern for the next twelve months from the issuance of these consolidated financial statements. Of the above mentioned financings of \$17,760,635, the Company raised approximately \$10,900,000 in the fourth quarter through private placements of common stock and warrants, and subsequent to June 30, 2019, the Company raised approximately an additional \$975,000 through private placements of common stock and exercises of outstanding investor warrants, which resulted in the Company having approximately \$7,735,000 in cash and cash equivalents at September 23, 2019. Based on its budgeted cash flow requirements, the Company believes these funds are sufficient to fund its ongoing operations for at least one year after the issuance of these consolidated financial statements. The Company expects that the cash burn rate for the 12 months ended September 30, 2020, will be between \$5-6 million, which includes approximately \$2 million of discretionary research and development ("R&D") spending, as the data analysis on the Phase 2a clinical trial is completed and the planning and preparation for the next clinical trial is conducted. Regardless of the results of any ongoing clinical trial, we have control over our expenditures and have the ability to adjust spending accordingly based on the budgeted cash flow requirements developed and the excess cash on hand.

The results of the Company's ongoing clinical trial, when known, will impact the size and scope of any subsequent trials, and will affect the timing of additional financings through public or private sales of equity or debt securities or from bank or other loans or through strategic collaboration and/or licensing agreements. Any such expenditures related to any subsequent trials will not be incurred until such additional financing is raised. Further, additional financing related to subsequent trials does not affect the Company's conclusion that based on the cash on hand and the budgeted cash flow requirements, the Company has sufficient funds to maintain operations for the next twelve months from the issuance of these consolidated financial statements.

Effects of Inflation

Our assets are primarily monetary, consisting of cash and cash equivalents. Because of their liquidity, these assets are not directly affected by inflation. Because we intend to retain and continue to use our equipment, we believe that the incremental inflation related to replacement costs of such items will not materially affect our operations. However, the rate of inflation affects our expenses, such as those for employee compensation and contract services, which could increase our level of expenses and the rate at which we use our resources.

Contractual Obligations

The following tables sets forth our contractual obligations for the next five years and thereafter:

	<u>Total</u>	<u>Less than 1 year</u>	<u>1 - 2 years</u>	<u>3 - 5 years</u>	<u>More than 5 years</u>
Office lease	\$ 45,000	\$ 45,000	\$ -	\$ -	\$ -
	-	-	-	-	-
	-	-	-	-	-
Total obligations	<u>\$ 45,000</u>	<u>\$ 45,000</u>	<u>\$ -</u>	<u>\$ -</u>	<u>\$ -</u>

The following tables sets forth selected cash flow information for the periods indicated below:

	<u>For the Year Ended June 30, 2019</u>	<u>For the Year Ended June 30, 2018</u>
Cash used in operating activities	\$ (10,497,854)	\$ (6,002,078)
Cash used in investing activities	-	(12,391)
Cash raised in financing activities	17,475,465	6,542,900
Net increase in cash and cash equivalents	<u>6,977,611</u>	<u>\$ 528,431</u>

For the years ended June 30, 2019 and 2018, cash used in operating activities was \$10,497,854 and \$6,002,078, respectively, primarily due to the net loss for each respective period, of approximately \$17,318,100 and \$8,960,900, respectively. This was offset by non-cash expenses which primarily consisted of stock-based compensation of \$1,213,996 and \$517,999, the change in the fair value of derivative liabilities of \$54,634 and \$708,901, loss on extinguishment of promissory note of \$3,774,468 and \$0 and amortization of deferred financing costs of \$661,168 and \$1,029,183, respectively, for the years ended June 30, 2019 and 2018. There were changes in operating assets and liabilities for the years ended June 30, 2019 and 2018 of approximately \$1,140,500 and \$700,100, respectively.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that is material to investors.

Seasonality

We do not have a seasonal business cycle.

Critical Accounting Policies and Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses for the reporting period. Actual results could differ from those estimates. The significant estimates are incurred costs of clinical studies, stock-based compensation expense, valuation of derivative financial liabilities, and income taxes and valuation of deferred tax assets.

Research and Development

Research and development costs primarily consist of research contracts for the advancement of product development, salaries and benefits, stock-based compensation, and consultants. The Company expenses all research and development costs in the period incurred. The Company makes an estimate of costs in relation to clinical study contracts. The Company analyzes the progress of studies, including the progress of clinical studies and phases, invoices received and contracted costs when evaluating the adequacy of the amount expensed and any related prepaid asset and accrued liability.

Stock-Based Compensation

The Company measures the cost of employee services received in exchange for an award of equity instruments based on the grant-date fair value of the award. That cost is recognized over the period during which an employee is required to provide service in exchange for the award - the requisite service period. The grant-date fair value of employee share options is estimated using the Black-Scholes option pricing model adjusted for the unique characteristics of those instruments. Compensation expense for warrants granted to non-employees is determined by the fair value of the consideration received or the fair value of the equity instruments issued, whichever is more reliably measured, and is recognized over the service period. The expense is subsequently adjusted to fair value at the end of each reporting period until such warrants vest, and the fair value of such instruments, as adjusted, is expensed over the related vesting period. Adjustments to fair value at each reporting date may result in income or expense, depending upon the estimate of fair value and the amount of expense recorded prior to the adjustment. The Company reviews its agreements and the future performance obligation with respect to the unvested warrants for its vendors or consultants. When appropriate, the Company will expense the unvested warrants at the time when management deems the service obligation for future services has ceased.

Income Taxes

The Company accounts for income taxes using the asset and liability method. Accordingly, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in the tax rate is recognized in income or expense in the period that the change is effective. Tax benefits are recognized when it is probable that the deduction will be sustained. A valuation allowance is established when it is more likely than not that all or a portion of a deferred tax asset will either expire before the Company is able to realize the benefit, or that future deductibility is uncertain. As of June 30, 2019 and 2018, the Company recorded a valuation allowance to the full extent of our net deferred tax assets since the likelihood of realization of the benefit does not meet the more likely than not threshold.

Derivatives

All derivatives are recorded at fair value on the balance sheet. The Company has determined fair values using market based pricing models incorporating readily prices and or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (supported by little or no market activity) that requires judgment and estimates.

Recent Accounting Pronouncements

The Company lists material recent accounting pronouncements in Note 2 of the consolidated financial statements.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest rate risk

Our cash and cash equivalents include all highly liquid investments with an original maturity of three months or less. Our cash equivalents are in a money market account. Because of the short-term maturities of our cash and cash equivalents, we do not believe that an increase in market rates would have a significant impact on the realized value of our investments. We place our cash and cash equivalents on deposit with financial institutions in the United States. The Federal Deposit Insurance Corporation limits coverage for all depository accounts. Our cash and cash equivalents at times may exceed covered limits.

Foreign currency exchange risk

We currently have limited, but may in the future have increased, clinical and commercial manufacturing agreements which are denominated in Euros or other foreign currencies. As a result, our financial results could be affected by factors such as a change in the foreign currency exchange rate between the U.S. dollar and the Euro or other applicable currencies, or by weak economic conditions in Europe or elsewhere in the world. We are not currently engaged in any foreign currency hedging activities.

Market indexed security risk

We have issued warrants to various holders underlying shares of our common stock. These warrants are re-measured to their fair value at each reporting period with changes in their fair value recorded as derivative gain (loss) in the accompanying consolidated statement of operations. We use the Black-Scholes model for valuation of the warrants.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Our audited consolidated financial statements for the years ended June 30, 2019 and 2018 are included beginning on Page F-1 immediately following the signature page to this report. See Item 15 for a list of the financial statements included herein.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we carried out an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer has concluded that, at June 30, 2019, such disclosure controls and procedures were effective.

Disclosure controls and procedures are controls and other procedures that are designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified by the SEC. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, or persons performing similar functions, as appropriate, to allow timely decisions regarding required disclosure.

Limitations on the Effectiveness of Controls

Our disclosure controls and procedures are designed to provide reasonable, not absolute, assurance that the objectives of our disclosure control system are met. Because of inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, if any, within a company have been detected. Our Chief Executive Officer and Chief Financial Officer has concluded, based on his evaluation as of the end of the period covered by this Report that our disclosure controls and procedures were effective to provide reasonable assurance that the objectives of our disclosure control system were met.

Changes in Internal Control Over Financial Reporting

There were no changes in the Company's internal controls over financial reporting that occurred during the fourth quarter of the fiscal year covered by this Annual Report on Form 10-K that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

Management's Report on Internal Control Over Financial Reporting

As required by the SEC rules and regulations for the implementation of Section 404 of the Sarbanes-Oxley Act, our management is responsible for establishing and maintaining adequate internal control over financial reporting. Our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of our consolidated financial statements for external reporting purposes in accordance with GAAP. Our internal control over financial reporting includes those policies and procedures that:

- (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of our company,
- (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of consolidated financial statements in accordance with accounting principles generally accepted in the United States of America, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors, and
- (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the consolidated financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect errors or misstatements in our consolidated financial statements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree or compliance with the policies or procedures may deteriorate. Management assessed the effectiveness of our internal control over financial reporting at June 30, 2019. In making these assessments, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission COSO (2013 framework). Based on our assessments and those criteria, management determined that we did maintain effective internal control over financial reporting at June 30, 2019.

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS, AND CORPORATE GOVERNANCE

The following sets forth information about our directors and executive officers as of September 18, 2019:

Name	Age	Position
Sergio Traversa, PharmD.	59	Chief Executive Officer, and Director
Charles Ence	59	Chief Financial Officer
Ottavio Vitolo	47	Senior Vice President, Head of R&D and Chief Medical Officer
Charles J. Casamento	74	Chairman of the Board and Director
Paul Kelly	62	Director
Maged Shenouda, R.Ph, MBA	55	Director

Sergio Traversa, PharmD, MBA has been our Chief Executive Officer and director since April 2012. Mr. Traversa was our Interim Chief Financial Officer from February 2017 to July 2019. Previously, from January 2010 to April 2012 he was the CEO of Medcor Inc., a spinoff pharmaceutical company from Cornell University. From January 2008 to January 2010 Dr. Traversa was a partner at Ardana Capital. Dr. Traversa has over thirty years of experience in the healthcare sector in the United States and Europe, ranging from management positions in the pharmaceutical industry to investing and strategic advisory roles. He has held financial analyst, portfolio management and strategic advisory positions at large U.S. investment firms specializing in healthcare, including Mehta & Isaly and Mehta Partners, ING Barings, Merlin BioMed and Rx Capital. In Europe, he held the position of Area Manager for Southern Europe of Therakos Inc., a cancer and immunology division of Johnson & Johnson. Prior to Therakos, Dr. Traversa was at Eli Lilly, where he served as Marketing Manager of the Hospital Business Unit. He was also a member of the CNS (Central Nervous System) team at Eli Lilly, where he participated in the launch of Prozac and the early development of Zyprexa and Cymbalta. Dr. Traversa started his career as a sales representative at Farmitalia Carlo Erba, the largest pharmaceutical company in Italy, now part of Pfizer. Dr. Traversa served as a board member and previously as interim CEO and CFO of Actinium Pharmaceuticals. Dr. Traversa holds a Laurea degree in Pharmacy from the University of Turin (Italy) and an MBA in Finance and International Business from the New York University Leonard Stern School of Business. As Chief Executive Officer of the Company, Dr. Traversa is the most senior executive of the Company and as such provides our Board of Directors with the greatest insight into the Company's business and the challenges and material risks it faces. Dr. Traversa has approximately 30 years of healthcare industry experience and is especially qualified to understand the risks and leadership challenges facing a growing pharmaceutical company from a senior management and financial expertise perspective led us to conclude that Dr. Traversa should serve as Chief Executive Officer and Director of the Company.

Charles Ence was appointed as our Chief Financial Officer on July 29, 2019. From August 2003 until June 2019, Mr. Ence was Chief Financial Officer/Corporate Controller of New Age Beverages Corp/Xing Beverages, LLC located in Denver, Colorado. He managed all the financial affairs of New Age and their other portfolio companies helping lead the firm into becoming one of the top 100 non-alcoholic beverage companies worldwide. He helped guide the expansion of the business to ultimately penetration of 46 states domestically and 10 countries internationally, with consistent growth and profitability throughout his tenure. Prior to New Age, Mr. Ence was a senior executive, Planning Manager and Director of Finance for Quantum Corp. Following Quantum he served as a Director of Finance and Investor Relations at On Command Corp. Mr. Ence began his career at PepsiCo. During his 12 years at PepsiCo, Mr. Ence served as a financial analyst, planning supervisor, planning and analysis manager and ultimately controller.

He received his Bachelor of Arts in Business Administration and Accounting from Southern Utah University in 1984, and obtained a Masters in Business Administration in Finance from Arizona State University School of Business in 1985.

Ottavio V. Vitolo, M.D., M.M.Sc. has been our Senior Vice President, Head of R&D and Chief Medical Officer since April 2018. Dr. is a neuropsychiatrist and clinical researcher with 20 years of pre-clinical and clinical research experience both in academia and industry. His expertise includes psychiatric and neurological disorders, such as depression, schizophrenia, Alzheimer's disease, Parkinson's disease, and rare diseases, such as Duchenne's muscular dystrophy, Huntington's disease, Friedreich's ataxia and phenylketonuria.

Prior to joining Relmada, from January 2017 to March 2018, Dr. Vitolo was Vice President of Clinical Development at Homology Medicines, Inc., a gene therapy and gene editing company, where he led the clinical development for the company lead gene therapy program and built the clinical strategy for the company portfolio. From May 2013 to January 2017, he held positions of increasing responsibility at Pfizer Inc., overseeing studies and programs ranging from small molecules to biologics to gene therapy, first in the Neuroscience Research Unit and later in the Rare Disease Research Unit, where he served as Senior Medical Director and Head of Neuromuscular Clinical Research. Prior to Pfizer, from July 2012 to April 2013, he was an Associate Medical Director in Discovery Research at Shire Human Genetic Therapies (HGT). Since 2011, Dr. Vitolo has held a position as an Assistant Psychiatrist at Massachusetts General Hospital and has been an Instructor in Psychiatry at Harvard Medical School since 2009.

Dr. Vitolo received a master of medical sciences in clinical investigation (M.M.Sc.) from Harvard Medical School, and a medical degree (M.D.), *summa cum laude*, in medicine and surgery from the University of Rome - La Sapienza. He trained in psychiatry at Barnes Jewish Hospital and Washington University in St. Louis Medical School and in behavioral neurology and neuropsychiatry at Brigham and Women's Hospital and Harvard Medical School.

Board of Directors

Charles J. Casamento, MBA has been our Chairman of the Board since June 2017 and a director since July 2015. Mr. Casamento is also Chairman of our Audit Committee and a member of Compensation Committee and Corporate Governance and Nominating Committee. Since 2007 Mr. Casamento is Executive Director and Principal of The Sage Group, a health care advisory group specializing in business development strategies and transactions. Prior to The Sage Group he was President and CEO of Osteologix from October 2004 until April 2007. Originally a private VC funded company in Copenhagen, Denmark which had discovered a new drug for the treatment of Osteoporosis, Mr. Casamento commenced operations and initiated clinical trials in the US, completed a financing with Rodman & Renshaw and Roth Capital Partners and took the company public through a merger with a public shell company. The product was eventually acquired by Servier a major French pharmaceutical company. Osteologix was Mr. Casamento's fifth startup company, all of which were successfully taken public, during his tenure, either through IPOs or through reverse mergers.

He was Senior Vice President & General Manager for Pharmaceuticals and Biochemicals at Genzyme. He joined Genzyme in 1985 while it was an early stage venture backed company and was there during the time Genzyme was taken public. In 2011 Genzyme was acquired by Sanofi for an estimated \$20 Billion. In 1989 he co-founded and later took public, Interneuron Pharmaceuticals (Indevus) which eventually reached a \$1.6 billion market valuation after a weight loss product that was developed during his tenure was approved by FDA. Indevus was acquired in 2009 by Endo for nearly \$1 Billion. In 1993 Mr. Casamento joined RiboGene as Chairman, President and CEO. He took the Company public and completed several major corporate collaborations and R&D collaboration agreements as well as a merger with a public corporation in 1998 to form Questcor Pharmaceuticals, where he was Chairman, CEO and President until August 2004. He acquired Acthar, a product for West Syndrome and MS, for a \$100,000 cash payment plus a 1% royalty. Questcor was acquired by Mallinckrodt in 2014 at a valuation of \$6 Billion and Acthar has revenue at a run rate of \$1 Billion for 2014.

Prior to joining Genzyme in 1985 Mr. Casamento has held a number of marketing, sales, finance and business development positions with Novartis, Hoffmann-LaRoche, Johnson & Johnson and American Hospital Supply Corporation where he was Vice President of Business Development and Strategic Planning for the Critical Care Division from January 1983 until May 1985. During his career he has completed well over 100 major business development/M&A deals which had the effect of enhancing and expediting the growth and development of his businesses. He took four biotechnology companies public and secured public and VC financing for five biotechnology companies.

Mr. Casamento currently serves as an Independent Director for AzurRx Biopharma. During his career he has served on the boards of twelve public companies and two private companies. Mr. Casamento also served as Chairman of the Audit Committee of Astex Pharmaceuticals and is a SOX defined financial expert. He is a member of the Fordham University Science Council and has been a guest lecturer at Fordham University. He was previously Vice Chairman of the Catholic Medical Mission Board, a large not for profit organization providing health care services to third world countries. A graduate of Fordham University in New York City and Iona College in New Rochelle, New York. Mr. Casamento has a degree in Pharmacy and an MBA.

Maged Shenouda, R.Ph, MBA, Maged Shenouda, R.Ph, MBA, has been our director since November 2015. Mr. Shenouda is also a member of the Audit Committee and Compensation Committee, and is Chairman of the Corporate Governance and Nominating Committee. Mr. Shenouda has over 25 years of biotechnology and equity research experience. Mr. Shenouda is currently the Chief Financial Officer of AzurRx Biopharma where he also serves as a Director. Prior to this Mr. Shenouda was the Head of Business Development and Licensing at Retrophin, Inc. from January 2014 to November 2014. Prior to that, he spent the bulk of his career as an equity analyst. He has held senior level positions at UBS, JP Morgan and Stifel Nicolaus, covering a broad range of small and large capitalization biotechnology companies. Mr. Shenouda started his sell-side equity research career at Citigroup and Bear Stearns where his coverage universe focused on U.S and European pharmaceutical companies. Before entering Wall Street, he was a management consultant with PricewaterhouseCoopers Pharmaceutical Consulting practice and also spent time in pharmaceutical sales, having worked as a hospital representative and managed care specialist for Abbott Laboratories Pharmaceutical Products Division. He earned a B.S. in Pharmacy from St. John's University and is a registered pharmacist in New Jersey and California. He also received an M.B.A from Rutgers Graduate School of Management. That Mr. Shenouda brings over 25 years of biotechnology and equity research experience to our Board of Directors, having served in various executive-level positions over the course of his career, and that Mr. Shenouda has developed significant management and leadership skills relating to the pharmaceutical industry, led us to conclude that Mr. Shenouda should serve as a director.

Paul Kelly has been a director of the Company since November 2015. Mr. Kelly is also Chairman of the Compensation Committee, and a member of the Audit Committee and Corporate Governance and Nominating Committee. Mr. Kelly has been actively involved as an analyst, consultant and investor in the biotechnology sector for the past twenty years. He began as an equity analyst at Mabon Securities in 1993, and served in the same capacity at UBS Securities, Volpe, Brown, Whalen, ING Securities and Merrill Lynch. Mr. Kelly was named to the inaugural Fortune magazine All Star Analyst team in 2000. Subsequently, since 2007 Mr. Kelly has engaged in consulting for both private and public biotechnology companies and for hedge funds. He currently manages his own investments and continues his industry consulting activities. Mr. Kelly has advised Spring Bank Pharmaceuticals, Inc. and VisionGate, Inc. Mr. Kelly holds an A.B. in Biochemistry from Brown University, from which he was graduated magna cum laude, Sigma Xi and Phi Beta Kappa. He attended the University of Rochester School of Medicine and received an MBA in Finance from the William E. Simon School at the University of Rochester. That Mr. Kelly brings over 25 years of biotechnology experience to our Board of Directors, having served in various executive-level positions over the course of his career, and that he has developed significant management and leadership skills relating to the pharmaceutical industry, led us to conclude that Mr. Kelly should serve as a director.

CORPORATE GOVERNANCE

Board of Directors

The Board of Directors oversees our business affairs and monitors the performance of management. In accordance with our corporate governance principles, the Board of Directors does not involve itself in day-to-day operations of the Company. The directors keep themselves informed through discussions with the Chief Executive Officer, other key executives and by reading the reports and other materials that we send them and by participating in Board of Directors and committee meetings.

Term of Office

Directors are appointed until the director resigns or by reason of death or other cause is unable to serve in the capacity of a director. Our officers are appointed by our Board and hold office until removed by our Board.

All officers and directors listed above will remain in office until their successors have been duly elected and qualified. Our bylaws provide that our Board appoints officers and each executive officer serves at the discretion of our Board.

The term of each director is set forth below or until their successors are duly elected. The table below shows the term of each director under our amended Articles of Incorporation:

Director	Class	Term (from 2018 Annual Meeting)
Maged Shenouda	Class I	36 months
Charles J. Casamento	Class II	12 months
Sergio Traversa	Class II	12 months
Paul Kelly	Class III	24 months

Directors elected at each annual meeting commencing in 2015 shall be elected for a 3-year term.

Director Independence

We use the definition of “independence” of the NYSE American to make this determination. We are not listed on the NYSE American, so although we use its definition of “independence”, its “independence” rules are inapplicable to us. NYSE American corporate governance rule Sec. 803(A)(2) provides that an “independent director” means a person other than an executive officer or employee of the company. No director qualifies as independent unless the issuer’s board of directors affirmatively determines that the director does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. The following is a non-exclusive list of persons who shall not be considered independent under NYSE American rules:

- a director who is, or during the past three years was, employed by the company, other than prior employment as an interim executive officer (provided the interim employment did not last longer than one year);
- a director who accepted or has an immediate family member who accepted any compensation from the company in excess of \$120,000 during any period of twelve consecutive months within the three years preceding the determination of independence, other than the following:
 - (i) compensation for board or board committee service,
 - (ii) compensation paid to an immediate family member who is an employee (other than an executive officer) of the company,
 - (iii) compensation received for former service as an interim executive officer (provided the interim employment did not last longer than one year), or
 - (iv) benefits under a tax-qualified retirement plan, or non-discretionary compensation
- a director who is an immediate family member of an individual who is, or at any time during the past three years was, employed by the company as an executive officer;
- a director who is, or has an immediate family member who is, a partner in, or a controlling shareholder or an executive officer of, any organization to which the company made, or from which the company received, payments (other than those arising solely from investments in the company’s securities or payments under non-discretionary charitable contribution matching programs) that exceed 5% of the organization’s gross revenues for that year, or \$200,000, whichever is more, in any of the most recent three fiscal years;
- a director who is, or has an immediate family member who is, employed as an executive officer of another entity where at any time during the most recent three fiscal years any of the issuer’s executive officers serve on the compensation committee of such other entity; or
- a director who is, or has an immediate family member who is, a current partner of the company’s outside auditor, or was a partner or employee of the company’s outside auditor who worked on the company’s audit at any time during any of the past three years.

Our Common Stock is not currently quoted or listed on any national exchange or interdealer quotation system with a requirement that a majority of our board of directors be independent and, therefore, the Company is not subject to any director independence requirements. Under the above-mentioned NYSE American director independence rules Charles J. Casamento, Maged Shenouda, and Paul Kelly are independent directors of the Company.

Board Leadership Structure

Our Board of Directors has a policy that calls for the leadership role of the Board of Directors and Company management, namely the Chairman of the Board of Directors and the Chief Executive Officer, to be separate as it believes that the most effective leadership structure for us at this time is not to have these roles combined. Sergio Traversa, PharmD, MBA serves as our Chief Executive Officer and Charles J. Casamento, R.Ph, MBA is our Chairman of the Board. We believe this structure of having a separate Chief Executive Officer and Chairman of the Board provides proper oversight of the Company and its operations.

Board Risk Oversight

Risk management is primarily the responsibility of the Company's management; however, the Board of Directors has responsibility for overseeing management's identification and management of those risks. The Board of Directors considers risks in making significant business decisions and as part of the Company's overall business strategy. The Board of Directors and its committees, as appropriate, discuss and receive periodic updates from senior management regarding significant risks, if any, to the Company in connection with the annual review of the Company's business plan and its review of budgets, strategy and major transactions.

Board of Directors Meetings and Attendance

During the fiscal year ended June 30, 2019, the Board of Directors held 11 meetings. All directors attended the board meetings.

Code of Ethics and Business Conduct

We adopted a Code of Ethics and Business Conduct that applies to all of our directors, officers and employees, including our principal executive officer and principal financial and accounting officer. A copy of the Code of Ethics and Business Conduct is available on the Company's website, under About Relmada using the tab Governance/Compliance at www.relmada.com. We will post on our website any amendment to our Code of Ethics and Business Conduct or waivers of our Code of Ethics and Business Conduct for directors and executive officers.

Communications with Directors

The Board of Directors has procedures for stockholders to send communications to individual directors or the non-employee directors as a group. Written correspondence should be addressed to the director or directors in care of Charles J. Casamento, Chairman of the Board of Relmada Therapeutics, Inc., 880 Third Avenue, 12th Floor, New York, New York 10022. Correspondence received that is addressed to the non-employee directors will be reviewed by our Chairman of the Board or his designee, who will regularly forward to the non-employee directors a summary of all such correspondence and copies of all correspondence that, in the opinion of our Chairman of the Board, deals with the functions of the Board of Directors or committees thereof or that the Chairman of the Board otherwise determines requires their attention. Directors may at any time review a log of all correspondence received by Relmada Therapeutics, Inc. that is addressed to the non-employee members of the Board of Directors and request copies of any such correspondence. You may also contact individual directors by calling our principal executive offices at (646) 876-3459.

Committees of the Board of Directors

On July 14, 2015, the Company's board of directors formed an Audit Committee and Compensation Committee. Actions taken by these committees are reported to the full board. On March 28, 2017, the Company's board of directors formed a Corporate Governance and Nominating Committee. Actions taken by these committees are reported to the full board. The membership of these committees is set forth below.

Audit Committee	Corporate Governance and Nominating Committee	Compensation Committee
Charles J. Casamento*	Maged Shenouda*	Paul Kelly*
Paul Kelly	Paul Kelly	Charles J. Casamento
Maged Shenouda	Charles Casamento	Maged Shenouda

* Indicates committee chair

Audit Committee

Our audit committee, which currently consists of three directors, provides assistance to our board in fulfilling its legal and fiduciary obligations with respect to matters involving the accounting, financial reporting, internal control and compliance functions of the company. The committee met four times in 2019 and has a charter which is reviewed annually. Our audit committee employs an independent registered public accounting firm to audit the financial statements of the company and perform other assigned duties. Further, our audit committee provides general oversight with respect to the accounting principles employed in financial reporting and the adequacy of our internal controls. In discharging its responsibilities, our audit committee may rely on the reports, findings and representations of the company's auditors, legal counsel, and responsible officers. Our board has determined that all members of the audit committee are financially literate within the meaning of SEC rules and under the current listing standards of the NYSE MKT. Charles J. Casamento is the chairman of the audit committee.

Corporate Governance and Nominating Committee

Our board of directors has a Corporate Governance and Nominating Committee composed of Maged Shenouda, Charles J. Casamento and Paul Kelly. Mr. Shenouda serves as the chairman of the committee. The committee is charged with the responsibility of reviewing our corporate governance policies and with proposing potential director nominees to the board of directors for consideration. The committee met one time in 2019 and has a charter which is reviewed annually. All members of the Nominating and Corporate Governance Committee are independent directors as defined by the rules of the NASDAQ Stock Market. The Nominating and Corporate Governance Committee will assess all director nominees using the same criteria. During 2019, we did not pay any fees to any third parties to assist in the identification of nominees. During 2019, we did not receive any director nominee suggestions from stockholders.

Compensation Committee

Our compensation committee, which currently consists of three directors, establishes executive compensation policies consistent with the company's objectives and stockholder interests. The committee met one time in 2018 and has a charter which is reviewed annually. Our compensation committee also reviews the performance of our executive officers and establishes, adjusts and awards compensation, including incentive-based compensation, as more fully discussed below. In addition, our compensation committee generally is responsible for:

- establishing and periodically reviewing our compensation philosophy and the adequacy of compensation plans and programs for our directors, executive officers and other employees;
- overseeing our compensation plans, including the establishment of performance goals under the company's incentive compensation arrangements and the review of performance against those goals in determining incentive award payouts;
- overseeing our executive employment contracts, special retirement benefits, severance, change in control arrangements and/or similar plans;
- acting as administrator of any company stock option plans; and
- overseeing the outside consultant, if any, engaged by the compensation committee.

Our compensation committee periodically reviews the compensation paid to our non-employee directors and the principles upon which their compensation is determined. The compensation committee also periodically reports to the board on how our non-employee director compensation practices compare with those of other similarly situated public corporations and, if the compensation committee deems it appropriate, recommends changes to our director compensation practices to our board for approval.

Outside consulting firms retained by our compensation committee and management also will, if requested, provide assistance to the compensation committee in making its compensation-related decisions.

Family Relationships

There are no family relationships among any of our officers or directors.

Involvement in Certain Legal Proceedings

None of our current directors or executive officers has, during the past ten years:

- been convicted in a criminal proceeding or been subject to a pending criminal proceeding (excluding traffic violations and other minor offenses);
- had any bankruptcy petition filed by or against the business or property of the person, or of any partnership, corporation or business association of which he was a general partner or executive officer, either at the time of the bankruptcy filing or within two years prior to that time;
- been subject to any order, judgment, or decree, not subsequently reversed, suspended or vacated, of any court of competent jurisdiction or federal or state authority, permanently or temporarily enjoining, barring, suspending or otherwise limiting, his involvement in any type of business, securities, futures, commodities, investment, banking, savings and loan, or insurance activities, or to be associated with persons engaged in any such activity;
- been found by a court of competent jurisdiction in a civil action or by the SEC or the Commodity Futures Trading Commission to have violated a federal or state securities or commodities law, and the judgment has not been reversed, suspended, or vacated;
- been the subject of, or a party to, any federal or state judicial or administrative order, judgment, decree, or finding, not subsequently reversed, suspended or vacated (not including any settlement of a civil proceeding among private litigants), relating to an alleged violation of any federal or state securities or commodities law or regulation, any law or regulation respecting financial institutions or insurance companies including, but not limited to, a temporary or permanent injunction, order of disgorgement or restitution, civil money penalty or temporary or permanent cease-and-desist order, or removal or prohibition order, or any law or regulation prohibiting mail or wire fraud or fraud in connection with any business entity; or
- been the subject of, or a party to, any sanction or order, not subsequently reversed, suspended or vacated, of any self-regulatory organization (as defined in Section 3(a)(26) of the Exchange Act), any registered entity (as defined in Section 1(a)(29) of the Commodity Exchange Act), or any equivalent exchange, association, entity or organization that has disciplinary authority over its members or persons associated with a member.

Except as set forth in our discussion below in “Certain Relationships and Related Transactions,” none of our directors or executive officers has been involved in any transactions with us or any of our directors, executive officers, affiliates or associates which are required to be disclosed pursuant to the rules and regulations of the SEC.

Shareholder Communications

Currently, we do not have a policy with regard to the consideration of any director candidates recommended by security holders. To date, no security holders have made any such recommendations.

Whistle Blowing Policy

We have adopted a Company Whistle Blowing Policy, for which a copy will be provided to any person requesting same without charge. To request a copy of our Whistle Blowing Policy please make written request to our CEO, at Relmada Therapeutics, Inc. 880 Third Avenue, 12th Floor, New York, New York 10022. We believe our Whistle Blowing Policy is reasonably designed to provide an environment where our employees and consultants may raise concerns about any and all dishonest, fraudulent or unacceptable behavior, which, if disclosed, could reasonably be expected to raise concerns regarding the integrity, ethics or bona fides of the Company.

Compliance with Section 16(a) of the Exchange Act

Based solely upon a review of copies of such forms filed on Forms 3, 4, and 5, and amendments thereto furnished to us, except as noted below, we believe that as of the date of this Report, our executive officers, directors and greater than 10 percent beneficial owners have complied on a timely basis with all Section 16(a) filing requirements.

ITEM 11. EXECUTIVE COMPENSATION

EXECUTIVE COMPENSATION

The following table provides information regarding the compensation earned during the years ended June 30, 2019 and 2018 for our Executive Officers:

Name/Position	Year	Salary	Bonus	Option Awards (a)	All other compensation (b)	Total
Sergio Traversa (1) Chief Executive Officer and Director	June 30, 2019	\$ 367,500	\$ 25,000	\$ 316,981	\$ -	\$ 709,481
	June 30, 2018	\$ 376,250	\$ 46,000	\$ 552,267	\$ -	\$ 974,517
Ottavio Vitolo, MD (2) Senior Vice President, Head of R&D and Chief Medical Officer	June 30, 2019	\$ 330,000	-	\$ 169,210	\$ -	\$ 499,210
	June 30, 2018	\$ 82,500	\$ 20,000	\$ 211,944	\$ -	\$ 314,444

- (1) Hired as CEO on April 18, 2012. Mr. Traversa was awarded discretionary performance bonuses of \$46,000 in 2018 and \$25,000 in 2019.
- (2) Hired as Senior Vice President, Head of R&D and Chief Medical Officer on April 2, 2018. Dr. Vitolo was awarded a bonus of \$20,000 in 2018.
- (a) This column shows the grant date fair value of awards computed in accordance with stock-based compensation accounting rules under Accounting Standards Codification Topic 718.
- (b) This column shows all other compensation, including severance, relocation expense reimbursement, reimbursement for taxes paid by employees for restricted stock vesting, and payment for vacation days remaining upon termination.

Employment Agreements

Compensatory Plan with Sergio Traversa (Principal Executive Officer)

Effective August 5, 2015, the Company and Sergio Traversa entered into an amended and restated agreement (the Employment Agreement), to employ Mr. Traversa (Employee) as the Company's Chief Executive Officer. The term of the agreement is three years provided that Mr. Traversa's employment with the Company will be on an "at will" basis, meaning that either Mr. Traversa or the Company may terminate his employment at any time for any reason or no reason, without further obligation or liability, except as provided in the Employment Agreement.

Salary

- Mr. Traversa's current base annual salary is \$367,500.

Bonus

- Mr. Traversa shall be entitled to participate in an executive bonus program, which shall be established by the board pursuant to which the board shall award bonuses to Mr. Traversa, based upon the achievement of written individual and corporate objectives such as the board shall determine. Upon the attainment of such performance objectives, in addition to base salary, Mr. Traversa shall be entitled to a cash bonus in an amount to be determined by the board with a target of forty percent (40%) of the base salary.

Options

- During the term of the agreement, Mr. Traversa may also be awarded grants under the Company's 2014 Stock Option and Equity Incentive Plan, as amended, subject to board approval.

Termination

- Termination for death or disability or cause. In the event that employment is terminated because of death or disability, the Company's only obligation to Mr. Traversa shall be to pay earned, but unpaid, base salary (as of the date of termination) and provide to Mr. Traversa, if eligible, with the option to elect health coverage under the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended (COBRA); provided that upon termination of employment due to death, Mr. Traversa's estate also shall be entitled to receive a single lump sum payment equal to three (3) months of base salary, payable within 30 days of your death. Upon termination of employment for cause (as defined in the Employment Agreement) Mr. Traversa shall be paid any accrued and unpaid base salary and benefits through the date of termination and shall have no further rights to any compensation or any other benefits under the agreement or otherwise.
- Termination of Employment Other Than for Cause or Resignation for Good Reason (Not in Connection with a Change in Control) If the Company terminates employment other than for cause or if he resigns for Good Reason (as defined in the Employment Agreement), Mr. Traversa shall be entitled to (i) a single lump sum payment equal to 24 months of compensation (at the rate in effect as of the date of termination), (ii) continued health benefits for the 24-month period beginning on the date of termination, and (iii) all outstanding equity awards granted under the Company's equity compensation plans shall become immediately vested and exercisable (as applicable) as of the date of such termination and the performance goals with respect to such outstanding performance awards, if any, will deemed satisfied at "target".
- Change in Control. If the Company terminates employment other than for cause or if Mr. Traversa resigns for Good Reason (as defined in the Employment Agreement), in any case during the 12-month period beginning on the date of a Change in Control (as defined in the 2014 Equity Incentive Plan, as amended), Mr. Traversa shall be entitled to (i) a single lump sum payment equal to thirty (30) months of your compensation (at the rate in effect as of the date of termination), (ii) continued health benefits for the 24-month period beginning on the date of termination, (iii) all outstanding equity awards granted to Mr. Traversa under the Company's equity compensation plans shall become immediately vested and exercisable (as applicable) as of the date of such termination and the performance goals with respect to such outstanding performance awards, if any, will deemed satisfied at "target".

Non-Solicitation

- Mr. Traversa agreed that during the term of employment with the Company, and for a period of 24 months following the cessation of employment with the Company for any reason or no reason, Mr. Traversa shall not directly or indirectly solicit, induce, recruit or encourage any of the Company's employees or consultants to terminate their relationship with the Company, or attempt any of the foregoing, either for himself or any other person or entity. For a period of 24 months following cessation of employment with the Company for any reason or no reason, Mr. Traversa shall not attempt to negatively influence any of the Company's clients or customers from purchasing Company products or services or to solicit or influence or attempt to influence any client, customer or other person either directly or indirectly, to direct his or its purchase of products and/or services to any person, firm, corporation, institution or other entity in competition with the business of the Company.

Indemnification

- Mr. Traversa entered into an Indemnification Agreement with the Company on the effective date whereby the Company agreed to indemnify Mr. Traversa in certain situations.

Compensatory Plan with Charles Ence (Principal Financial and Accounting Officer)

On July 29, 2019, the Company and Mr. Ence entered into a consulting agreement (the "Consulting Agreement"). Pursuant to the Consulting Agreement, Mr. Ence and the Company agreed to the following:

Term.

- Mr. Ence's term as Chief Financial Officer commenced on July 29, 2019 and continues until January 31, 2020 (the "Initial Term"), and shall automatically renew for successive three-month periods (each, an "Additional Term" and, collectively with the Initial Term, the "Term"). The Company may terminate Mr. Ence at any time, upon thirty (30) days' written notice. Mr. Ence may resign by giving the Company no less than 30 days' written notice of such termination prior to the end of such Initial Term or Additional Term with such termination being effective at the end of the Initial Term or Additional Term, as the case may be.

Consulting Fee

- Mr. Ence will be paid a monthly base consulting fee of \$20,000. He is entitled to a cash bonus of \$60,000, that is contingent on the Company's common stock being approved for listing on the Nasdaq Stock Market LLC. Such bonus is payable on January 31, 2020, so long as Mr. Ence is a consultant of the Company at such time. If the Company terminates Mr. Ence before January 31, 2020, without cause, the \$60,000 cash bonus will also be paid.

Option Grant.

- The board granted to Mr. Ence an option to purchase 100,000 shares of common stock (the "Options") of the Company under the Company's current Stock Option and Equity Incentive Plan at an exercise price equal to the closing price of the Company's common stock on July 29, 2019. The options have a term of 10 years starting from the first day of his consulting relationship with the Company.

Vesting Schedule

- The above referenced options shall vest on January 31, 2020, so long as Mr. Ence is a consultant of the Company at such time and the Company's common stock is approved for listing on the Nasdaq Stock Market LLC. If the Company terminates Mr. Ence before January 31, 2020, without cause, the Options shall vest immediately.

Non-Solicitation

- The agreement also contains a non-solicitation provision that, among other things, provides that during the term of the consulting relationship and for a period of 24 months following the cessation of the consulting relationship, Mr. Ence shall not directly or indirectly solicit, induce, recruit or encourage any of the Company's employees or consultants to terminate their relationship with the Company, or attempt any of the foregoing, either for himself or any other person or entity.

Indemnification/Confidentiality.

- The Company also entered in a standard indemnification agreement (the "Indemnification Agreement") with Mr. Ence where the Company agreed to indemnify him in certain situations for his role as Chief Financial Officer. Mr. Ence also entered in a standard Confidential Information and Invention Assignment Agreement (the "Confidentiality Agreement") with the Company where Mr. Ence agreed to certain confidentiality and assignment of invention provisions.

Compensatory Plan with Ottavio Vitolo (Chief Medical Officer)

Effective April 2, 2018, the Company and Ottavio Vitolo entered into an agreement (the Employment Agreement), to employ Dr. Vitolo (Employee) as the Company's Senior Vice President Head of R&D and Chief Medical Officer. Dr. Vitolo's employment with the Company will be on an "at will" basis, meaning that either Dr. Vitolo or the Company may terminate his employment at any time for any reason or no reason, without further obligation or liability, except as provided in the Employment Agreement.

Salary

- Dr. Vitolo's current base annual salary is \$330,000.

Bonus

- Dr. Vitolo shall be entitled to participate in an executive bonus program, which shall be established by the board pursuant to which the board shall award bonuses to Dr. Vitolo, based upon the achievement of written individual and corporate objectives such as the board shall determine. Upon the attainment of such performance objectives, in addition to base salary, Dr. Vitolo shall be entitled to a cash bonus in an amount to be determined by the board with a target of forty percent (40%) of the base salary.

Options

- During the term of the agreement, Dr. Vitolo may also be awarded grants under the Company's 2014 Stock Option and Equity Incentive Plan, as amended, subject to board approval.

Termination

- In the event of termination other than for cause, Dr. Vitolo will be entitled to severance equal to six months of base salary and health benefits.

Non-Solicitation

- Dr. Vitolo agreed that during the term of employment with the Company, and for a period of 24 months following the cessation of employment with the Company for any reason or no reason, Dr. Vitolo shall not directly or indirectly solicit, induce, recruit or encourage any of the Company's employees or consultants to terminate their relationship with the Company, or attempt any of the foregoing, either for himself or any other person or entity. For a period of 24 months following cessation of employment with the Company for any reason or no reason, Dr. Vitolo shall not attempt to negatively influence any of the Company's clients or customers from purchasing Company products or services or to solicit or influence or attempt to influence any client, customer or other person either directly or indirectly, to direct his or its purchase of products and/or services to any person, firm, corporation, institution or other entity in competition with the business of the Company.

Indemnification

- Dr. Vitolo entered into a standard Indemnification Agreement with the Company on the effective date whereby the Company agreed to indemnify Dr. Vitolo in certain situations.

Director Compensation

Non-management Directors of the Company receive a quarterly cash retainer of \$10,000 per calendar quarter for their service on the Board of Directors. They also receive reimbursement for out-of-pocket expenses and certain directors have received stock option grants for shares of Company Common Stock as described below. Our Chairman of the Board receives additional compensation of \$50,000 per year for his role as chairman.

Board committee members will receive the following annual compensation for committee participation:

BOD Committee	Chairman	Member
Audit	\$ 18,000	\$ 8,000
Compensation	\$ 13,000	\$ 6,000
Corporate Governance and Nominating	\$ 13,000	\$ 6,000

The following table sets forth the compensation of our directors for the years ended June 30, 2019 and 2018:

<u>Name</u>	<u>Year</u>	<u>Fees Earned or Paid in Cash</u>	<u>Stock Awards</u>	<u>Option Awards (a)</u>	<u>All Other Compensation</u>	<u>Total</u>
Charles J. Casamento (1)	2019	\$ 120,000	\$ -	\$ 161,093	\$ -	\$ 281,093
Charles J. Casamento	2018	\$ 120,000	\$ -	\$ 276,134	\$ -	\$ 396,134
Maged Shenouda (2)	2019	\$ 67,000	\$ -	\$ 139,735	\$ -	\$ 206,735
Maged Shenouda	2018	\$ 67,000	\$ -	\$ 276,134	\$ 65,918	\$ 409,052
Paul Kelly (2)	2019	\$ 67,000	\$ -	\$ 150,005	\$ -	\$ 217,005
Paul Kelly	2018	\$ 67,000	\$ -	\$ 292,377	\$ -	\$ 359,377

(a) This column shows the grant date fair value of awards computed in accordance with stock-based compensation accounting rules Accounting Standards Codification Topic 718.

(1) On July 14, 2015, Relmada Therapeutics, Inc.'s (the Company) board of directors appointed Charles J. Casamento as a director of the Company.

(2) On November 12, 2015, the Company's board of directors appointed Maged Shenouda as a Class I director of the Company and Paul Kelly as a Class III director.

The following distinguished individuals serve as scientific and business advisors.

Dr. Maurizio Fava is Director, Division of Clinical Research of the Massachusetts General Hospital (MGH) Research Institute, Executive Vice Chair of the MGH Department of Psychiatry and Executive Director of the MGH Clinical Trials Network and Institute, and Associate Dean for Clinical and Translational Research and the Slater Family Professor of Psychiatry at Harvard Medical School.

Dr. Fava is a world leader in the field of depression. He has authored or co-authored more than 800 original articles published in medical journals with international circulation, edited eight books, and published more than 50 chapters and over 500 abstracts. The citation impact of Dr. Fava's work is extremely high, as his articles have been cited more than 55,000 times in the literature, with an h index of over 115.

Dr. Fava obtained his medical degree from the University of Padova School of Medicine and completed residency training in endocrinology at the same university. He then moved to the United States and completed residency training in psychiatry at the MGH. He founded and was Director of the hospital's Depression Clinical and Research Program from 1990 until 2014. In 2007, he also founded and is now the Executive Director of the MGH Psychiatry Clinical Trials Network and Institute, the first academic contract research organization specialized in the planning and coordination of multi-center clinical trials in psychiatry.

Under Dr. Fava's direction, the Depression Clinical and Research Program became one of the most highly regarded depression programs in the country, a model for academic programs that link, in a bi-directional fashion, clinical and research work.

Dr. Fava has been successful in obtaining funding as principal or co-principal investigator from both the National Institutes of Health and other sources for a total of more than \$95,000,000. Dr. Fava's prominence in the field is reflected in his role as the co-principal investigator of STAR*D, the largest research study ever conducted in the area of depression, and of the RAPID Network, the NIMH-funded series of studies of novel, rapidly-acting antidepressant therapies.

Dr. Fava has received several awards during his career and is on the editorial board of five international medical journals. Since 1990, Dr. Fava has also mentored more than 50 trainees who have gone on to become lead investigators in the area of psychiatry. He has developed with Dr. David Schoenfeld a novel design (with over five patents) to address the problem of excessive placebo response in drug trials and to markedly reduce sample size requirements for these trials. In 2009, Dr. Fava received the A. Clifford Barger Excellence in Mentoring Award from Harvard Medical School, and in 2013 the John T. Potts, Jr., MD Faculty Mentoring Award from Massachusetts General Hospital.

Dr. Fava is a well-known national and international lecturer, having given more than 300 presentations at national and international meetings.

Charles E. Inturrisi, PhD, is professor of pharmacology, Weill Medical College of Cornell University; professor, Programs in Pharmacology and Neuroscience, Weill Graduate School of Medical Sciences of Cornell University; and visiting investigator, Pain and Palliative Care Service, Memorial Sloan-Kettering Cancer Center.

Dr. Inturrisi's current research activities are directed toward determining the comparative effectiveness of interventions used for chronic pain management. This research prospectively and retrospectively examines the long-term outcomes of treatments for chronic cancer and noncancer pain received by patients at the four New York City hospital-based outpatient pain clinics. The effectiveness information obtained determines which patients benefit from the currently available interventions used for the management of chronic pain and the cost-effectiveness of these treatments. This approach is expected to improve pain management worldwide.

Dr. Inturrisi continues to have an interest the role of glutamate receptors in injury-induced pain opioid tolerance, dependence, and addictive behaviors. These studies are intended to discover new treatments for pain and drug addiction.

Dr. Inturrisi, who was APS president between 2008 and 2010, has received the John J. Bonica Lectureship Award (Eastern Pain Association, 1994), Excellence in Mentoring Award (Weill Cornell Medical College Postdoctoral Association, 2007), Graduate Dean's Award for Excellence in Teaching and Mentoring of Graduate Students (Weill Cornell Graduate School of Medical Sciences, 2008), and many other awards and honors. He has been an editorial board member for *The Journal of Pain and Symptom Management* since 1990.

Dr. Paolo Manfredi is specialized in neurology and psychiatry. He has completed fellowships at MD Anderson Cancer Center and Massachusetts General Hospital, where he obtained the Golden Needle Award. Dr. Manfredi worked at Mount Sinai Medical Center and was appointed Assistant Professor in Neurology and Psychiatry, Anesthesia and Geriatric Medicine at Mount Sinai School of Medicine. He then worked for over ten years at Memorial Sloan Kettering Cancer Center and was assistant Professor of Neurology and Psychiatry at Cornell University. He is the author of over fifty peer-reviewed publications and is an expert on the medical applications of methadone and its isomers. Dr. Manfredi is co-inventor of pharmaceutical patents disclosing new chemical entities acting as NMDA receptor modulators for the treatment of psychiatric and neurological disorders.

Dr. Michael E. Thase joined the faculty of the Perelman School of Medicine at the University of Pennsylvania in 2007 as Professor of Psychiatry after more than 27 years at the University of Pittsburgh Medical Center and the Western Psychiatric Institute and Clinic.

Dr. Thase's research focuses on the assessment and treatment of mood disorders, including studies of the differential therapeutics of both depression and bipolar affective disorder.

A 1979 graduate of the Ohio State University College of Medicine, Dr. Thase is a Distinguished Fellow of the American Psychiatric Association, a Founding Fellow of the Academy of Cognitive Therapy, a member of the Board of Directors of the American Society of Clinical Psychopharmacology, and Vice Chairman of the Scientific Advisory Board of the National Depression and Bipolar Support Alliance. Dr. Thase has been elected to the membership of the American College of Psychiatrists and the American College of Neuropsychopharmacology.

Dr. Thase has authored or co-authored more than 500 scientific articles and book chapters, as well as 15 books.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table shows the pro forma beneficial ownership of our common stock as of September 11, 2019. The table shows the common stock holdings of (i) each person known to us to be the beneficial owner of at least five percent (5%) of our common stock; (ii) each director; (iii) each executive officer; and (iv) all directors and executive officers as a group.

Beneficial ownership is determined in accordance with the rules of the SEC, and generally includes voting power and/or investment power with respect to the securities held. Shares of common stock subject to options and warrants currently exercisable or exercisable within 60 days as of September 11, 2019, are deemed outstanding and beneficially owned by the person holding such options or warrants for purposes of computing the number of shares and percentage beneficially owned by such person, but are not deemed outstanding for purposes of computing the percentage beneficially owned by any other person. Except as indicated in the footnotes to this table, the persons or entities named have sole voting and investment power with respect to all shares of our common stock shown as beneficially owned by them.

The percentages in the table below are based on 38,978,555 outstanding shares of common stock. Unless otherwise indicated, the principal mailing address of each of the persons below is c/o Relmada Therapeutics, Inc., 880 Third Avenue, 12th Floor, New York, New York 10022. The Company's executive office is also located at 880 Third Avenue, 12th Floor, New York, New York 10022.

5% Stockholders	Number of Common Shares Beneficially Owned	Percentage Ownership
John Kemmerer ⁽¹⁾ Kemmerer Resources Corp., 323 Main Street, Chatham, NJ 07928	2,743,936	6.89%
Bruce Conway ⁽²⁾ 5403 Drane Drive, Dallas, TX 75209	2,181,134	5.48%
Chris Laffey ⁽³⁾ 124 Hardscrabble Road, Bernardsville, NJ 07924	2,277,020	5.56%
Paul Kelly ⁽⁴⁾ Director	1,117,998	2.82%
Sergio Traversa, PharmD, MBA ⁽⁵⁾ Director and Chief Executive Officer	1,132,284	2.83%
Charles Ence ⁽⁶⁾ Chief Financial Officer	0	0%
Charles J. Casamento ⁽⁷⁾ Chairman of the Board	359,700	0.91%
Maged Shenouda ⁽⁸⁾ Director	358,890	0.91%
Ottavio Vitolo ⁽⁹⁾ SVP, Chief Medical Officer	346,875	0.88%
All Directors and Executive Officers	3,315,747	7.96%

(1) Includes 1,918,935 common stock; Includes 99,999 warrants that have an exercise price of \$2.25; Includes 725,002 warrants that have an exercise price of \$1.50.

(2) Includes 1,368,634 common stock; Includes 150,000 warrants that have an exercise price of \$2.25; Includes 662,500 warrants that have an exercise price of \$1.50.

- (3) Includes 298,302 common stock; Includes 1,095,200 warrants that have an exercise price of \$1.65; Includes 24,000 warrants that have an exercise price of \$0.75; Includes 726,185 warrants that have an exercise price of \$0.99; Includes 133,333 warrants that have an exercise price of \$1.50.
- (4) Includes 488,483 common stock; Includes 50,000 warrants that have an exercise price of \$2.25; Includes 197,500 warrants that have an exercise price of \$1.50. Includes: 25,765 vested options with an exercise price of \$3.45, and 225,000 vested options with an exercise price of \$0.81, and 93,750 vested options with an exercise price of \$1.15, and 37,500 vested options with an exercise price of \$2.20. Excludes 225,000 unvested options with an exercise price of \$0.81, and 406,250 unvested options with an exercise price of \$1.15, and 562,500 unvested options with an exercise price of \$2.20
- (5) Includes 118,542 common stock; Includes: 268,742 vested options with an exercise price of \$4.00, and 45,000 vested options with an exercise price of \$13.50, and 425,000 vested options with an exercise price of \$0.81, and 168,750 vested options with an exercise price of \$1.15, and 106,250 vested options with an exercise price of \$2.20. Excludes 425,000 unvested options with an exercise price of \$0.81, and 731,250 unvested options with an exercise price of \$1.15, and 1,593,750 unvested options with an exercise price of \$2.20
- (6) Mr. Ence has 100,000 unvested options with an exercise price of \$2.20.
- (7) Includes 4,200 common stock; Includes: 25,765 vested options with an exercise price of [\$8.45], and 212,500 vested options with an exercise price of \$0.81, and 84,375 vested options with an exercise price of \$1.15, and 31,250 vested options with an exercise price of \$2.20. Excludes 212,500 unvested options with an exercise price of \$0.81, and 365,625 unvested options with an exercise price of \$1.15, and 468,750 unvested options with an exercise price of \$2.20
- (8) Includes 5,000 common stock; Includes: 25,765 vested options with an exercise price of \$3.45, and 212,500 vested options with an exercise price of \$0.81, and 84,375 vested options with an exercise price of \$1.15, and 31,250 vested options with an exercise price of \$2.20. Excludes 212,500 unvested options with an exercise price of \$0.81, and 365,625 unvested options with an exercise price of \$1.15, and 468,750 unvested options with an exercise price of \$2.20
- (9) Includes common stock; Includes: 112,250 vested options with an exercise price of \$0.88, and 150,000 vested options with an exercise price of \$0.80, and 75,000 vested options with an exercise price of \$1.15, and 9,375 vested options with an exercise price of \$2.20. Excludes 187,500 unvested options with an exercise price of \$0.88, and 325,000 unvested options with an exercise price of \$1.15, and 140,625 unvested options with an exercise price of \$2.20

Equity Compensation Plan Information

The Company has established the 2014 Stock and Equity Incentive Option Plan, as amended (the Plan), which allows for the granting of common stock awards, stock appreciation rights, and incentive and nonqualified stock options to purchase shares of the Company's common stock to designated employees, non-employee directors, and consultants and advisors. In August 2015, the board approved an amendment to the Plan (the 2015 Plan Amendment). Among other things, the 2015 Plan Amendment updated the definition of "change of control" and provided for accelerated vesting of all awards granted under the plan in the event of a change of control of the Company. In December 2017, the board approved an amendment to the Plan (the 2017 Plan Amendment) that increased the number of shares of Common Stock authorized for issuance under the Plan to 6,611,768. In December 2018, the board approved an amendment to the Plan (the 2018 Plan Amendment) that increased the number of shares of Common Stock authorized for issuance under the Plan to 10,111,768. At June 30, 2019, no stock appreciation rights have been issued. Stock options are exercisable generally for a period of 10 years from the date of grant and generally vest over four years. As of June 30, 2019, 4,668,153 shares were available for future grants under the Plan.

Outstanding Equity Awards at Fiscal Year-End Table

OUTSTANDING EQUITY AWARDS AT JUNE 30, 2019

The following table sets forth all unexercised options and unvested restricted stock that have been awarded to our named executives by the Company and were outstanding as of June 30, 2019.

Name (a)	Option Awards					Stock Award			
	Number of Securities Underlying Unexercised Options (#) (Exercisable) (b)	Number of Securities Underlying Unexercised Options (#) (Unexercisable) (c)	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Options (#) (d)	Option Exercise Price(\$)(e)	Option Expiration Date (f)	Number of Shares or Units of Stock That Have Not Vested (#) (g)	Market Value of Shares or Units of Stock That Have Not Vested () (\$)(h)	Unearned Shares, Units or Other Rights That Have Not Vested (#) (i)	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights That Have Not Vested (\$)(j)
Sergio Traversa	135,592	-	-	4.00	07/10/2022	-	-	-	-
Sergio Traversa	133,150	-	-	4.00	09/30/2023	-	-	-	-
Sergio Traversa	45,000	-	-	13.50	02/23/2025	-	-	-	-
Sergio Traversa	318,750	531,250	-	0.81	10/20/2027	-	-	-	-
Sergio Traversa	112,500	787,500	-	1.15	12/20/2028	-	-	-	-
Ottavio Vitolo	75,000	225,999	-	0.88	04/02/2028	-	-	-	-
Ottavio Vitolo	-	150,000	-	0.80	06/27/2027	-	-	-	-
Ottavio Vitolo	50,000	350,000	-	1.15	12/20/2028	-	-	-	-
	<u>869,992</u>	<u>2,043,750</u>							

Indemnification of Directors and Officers

We are a Nevada corporation and generally governed by the Nevada Private Corporations Code, Title 78 of the Nevada Revised Statutes, or NRS. Section 78.138 of the NRS provides that, unless the corporation's Articles of Incorporation provide otherwise, a director or officer will not be individually liable unless it is proven that (i) the director's or officer's acts or omissions constituted a breach of his or her fiduciary duties, and (ii) such breach involved intentional misconduct, fraud, or a knowing violation of the law. Our Articles of Incorporation provide that no director or officer shall be personally liable to the corporation or any of its stockholders for damages for any breach of fiduciary duty as a director or officer except for liability of a director or officer for (i) acts or omissions involving intentional misconduct, fraud, or a knowing violation of law or (ii) payment of dividends in violation of Section 78-300 of the NRS.

Section 78.7502 of the NRS permits a company to indemnify its directors and officers against expenses, judgments, fines, and amounts paid in settlement actually and reasonably incurred in connection with a threatened, pending, or completed action, suit, or proceeding, if the officer or director (i) is not liable pursuant to NRS 78.138, or (ii) acted in good faith and in a manner the officer or director reasonably believed to be in or not opposed to the best interests of the corporation and, if a criminal action or proceeding, had no reasonable cause to believe the conduct of the officer or director was unlawful. Section 78.7502 of the NRS also precludes indemnification by the corporation if the officer or director has been adjudged by a court of competent jurisdiction, after exhaustion of all appeals, to be liable to the corporation or for amounts paid in settlement to the corporation, unless and only to the extent that the court determines that in view of all the circumstances, the person is fairly and reasonably entitled to indemnity for such expenses and requires a corporation to indemnify its officers and directors if they have been successful on the merits or otherwise in defense of any claim, issue, or matter resulting from their service as a director or officer.

Section 78.751 of the NRS permits a Nevada company to indemnify its officers and directors against expenses incurred by them in defending a civil or criminal action, suit, or proceeding as they are incurred and in advance of final disposition thereof, upon determination by the stockholders, the disinterested board members, or by independent legal counsel. Section 78.751 of NRS requires a corporation to advance expenses as incurred upon receipt of an undertaking by or on behalf of the officer or director to repay the amount if it is ultimately determined by a court of competent jurisdiction that such officer or director is not entitled to be indemnified by the company if so provided in the corporation's articles of incorporation, bylaws, or other agreement. Section 78.751 of the NRS further permits the company to grant its directors' and officers' additional rights of indemnification under its articles of incorporation, bylaws, or other agreement.

Section 78.752 of the NRS provides that a Nevada company may purchase and maintain insurance or make other financial arrangements on behalf of any person who is or was a director, officer, employee, or agent of the company, or is or was serving at the request of the company as a director, officer, employee, or agent of another company, partnership, joint venture, trust, or other enterprise, for any liability asserted against him and liability and expenses incurred by him in his capacity as a director, officer, employee, or agent, or arising out of his status as such, whether or not the company has the authority to indemnify him against such liability and expenses.

The Bylaws implement the indemnification and insurance provisions permitted by Chapter 78 of the NRS.

At the present time, except as provided in "Legal Proceedings" above, there is no pending litigation or proceeding involving a director, officer, employee, or other agent of ours in which indemnification would be required or permitted. Except as described in "Legal Proceedings" above, we are not aware of any threatened litigation or proceeding that may result in a claim for such indemnification.

Equity Compensation Plan Information

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

None.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES*Audit Fees*

The aggregate fees billed to us by our principal independent public accountant for services rendered for the years ended June 30, 2019 and 2018, are set forth in the table below:

Fee Category	For the Year Ended June 30, 2019	For the Year Ended June 30, 2018
Audit fees (1)		
GBH CPAs PC	\$ -	\$ 54,000
Marcum LLP	137,000	57,000
Audit-related fees (2)	-	-
Tax fees	-	-
All other fees (4)	-	-
Total fees	<u>\$ 137,000</u>	<u>\$ 104,000</u>

- (1) Audit fees consist of fees incurred for professional services rendered for the audit of consolidated financial statements, for reviews of our interim consolidated financial statements included in our quarterly reports on Forms 10-Q and for services that are normally provided in connection with statutory or regulatory filings or engagements. Includes professional services performed for filing of the Company's registration statement on Form S-1 and for the Company's equity offerings.
- (2) Audit-related fees consist of fees billed for professional services that are reasonably related to the performance of the audit or review of our consolidated financial statements, but are not reported under "Audit fees."
- (3) Tax fees consist of fees billed for professional services relating to tax compliance, tax planning, and tax advice.
- (4) All other fees consist of fees billed for all other services.

Audit Committee's Pre-Approval Practice

In July 2015, the Company's Board of Directors formed an Audit Committee and Compensation Committee. Actions taken by these committees are reported to the full board. Our board of directors selected Marcum LLP, as our independent registered public accounting firm for purposes of auditing our financial statements for the years ended June 30, 2019 and 2018, respectively. In accordance with board of director's practice, Marcum LLP's services were pre-approved to perform these audit services for us prior to its engagement.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

Financial Statement Schedules

Our consolidated financial statements are listed on the Index to Financial Statements on this annual report on Form 10-K beginning on page F-1.

All financial statement schedules are omitted because they are not applicable or the required information is shown in the financial statements or notes thereto.

RELMADA THERAPEUTICS, INC.
Audited Financial Statements

As of June 30, 2019 and 2018
and for the years then ended

RELMADA THERAPEUTICS, INC.
(INDEX TO FINANCIAL STATEMENTS)

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and Board of Directors of
Relmada Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Relmada Therapeutics, Inc. (the "Company") as of June 30, 2019 and 2018, the related consolidated statements of operations, stockholders' equity (deficit) and cash flows for each of the two years in the period ended June 30, 2019 and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of June 30, 2019 and 2018, and the results of its operations and its cash flows for the years ended June 30, 2019 and 2018, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's 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 audits to obtain reasonable assurance about whether the 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 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 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 financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Marcum Ilp

Marcum Ilp

We have served as the Company's auditor since 2014.

Houston, Texas
September 24, 2019

Relmada Therapeutics, Inc.
Consolidated Balance Sheets

	<u>As of June 30, 2019</u>	<u>As of June 30, 2018</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 9,216,554	\$ 2,238,943
Other receivable	176,980	7,617
Lease payments receivable – short term	70,102	64,486
Prepaid expenses	520,745	426,921
Total current assets	<u>9,984,381</u>	<u>2,737,967</u>
Fixed assets, net of accumulated depreciation	7,210	12,080
Other assets	25,000	24,788
Lease payments receivable – long term	203,142	273,244
Total assets	<u>\$ 10,219,733</u>	<u>\$ 3,048,079</u>
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	\$ 924,359	\$ 765,439
Accrued expenses	1,317,855	659,455
Notes payable	364,204	285,170
Derivative liabilities	-	4,194,634
Total current liabilities	<u>2,606,418</u>	<u>5,904,698</u>
Promissory notes payable, net of discount of \$0 and \$4,548,543	-	2,656,457
Total liabilities	<u>2,606,418</u>	<u>8,561,155</u>
Commitments and contingencies		
Stockholders' Equity (Deficit) :		
Preferred stock, \$0.001 par value, 200,000,000 shares authorized, none issued and outstanding	-	-
Class A convertible preferred stock, \$0.001 par value, 3,500,000 shares authorized, none issued and outstanding	-	-
Common stock, \$0.001 par value, 200,000,000 shares authorized, 38,978,555 and 12,549,870 shares issued and outstanding, respectively	38,978	12,550
Additional paid-in capital	119,236,704	88,818,681
Accumulated deficit	(111,662,367)	(94,344,307)
Total stockholders' equity (deficit)	<u>7,613,315</u>	<u>(5,513,076)</u>
Total liabilities and stockholders' equity (deficit)	<u>\$ 10,219,733</u>	<u>\$ 3,048,079</u>

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

Relmada Therapeutics, Inc.
Consolidated Statements of Operations
For the Years Ended June 30, 2019 and 2018

	2019	2018
Operating expenses:		
Research and development	\$ 7,024,747	\$ 2,942,625
General and administrative	5,703,173	3,974,850
Total operating expenses	12,727,920	6,917,475
Loss from operations	(12,727,920)	(6,917,475)
Other income (expenses):		
Change in fair value of derivative liabilities	(54,634)	(708,901)
Interest expense, net	(761,038)	(1,336,826)
Other	-	2,350
Loss on Extinguishment of debt	(3,774,468)	-
Total other income (expenses)	(4,590,140)	(2,043,377)
Net loss	\$ (17,318,060)	\$ (8,960,852)
Net loss per common share – basic and diluted	\$ (0.69)	\$ (0.71)
Weighted average number of common shares outstanding – basic and diluted	25,247,075	12,545,342

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

Relmada Therapeutics, Inc.
Consolidated Statements of Stockholders' Equity (Deficit)
For the Years Ended June 30, 2019 and 2018

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total
	Shares	Par Value			
Balance - June 30, 2017	12,528,374	\$ 12,528	\$ 86,831,211	\$ (85,383,455)	\$ 1,460,284
Issuance of restricted common stock	3,750	4		-	4
Issuance of common stock for cashless exercises of warrants from consultants and Series A Preferred Stock warrant holder	17,746	18	(18)	-	-
Stock-based compensation expense	-	-	517,999	-	517,999
Issuance of warrants to promissory notes payable placement agent			200,658		200,658
Issuance of warrants to holders of promissory notes payable			1,268,831		1,268,831
Net loss	-	-	-	(8,960,852)	(8,960,852)
Balance - June 30, 2018	12,549,870	\$ 12,550	\$ 88,818,681	\$ (94,344,307)	\$ (5,513,076)
Cumulative effect of Write-off of Derivative Liabilities under ASU 2017-11			59,397		59,397
Adjusted Balance as at June 30, 2018	12,549,870	\$ 12,550	\$ 88,878,078	\$ (94,344,307)	\$ (5,453,679)
Stock-based compensation expense	-		1,213,996	-	1,213,996
Conversion of notes and accrued interest	10,731,669	10,731	11,794,102		11,804,833
Equity Units issued for cash, net	15,900,444	15,900	17,744,735	-	17,760,635
Shares relinquished by former officer	(303,392)	(303)	(394,107)	-	(394,410)
Issuance of common stock for cashless exercises of warrants from consultants and Series A Preferred Stock warrant holder	99,964	100	(100)	-	-
Net loss	-	-	-	(17,318,060)	(17,318,060)
Balance - June 30, 2019	38,978,555	\$ 38,978	\$ 119,236,704	\$ (111,662,367)	\$ 7,613,315

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

Relmada Therapeutics, Inc.
Consolidated Statements of Cash Flows
For the Years Ended June 30, 2019 and 2018

	<u>2019</u>	<u>2018</u>
Cash flows from operating activities		
Net loss	\$ (17,318,060)	\$ (8,960,852)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	4,870	2,627
Stock-based compensation	1,213,996	517,999
Amortization of deferred financing costs	661,168	1,029,183
Change in fair value of derivative liabilities	54,634	708,901
Fair value of shares relinquished	(394,410)	
Loss on promissory note extinguishment	3,774,468	
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	270,167	42,741
Other receivable	(169,363)	224,980
Lease payment receivable	64,486	59,319
Accounts payable	158,920	157,392
Accrued expenses	1,181,270	215,632
Net cash used in operating activities	<u>(10,497,854)</u>	<u>(6,002,078)</u>
Cash flows from investing activities		
Purchase of fixed assets	-	(12,391)
Net cash used in investing activities	<u>-</u>	<u>(12,391)</u>
Cash flows from financing activities		
Proceeds from promissory notes and warrants, net of fees	-	6,534,400
Proceeds from sale of equity units, net of fees	17,760,635	
Payment on notes payable	(285,170)	8,500
Net cash provided by financing activities	<u>17,475,465</u>	<u>6,542,900</u>
Net Increase in cash and cash equivalents	6,977,611	528,431
Cash and cash equivalents at beginning of the year	<u>2,238,943</u>	<u>1,710,512</u>
Cash and cash equivalents at end of the year	<u>\$ 9,216,554</u>	<u>\$ 2,238,943</u>

Relmada Therapeutics, Inc.
Consolidated Statements of Cash Flows (continued)
For the Years Ended June 30, 2019 and June 30, 2018

	2019	2018
Supplemental disclosure of cash flows information:		
Cash paid during the period for:		
Income taxes	\$ -	\$ -
Interest	\$ 5,933	\$ 2,559
Non-cash investing and financing transactions:		
Notes payable issued in connection with director and officer insurance policies	\$ 364,204	\$ 285,170
Derivative liabilities associated with issuance of promissory notes	\$ -	\$ 3,309,880
Issuance of warrants to promissory notes payable placement agent	\$ -	\$ 200,658
Issuance of warrants to holders of promissory notes payable	\$ -	\$ 1,268,832
Cashless exercise of warrants for common stock	\$ 100	\$ 18
Issuance of restricted stock for service	\$ -	\$ 4
Write off for derivative liability due to adoption of ASU 2017-11	\$ 59,397	\$ -
Conversion of promissory notes and accrued interest to common stock	\$ 8,030,365	\$ -

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

Relmada Therapeutics, Inc.
Notes to Consolidated Financial Statements

NOTE 1 - BUSINESS

Relmada is a clinical-stage, publicly traded biotechnology company focused on the development of d-methadone (dextromethadone, REL-1017), an N-methyl-D-aspartate (NMDA) receptor antagonist. d-methadone is a new chemical entity that potentially addresses areas of high unmet medical need in the treatment of central nervous system (CNS) diseases and other disorders.

Our lead product candidate, d-methadone, is a New Chemical Entity (NCE) being developed as a rapidly acting, oral agent for the treatment of depression and other potential indications. We have completed Phase 1 single and multiple ascending dose studies. A Phase 2 study in major depressive disorder is ongoing, with first patient dosed in June 2018 and last patient dosed in July 2019. We expect to have top line results in the second half of 2019.

In addition to the normal risks associated with a new business venture, there can be no assurance that the Company's research and development will be successfully completed or that any product will be approved or commercially viable. The Company is subject to risks common to companies in the biotechnology industry including, but not limited to, dependence on collaborative arrangements, development by the Company or its competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, and compliance with the Food and Drug Administration (FDA) and other governmental regulations and approval requirements.

NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation and Principles of Consolidation

The accompanying consolidated financial statements and related notes have been prepared in accordance with accounting principles generally accepted in the United States of America (U.S. GAAP). The consolidated financial statements include the Company's accounts and those of the Company's wholly-owned subsidiary. All significant intercompany accounts and transactions have been eliminated in consolidation.

Liquidity

As shown in the accompanying financial statements, the Company incurred negative operating cash flows of \$10,497,854 for the year ended June 30, 2019 and has an accumulated deficit of \$111,662,367 from inception through June 30, 2019. During the year ended June 30, 2019, the Company incurred non-recurring expenses of approximately \$1,600,000 related to the settlement with Najib Babul (see Note 12) and related legal fees.

Relmada has funded its past operations through equity raises and most recently in the year ended June 30, 2019 Relmada raised net proceeds from the sale of common stock and warrants of \$17,760,635. Further, the Company was able to reduce its debt obligations by converting \$8,030,365 of promissory notes and accrued interest into common stock.

In Note 2 of the notes to the Company's audited consolidated financial statements as of and for the year ended June 30, 2018, and subsequently in each of the Company's quarterly unaudited condensed consolidated financial statements, management stated that the Company had incurred significant losses, negative operating cash flows and as of those dates needed to raise additional funds to meet its obligations and sustain its operations. As a result, the Company concluded that there was substantial doubt as to the Company's ability to continue as a going concern.

Management believes that due to the following it has obtained sufficient funding to alleviate the probability of substantial doubt about the Company's ability to continue as a going concern for the next twelve months from the issuance of these consolidated financial statements. Of the above mentioned financings of \$17,760,635, the Company raised approximately \$10,900,000 in the fourth quarter through private placements of common stock and warrants, and subsequent to June 30, 2019, the Company raised approximately an additional \$975,000 through private placements of common stock and exercises of outstanding investor warrants, which resulted in the Company having approximately \$7,735,000 in cash and cash equivalents at September 23, 2019. Based on its budgeted cash flow requirements, the Company believes these funds are sufficient to fund its ongoing operations for at least one year after the issuance of these consolidated financial statements. The Company expects that the cash burn rate for the 12 months ended September 30, 2020, will be between \$5-6 million, which includes approximately \$2 million of discretionary research and development ("R&D") spending, as the data analysis on the Phase 2a clinical trial is completed and the planning and preparation for the next clinical trial is conducted. Regardless of the results of any ongoing clinical trial, we have control over our expenditures and have the ability to adjust spending accordingly based on the budgeted cash flow requirements developed and the excess cash on hand.

The results of the Company's ongoing clinical trial, when known, will impact the size and scope of any subsequent trials, and will affect the timing of additional financings through public or private sales of equity or debt securities or from bank or other loans or through strategic collaboration and/or licensing agreements. Any such expenditures related to any subsequent trials will not be incurred until such additional financing is raised. Further, additional financing related to subsequent trials does not affect the Company's conclusion that based on the cash on hand and the budgeted cash flow requirements, the Company has sufficient funds to maintain operations for the next twelve months from the issuance of these consolidated financial statements.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses for the reporting period. Actual results could differ from those estimates. The significant estimates are the valuation of derivative liabilities, stock-based compensation expenses and recorded amounts related to income taxes.

Cash and Cash Equivalents

The Company considers cash deposits and all highly liquid investments with a maturity of three months or less when purchased to be cash equivalents. The Company's cash deposits are held at two high-credit-quality financial institutions. The Company's cash deposits of \$9,216,600 at June 30, 2019 at these institutions exceed federally insured limits.

Patents

Costs related to filing and pursuing patent applications are recorded as general and administrative expense and expensed as incurred since recoverability of such expenditures is uncertain.

Fixed Assets

Fixed assets are stated at cost less accumulated depreciation. Fixed assets are comprised of computers and software. Depreciation is calculated using the straight-line method over the estimated useful life of the assets. Computers and software have an estimated useful life of three years. Furniture and fixtures have an estimated useful life of approximately seven years.

Derivatives

All derivatives are recorded at fair value on the balance sheet. The Company has determined fair values using market based pricing models incorporating readily available prices and or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (supported by little or no market activity) that requires judgment and estimates.

Relmada Therapeutics, Inc.
Notes to Consolidated Financial Statements

Fair Value of Financial Instruments

The Company's financial instruments primarily include cash, derivative liabilities and accounts payable. Due to the short-term nature of cash, other receivable and accounts payable the carrying amounts of these assets and liabilities approximate their fair value. Derivatives are recorded at fair value at each period end. Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants at the reporting date. The accounting guidance establishes a three-tiered hierarchy, which prioritizes the inputs used in the valuation methodologies in measuring fair value:

Fair value is defined as the price that would be received to sell an asset, or paid to transfer a liability, in an orderly transaction between market participants. A fair value hierarchy has been established for valuation inputs that gives the highest priority to quoted prices in active markets for identical assets or liabilities and the lowest priority to unobservable inputs. The fair value hierarchy is as follows:

Level 1 Inputs - Unadjusted quoted prices in active markets for identical assets or liabilities that the reporting entity has the ability to access at the measurement date.

Level 2 Inputs - Inputs other than quoted prices included in Level 1 that are observable for the asset or liability, either directly or indirectly. These might include quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active, inputs other than quoted prices that are observable for the asset or liability (such as interest rates, volatilities, prepayment speeds, credit risks, etc.) or inputs that are derived principally from or corroborated by market data by correlation or other means.

Level 3 Inputs - Prices or valuation techniques that require inputs that are both significant to the fair value measurement and unobservable (supported by little or no market activity).

Fair Value on a Recurring Basis

As required by Accounting Standard Codification (ASC) Topic No. 820 - 10 *Fair Value Measurement*, financial assets and liabilities are classified based on the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the fair value measurement requires judgment and may affect the valuation of the fair value of assets and liabilities and their placement within the fair value hierarchy levels. The estimated fair value of the derivative instruments resulting from equity offerings in May 2014 and June 2014 have a down-round protection provision that was calculated with the Black Scholes option pricing model. Sensitivity analysis for the Black-Scholes has many inputs and is subject to judgement which includes volatility. Volatility is based upon the Company's historical volatility and the expected term is based upon the expiration date of the warrants. The estimated fair value of the derivative instruments from the convertible promissory notes issued during the year ended June 30, 2018, which have a redemption feature was estimated using the Monte Carlo pricing model. The assumptions used in the valuation model at June 30, 2018 consider the probability of redemption, the length of time to maturity and the value of the redemption feature.

The Company's financial liabilities accounted for at fair value were all converted to equity during the year and as of June 30, 2019 there were no financial liabilities accounted for at fair value, See Note 7.

Income Taxes

The Company accounts for income taxes using the asset and liability method. Accordingly, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in the tax rate is recognized in income or expense in the period that the change is effective. Tax benefits are recognized when it is probable that the deduction will be sustained. A valuation allowance is established when it is more likely than not that all or a portion of a deferred tax asset will either expire before the Company is able to realize the benefit, or that future deductibility is uncertain. At June 30, 2019 and 2018, the Company had recorded a valuation allowance to the full extent of the Company's net deferred tax assets since the likelihood of realization of the benefit does not meet the more likely than not threshold.

The Company files a U.S. Federal income tax return and various state returns. Uncertain tax positions taken on our tax returns will be accounted for as liabilities for unrecognized tax benefits. The Company will recognize interest and penalties, if any, related to unrecognized tax benefits in general and administrative expenses in the statements of operations. There were no liabilities recorded for uncertain tax positions at June 30, 2019 and 2018. The open tax years, subject to potential examination by the applicable taxing authority, for the Company are from June 30, 2016 through June 30, 2019.

Research and Development

Research and development costs primarily consist of research contracts for the advancement of product development, salaries and benefits, stock-based compensation, and consultants. The Company expenses all research and development costs in the period incurred. The Company makes an estimate of costs in relation to clinical study contracts. The Company analyzes the progress of studies, including the progress of clinical studies and phases, invoices received and contracted costs when evaluating the adequacy of the amount expensed and the related prepaid asset and accrued liability.

Relmada Therapeutics, Inc.
Notes to Consolidated Financial Statements

Stock-Based Compensation

The Company measures the cost of employee services received in exchange for an award of equity instruments based on the grant-date fair value of the award. That cost is recognized over the period during which an employee is required to provide service in exchange for the award - the requisite service period. The grant-date fair value of employee share options is estimated using the Black-Scholes option pricing model adjusted for the unique characteristics of those instruments. Compensation expense for warrants granted to non-employees is determined by the fair value of the consideration received or the fair value of the equity instruments issued, whichever is more reliably measured, and is recognized over the service period. The expense is subsequently adjusted to fair value at the end of each reporting period until such warrants vest, and the fair value of such instruments, as adjusted, is expensed over the related vesting period. Adjustments to fair value at each reporting date may result in income or expense, depending upon the estimate of fair value and the amount of expense recorded prior to the adjustment. The Company reviews its agreements and the future performance obligation with respect to the unvested warrants for its vendors or consultants. When appropriate, the Company will expense the unvested warrants at the time when management deems the service obligation for future services has ceased.

Net Loss per Common Share

Basic net loss per common share attributable to common stockholders is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of common shares outstanding for the period, without consideration for common stock equivalents. Diluted net loss per common share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted-average number of common share equivalents outstanding for the period determined using the treasury-stock method. Dilutive common stock equivalents are comprised of Class A convertible preferred stock, Series A preferred stock, restricted stock awards, options and warrants to purchase common stock. For all periods presented, there is no difference in the number of shares used to calculate basic and diluted shares outstanding due to the Company's net loss position.

The potentially dilutive securities that would be anti-dilutive due to the Company's net loss are not included in the calculation of diluted net loss per share attributable to common stockholders. The anti-dilutive securities are as follows (in common stock equivalent shares):

	Year Ended June 30, 2019	Year Ended June 30, 2018
Common stock warrants	17,719,870	9,815,025
Common stock options	5,893,240	3,068,865
Total	<u>23,613,110</u>	<u>12,883,890</u>

Recent Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2016-02, "Leases" (Topic 842), whereby lessees will be required to recognize for all leases at the commencement date a lease liability, which is a lessee's obligation to make lease payments arising from a lease, measured on a discounted basis; and a right-of-use asset, which is an asset that represents the lessee's right to use, or control the use of, a specified asset for the lease term. A modified retrospective transition approach is required, applying the new standard to all leases existing at the date of initial application. An entity may choose to use either (1) its effective date or (2) the beginning of the earliest comparative period presented in the financial statements as its date of initial application. If an entity chooses the second option, the transition requirements for existing leases also apply to leases entered into between the date of initial application and the effective date. The entity must also recast its comparative period financial statement and provide the disclosures required by the new standard for the comparative periods. The Company adopted the new standard on July 1, 2019 and used the effective date as our date of initial application. Consequently, financial information will not be updated and the disclosures required under the new standard will not be provided for dates and periods before July 1, 2019. We are currently evaluating the impact that the guidance will have on our consolidated financial statements.

In July 2017, the FASB issued ASU No. 2017-11, *Earnings Per Share* (Topic 260); *Distinguishing Liabilities from Equity* (Topic 480); *Derivatives and Hedging* (Topic 815): (Part I) *Accounting for Certain Financial Instruments with Down Round Features*. These amendments simplify the accounting for certain financial instruments with down round features. The amendments require companies to disregard the down round feature when assessing whether the instrument is indexed to its own stock, for purposes of determining liability or equity classification. The Company elected to early adopt ASU 2017-11 effective October 1, 2018. As a result, the Company reversed \$59,397 of derivative liabilities recorded on the Company's books, as of July 1, 2018, into equity to reflect the results of this adoption as of the beginning of the fiscal year as required by this standard.

In June 2018, the FASB issued ASU 2018-07, *Compensation-Stock Compensation* (Topic 718): *Improvements to Non-employee Share-Based Payment Accounting*, which simplifies the accounting for share-based payments made to non-employees so the accounting for such payments is substantially the same as those made to employees. Under this ASU, share based awards to non-employees will be measured at fair value on the grant date of the awards, entities will need to assess the probability of satisfying performance conditions if any are present, and awards will continue to be classified according to ASC 718 upon vesting which eliminates the need to reassess classification upon vesting, consistent with awards granted to employees. The Company elected to early adopt ASU 2018-07 effective July 1, 2018. The adoption of this standard had no impact on the Company's consolidated financial statements.

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Notes to Consolidated Financial Statements

Subsequent Events

The Company's management reviewed all material events through the date the financial statements were issued for subsequent event disclosure consideration.

NOTE 3 - PREPAID EXPENSES

Prepaid expenses consisted of the following (rounded to nearest \$00):

	<u>June 30, 2019</u>	<u>June 30, 2018</u>
Rent	\$ -	\$ 9,200
Research and development	-	20,800
Insurance	451,500	345,700
Legal	7,500	10,000
Other	61,800	41,200
Total	<u>\$ 520,800</u>	<u>\$ 426,900</u>

NOTE 4 - FIXED ASSETS

Fixed assets consisted of the following (rounded to nearest \$00):

	<u>Useful lives</u>	<u>June 30, 2019</u>	<u>June 30, 2018</u>
Computer and software	3 years	\$ 16,700	\$ 16,700
Less: accumulated depreciation		(9,500)	(4,600)
Fixed assets, net		<u>\$ 7,200</u>	<u>\$ 12,100</u>

In June 2015, the Company entered into an Agreement of Lease (the Lease) for office space located at 275 Madison Avenue, 7th Floor, New York, New York 10016, its former corporate headquarter, with a third party. On March 10, 2016 and effective as of January 1, 2016, the Company entered into an Office Space License Agreement (the License) with Actinium Pharmaceuticals, Inc. (Actinium), with whom the Company shared two common board members until June 6, 2017, for the office space. The term of the License was three years from the effective date, with an automatic renewal provision. The cost of the License was approximately \$16,600 per month for Actinium, subject to customary escalations and adjustments. The Company recorded the license fees as other income in the consolidated statements of operations.

On June 8, 2017, the Company entered into an Amended and Restated License Agreement with Actinium. Pursuant to the terms of the agreement, Actinium will continue to license the furniture, fixtures, equipment and tenant improvements located in the office (FFE) for a license fee of \$7,529 per month until December 8, 2022. Actinium shall have at any time during the term of this agreement the right to purchase the FFE for \$496,914, less any previously paid license fees. The license of FFE qualifies as a sales-type lease. On June 8, 2017 the Company derecognized the underlying assets of \$493,452, recognized discounted lease payments receivable of \$397,049 using the discount rate of 8.38% and recognized loss on sales-type lease of fixed assets of \$96,403. As of June 30, 2019 and June 30, 2018, the balance of unearned interest income was approximately \$43,000 and 68,800 respectively.

The future minimum lease payments to be received under the lease for each of the fiscal years as of June 30 are as follows:

2020	90,348
2021	90,348
2022	90,348
2023	45,175
Total	<u>\$ 316,219</u>

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Notes to Consolidated Financial Statements

NOTE 5 - ACCRUED EXPENSES

Accrued expenses consisted of the following (rounded to nearest \$00):

	June 30, 2019	June 30, 2018
Research and development	\$ 563,400	\$ 10,400
Professional fees	98,400	173,600
Interest on promissory notes	-	371,600
Accrued vacation	96,700	48,000
Legal Settlement	500,000	-
Other	59,400	55,900
Total	\$ 1,317,900	\$ 659,500

NOTE 6 - NOTES PAYABLE

In June 2019, the Company entered into a note for approximately \$364,200 in conjunction with a renewal of its director and officer insurance policy. The interest rate was 3.09% per annum. The note matures on April 9, 2020.

In June 2018, the Company entered into a note for approximately \$285,200 in conjunction with a renewal of its director and officer insurance policy. The interest rate was 2.35% per annum. The note matured on April 9, 2019 and was repaid.

At June 30, 2019 and 2018, the note payable outstanding balances were approximately \$364,200 and \$285,200, respectively.

NOTE 7 - DERIVATIVE LIABILITIES

ASC Topic No. 815 - *Derivatives and Hedging* provides guidance on determining what types of instruments or embedded features in an instrument issued by a reporting entity can be considered indexed to its own stock for the purpose of evaluating the first criteria of the scope exception in the pronouncement on accounting for derivatives. These requirements can affect the accounting for warrants and convertible preferred instruments issued by the Company.

At June 30, 2018, the Company had warrants resulting from equity offerings in May 2014 and June 2014 that do not have fixed settlement provisions because their conversion and exercise prices may be lowered if the Company issues securities at lower prices in the future. The Company concluded that the instruments are not indexed to the Company's stock. These 2,574,570 warrants expired in the year ended June 30, 2019.

Until September 30, 2018, the Company followed ASC Topic No 815 and treated the warrants as derivative liabilities. In determining the fair value of the derivative liabilities, the Company used the Black-Scholes option pricing model at June 30, 2018.

As noted in Note 2, the Company elected to early adopt ASU 2017-11 and reversed the July 1, 2018 derivative liability in the amount of \$59,397 into equity effective October 1, 2018.

The following is a summary of the assumptions used in the valuation model at June 30, 2018:

	June 30, 2018
Market value of common stock on measurement date	\$ 1.01
Exercise price	\$ 7.50 and \$11.25
Risk free interest rate (1)	2.33%
Expected life in years	0.95
Expected volatility (2)	102%
Expected dividend yields (3)	None

(1) The risk-free interest rate was determined by management using the applicable Treasury Bill as of the measurement date.

(2) The historical trading volatility was determined by calculating the volatility of the Company's common stock.

(3) The Company does not expect to pay a dividend in the foreseeable future.

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Until October 18, 2018, the Company had promissory notes with a redemption feature that was not clearly and closely related to the host instrument and therefore was considered an embedded derivative which was bifurcated and recorded as a derivative liability. In determining the fair value of the derivative liabilities, the Company used the Monte-Carlo pricing model. The assumptions used in the valuation model considers the probability of redemption, the length of time to maturity and value of the redemption feature.

On October 12 and 18, 2018, the Company conducted closings on its private placement of securities. As a result of these closings, the outstanding promissory notes converted into common stock. The redemption feature associated with the promissory notes was valued on October 18, 2018 using the Black-Scholes model. The change in value of the derivative between July 1, 2018 and the October 18, 2018 was recorded as income. The notes were converted to common stock on October 18, 2018.

The Company had no financial liabilities accounted for at fair value on a recurring basis as of June 30, 2019.

The following table sets forth, by level within the fair value hierarchy, the Company's financial liabilities that were accounted for at fair value on a recurring basis as of June 30, 2018:

Description	Markets for Identical Assets (Level 1)	Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Carrying Value as of June 30, 2018
Derivative liability – warrant instruments	\$ -	\$ -	\$ 30,526	\$ 30,526
Derivative liabilities – embedded redemption feature of promissory notes	-	-	4,164,108	4,164,108
	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 4,194,634</u>	<u>\$ 4,194,634</u>

The following table sets forth a reconciliation of changes in the fair value of financial liabilities classified as level 3 in the fair value hierarchy for the year ended June 30, 2019 and 2018:

	Year ended	
	June 30, 2019	June 30, 2018
Beginning balance	\$ 4,194,634	\$ 175,853
Adoption of ASU 2017-11 – warrants	(59,397)	-
Fair value of derivative liabilities for redemption feature of promissory notes payable	-	3,309,880
Change in fair value of derivative liabilities	54,634	708,901
Extinguishment of derivative liabilities on conversion of promissory notes.	(4,189,871)	-
Ending balance	<u>\$ -</u>	<u>\$ 4,194,634</u>

NOTE 8 - PROMISSORY NOTES PAYABLE

During the year ended June 30, 2018 the Company issued two year Convertible Promissory Notes, (the Notes) and warrants, for aggregate gross proceeds of \$7,205,000, \$6,534,400 net of direct debt issuance costs. The Notes had a stated interest rate of 7% per annum.

In accordance with the terms of the Notes, as a result of financings in October 2018, the Convertible Promissory Notes were automatically converted into 10,731,669 shares of its common stock, with a fair value of \$11,804,833. As a result, on October 18, 2018, the Company incurred a loss on extinguishment of debt, a non-cash item, of \$3,774,468. This consisted of liabilities in the amount of \$8,030,365, which related to the promissory notes payable with a balance of \$3,317,625 (net of the unamortized discount on the notes of \$3,887,375), the accumulated interest amounting to \$522,869 and the associated derivative liability related to the redemption feature of \$4,189,871.

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Notes to Consolidated Financial Statements

NOTE 9 - STOCKHOLDERS' EQUITY

Common Stock

During the years ended June 30, 2019 and 2018, the Company issued 99,964 and 17,746 shares of common stock for cashless exercise of 100,014 and 17,770 warrants, respectively.

During the year ended June 30, 2019, the Company closed on private placements of securities pursuant to Unit Purchase Agreements and Subscription Agreements, each dated as shown below. The price per unit (comprising one common stock and a 5 year warrant to purchase 0.65 or 0.50 of a share of common stock) was \$0.90, \$1.40 or \$1.50. The Company issued an aggregate of 15,900,443 shares of common stock to investors in these closings, for net proceeds of \$17,839,656. Approximately \$79,000 of legal costs were incurred that were not allocated to the individual closings.

<u>Date of closing</u>	<u>Common Stock Issued</u>	<u>Warrants issued</u>	<u>Unit Price</u>	<u>Net proceeds</u>	<u>Warrant exercise price</u>	<u>Warrant coverage</u>
October 12, 2018	2,004,106	1,302,669	\$ 0.90	\$ 1,630,991	\$ 1.50	.65
October 18, 2018	1,640,334	1,066,218	\$ 0.90	\$ 1,287,007	\$ 1.50	.65
November 2, 2018	1,499,456	974,645	\$ 0.90	\$ 1,215,242	\$ 1.50	.65
December 5, 2018	1,338,775	870,200	\$ 0.90	\$ 1,083,307	\$ 1.50	.65
February 12, 2019	805,554	523,610	\$ 0.90	\$ 725,000	\$ 1.50	.65
March 27, 2019	714,285	357,142	\$ 1.40	\$ 1,000,000	\$ 2.25	.50
May 14, 2019	2,276,329	1,138,161	\$ 1.50	\$ 3,168,865	\$ 2.25	.50
June 14, 2019	2,451,654	1,225,824	\$ 1.50	\$ 3,274,331	\$ 2.25	.50
June 20, 2019	2,883,195	1,441,593	\$ 1.50	\$ 4,059,050	\$ 2.25	.50
June 28, 2019	286,756	143,377	\$ 1.50	\$ 395,863	\$ 2.25	.50
Total	15,900,444	9,043,439		\$ 17,839,656		

Approximately \$177,000 of the June 28 financing was in Other Receivable at June 30, 2019 and was received in July, 2019. The October 12, 2018 and October 18, 2018 financings represented an Equity Financing as defined in the Convertible Promissory Note agreement. As a result of the October 12, 2018 and October 18, 2018 financings, the Company's outstanding 7% Convertible Promissory Notes and accumulated interest converted into 10,731,669 shares of common stock.

During the years ended June 30, 2019 and 2018, the Company issued 0 and 3,750 shares of common stock for issuances of restricted common stocks, respectively.

Placement Agent Warrants

During the year ended June 30, 2019, the Company issued an aggregate of 1,429,584 warrants to the placement agent in connection with the closings. The agent warrants have an exercise price between \$0.99 and \$2.25, are non-cancellable, vest upon issuance and expire on the fifth anniversary of the warrant date of issuance. Warrants have a five year term and an aggregate fair value of approximately \$1,809,535 calculated using the Black-Scholes option-pricing model. Variables used in the Black-Scholes option-pricing model include: (1) discount rates between 1.74-3.09% (2) expected life of 5 years, (3) expected volatility between 100.7-103.4%, and (4) zero expected dividends.

Stock-based compensation - options

The Company uses the simplified method for share-based compensation to estimate the expected term for employee option awards for share-based compensation in its option-pricing model. Prior to the adoption of ASU 2018-07 on October 1, 2018, the Company used the contractual term for non-employee options to estimate the expected term, for share-based compensation in its option-pricing model.

On December 20, 2018, the Company granted various employees options to purchase a total of 2,700,000 shares of common stock. The options have a ten-year term and have an exercise price of \$1.15 and vest over 4 years. The options have an aggregate fair value of \$2,500,000 calculated using the Black-Scholes option-pricing model. Variables used in the Black-Scholes option-pricing model include: (1) discount rate of 2.69% (2) expected life of 6.25 years, (3) expected volatility of 102.3%, and (4) zero expected dividends.

On April 1, 2019, the Company granted various employees options to purchase a total of 150,000 shares of common stock. The options have a ten-year term and have an exercise price of \$1.76 and vest over 4 years. The options have an aggregate fair value of \$214,000 calculated using the Black-Scholes option-pricing model. Variables used in the Black-Scholes option-pricing model include: (1) discount rate of 2.37% (2) expected life of 6.25 years, (3) expected volatility of 101.5%, and (4) zero expected dividends.

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During the year ended June 30, 2018, the Company granted various employees options to purchase a total of 2,650,000 shares of common stock. The options have a ten-year term and have an exercise price ranging from \$0.80 to \$0.88 per share. 2,450,000 options vest at a rate of 6.25% each quarter over 4 years. 200,000 options vest on the accomplishment of a clinical trial event. During the year ended June 30, 2019 the company recorded approximately \$133,000 of compensation expense based on the probability of the clinical trial event occurring. The fair value of the options on the grant date ranges from \$0.65 to \$0.71 per share using the Black-Scholes Option pricing model.

A summary of the changes in options outstanding for the years ended June 30, 2019 and 2018 is as follows:

	Number of Shares	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding and expected to vest at June 30, 2017	559,972	\$ 6.41	6.7	\$ -
Granted	2,650,000	0.82	9.3	511,000
Forfeited	(141,107)	9.25	-	-
Outstanding and expected to vest at June 30, 2018	3,068,865	\$ 1.45	8.8	\$ 511,000
Granted	2,850,000	1.18	9.5	\$ 1,917,750
Forfeited	(25,625)	-	-	\$ -
Outstanding and expected to vest at June 30, 2019	5,893,240	\$ 1.29	8.6	\$ 4,668,153
Options exercisable at June 30, 2019	1,605,424	\$ 1.98	7.6	\$ 1,153,708

At June 30, 2019, the Company has unrecognized stock-based compensation expense of approximately \$3,380,000 related to unvested stock options over the weighted average remaining service period of 3.15 years. The weighted average fair value of options granted during the years ended June 30, 2019 and 2018 was approximately \$0.96 and \$0.66 per share, respectively, on the date of grant using the Black-Scholes option pricing model with the following assumptions:

	Year Ended June 30, 2019	Year Ended June 30, 2018
Risk free interest rate	2.37 to 2.69%	2.14 to 2.61%
Dividend yield	0%	0%
Volatility	101.5-102.3%	99.9-101.6%
Expected term (in years)	6.25	6.25

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Stock-based compensation – restricted common stock

A summary of the changes in outstanding restricted stocks during the years ended June 30, 2019 and 2018 is as follows:

	Number of Shares	Weighted Average Fair Value Per Share
Outstanding and expected to issue at June 30, 2017	8,750	\$ 15.25
Issued	(3,750)	\$ 15.25
Forfeited	(5,000)	\$ 15.25
Outstanding and vested at June 30, 2018	-	\$ -
Issued	-	\$ -
Forfeited	-	\$ -
Outstanding and vested at June 30, 2019	-	-

As of June 30, 2019 and 2018, all restricted stock shares are issued.

Warrants

A summary of the changes in outstanding warrants during the years ended June 30, 2019 and 2018 is as follows:

	Number of Shares	Weighted Average Exercise Price Per Share
Outstanding and vested at June 30, 2017	3,886,866	\$ 7.71
Issued	5,945,929	\$ 1.50
Exercised	(17,770)	\$ 0.001
Outstanding and vested at June 30, 2018	9,815,025	\$ 3.96
Issued	10,764,452	\$ 1.77
Exercised	(100,014)	\$ 0.001
Forfeited/Expired	(2,759,588)	4.74
Outstanding and vested at June 30, 2019	17,719,875	\$ 1.78

Included in the warrants outstanding at June 30, 2018 are 2,574,570 warrants with an exercise price that is subject to downward adjustment on the sale of equity at prices below their original exercise price. These 2,574,570 warrants expired in the year ended June 30, 2019.

On December 20, 2018, the Company granted 100,000 warrants to a contractor with exercise price of \$1.15, a 10-year term and immediate vesting. The warrants have an aggregated fair value of \$93,762 that was calculated using the Black-Scholes option-pricing model. Variables used in the Black-Scholes option-pricing model include: (1) discount rate of 2.69% (2) expected life of 6.25 years, (3) expected volatility of 102.3%, and (4) zero expected dividends.

On January 1, 2019, the Company granted 120,000 warrants to a contractor with exercise price of \$1.15, a 10-year term and quarterly vesting over four years vesting. The warrants have an aggregated fair value of \$112,183 that was calculated using the Black-Scholes option-pricing model. Variables used in the Black-Scholes option-pricing model include: (1) discount rate of 2.49% (2) expected life of 6.25 years, (3) expected volatility of 102.0%, and (4) zero expected dividends.

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On March 9, 2019, the Company granted 71,429 warrants to a consultant with exercise price of \$1.75, a 5-year term and immediate vesting. The warrants have an aggregated fair value of \$95,131 that was calculated using the Black-Scholes option-pricing model. Variables used in the Black-Scholes option-pricing model include: (1) discount rate of 2.42% (2) expected life of 5 years, (3) expected volatility of 102.0%, and (4) zero expected dividends.

During the year ended June 30, 2019, the Company issued an aggregate of 9,043,439 warrants to investors in connection with private placements, with a fair value of approximately \$11,420,300. The exercise price ranges from \$1.50 to \$2.25, vested upon issuance, are non-cancellable and expire on the fifth anniversary from issuance. Variables used in the Black-Scholes option-pricing model include: (1) discount rates of 1.74-3.09% (2) expected life of 5 years, (3) expected volatility of 100.7-103.4%, and (4) zero expected dividends.

During the year ended June 30, 2018, the Company issued an aggregate of 338,600 warrants to consultants for services rendered. The exercise price was determined on trading price of the Company's common stock at warrant issuance date and range from \$0.75 to \$1.65 per share. The warrants are non-cancellable, vest upon issuance or over the service period and expire on the tenth or the seventh anniversary of the date of issuance.

In addition, the Company issued an aggregate of 4,803,330 and 804,000 warrants to the holders of promissory notes payable and placement agent, respectively, during the year ended June 30, 2018. These warrants have exercise price from \$1.50 to \$1.65. The warrants are non-cancellable, vest upon issuance or over the service period and expire the seventh anniversary of the date of issuance

At June 30, 2019 and 2018, the Company has \$155,000 and \$81,000 unrecognized stock based compensation expense related to outstanding warrants. At June 30, 2019 and 2018, the aggregate intrinsic value of warrants vested and outstanding was approximately \$4,796,081 and \$215,000, respectively. During the years ended June 30, 2019 and June 30, 2018, the Company recorded approximately \$0 and \$50,000 of expenses from issuances of warrants.

Stock-based compensation by class of expense

The following summarizes the components of stock-based compensation expense which includes common stock, stock options, warrants and restricted stock in the consolidated statements of operations for the years ended June 30, 2019 and 2018 (rounded to nearest \$00) respectively:

	Year ended June 30, 2019	Year ended June 30, 2018
Research and development	215,900	\$ 62,500
General and administrative	998,100	455,500
Total	1,214,000	\$ 518,000

NOTE 10 - RELATED PARTY TRANSACTIONS

Advisory Firm

The Company had an Advisory and Consulting Agreement (the "Consulting Agreement") with Sandesh Seth, the Company's Chairman of the Board. Mr. Seth has substantial experience in, among other matters, business development, corporate planning, corporate finance, strategic planning, investor relations and public relations, and an expansive network of connections spanning the biopharmaceutical industry, accounting, legal and corporate communications professions. Mr. Seth will provide advisory and consulting services to assist the Company with strategic advisory services, assist in prioritizing product development programs per strategic objectives, assist in recruiting of key personnel and directors, corporate planning, business development activities, corporate finance advice, and assist in investor and public relations services. The Company agreed to pay Mr. Seth \$12,500 per month for his services on an ongoing basis. On June 6, 2017, Mr. Seth resigned from the Company to focus his attention on matters external to Relmada. The Company agreed to continue its advisory and consulting arrangement with Mr. Seth through December 31, 2017.

Consulting Agreement

On June 12, 2017, the Company and Maged Shenouda, a director of the Company, entered into a Consulting Agreement. Pursuant to the terms of the agreement, Mr. Shenouda assisted the Company with matters requested by the Company. Mr. Shenouda was paid a consulting fee of \$10,000 per month. The agreement was terminated effective December 31, 2017.

There were no related party transactions during the year ended June 30, 2019.

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NOTE 11 - INCOME TAXES

No provision or benefit for federal or state income taxes has been recorded because the Company has incurred net losses for all periods presented and has recorded a valuation allowance against its deferred tax assets.

The components of the Company's deferred tax assets are as follows at:

	June 30, 2019	June 30, 2018
Deferred tax assets:		
Federal net operating loss	\$ 21,807,000	\$ 17,801,000
Research and development tax credits	1,230,000	1,081,000
Accruals	206,000	13,000
Other	46,000	37,000
Less: valuation allowance	(23,289,000)	(18,932,000)
Total	<u>\$ -</u>	<u>\$ -</u>

The Company has maintained a full valuation allowance against its deferred tax assets at June 30, 2019 and 2018. A valuation allowance is required to be recorded when it is more likely than not that some portion or all of the net deferred tax assets will not be realized. Since the Company cannot be assured of realizing the net deferred tax asset, a full valuation allowance has been provided. The valuation allowance increased/(decreased) for the years ended June 30, 2019 and 2018, by approximately \$4,375,000 and \$(235,000), respectively. The deferred tax asset for net operating losses at June 30 2018 was adjusted with a corresponding offset to the 2018 valuation allowance.

At June 30, 2019 the Company had Federal, New York State and New York City net operating loss (NOL) carryforwards of approximately \$64,546,000, \$60,892,000 and \$60,509,000, which begin expiring in 2027, 2032 and 2032, respectively. Approximately \$19,075,000 Federal NOL can be carried forward indefinitely but is limited to 80% of future taxable income. The Company also has federal research and development tax credit carryforwards of approximately \$1,230,000 that will begin to expire in 2028. The Company's ability to use its NOL carryforwards may be limited if it experiences an "ownership change" as defined in Section 382 (Section 382) of the Internal Revenue Code of 1986, as amended. An ownership change generally occurs if certain stockholders increase their aggregate percentage ownership of a corporation's stock by more than 50 percentage points over their lowest percentage ownership at any time during the testing period, which is generally the three-year period preceding any potential ownership change. The Company has not completed an analysis to determine whether any such limitations have been triggered as of June 30, 2019.

A reconciliation of the statutory tax rate to the effective tax rate is as follows:

	Year Ended June 30, 2019	Year Ended June 30, 2018
Statutory federal income tax rate	21.0%	27.5%
State (net of federal benefit)	9.5%	6.0%
Non-deductible expenses	(6.3)%	(6.0)%
Impact of Tax Cuts and Jobs Act	-%	(71.6)%
Other	1.0%	
Change in valuation allowance	(25.2)%	(44.1)%
Effective income tax rate	<u>0%</u>	<u>0%</u>

The Company does not have any uncertain tax positions at June 30, 2019 and 2018 that would affect its effective tax rate. The Company does not anticipate a significant change in the amount of unrecognized tax benefits over the next twelve months. Because the Company is in a loss carryforward position, the Company is generally subject to US federal and state income tax examinations by tax authorities for all years for which a loss carryforward is available. If and when applicable, the Company will recognize interest and penalties as part of income tax expense.

On December 22, 2017, the Tax Cuts and Jobs Act (The Act) was enacted into law. The Act provides for significant changes to the U.S. Internal Revenue Code of 1986 that impact corporate taxation requirements, such as the reduction of the federal tax rate for corporations from 34% to 21%. As a result of the Tax Act, deferred tax assets decreased by approximately \$6,197,000, with an offsetting decrease to the valuation allowance. Shortly after the Tax Act was enacted, the SEC staff issued Staff Accounting Bulletin No. 118, "Income Tax Accounting Implications of the Tax Cuts and Jobs Act" ("SAB 118"), which provided guidance on accounting for the tax effects on the Tax Act. SAB 118 provided a one-year measurement period from the enacted date to complete accounting under ASC 740. In accordance with the expiration of the SAB 118 measurement period, we completed our accounting for tax effects of the Tax Act during fiscal 2019, with no adjustments recorded to the provisional amounts.

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NOTE 12 - COMMITMENTS AND CONTINGENCIES

License Agreements

Wongpung

On August 20, 2007, the Company entered into a License Development and Commercialization Agreement with Wongpung Mulsan Co, a shareholder of the Company. Wongpung has exclusive territorial rights in countries it selects in Asia to market up to two drugs the Company is currently developing and a right of first refusal (ROFR) for up to an additional five drugs that the Company may develop in the future as defined in more detail in the license agreement.

The Company received an upfront license fee of \$1,500,000 and will earn royalties of up to 12% of net sales for up to two licensed products it is currently developing. The licensing terms for the ROFR products are subject to future negotiations and binding arbitration. The terms of each licensing agreement will expire on the earlier of any time from 15 years to 20 years after licensing or on the date of commercial availability of a generic product to such licensed product in the licensed territory. The Company's current focus is on developing and marketing its products in the United States and not Asia.

Third Party Licensor

Based upon a prior acquisition, the Company assumed an obligation to pay a third party: (A) royalty payments up to 2% on net sales of licensed products that are not sold by sublicensee and (B) on each and every sublicense earned royalty payment received by licensee from its sublicensee on sales of license product by sublicensee, the higher of (i) 20% of the royalties received by licensee; or (ii) up to 2% of net sales of sublicensee. The Company will also make milestone payments of up to \$4 or \$2 million, for the first commercial sale of product in the field that has a single active pharmaceutical ingredient, and for the first commercial sale of product in the field of product that has more than one active pharmaceutical ingredient, respectively. As of June 30, 2019, the Company has not generated any revenue related to this license agreement.

Inturrisi / Manfredi

In January 2018, we entered into an Intellectual Property Assignment Agreement (the Assignment Agreement) and License Agreement (the "License Agreement" and together with the Assignment Agreement, the Agreements) with Dr. Charles E. Inturrisi and Dr. Paolo Manfredi (collectively, the Licensor). Pursuant to the Agreements, Relmada assigned its existing rights, including patents and patent applications, to d-methadone in the context of psychiatric use (the Existing Invention) to Licensor. Licensor then granted Relmada under the License Agreement a perpetual, worldwide, and exclusive license to commercialize the Existing Invention and certain further inventions regarding d-methadone in the context of other indications such as those contemplated above. In consideration of the rights granted to Relmada under the License Agreement, Relmada paid the Licensor an upfront, non-refundable license fee of \$180,000. Additionally, Relmada will pay Licensor \$45,000 every three months until the earliest to occur of the following events: (i) the first commercial sale of a licensed product anywhere in the world, (ii) the expiration or invalidation of the last to expire or be invalidated of the patent rights anywhere in the world, or (iii) the termination of the License Agreement. Relmada will also pay Licensor tiered royalties with a maximum rate of 2%, decreasing to 1.75%, and 1.5% in certain circumstances, on net sales of licensed products covered under the License Agreement. Relmada will also pay Licensor tiered payments up to a maximum of 20%, and decreasing to 17.5%, and 15% in certain circumstances, of all consideration received by Relmada for sublicenses granted under the License Agreement.

Leases

The Company incurred rent expense of approximately \$114,800, and \$95,500 for the years ended June 30, 2019 and 2018, respectively.

As of June 30, 2017, the Company changed its corporate headquarters to 750 Third Avenue, 9th Floor, New York, New York 10017 pursuant to a lease agreement with an initial monthly rent of \$8,294. The lease contract periods were for 6 month periods. The lease expired on January 1, 2019, at a monthly rent of \$9,454.

As of January 1, 2019, the Company changed its corporate headquarters to 880 Third Avenue, 12th Floor, New York, New York 10022 pursuant to a lease agreement with an initial monthly rent of \$7,500. The lease period is for one year.

Relmada Therapeutics, Inc.
Notes to Consolidated Financial Statements

Legal

From time to time, the Company may become involved in lawsuits and other legal proceedings that arise in the course of business. Litigation is subject to inherent uncertainties, and it is not possible to predict the outcome of litigation with total confidence. Except as disclosed below, the Company is currently not aware of any legal proceedings or potential claims against it whose outcome would be likely, individually or in the aggregate, to have a material adverse effect on the Company's business, financial condition, operating results, or cash flows.

Lawsuit Brought by Former Officer

In 2014, Relmada dismissed with prejudice its lawsuit against Najib Babul, which had sought to compel Dr. Babul, Relmada's former President, to account for questionable expenditures of Relmada funds made while Babul controlled the Company. Relmada's decision to end its claims was informed by the fact that Babul came forward with plausible explanations for some of the expenditures, and the fact that, because Babul was a former officer and director of Relmada being sued for his conduct in office, the Company was required to advance his expenses of the litigation; hence, Relmada was paying all the lawyers and consultants on both sides of the dispute. Relmada also agreed to reinstate certain stock purchase warrants in Babul's name, which had been cancelled during the pendency of the litigation, and offered Babul the right to exchange his shares in Relmada Therapeutics, Inc. (a Delaware corporation and subsidiary of the Company) for shares in the Company.

Babul has brought a second lawsuit against Relmada. Ruling on Relmada's Motion to Dismiss, the United States District Court for the Eastern District of Pennsylvania dismissed Babul's claims for breach of contract and intentional infliction of emotional distress, and left intact his claims for defamation, and wrongful use of civil process.

On February 6, 2019, the Company entered into a settlement agreement in which Babul relinquished his 303,392 shares in Relmada, signed a consulting contract and Relmada committed to a \$500,000 initial payment and four subsequent payments of \$250,000 on March 31, 2019, June 30, 2019, September 30, 2019 and December 31, 2019.

For accounting purposes, no fair value was attributed to the consulting agreement. The Company recorded a loss on settlement of \$1,105,590 included in the general and administrative expenses for the year ended June 30, 2019. The loss represents the total cash payments of \$1,500,000 less the fair value of the shares relinquished of \$394,410.

NOTE 13 - SUBSEQUENT EVENTS

In September 2019, 300,000 warrants with exercise price of \$1.50 were exercised, for net proceeds of \$450,000.

On September 23, 2019, the Company closed on private placements of equity securities pursuant to Share Purchase Agreements and Subscription Agreements, dated September 23, 2019. The price per share was \$1.75. The Company issued an aggregate of 300,431 shares of common stock in this closing, for net proceeds of \$525,750.

Exhibits

Certain of the agreements filed as exhibits to this Report contain representations and warranties by the parties to the agreements that have been made solely for the benefit of the parties to the agreement. These representations and warranties:

- may have been qualified by disclosures that were made to the other parties in connection with the negotiation of the agreements, which disclosures are not necessarily reflected in the agreements;
- may apply standards of materiality that differ from those of a reasonable investor; and
- were made only as of specified dates contained in the agreements and are subject to subsequent developments and changed circumstances.

Accordingly, these representations and warranties may not describe the actual state of affairs as of the date that these representations and warranties were made or at any other time. Investors should not rely on them as statements of fact.

Exhibit Number	Description
2.1	Share Exchange Agreement, dated May 20, 2014, by and among Camp Nine, Inc., Relmada Therapeutics, Inc., and the stockholders of Relmada Therapeutics, Inc. (incorporated by reference to Exhibit 2.1 of Relmada's Form 8-K filed with the SEC on May 27, 2014).
3.1	(i) Articles of Incorporation of Camp Nine, Inc. (incorporated by reference to Exhibit 3.1 of Relmada's Registration Statement on Form S-1 filed with the SEC on November 13, 2012).
	(ii) Certificate of Designation dated May 13, 2014 (incorporated by reference to Exhibit 4.1 to Relmada's Report on Form 8-K filed with the SEC on May 19, 2014).
	(iii) Nevada Certificate of Amendment to Articles of Incorporation of Camp Nine, Inc., effective May 30, 2014 (incorporated by reference to Exhibit 3.1 of Relmada's Form 8-K filed with the SEC on June 2, 2014).
	(iv) Nevada Certificate of Amendment to Articles of Incorporation of Camp Nine, Inc., effective July 8, 2014 (incorporated by reference to Exhibit 3.1 of Relmada's Form 8-K filed with the SEC on July 14, 2014).
3.2	(i) Amended and Restated Certificate of Incorporation of Relmada Therapeutics, Inc. (incorporated by reference to Exhibit 3.2(i) of Relmada's Form 8-K filed with the SEC on May 27, 2014).
	(ii) Amendment effective April 19, 2013 to Certificate of Incorporation of Relmada Therapeutics, Inc. (incorporated by reference to Exhibit 3.2(ii) of Relmada's Form 8-K filed with the SEC on May 27, 2014).
	(iii) Certificate of Amendment to Articles of Incorporation of Relmada Therapeutics, Inc. (incorporated by reference to Exhibit 3.1 of Relmada's Form 10-O filed with the SEC on February 13, 2015).
	(iv) Certificate of Change of Relmada Therapeutics, Inc. dated August 4, 2015 (incorporated by reference to Exhibit 3.1 of Relmada's Form 8-K filed with the SEC on August 10, 2015).
3.3	Second Amended and Restated Bylaws of Relmada Therapeutics, Inc. (incorporated by reference to Exhibit 3.2 of Relmada's Form 8-K filed with the SEC on November 25, 2015).
4.1	Form of Warrants to Purchase Common Stock issued in 2012 and 2013 in connection with Relmada Therapeutics, Inc. Series A Preferred Stock (incorporated by reference to Exhibit 4.1 of Relmada's Form 8-K filed with the SEC on May 27, 2014).
4.2	Form of Warrants to Purchase Common Stock issued in 2012 and 2013 in connection with Relmada Therapeutics, Inc. 8% Senior Subordinated Promissory Notes (incorporated by reference to Exhibit 4.2 of Relmada's Form 8-K filed with the SEC on May 27, 2014).
4.3	Form of B Warrant dated May __, 2014 issued to investors by Relmada Therapeutics, Inc. (incorporated by reference to Exhibit 4.4 of Relmada's Form 8-K filed with the SEC on May 27, 2014).
4.4	Form of B Warrant dated June 10, 2014 issued to investors by Camp Nine, Inc. (incorporated by reference to Exhibit 4.2 of Relmada's Form 8-K filed with the SEC on June 16, 2014).
4.5	Form of Convertible Promissory Note (incorporated by reference to Exhibit 4.1 of Relmada's Form 10-Q filed with the SEC on February 12, 2018).
4.6	Form of Warrant to Purchase Common Stock (incorporated by reference to Exhibit 4.2 of Relmada's Form 10-Q filed with the SEC on February 12, 2018).

Exhibit Number	Description
4.7	Form of 2018 Warrant (incorporated by reference to Exhibit 4.1 of Relmada's Form 10-Q filed with the SEC on November 13, 2018).
4.8	Form of 2019 Warrant (incorporated by reference to Exhibit 4.1 of Relmada's Form 10-Q filed with the SEC on May 15, 2019).
10.1	Agreement and Plan of Merger dated as of December 31, 2013 between Relmada Therapeutics, Inc. and Medeor, Inc. (incorporated by reference to Exhibit 10.1 of Relmada's Form 8-K filed with the SEC on May 27, 2014).
10.2	Non-Disclosure, Assignment of Inventions, Non-Solicitation and Non-Compete Agreement dated as of April 18, 2012 between Sergio Traversa and Relmada Therapeutics, Inc. (incorporated by reference to Exhibit 10.2 of Relmada's Form 8-K filed with the SEC on May 27, 2014).
10.3	Form of Unit Purchase Agreement dated May __, 2014 by and among Relmada Therapeutics, Inc. and the Purchasers party thereto (incorporated by reference to Exhibit 10.7 of Relmada's Form 8-K filed with the SEC on May 27, 2014).
10.4	Form of 2014 Unit Investor Rights Agreement dated _____, 2014 by and among Relmada Therapeutics, Inc. and the Investors party thereto (incorporated by reference to Exhibit 10.8 of Relmada's Form 8-K filed with the SEC on May 27, 2014).
10.5	Form of Subscription Agreement dated as of May 12, 2014 and May 15, 2014 by and among Relmada Therapeutics, Inc. and the Purchasers party thereto (incorporated by reference to Exhibit 10.9 of Camp Nine's Form 8-K filed with the SEC on May 27, 2014).
10.6	Indemnification Agreement dated July 10, 2012 between Relmada Therapeutics, Inc. and Sergio Traversa (incorporated by reference to Exhibit 10.10 of Relmada's Form 8-K filed with the SEC on May 27, 2014).
10.7	2012 Relmada Therapeutics, Inc. Stock Option and Equity Incentive Plan (incorporated by reference to Exhibit 10.11 of Relmada's Form 8-K filed with the SEC on May 27, 2014).
10.8	Unit Purchase Agreement, dated June 10, 2014, by and among Camp Nine, Inc. and signatories thereto (incorporated by reference to Exhibit 10.1 of Relmada's Form 8-K filed with the SEC on June 16, 2014).
10.9	Subscription Agreement, dated June 10, 2014, by and among Camp Nine, Inc. and signatories thereto (incorporated by reference to Exhibit 10.2 of Relmada's Form 8-K filed with the SEC on June 16, 2014).
10.10	Form of Investor Rights Agreement, dated June 10, 2014, by and among Camp Nine, Inc. and signatories thereto (incorporated by reference to Exhibit 10.3 of Relmada's Form 8-K filed with the SEC on June 16, 2014).
10.11	2014 Stock Option and Equity Incentive Plan (incorporated by reference to Exhibit 10.14 of Relmada's Form S-1/A filed with the SEC on December 9, 2014)
10.12	Agreement of Lease, dated June 9, 2015, by and between Relmada Therapeutics, Inc. and GP 275 Owner, LLC (incorporated by reference to Exhibit 99.1 of Relmada's Form 8-K filed with the SEC on June 15, 2015)
10.13	Director Agreement, dated July 14, 2015, by and between Charles J. Casamento and Relmada Therapeutics, Inc. (incorporated by reference to Exhibit 10.1 of Relmada's Form 8-K filed with the SEC on July 16, 2015)
10.14	Director Indemnity Agreement, dated July 14, 2015, by and between Charles J. Casamento and Relmada Therapeutics, Inc. (incorporated by reference to Exhibit 10.2 of Relmada's Form 8-K filed with the SEC on July 16, 2015)

Exhibit Number	Description
10.15	<u>Amended 2014 Stock Option and Equity Incentive Plan (incorporated by reference to Exhibit 10.1 of Relmada's Form 8-K filed with the SEC on August 7, 2015).</u>
10.16	<u>Form of Indemnification Agreement (incorporated by reference to Exhibit 10.2 of Relmada's Form 8-K filed with the SEC on August 7, 2015).</u>
10.17	<u>Amended and Restated Employment Agreement, dated August 5, 2015, by and between Relmada Therapeutics, Inc. and Sergio Traversa (incorporated by reference to Exhibit 10.4 of Relmada's Form 8-K filed with the SEC on August 7, 2015).</u>
10.18	<u>Advisory and Consulting Agreement, dated August 4, 2015, by and between Relmada Therapeutics, Inc. and Sandesh Seth (incorporated by reference to Exhibit 10.6 of Relmada's Form 8-K filed with the SEC on August 7, 2015).</u>
10.19	<u>Agreement dated, September 6, 2016, by and between Shreeram Agharkar and Relmada Therapeutics, Inc. (incorporated by reference to Exhibit 10.25 of Relmada's Form 10-K filed with the SEC on September 9, 2016).</u>
10.20	<u>Consulting Agreement, dated February 15, 2017, between Relmada Therapeutics, Inc. and MDB Consulting LLC. (incorporated by reference to Exhibit 10.20 of Relmada's Form 10-K filed with the SEC on September 28, 2017).</u>
10.21	<u>Assignment and Consent Agreement, dated June 6, 2017, among 275 Madison Avenue RPW 1 LLC, 275 Madison Avenue RPW 2, LLC, Actinium Pharmaceuticals, Inc. and Relmada Therapeutics, Inc. (incorporated by reference to Exhibit 10.21 of Relmada's Form 10-K filed with the SEC on September 28, 2017).</u>
10.22	<u>Lease Agreement, dated May 2, 2017, between Relmada Therapeutics, Inc. and Regus Management Group, LLC. (incorporated by reference to Exhibit 10.22 of Relmada's Form 10-K filed with the SEC on September 28, 2017).</u>
10.23	<u>Amended and Restated License Agreement, dated June 8, 2017, between Actinium Pharmaceuticals, Inc. and Relmada Therapeutics, Inc. (incorporated by reference to Exhibit 10.23 of Relmada's Form 10-K filed with the SEC on September 28, 2017).</u>
10.24	<u>Agreement, dated June 6, 2017, between Relmada Therapeutics, Inc. and Sandesh Seth. (incorporated by reference to Exhibit 10.24 of Relmada's Form 10-K filed with the SEC on September 28, 2017).</u>
10.25	<u>Consulting Agreement, dated June 12, 2017, between Relmada Therapeutics, Inc. and Maged Shenouda. (incorporated by reference to Exhibit 10.20 of Relmada's Form 10-K filed with the SEC on September 28, 2017).</u>
10.26	<u>Consulting Agreement Termination Agreement, dated November 13, 2017, between Relmada Therapeutics, Inc. and Maged Shenouda (incorporated by reference to Exhibit 10.1 of Relmada's Form 10-Q filed with the SEC on November 14, 2017).</u>

Exhibit Number	Description
10.27	License Agreement, dated January 16, 2018, between Relmada Therapeutics, Inc. Dr. Charles E. Inturrisi and Dr. Paolo Manfredi (incorporated by reference to Exhibit 10.1 of Relmada's Form 8-K filed with the SEC on January 19, 2018).
10.28	Intellectual Property Assignment Agreement, dated January 16, 2018, between Relmada Therapeutics, Inc. Dr. Charles E. Inturrisi and Dr. Paolo Manfredi (incorporated by reference to Exhibit 10.2 of Relmada's Form 8-K filed with the SEC on January 19, 2018).
10.29	Form of Note and Warrant Purchase Agreement (incorporated by reference to Exhibit 10.1 of Relmada's Form 10-Q filed with the SEC on February 12, 2018).
10.30	Offer Letter, Dated March 28, 2018, between Relmada Therapeutics, Inc. and Ottavio Vitolo (incorporated by reference to Exhibit 10.1 of Relmada's Form 10-Q filed with the SEC on May 14, 2018).
10.31	Indemnification Agreement, dated April 2, 2018, between Relmada Therapeutics, Inc. and Ottavio Vitolo (incorporated by reference to Exhibit 10.2 of Relmada's Form 10-Q filed with the SEC on May 14, 2018).
10.32	Third Amendment to the 2014 Stock Option and Equity Incentive Plan, as amended (incorporated by reference to Exhibit 10.3 of Relmada's Form 10-Q filed with the SEC on May 14, 2018).
10.33	Form of Unit Purchase Agreement among Relmada Therapeutics, Inc. and certain accredited investors (incorporated by reference to Exhibit 10.1 of Relmada's Form 10-Q filed with the SEC on November 13, 2018).
10.34	Form of Subscription Agreement among Relmada Therapeutics, Inc. and certain accredited investors (incorporated by reference to Exhibit 10.2 of Relmada's Form 10-Q filed with the SEC on November 13, 2018).
10.35	Form of Registration Rights Agreement among Relmada Therapeutics, Inc. and certain accredited investors (incorporated by reference to Exhibit 10.3 of Relmada's Form 10-Q filed with the SEC on November 13, 2018).
10.36	Lease Agreement, effective January 1, 2019, between Relmada Therapeutics, Inc. and 880 Third Avenue Tenant LLC (incorporated by reference to Exhibit 10.1 of Relmada's Form 10-Q filed with the SEC on February 13, 2019).
10.37	Settlement Agreement, dated February 6, 2019, among Najib Babul, Laidlaw & Company (UK) Ltd., Sandesh Seth, and Sergio Traversa (incorporated by reference to Exhibit 10.2 of Relmada's Form 10-Q filed with the SEC on February 13, 2019).
10.38	Consulting Agreement, effective March 25, 2019, between Relmada Therapeutics, Inc. and Najib Babul (incorporated by reference to Exhibit 10.3 of Relmada's Form 10-Q filed with the SEC on February 13, 2019).
10.39	Amendment No. 4 to the Relmada Therapeutics, Inc. 2014 Stock Option and Equity Incentive Plan, as amended (incorporated by reference to Exhibit 10.1 of Relmada's Form 10-Q filed with the SEC on May 15, 2019).
10.40	Form of Unit Purchase Agreement (incorporated by reference to Exhibit 10.2 of Relmada's Form 10-Q filed with the SEC on May 15, 2019).
10.41	Form of Subscription Agreement (incorporated by reference to Exhibit 10.3 of Relmada's Form 10-Q filed with the SEC on May 15, 2019).
10.42	Form of Registration Rights Agreement (incorporated by reference to Exhibit 10.4 of Relmada's Form 10-Q filed with the SEC on May 15, 2019).
10.43	Consulting Agreement, dated July 29, 2019, by and between Charles S. Ence and Relmada Therapeutics, Inc. (incorporated by reference to Exhibit 10.1 of Relmada's Form 8-K filed with the SEC on July 29, 2019).

Exhibit Number	Description
10.44	Indemnification Agreement, dated July 29, 2019, by and between Charles S. Ence and Relmada Therapeutics, Inc. (incorporated by reference to Exhibit 10.2 of Relmada's Form 8-K filed with the SEC on July 29, 2019).
10.45	Confidential Information and Invention Assignment Agreement, dated July 29, 2019, by and between Charles S. Ence and Relmada Therapeutics, Inc. (incorporated by reference to Exhibit 10.3 of Relmada's Form 8-K filed with the SEC on July 29, 2019).
21.1	List of Subsidiaries (incorporated by reference to Exhibit 21.1 of Relmada's Form 10-K filed with the SEC on September 9, 2014).
31.1*	Certification of Principal Executive Officer, pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial and Accounting Officer, pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Principal Executive Officer, pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Principal Financial and Accounting Officer, pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS *	XBRL Instance Document
101.SCH *	XBRL Taxonomy Schema
101.CAL *	XBRL Taxonomy Calculation Linkbase
101.DEF *	XBRL Taxonomy Definition Linkbase
101.LAB*	XBRL Taxonomy Label Linkbase
101.PRE *	XBRL Taxonomy Presentation Linkbase

* Filed herewith

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following person on behalf of the Registrant.

Dated: September 24, 2019

RELMADA THERAPEUTICS, INC.

By: /s/ Sergio Traversa
Sergio Traversa
Chief Executive Officer
(Duly Authorized Officer and
Principal Executive Officer)

By: /s/ Charles Ence
Charles Ence
Chief Financial Officer
(Duly Authorized Officer and
Principal Financial and Accounting Officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following person on behalf of the Registrant and in the capacities and on the dates indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Sergio Traversa</u> Sergio Traversa	Chief Executive Officer, and Director	September 24, 2019
<u>/s/ Charles Ence</u> Charles Ence	Chief Financial Officer	September 24, 2019
<u>/s/ Charles J. Casamento</u> Charles J. Casamento	Chairman of the Board	September 24, 2019
<u>/s/ Paul Kelly</u> Paul Kelly	Director	September 24, 2019
<u>/s/ Maged Shenouda</u> Maged Shenouda	Director	September 24, 2019

**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO 18U.S.C SECTION
1350 AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXELY ACT OF 2002**

I, Sergio Traversa, certify that:

1. I have reviewed this report on Form 10-K of Relmada Therapeutics, Inc. for the year ended June 30, 2019.
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiary, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Sergio Traversa

Sergio Traversa
Chief Executive Officer
(Principal Executive Officer)

Date: September 24, 2019

**CERTIFICATION OF PRINCIPAL FINANCIAL AND ACCOUNTING OFFICER PURSUANT TO 18U.S.C SECTION
1350 AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXELY ACT OF 2002**

I, Chuck Ence, certify that:

1. I have reviewed this report on Form 10-K of Relmada Therapeutics, Inc. for the year ended June 30, 2019.
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiary, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Chuck Ence

Chuck Ence
Chief Financial Officer
(Principal Financial and Accounting Officer)

Date: September 24, 2019

**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER, PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report of Relmada Therapeutics, Inc. a Nevada corporation (the "Company"), on Form 10-K for the year ended June 30, 2019 as filed with the Securities and Exchange Commission (the "Report"), I, Sergio Traversa, Chief Executive Officer of the Company, certify, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350), that to my knowledge:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m or 78o(d)); and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Sergio Traversa

Sergio Traversa
Chief Executive Officer
(Principal Executive Officer)

Date: September 24, 2019

**CERTIFICATION OF PRINCIPAL FINANCIAL AND ACCOUNTING OFFICER,
PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report of Relmada Therapeutics, Inc. a Nevada corporation (the "Company"), on Form 10-K for the year ended June 30, 2019 as filed with the Securities and Exchange Commission (the "Report"), I, Chuck Ence, Chief Financial Officer of the Company, certify, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350), that to my knowledge:

- (1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m or 78o(d)); and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Chuck Ence

Chuck Ence

Chief Financial Officer

(Principal Financial and Accounting Officer)

Date: September 24, 2019