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

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

For the transition period from July 1, 2019 to December 31, 2019

Commission file number: 000-55347

Relmada Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Nevada	**45-5401931**
(State or other jurisdiction of incorporation or organization)	(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:

Title of each class	**Name of Market Where Traded**
Common Stock ($.001 par value)	The NASDAQ Capital Market

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 June 30, 2019, the aggregate market value of the registrant's common stock held by non-affiliates of the registrant was $70,128,991 based on the closing price as reported on the NASDAQ.

As of March 26, 2020, there were 14,939,808 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 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 Report, which may cause our or our industry's actual results, levels of activity, performance or achievements to differ materially from those 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 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 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 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 Therapeutics, Inc. (Relmada, the Company, we or us) (a Nevada corporation), is a clinical-stage 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 (NCE) that potentially addresses areas of high unmet medical need in the treatment of central nervous system (CNS) diseases and other disorders.

On October 7, 2019, our application to list our common stock on the Nasdaq Capital Market was approved. On October 10, 2019, our common stock began trading on Nasdaq under our existing symbol, "RLMD."

On December 19, 2019, the Board of Directors of the Company approved a change to its end of fiscal year from June 30 to December 31. The change in fiscal year will become effective for the Company's 2020 fiscal year, which will begin January 1, 2020 and end December 31, 2020. Accordingly the Company is filing this transition report on Form 10-KT for the six-month period from July 1, 2019 through December 31, 2019 within the time period prescribed by the Securities and Exchange Commission.

Our lead product candidate, d-methadone, is an NCE being developed as a rapidly acting, oral agent for the treatment of depression and other potential indications. We have previously completed Phase 1 single and multiple ascending dose studies and on October 15, 2019 we reported top-line data from study REL-1017-202. This was a double-blind, placebo-controlled Phase 2 clinical trial evaluating the safety, tolerability and efficacy of two oral doses of REL-1017, 25 mg once a day and 50 mg once a day, as an adjunctive treatment in patients with major depressive disorder (MDD), who experienced an inadequate response to 1 to 3 adequate antidepressant treatments with an antidepressant medication.

In the REL-1017-202 study, 62 subjects, average age 49.2 years, with an average Hamilton Depression Rating Scale score of 25.3 and an average Montgomery-Asberg Depression Rating Scale (MADRS) score of 34.0 (severe depression), were randomized. Other demographic characteristics were balanced across all arms. After an initial screening period, subjects were randomized to one of three arms: placebo, REL-1017 25 mg or REL-1017 50 mg, in addition to stable background antidepressant therapy. Subjects in the REL-1017 treatment arms received one loading dose of either 75 mg (25 mg arm) or 100 mg (50 mg arm) of REL-1017. Subjects were treated inpatient for 7 days and discharged home at Day 9. They returned for follow-up visits at Day 14 and Day 21. Efficacy was measured on Days 2, 4 and 7 in the dosing period and on Day 14, one week after treatment discontinuation. 61 subjects received all treatment doses and were included in the per-protocol population (PPP) treatment analysis; 57 subjects completed all visits. All 62 randomized subjects were part of the intention-to-treat (ITT) analysis. No differences were observed between the ITT and PPP analyses and results.

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 an NMDA receptor antagonist can have potential applications in a number of disease indications which mitigates risk and offers significant upside.

Key findings:

We observed that subjects in both the REL-1017 25 mg and 50 mg treatment groups experienced statistically significant improvement on all efficacy measures tested as compared to subjects in the placebo group, including: the Montgomery-Asberg Depression Rating Scale (MADRS); the Clinical Global Impression – Severity (CGI-S) scale; the Clinical Global Impression – Improvement (CGI-I) scale; and the Symptoms of Depression Questionnaire (SDQ). SDQ scores demonstrated moderate effect size differences between subjects receiving REL-1017 and a placebo from day 4 to day 7 and demonstrated statistically significant differences and large effect size for both 25 mg (P=0.0066; d=0.9) and 50 mg (P=0.0014; d=1.1) arms at day 14.

The improvement on the MADRS appeared on Day 4 in both REL-1017 dose groups and continued through Day 7 and Day 14, seven days after treatment discontinuation, with P values< 0.03 and large effect sizes (a measure of quantifying the difference between two groups), ranging from 0.7 to 1.0. Similar findings emerged from the CGI-S and CGI-I scales.

MADRS: Analysis of Change from Baseline to Day 7 and to Day 14 ITT Population

	Day 2			Day 4			Day 7			Day 14		
	LS Means Difference	P-value	d	LS Means Difference	P-value	d	LS Means Difference	P-value	D	LS Means Difference	P-value	d
REL-1017 25mg vs Placebo	-1.9	0.4340	0.3	-7.9	0.0087	0.9	-8.7	0.0122	0.8	-9.4	0.0103	0.9
REL-1017 50mg vs Placebo	-0.3	0.9092	0.0	-7.6	0.0096	0.8	-7.2	0.0308	0.7	-10.4	0.0039	1.0

LS = Least Squares; d = Cohen's effect size

The study also supported the favorable tolerability profile of REL-1017, which was also observed in the Phase 1 studies. Subjects experienced mild and moderate adverse events (AEs), and no serious adverse events, without significant differences between placebo and treatment groups. The AEs observed in the Phase 2a clinical study were of the same nature as those observed in the Phase 1 clinical studies in d-Methadone, and there was no evidence of either treatment induced psychotomimetic and dissociative AEs or withdrawal signs and symptoms upon treatment discontinuation.

Key Upcoming Anticipated Milestones

We expect multiple key milestones over the next 12-18 months. These include:

- Presentation of full details of the Phase 2 data for REL-1017.
- Meeting with the U.S. Food and Drug Administration (FDA) in an End-of-Phase 2 meeting for the REL-1017 program at the end of the first half of 2020. We intend to discuss the registrational plan for REL-1017 as an adjunctive treatment of MDD.
- Start of pivotal studies for REL-1017 as an adjunctive treatment of MDD.
- Start of Phase 2 study in MDD. We plan to start Phase 2 MDD studies in the second half of 2020, though development plans may change based on the FDA's feedback and other factors.

Our Development Programs

Our four development projects are briefly described below:

d-Methadone (dextromethadone, REL-1017)

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.

In addition to the high failure rate, only one of the marketed products for depression, esketamine (marketed by Johnson and Johnson as Spravato), an in-clinic nasal spray treatment can demonstrate rapid antidepressant effects, while the other currently approved products can take two to four weeks to show activity. 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 and never officially approved by FDA for the treatment of depression and the single isomer esketamine can lift depression in many patients within hours. However, we believe it is unlikely that ketamine or esketamine will become practical treatments for most cases of depression. They must be administered through intravenous infusion or intranasally, requiring a hospital or clinic 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, hepatoxicity. Ketamine and esketamine also have not been thoroughly studied for long-term safety and effectiveness.

d-Methadone Overview and Mechanism of Action

d-Methadone's mechanism of action, as a low affinity, non-competitive NMDA channel blocker or antagonist, is fundamentally differentiated from most 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 and esketamine but potentially lacking its adverse side effects, d-methadone is being developed as a rapidly acting, oral agent for the treatment of depression and potentially other CNS 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-superimposable (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.

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, at the currently therapeutic doses used in development is virtually inactive as an opioid while maintaining affinity for the NMDA receptor.

NMDA receptors are present in many parts of the CNS 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 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 2 study of REL-1017 as an adjunctive treatment in patients with MDD, who experienced an inadequate response to 1 to 3 adequate antidepressant treatments with an antidepressant medication.

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 our 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 induced statistically significant decrease of 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 further assess the antidepressant-like effect of d-methadone 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 hours 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 induced a significant increase of the time male rats spent engaged in sniffing female urine compared to vehicle group. Similarly, a single dose of d-methadone produced a statistically significant increase of 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 open field. In contrast, neither ketamine nor d-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 esketamine.

Phase 2 Study for d-Methadone

Combined with the results of our Phase 1 studies, the encouraging results of in vivo and in vitro studies supported further evaluation of d-methadone. We submitted an Investigational New Drug (IND) application for REL-1017 to the FDA and proposed REL-1017-202 Phase 2 study of REL-1017 as an adjunctive treatment in MDD, 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, Relmada 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 as adjunctive treatment in adults 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.

On October 15, 2019, we reported top-line data from our Phase 2 study of d-methadone in adults with major depressive disorder. Subjects in both dose groups experienced statistically significant improvement of their depression compared to subjects in the placebo group on all efficacy measures, including: the Montgomery-Asberg Depression Rating Scale (MADRS); the Clinical Global Impression – Severity (CGI-S) scale; the Clinical Global Impression – Improvement (CGI-I) scale; and the Symptoms of Depression Questionnaire (SDQ). The improvement on the MADRS appeared on Day 4 in both REL-1017 dose groups and continued through Day 7 and Day 14, seven days after treatment discontinuation, with P values < 0.03 and large effect sizes (a measure of quantifying the difference between two groups), ranging from 0.7 to 1.0. Similar findings emerged from the CGI-S and CGI-I scales. The study also confirmed the favorable safety and tolerability profile of d-methadone, which was also observed in the Phase 1 studies. Subjects experienced mild and moderate adverse events (AEs), and no serious adverse events, without significant differences between placebo and treatment groups. There was no evidence of either treatment induced psychotomimetic and dissociative AEs or withdrawal signs and symptoms upon treatment discontinuation.

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

In addition to developing d-methadone as an adjunctive treatment of MDD, we are planning to evaluate the utility of d-methadone as a front line monotherapy treatment for MDD.

Additionally, other indications that Relmada may explore in the future, include, 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.

Our Corporate History and Background

We are a clinical-stage, publicly traded biotechnology company developing NCEs and 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 product candidates 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 $8,196,600 and $10,509,000 for the six months ended December 31, 2019 and 2018, respectively and $17,318,000 and $8,960,900 for the years ended June 30, 2019 and 2018, respectively. At December 31, 2019, we have an accumulated deficit of approximately $119,858,900.

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 CNS diseases. 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 our priority program. As the drug d-methadone is a NCE, the regulatory pathway required to support and NDA submission will consist of conducting a full clinical development program. 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.

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 us. 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.

The depression treatment market is segmented on the basis of antidepressants drugs, devices, and therapies. Antidepressants are the largest and most popular market segment. 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), Zulresso (Sage) and Spravato (Johnson & Johnson).

Intellectual Property Portfolio and Market Exclusivity

We have secured three Orphan Drug Designations from the FDA for d-methadone for "the treatment of postherpetic neuralgia. 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 over fifty US and foreign filed and issued 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:

d-Methadone:

U.S. Patent No. 9,468,611 issued on 10/18/2016 (filed 3/14/2013), "d-Methadone for the Treatment of Psychiatric Symptoms." Licensed to Relmada. Estimated expiry in 2033.

U.S. Patent No. 9,855,226 issued on 1/2/2018 (filed 7/7/2016), "d-Methadone for the Treatment of Psychiatric Symptoms." Licensed to Relmada. Estimated expiry in 2033.

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." Licensed to Relmada. Estimated expiry in 2033.

European Patent No. 2,906,209 granted on 6/20/2018 (filed 9/25/2013), "d-Methadone for the Treatment of Psychiatric Symptoms." Licensed to Relmada. Estimated expiry in 2033.

Australian Patent Application No. 2017276189 (filed 9/25/2013), "d-Methadone for the Treatment of Psychiatric Symptoms." Licensed to Relmada.

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

Chinese Patent No. ZL201380061197.3 issued on 9/14/2019 (filed 9/25/2013), “d-Methadone for the Treatment of Psychiatric Symptoms.” Licensed to Relmada.

Hong Kong Patent Application No. 16101841.1 (filed 9/25/2013), “d-Methadone for the Treatment of Psychiatric Symptoms.” Licensed to 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.” Licensed to Relmada.

Mexican Patent Application No. 2015/006720 (filed 9/25/2013), “d-Methadone for the Treatment of Psychiatric Symptoms.” Licensed to Relmada.

South Korean Patent No. 1969667 issued 4/10/2019 (filed 9/25/2013), “d-Methadone for the Treatment of Psychiatric Symptoms.” Licensed to Relmada.

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.”

Australian Patent Application No. 2018215056 (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.” Licensed to Relmada.

Brazilian Patent Application No. BR112019015286-5 (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.” Licensed to Relmada.

Canadian Patent Application No. 3052273 (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.” Licensed to Relmada.

Chinese Patent Application No. 201880020508.4 (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.” Licensed to Relmada.

EP Patent Application No. 18706021.5 (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.” Licensed to Relmada.

Indian Patent Application No. 201917033638 (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.” Licensed to Relmada.

Japanese Patent Application No. (appl’n no. not yet assigned) (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.” Licensed to Relmada.

Mexican Patent Application No. 2019/009038 (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." Licensed to Relmada.

South Korean Patent Application No. 2019-7025398 (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." Licensed to Relmada.

U.S. Provisional Patent Application No. 62/852,537 (filed 5/24/2019), "Dextromethadone for the Prevention and Treatment of Diseases and Conditions in Asian Subjects." Licensed to Relmada.

U.S. Provisional Patent Application No. 62/798,709 (filed 1/31/2019), "Structurally Modified Opioids for the Prevention and Treatment of Diseases and Conditions," Licensed to Relmada.

International (PCT) Patent Application No. PCT/US2019/055590 (filed 10/10/2019), "Structurally Modified Opioids for the Prevention and Treatment of Diseases and Conditions," Licensed to Relmada.

Below are patents owned by the Company, but not currently in development:

Levorphanol:

US Patent No. 9,125,833, filed 4/26/08, granted on 9/8/15. Multimodal Abuse Resistant and Extended Release Opioid Formulations. Owned by Relmada. Estimated expiry in 2029. This patent may cover 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.

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

U.S. 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.

EP Patent Application No. 16158311.7 filed 2/26/10, Extended Release Oral Pharmaceutical. Owned by Relmada. Currently pending.

Buprenorphine:

U.S. Patent application 12/988,209 (filed 3/9/2009), "Oral Pharmaceutical Compositions of Buprenorphine and Method of Use." Owned by Relmada.

U.S. Patent Application No. 13/229,505 (filed 9/9/2011), "Oral Pharmaceutical Compositions of Buprenorphine." Owned by Relmada.

U.S. Patent Application No. 15/057,358 (filed 3/1/2016), "Oral Pharmaceutical Compositions of Buprenorphine." Owned by Relmada.

EP Patent Application No. 9719755.2 (filed 3/9/2009), "Oral Pharmaceutical Compositions of Buprenorphine and Method of Use." Owned by Relmada.

EP Patent Application No. 09841608.4 (filed 9/28/2009), "Modified Release Pharmaceutical Compositions of Buprenorphine." Owned by Relmada.

Mepivacaine:

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 2031.

Chinese Patent No. ZL201180027559.8 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 2031.

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 2031.

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 No. 2016259348 issued 2/21/2019 (filed 4/13/2011), "Dermal Pharmaceutical Compositions of 1-Methyl-2,6-Pipecoloxylidide and Method of Use." Owned by Relmada.

European Patent No. 2557924 issued 6/12/2019 (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. 10-2018-7017167 (filed 4/13/2011), “Dermal Pharmaceutical Compositions of 1-Methyl-2,6-Pipecoloxylidide and Method of Use.” Owned by Relmada.

Chinese Patent Application No. 20171323695.0 (filed 4/13/2011), “Dermal Pharmaceutical Compositions of 1-Methyl-2,6-Pipecoloxylidide and Method of Use.” Owned by Relmada.

Hong Kong Patent Application No. 18102952.2 (filed 4/13/2011), “Dermal Pharmaceutical Compositions of 1-Methyl-2,6-Pipecoloxylidide and Method of Use.” Owned by Relmada.

d-Methadone License Agreement

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 Assignment Agreement, we assigned our existing rights, including patents and patent applications, to d-methadone in the context of psychiatric use to Licensor, and pursuant to the License Agreement, Licensor then granted us an exclusive, perpetual, worldwide license under the assigned intellectual property rights as well as patents and know-how covering new inventions developed by Licensor and relating to d-methadone in neurological and other uses, to develop and commercialize d-methadone in all fields of use. The License Agreement also grants to us rights in all future inventions developed by Licensor, whether or not in collaboration with us, that relate in any way to d-methadone or the use thereof. The License Agreement was amended in December 2019 to modify certain termination rights relating to the Chief Executive Officer, which are described further below.

In consideration of the rights granted to us under the License Agreement, we paid Licensor an upfront license fee of $180,000. Additionally, we are required to pay Licensor a quarterly license maintenance fee of $45,000 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. We will also pay Licensor royalties in the very low single digits on net sales of licensed products covered by the licensed intellectual property rights, including future licensed products, subject to certain reductions following expiration of the patent rights covering the licensed products, and a percentage of all consideration received by us for sublicenses granted under the License Agreement ranging from twenty percent down to the mid-teens, depending on the extent of patent coverage of the licensed products. We will be required to pay royalties and sublicensing revenue to Licensor as long as we continue to receive income derived from the intellectual property rights licensed to us under the License Agreement.

If we develop any new inventions relating to d-methadone, we are required to do so in collaboration with Licensor, and to file patents covering such inventions jointly in the name of the Company and Licensor. All such future inventions or patents shall be jointly owned by us and Licensor, and will be included in and subject to the financial and other terms of the License Agreement.

The License Agreement includes standard termination rights for Licensor in the event of our insolvency, challenge of the licensed patents and uncured material breach of our obligations under the License Agreement. In addition, the License Agreement contains certain "Key Man" provisions such that Licensor may terminate the License Agreement if we terminate the employment of our Chief Executive Officer Dr Sergio Traversa for any reason other than for specified causes determined by a majority of our Board of Directors (including fraud, gross negligence, unauthorized use of our confidential information, conduct including harassment or discrimination, breach of fiduciary duty or uncured material breach), or if we (a) substantially modify Dr Traversa's job responsibilities or decision-making rights in connection with the development and commercialization of d-methadone, (b) remove him from the role of Chief Executive Officer other than in connection with a permitted change-of-control transaction, (c) materially reduce his compensation, or (d) assign or transfer our rights under the License Agreement or the d-methadone intellectual property without Dr Traversa's consent, in each case (termination or the events in (a) through (d)) during the period commencing on the effective date and ending on the later of five years from the original effective date of the License Agreement or December 31, 2022 (the "Key Man Term"). The December 2019 amendment to the License Agreement made certain clarifications to the nature of a termination for Cause, including to clarify that termination due to Dr Traversa's death or disability does not give Licensor the right to terminate the License Agreement.

Wonpung License Agreement

In 2007, we entered into a License Development and Commercialization Agreement with Wonpung Mulsan Co (Wonpung), a shareholder of ours. Wonpung has exclusive territorial rights in countries it selects in Asia to market up to two drugs we are currently developing, as well as a right of first refusal (ROFR) for up to an additional five drugs that we may develop in the future and selected by Wonpung, as defined in more detail in the license agreement. In January 2018, Wonpung exercised its ROFR with respect to d-methadone for South Korea, Japan, the People's Republic of China, Taiwan, Singapore and Hong Kong. Wongpung and the Company would have to agree to terms of a license agreement for these areas in order for Wongpung to commence development under the ROFR. As of March 2020, no discussions are active between the Company and Wongpung.

We 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 we are currently developing. The licensing terms for products for which Wonpung may exercise the ROFR will be subject to future negotiations on a product-by-product basis, and are subject to binding arbitration if we are unable to agree upon the licensing terms. 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. Our current focus is on developing and marketing our products in the United States and not Asia.

Key Strengths

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

- Compelling lead product opportunity, d-methadone completed Phase 2a trial for the adjunctive treatment of MDD, including patients with TRD.
- Successful Phase 1 safety studies of d-methadone and strong clinical activity signal in depression established in three independent animal models.
- Potential in additional multiple indications in underserved markets with large patient population, such as MDD, other affective disorders, and cognitive disorders.
- 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, and University of Pennsylvania.
- Substantial IP portfolio and market protection: approved and filed patent applications provide coverage beyond 2030. In addition, some of our drugs, including d-methadone 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 considerable 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.

Government Regulation

Government authorities in the United States, at the federal, state and local level, and in other countries and jurisdictions extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting, and import and export of pharmaceutical products. The processes for obtaining regulatory approvals in the United States and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources.

FDA Approval Process

In the United States, pharmaceutical products are subject to extensive regulation by the FDA. The Federal Food, Drug, and Cosmetic Act (FD&C Act) and other federal and state statutes and regulations govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling and import and export of pharmaceutical products. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending new drug applications (NDAs), warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties and criminal prosecution.

Pharmaceutical product development for a new product or certain changes to an approved product in the U.S. typically involves preclinical laboratory and animal tests, the submission to FDA of an investigational new drug application (IND) which must become effective before clinical testing may commence, and adequate and well-controlled clinical trials to establish the safety and effectiveness of the drug for each indication for which FDA approval is sought. Satisfaction of FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity and novelty of the product or disease.

Preclinical tests include laboratory evaluation of product chemistry, formulation and toxicity, as well as animal trials to assess the characteristics and potential safety and efficacy of the product. The conduct of the preclinical tests must comply with federal regulations and requirements, including good laboratory practices. The results of preclinical testing are submitted to FDA as part of an IND along with other information, including information about product chemistry, manufacturing and controls, and a proposed clinical trial protocol. Long-term preclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted. A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. If FDA has neither commented on nor questioned the IND within this 30-day period, the clinical trial proposed in the IND may begin. Clinical trials involve the administration of the investigational new drug to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted: (i) in compliance with federal regulations; (ii) in compliance with good clinical practice, or GCP, an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators and monitors; as well as (iii) under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to FDA as part of the IND.

FDA may order the temporary, or permanent, discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. The study protocol and informed consent information for patients in clinical trials must also be submitted to an institutional review board (IRB) for approval. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions.

Clinical trials to support NDAs for marketing approval are typically conducted in three sequential phases, but the phases may overlap. In Phase 1, the initial introduction of the drug into healthy human subjects or patients, the drug is tested to assess metabolism, pharmacokinetics, pharmacological actions, side effects associated with increasing doses, and, if possible, early evidence of effectiveness. Phase 2 usually involves trials in a limited patient population to determine the effectiveness of the drug for a particular indication, dosage tolerance and optimum dosage, and to identify common adverse effects and safety risks. If a drug demonstrates evidence of effectiveness and an acceptable safety profile in Phase 2 evaluations, Phase 3 trials are undertaken to obtain the additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit FDA to evaluate the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the drug. In most cases, FDA requires two adequate and well-controlled Phase 3 clinical trials to demonstrate the efficacy of the drug. A single Phase 3 trial with other confirmatory evidence may be sufficient in rare instances, such as where the study is a large multicenter trial demonstrating internal consistency and a statistically very persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity or prevention of a disease with a potentially serious outcome and confirmation of the result in a second trial would be practically or ethically impossible.

The manufacturer of an investigational drug in a Phase 2 or 3 clinical trial for a serious or life-threatening disease is required to make available, such as by posting on its website, its policy on evaluating and responding to requests for expanded access.

After completion of the required clinical testing, an NDA is prepared and submitted to FDA. FDA approval of the NDA is required before marketing of the product may begin in the U.S. The NDA must include the results of all preclinical, clinical and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture and controls. The cost of preparing and submitting an NDA is substantial. The submission of most NDAs is additionally subject to a substantial application user fee, and the applicant under an approved NDA is also subject to an annual program fee for each prescription product. These fees are typically increased annually. Sponsors of applications for drugs granted Orphan Drug Designation are exempt from these user fees.

FDA has 60 days from its receipt of an NDA to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. Once the submission is accepted for filing, FDA begins an in-depth review. FDA has agreed to certain performance goals in the review of NDAs to encourage timeliness. Applications for most standard review drug products are reviewed within twelve months from submission of NDAs for new molecular entities (NMEs) and ten months from submission of NDAs for non-NMEs. Priority review can be applied to drugs that FDA determines offer major advances in treatment or provide a treatment where no adequate therapy exists. The review process for both standard and priority review may be extended by FDA for three additional months to consider certain late-submitted information or information intended to clarify information already provided in the submission.

FDA may also refer applications for novel drug products, or drug products that present difficult questions of safety or efficacy, to an outside advisory committee – typically a panel that includes clinicians and other experts – for review, evaluation and a recommendation as to whether the application should be approved. FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations.

Before approving an NDA, FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, FDA will inspect the facility or the facilities at which the drug is manufactured. FDA will not approve the product unless compliance with current good manufacturing practices (cGMPs) is satisfactory and the NDA contains data that provide substantial evidence that the drug is safe and effective in the indication studied.

After FDA evaluates the NDA and the manufacturing facilities, it issues either an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing, or information, in order for FDA to reconsider the application. If, or when, those deficiencies have been addressed to FDA's satisfaction in a resubmission of the NDA, FDA will issue an approval letter. FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. As a condition of NDA approval, FDA may require a risk evaluation and mitigation strategy (REMS) to help ensure that the benefits of the drug outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use (ETASU). ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring and the use of patient registries. The requirement for a REMS can materially affect the potential market and profitability of the drug. Moreover, product approval may require substantial post-approval testing and surveillance to monitor the drug's safety or efficacy. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or NDA supplement before the change can be implemented. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and FDA uses the same procedures and actions in reviewing NDA supplements as it does in reviewing NDAs.

Fast Track Designation

FDA is required to facilitate the development, and expedite the review, of drugs that are intended for the treatment of a serious or life-threatening disease or condition for which there is no effective treatment and which demonstrate the potential to address unmet medical needs for the condition. Under the Fast Track program, the sponsor of a new drug candidate may request that FDA designate the drug candidate for a specific indication as a Fast Track drug concurrent with, or after, the filing of the IND for the drug candidate. FDA must determine if the drug candidate qualifies for Fast Track Designation within 60 days of receipt of the sponsor's request.

If a submission is granted Fast Track Designation, the sponsor may engage in more frequent interactions with FDA, and FDA may review sections of the NDA before the application is complete. This rolling review is available if the applicant provides, and FDA approves, a schedule for the submission of the remaining information and the applicant pays applicable user fees. However, FDA's time period goal for reviewing an application does not begin until the last section of the NDA is submitted. Additionally, Fast Track Designation may be withdrawn by FDA if FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

Orphan Drugs

Under the Orphan Drug Act, FDA may grant Orphan Drug Designation to drugs intended to treat a rare disease or condition – generally a disease or condition that affects fewer than 200,000 individuals in the U.S. Orphan Drug designation must be requested before submitting an NDA. After FDA grants Orphan Drug Designation, the generic identity of the drug and its potential orphan use are disclosed publicly by FDA. Orphan Drug Designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. The first NDA applicant to receive FDA approval for a particular active ingredient to treat a particular disease with FDA Orphan Drug Designation is entitled to a seven-year exclusive marketing period in the U.S. for that product, for that indication. During the seven-year exclusivity period, FDA may not approve any other applications to market the same drug for the same disease, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity. Orphan drug exclusivity does not prevent FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition. Among the other benefits of Orphan Drug Designation are tax credits for certain research and an exemption from the NDA application user fee.

Disclosure of Clinical Trial Information

Sponsors of clinical trials of FDA regulated products, including drugs, are required to register and disclose certain clinical trial information. Information related to the product, patient population, phase of investigation, study sites and investigators, and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to discuss the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed in certain circumstances for up to two years after the date of completion of the trial. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs.

Pediatric Information

Under the Pediatric Research Equity Act (PREA), NDAs or supplements to NDAs must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. FDA may grant full or partial waivers, or deferrals, for submission of data. With certain exceptions, PREA does not apply to any drug for an indication for which orphan designation has been granted.

The Best Pharmaceuticals for Children Act (BPCA) provides NDA holders a six-month extension of any exclusivity – patent or nonpatent – for a drug if certain conditions are met. Conditions for exclusivity include FDA's determination that information relating to the use of a new drug in the pediatric population may produce health benefits in that population, FDA making a written request for pediatric studies, and the applicant agreeing to perform, and reporting on, the requested studies within the statutory timeframe. Applications under the BPCA are treated as priority applications, with all of the benefits that designation confers.

Post-Approval Requirements

Once an NDA is approved, a product will be subject to certain post-approval requirements. For instance, FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the internet. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved labeling.

Adverse event reporting and submission of periodic reports are required following FDA approval of an NDA. FDA also may require post-marketing testing, known as Phase 4 testing, REMS and surveillance to monitor the effects of an approved product, or FDA may place conditions on an approval that could restrict the distribution or use of the product. In addition, quality control, drug manufacture, packaging and labeling procedures must continue to conform to cGMPs after approval. Drug manufacturers and certain of their subcontractors are required to register their establishments with FDA and certain state agencies. Registration with FDA subjects entities to periodic unannounced inspections by FDA, during which the Agency inspects manufacturing facilities to assess compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money and effort in the areas of production and quality-control to maintain compliance with cGMPs. Regulatory authorities may withdraw product approvals or request product recalls if a company fails to comply with regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered.

The Hatch-Waxman Amendments

Orange Book Listing

In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent whose claims cover the applicant's product. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential generic competitors in support of approval of an abbreviated new drug application (ANDA). An ANDA provides for marketing of a drug product that has the same active ingredients in the same strengths and dosage form as the listed drug and has been shown through bioequivalence testing to be therapeutically equivalent to the listed drug. Other than the requirement for bioequivalence testing, ANDA applicants are not required to conduct, or submit results of, preclinical or clinical tests to prove the safety or effectiveness of their drug product. Drugs approved in this way are commonly referred to as "generic equivalents" to the listed drug and can often be substituted by pharmacists under prescriptions written for the original listed drug.

The ANDA applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA's Orange Book. Specifically, the applicant must certify that (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product. The ANDA applicant may also elect to submit a section viii statement certifying that its proposed ANDA label does not contain (or carve out) any language regarding the patented method-of-use rather than certify to a listed method-of-use patent. If the applicant does not challenge the listed patents, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired. A certification that the new product will not infringe the already approved product's listed patents, or that such patents are invalid, is called a Paragraph IV certification. If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit, or a decision in the infringement case that is favorable to the ANDA applicant.

The ANDA application also will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the referenced product has expired.

Exclusivity

Upon NDA approval of a new chemical entity (NCE), which is a drug that contains no active moiety that has been approved by FDA in any other NDA, that drug receives five years of marketing exclusivity during which FDA cannot receive any ANDA seeking approval of a generic version of that drug. An ANDA may be submitted one year before NCE exclusivity expires if a Paragraph IV certification is filed. If there is no listed patent in the Orange Book, there may not be a Paragraph IV certification, and, thus, no ANDA may be filed before the expiration of the exclusivity period. Certain changes to a drug, such as the addition of a new indication to the package insert, can be the subject of a three-year period of exclusivity if the application contains reports of new clinical investigations (other than bioavailability studies) conducted or sponsored by the sponsor that were essential to approval of the application. FDA cannot approve an ANDA for a generic drug that includes the change during the period of exclusivity.

In the case of a non-racemic drug containing as an active ingredient a single enantiomer that is contained in a racemic drug approved in another NDA, the NDA for the non-racemic drug may elect to have the single enantiomer not be considered the same active ingredient as that contained in the approved racemic drug and therefore eligible for NCE exclusivity, if certain conditions are met. These conditions include: (1) the single enantiomer has not been previously approved except in the approved racemic drug, (2) the NDA for the non-racemic drug includes full reports of new clinical investigations necessary for the approval of the product conducted or sponsored by the applicant and not submitted for approval of the racemic drug, and (3) the NDA for the non-racemic drug is not submitted for approval of a condition of use in a therapeutic category in which the approved racemic drug has been approved or for which any other enantiomer of the racemic drug has been approved. In addition, FDA will not approve the non-racemic drug for any condition of use in the therapeutic category in which the racemic drug has been approved for a period of 10 years after approval of the non-racemic drug, and the labeling of the non-racemic drug will include a statement in the indication that the non-racemic drug is not approved, and has not been shown to be safe and effective, for any condition of use of the racemic drug. The applicant for the non-racemic drug may make this election only in an application submitted before October 1, 2022.

Patent Term Extension

After NDA approval, owners of relevant drug patents may apply for up to a five-year patent extension. The allowable patent term extension is calculated as half of the drug's testing phase (the time between IND application and NDA submission) and all of the review phase (the time between NDA submission and approval up to a maximum of five years). The time can be shortened if FDA determines that the applicant did not pursue approval with due diligence. The total patent term after the extension may not exceed 14 years, and only one patent can be extended. For patents that might expire during the application phase, the patent owner may request an interim patent extension. An interim patent extension increases the patent term by one year and may be renewed up to four times. For each interim patent extension granted, the post-approval patent extension is reduced by one year. The director of the United States Patent and Trademark Office must determine that approval of the drug covered by the patent for which a patent extension is being sought is likely. Interim patent extensions are not available for a drug for which an NDA has not been submitted.

Controlled Substances

The federal Controlled Substances Act of 1970, or CSA, and its implementing regulations establish a closed chain of distribution for entities handling controlled substances. The CSA and regulations enforced by the United States Drug Enforcement Administration, or DEA, impose registration, security, recordkeeping and reporting, storage, manufacturing, distribution, importation, exportation, and other requirements on entities handling controlled substances. The DEA requires those individuals or entities that handle controlled substances to comply with these requirements in order to ensure legitimate use and prevent the diversion of controlled substances to illicit channels of commerce.

Facilities that manufacture, distribute, import or export any controlled substance must register annually with the DEA. The DEA registration is specific to a particular location, activity, and controlled substance schedule. For example, separate registrations are required for importation and manufacturing activities, and the authority granted under each registration determines which schedules of controlled substances the registrant may handle. However, certain DEA registrations permit coincident activities without obtaining a separate DEA registration, such as authorizing a manufacturer to also distribute controlled substances produced by that registrant.

The CSA categorizes controlled substances into one of five schedules – Schedule I, II, III, IV, or V – depending on the potential for abuse and physical or psychological dependence. Schedule I substances by definition have a high potential for abuse, have no currently accepted medical use in treatment in the U.S. and lack accepted safety for use under medical supervision. They may not be marketed or sold for dispensing to patients in the U.S. Pharmaceutical products having a currently accepted medical use and that are otherwise approved for marketing may be listed as Schedule II, III, IV, or V substances, with Schedule II substances presenting the highest potential for abuse and physical or psychological dependence, and Schedule V substances presenting the lowest relative potential for abuse and dependence. Schedule II substances (as well as substances defined as narcotics in any Schedule) are subject to most regulatory requirements and restrictions, such as recordkeeping, reporting and security. For example, all Schedule II drug prescriptions must be signed by a physician, physically presented to a pharmacist in most situations unless they are electronically prescribed pursuant to DEA regulations, and cannot be refilled. Schedules III, IV and V controlled substances are subject to fewer restrictions.

The DEA inspects manufacturers, distributors, importers, and exporters to review compliance with the CSA and DEA regulations including security, record keeping and reporting prior to issuing a controlled substance registration. The specific security requirements vary by the type of business activity and the schedule and quantity of controlled substances handled by the registrant. The most stringent requirements apply to manufacturers of Schedule I and Schedule II substances. Physical security for controlled substances includes storage in approved vaults, safes, and cages, and the use of alarm systems and surveillance cameras. Other security measures include restricted employee access to controlled substances. Once registered, manufacturing, distribution, exporting or importing facilities must maintain records documenting the manufacture, receipt, distribution, import, or export of all controlled substances. Manufacturers and distributors must also submit regular reports to the DEA of the distribution of Schedule I and II controlled substances, Schedule III narcotic substances, and other designated substances. All DEA registrants must report any controlled substance thefts or significant losses and must obtain authorization to destroy or dispose of controlled substances. In addition to maintaining an importer and/or exporter registration, importers and exporters of controlled substances must obtain a permit for every import or export of a Schedule I or II substance and a narcotic substance in Schedule III, IV and V. For all other drugs in Schedule III, IV and V, importers and exporters must submit an import or export declaration.

Practitioners such as pharmacies and physicians, as well as other types of entities that handle controlled substances, such as researchers and analytical laboratories, are also subject to DEA registration, recordkeeping, reporting, and security requirements on the receipt, storage, and dispensing of controlled substances.

The DEA establishes annually an aggregate production quota for the amount of substances within Schedules I and II and certain Schedule III substances, that may be produced in the U.S. based on the DEA's estimate of the quantity needed to meet legitimate medical, scientific, research and industrial needs. The aggregate quota for each controlled substance is allocated among the various individual manufacturers through an application process. Manufacturers may not exceed the manufacturing or procurement quota granted in a given year. The quotas apply equally to the manufacturing of the active pharmaceutical ingredient and production of dosage forms. The DEA may adjust aggregate production quotas and individual manufacturing or procurement quotas from time to time during the year, although the DEA has substantial discretion concerning whether or not to make such adjustments.

Failure to maintain compliance with applicable DEA requirements, particularly as manifested in the loss or diversion of controlled substances, can result in an enforcement action. The DEA may seek civil penalties, refuse to renew necessary registrations, or initiate administrative proceedings to revoke those registrations. In certain circumstances, violations could lead to criminal prosecution.

The various states, commonwealths, and the District of Columbia, also regulate controlled substances and impose similar licensing, recordkeeping, and reporting requirements on entities that handle controlled substances. Entities must independently comply with the various state requirements in addition to the federal controlled substance requirements.

Other Healthcare Laws

In the United States, biotechnology company activities are subject to regulation by various federal, state and local authorities in addition to the FDA, including but not limited to, the Centers for Medicare & Medicaid Services (CMS), other divisions of the U.S. Department of Health and Human Services (e.g., the Office of Inspector General and the Office for Civil Rights), the U.S. Department of Justice (DOJ) and individual U.S. Attorney offices within the DOJ, and state and local governments. For example, research, sales, marketing and scientific/educational grant programs have to comply with the anti-fraud and abuse provisions of the Social Security Act, the federal false claims laws, the privacy and security provisions of the Health Insurance Portability and Accountability Act (HIPAA) and similar state laws, each as amended, as applicable.

The federal Anti-Kickback Statute prohibits, among other things, any person or entity, from knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for purchasing, leasing, ordering, recommending or arranging for the purchase, lease or order of any item or service reimbursable under Medicare, Medicaid or other federal healthcare programs. The term remuneration has been interpreted broadly to include anything of value. The Anti- Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, and/or formulary managers on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution. The exceptions and safe harbors are drawn narrowly and practices that involve remuneration that may be alleged to be intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Practices may not in all cases meet all of the criteria for protection under a statutory exception or regulatory safe harbor. In addition, the statutory exceptions and regulatory safe harbors are subject to change.

Additionally, the intent standard under the Anti-Kickback Statute was amended by the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the ACA codified case law that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act (discussed below).

The civil monetary penalties statute imposes penalties against any person or entity who, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

Federal false claims laws, including the federal civil False Claims Act, prohibit, among other things, any person or entity from knowingly presenting, or causing to be presented, a false claim for payment to, or approval by, the federal government or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes “any request or demand” for money or property presented to the U.S. government. In addition, manufacturers can be held liable under the civil False Claims Act even when they do not submit claims directly to government payors if they are deemed to “cause” the submission of false or fraudulent claims. Pharmaceutical and other healthcare companies have been prosecuted under these laws for, among other things, allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies’ marketing of the product for unapproved, and thus generally non-reimbursable, uses and purportedly concealing price concessions in the pricing information submitted to the government for government price reporting purposes.

HIPAA created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the control or custody of, any healthcare benefit program, including private third-party payors and knowingly and willfully falsifying, concealing or covering up by trick, scheme or device, a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

Also, many states have similar fraud and abuse statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor.

Data privacy and security regulations by both the federal government and the states in which business is conducted may also be applicable. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, imposes requirements relating to the privacy, security and transmission of individually identifiable health information. HIPAA requires covered entities to limit the use and disclosure of protected health information to specifically authorized situations and requires covered entities to implement security measures to protect health information that they maintain in electronic form. Among other things, HITECH made HIPAA's security standards directly applicable to business associates, independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Additionally, the federal Physician Payments Sunshine Act within the ACA, and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) report to CMS information related to certain payments or other transfers of value made or distributed to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals and to report annually certain ownership and investment interests held by physicians and their immediate family members. The information is reported annually, and the reported data are made available in searchable form on a public website. Failure to submit required information may result in civil monetary penalties. Effective January 1, 2022, reporting on transfers of value to physician assistants, nurse practitioners or clinical nurse specialists, certified registered nurse anesthetists, and certified nurse-midwives will also be required.

Commercial distribution of products requires compliance with state laws that require the registration of manufacturers and wholesale distributors of drug and biological products in a state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain. In addition, several states have enacted legislation requiring pharmaceutical and biotechnology companies to establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities, and/or register their sales representatives, as well as to prohibit pharmacies and other healthcare entities from providing certain physician prescribing data to pharmaceutical and biotechnology companies for use in sales and marketing, and to prohibit certain other sales and marketing practices. Certain local jurisdictions also require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures. Sales and marketing activities are also potentially subject to federal and state consumer protection and unfair competition laws.

Violation of any of the federal and state healthcare laws described above or any other governmental regulations may result in penalties, including without limitation, significant civil, criminal and/or administrative penalties, damages, fines, disgorgement, exclusion from participation in government programs, such as Medicare and Medicaid, imprisonment, injunctions, private "qui tam" actions brought by individual whistleblowers in the name of the government, refusal to enter into government contracts, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings.

U.S. Healthcare Reform

In March 2010, President Obama enacted the ACA, which substantially changed healthcare financing and delivery by both governmental and private insurers and has significantly impacted the pharmaceutical and biotechnology industry.

Among the ACA provisions of importance to the pharmaceutical and biotechnology industries, in addition to those otherwise described above, are the following:

- An annual, nondeductible fee on any entity that manufacturers or imports certain specified branded prescription drugs and biologic agents apportioned among these entities according to their market share in some government healthcare programs;

- an annual, nondeductible fee on any entity that manufacturers or imports certain specified branded prescription drugs and biologic agents apportioned amount these entities according to their market share in some government healthcare programs;

- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13% of the average manufacturer price for most branded and generic drugs, respectively and capped the total rebate amount for innovator drugs at 100% of the Average Manufacturer Price, or AMP;

- a Medicare Part D coverage gap discount program, in which manufacturers must now agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturers' outpatient drugs to be covered under Medicare Part D;

- extension of manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;

- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability;

- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program; and

- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

Some of the provisions of the ACA have yet to be implemented, and there have been judicial and Congressional challenges to certain aspects of the ACA, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the ACA. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the ACA such as removing penalties, starting January 1, 2019, for not complying with the ACA's individual mandate to carry health insurance, and delaying the implementation of certain ACA-mandated fees, and increasing the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D. On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Cuts and Jobs Act of 2017. While the Texas U.S. District Court Judge, as well as the Trump administration and CMS, have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the ACA will impact the ACA.

There has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At the federal level, the Trump administration's budget proposals for fiscal years 2019 and 2020 contain further drug price control measures that could be enacted during the budget process or in other future legislation. Further, the Trump administration released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. HHS has started soliciting feedback on some of these measures and implementing others under its existing authority. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent the generation revenue, attainment profitability, or commercialization of products.

Coverage and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any products for which we may obtain regulatory approval. In the United States, sales of any product candidates for which regulatory approval for commercial sale is obtained will depend in part on the availability of coverage and adequate reimbursement from third-party payors. Third-party payors include government authorities and health programs in the United States such as Medicare and Medicaid, managed care providers, private health insurers and other organizations. These third-party payors are increasingly reducing reimbursements for medical products and services. The process for determining whether a payor will provide coverage for a drug product may be separate from the process for setting the reimbursement rate that the payor will pay for the drug product. Third-party payors may limit coverage to specific drug products on an approved list, or formulary, which might not include all of FDA-approved drugs for a particular indication. A payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Further, coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

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 Report.

A**vailable 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

Our business faces significant risks. You should carefully consider the risks described below, together with all of the other information included in our filings with the United States Securities and Exchange Commission (SEC) when evaluating our business. If any of the following risks actually occurs, our business, financial condition or results of operations could be materially adversely affected and the trading price of shares of our common stock could decline. The occurrence of any of the following risks could cause our actual results to differ materially from those contained in forward-looking statements we have made in this report and those we may make from time to time.

Risk Related to Our Business

Our business depends on the success of d-methadone (dextromethadone, REL-1017), our only product candidate currently under clinical development, which is in the early stages of clinical development and has not initiated pivotal clinical trials. If we are unable to obtain regulatory approval for and successfully commercialize REL-1017 or other future product candidates, or we experience significant delays in doing so, our business will be materially harmed.

To date, the primary focus of our product development has been d-methadone (dextromethadone, REL-1017) for the adjunctive treatment of patients with MDD. Currently, d-methadone is our only product candidate under clinical development. This may make an investment in our company riskier than similar companies that have multiple product candidates in active development and that therefore may be able to better sustain a failure of a lead candidate. Successful continued development and ultimate regulatory approval of d-methadone for the adjunctive treatment of MDD, and potentially as a monotherapy for MDD, or other indications is critical to the future success of our business. We have invested, and will continue to invest, a significant portion of our time and financial resources in the clinical development of d-methadone. If we cannot successfully develop, obtain regulatory approval for and commercialize d-methadone, we may not be able to continue our operations. The future regulatory and commercial success of d-methadone is subject to a number of risks, including the following:

- we may not have sufficient financial and other resources to complete the necessary clinical trials for d-methadone, including, but not limited to, the clinical trials needed to obtain drug approval;
- the mechanism of action of d-methadone is complex, and we do not know the degree to which it will translate into a therapeutic benefit, if any, in the adjunctive treatment of MDD, monotherapy for MDD or any other indication, and we do not know the degree to which the complex mechanism of action may contribute to long-term safety issues or adverse events, if any, when d-methadone is taken for prolonged periods such as in the adjunctive treatment of MDD, monotherapy for MDD or any other indication;
- we may not be able to obtain adequate evidence from clinical trials of efficacy and safety for d-methadone for the adjunctive treatment of MDD, monotherapy for MDD or other indications;
- we may not be able to demonstrate that the benefits of d-methadone for the adjunctive treatment of MDD, monotherapy for MDD or other indications outweigh the risks;
- in our clinical trials for d-methadone, we may need additional clinical trial sites than originally planned, which could delay our clinical trial progress;
- the results of our clinical trials may not meet the level of statistical or clinical significance required by the FDA or comparable foreign regulatory authorities for marketing approval;
- patients in our clinical trials may suffer serious adverse effects for reasons that may or may not be related to d-methadone, which could delay or prevent further clinical development;
- the standards implemented by clinical or regulatory agencies may change at any time and we cannot be certain what efficacy endpoints the FDA or foreign clinical or regulatory agencies may require in pivotal clinical trials with respect to the adjunctive treatment of MDD, monotherapy for MDD or any other indication for the approval of d-methadone;
- the results of later stage clinical trials may not be as favorable as the results we have observed to date in our preclinical studies and Phase 1 and 2a clinical trials;
- we cannot be certain of the number and type of clinical trials and preclinical or toxicology studies that the FDA or other regulatory agencies will require in order to approve d-methadone for the adjunctive treatment of MDD, monotherapy for MDD or any other indication;
- if approved for the adjunctive treatment of MDD or as a monotherapy for MDD, d-methadone will likely compete with products that may reach approval prior to d-methadone, products that are currently approved for the adjunctive treatment of MDD or as a monotherapy for MDD and the off-label use of currently marketed products for MDD; and
- we may not be able to obtain, maintain or enforce our patents and other intellectual property rights.

d-methadone and any future product candidates will be subject to rigorous and extensive clinical trials and extensive regulatory approval processes implemented by the FDA and comparable foreign regulatory authorities before obtaining marketing approval from these regulatory authorities, if at all. The drug development and approval process is lengthy and expensive, and approval is never certain. Investigational new drugs, such as d-methadone, may not prove to be safe and effective in clinical trials. We have no direct experience as a company in conducting later stage clinical trials required to obtain regulatory approval. We may be unable to conduct clinical trials at preferred sites, enlist clinical investigators, enroll sufficient numbers of participants or begin or successfully complete clinical trials in a timely fashion, if at all. In addition, the design of a clinical trial can determine whether its results will support approval of a product, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. Because we have limited experience as a company designing clinical trials, we may be unable to design and execute a clinical trial to support regulatory approval.

There is a high failure rate for drugs and biological products proceeding through clinical trials. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of d-methadone or any future product candidate may not be predictive of the results of later-stage clinical studies or trials and the results of studies or trials in one set of patients or line of treatment may not be predictive of those obtained in another. In fact, many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late stage clinical trials even after achieving promising results in preclinical studies and earlier stage clinical trials. In addition, data obtained from preclinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval. It is impossible to predict when or if d-methadone or any future product candidate will prove effective or safe in humans or will receive regulatory approval. Owing in part to the complexity of biological pathways, d-methadone or any future product candidate may not demonstrate in patients the biochemical and pharmacological properties we anticipate based on laboratory studies or earlier stage clinical trials, and they may interact with human biological systems or other drugs in unforeseen, ineffective or harmful ways. The number of patients exposed to product candidates and the average exposure time in the clinical development programs may be inadequate to detect rare adverse events or findings that may only be detected once a product candidate is administered to more patients and for greater periods of time. To date, our Phase 2a clinical study has involved a small population of subjects with TRD, and, because of the small sample size in such trial, the results of this clinical trial may be subject to substantial variability and may not be indicative of either future top-line results or final results. If we are unable to successfully demonstrate the safety and efficacy of d-methadone or other future product candidates and receive the necessary regulatory approvals, our business will be materially harmed.

Even if we do receive regulatory approval to market d-methadone, any such approval may be subject to limitations on the indicated uses or patient populations for which we may market the products. Accordingly, even if we are able to obtain the requisite financing to continue to fund our development programs, we may be unable to successfully develop or commercialize d-methadone. If we or any of our future development collaborators are unable to develop, or obtain regulatory approval for, or, if approved, successfully commercialize d-methadone, we may not be able to generate sufficient revenue to continue our business.

Top-line results may not accurately reflect the complete results of the clinical study.

In October 2019, we reported top-line data from our Phase 2a study of d-methadone in adults with MDD who did not respond to one to three courses of antidepressant treatment in their current episode. Although the top-line data indicated that subjects experienced statistically significant improvement of their depression compared to subjects in the placebo group, as well as a favorable safety and tolerability profile, the top-line data are based on preliminary analysis of key pharmacokinetic, safety and efficacy data, and such data may change following a more comprehensive review of the data and may not accurately reflect the complete results of the study. Preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data. As a result, preliminary data should be viewed with caution until the final data are available.

Our license agreement for d-methadone, our only product candidate currently under clinical development, could terminate under certain circumstances, including if we terminate our chief executive officer except for cause, and we would be unable to conduct our business as planned.

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 Assignment Agreement, we assigned our existing rights, including patents and patent applications, to d-methadone in the context of psychiatric use to Licensor, and pursuant to the License Agreement, Licensor then granted us an exclusive perpetual, worldwide license under the assigned intellectual property rights as well as patents and know-how covering certain new inventions developed by Licensor and relating to d-methadone in neurological and other uses, to develop and commercialize d-methadone in all fields of use. The License Agreement also grants to us rights in all future inventions developed by Licensor, whether or not in collaboration with us that relate in any way to d-methadone or the use thereof. The License Agreement was amended in December 2019 to modify certain termination rights relating to the Chief Executive Officer, which are described further below.

If we develop any new inventions relating to d-methadone, we are required to do so in collaboration with Licensor, and to file patents covering such inventions jointly in the name of the Company and Licensor. All such future inventions or patents shall be jointly owned by us and Licensor and, will be included in and subject to the financial and other terms of the License Agreement.

The License Agreement includes standard termination rights for Licensor in the event of our insolvency, challenge of the licensed patents and uncured material breach of our obligations under the License Agreement. In addition, the License Agreement contains certain "Key Man" provisions such that the Licensor may terminate the License Agreement if we terminate the employment of our Chief Executive Officer Mr. Sergio Traversa for any reason other than for specified causes determined by a majority of our Board of Directors (including fraud, gross negligence, unauthorized use of our confidential information, conduct including harassment or discrimination, breach of fiduciary duty or uncured material breach), or if we (a) substantially modify Mr. Traversa's job responsibilities or decision-making rights in connection with the development and commercialization of d-methadone, (b) remove him from the role of Chief Executive Officer other than in connection with a permitted change-of-control transaction, (c) materially reduce his compensation, or (d) assign or transfer our rights under the License Agreement or the d-methadone intellectual property without Mr. Traversa's consent, in each case (termination or the events in (a) through (d) during the period commencing on the effective date and ending on the later of five years from the original effective date of the License Agreement on December 31, 2022 (the "Key Man Term"). The December 2019 amendment to the License Agreement made certain clarifications to the nature of a termination for Cause, including to clarify that termination due to Mr. Traversa's death or disability does not give Licensor the right to terminate the License Agreement.

As a result of the provisions described above, we are limited in our ability to terminate, as well as to decrease the salary or authority of, our Chief Executive Officer until December 31, 2022. In addition, the agreement provides that any assignor that we assign the agreement to must agree in writing to all terms of the license, including the key man provisions, and as noted above, our Chief Executive Officer has the right to consent to any such assignment of the agreement unless previously terminated for cause or due to death. As the license agreement relates to our only product candidate currently under clinical development, these provisions may be deemed to have an anti-takeover effect and may delay, deter or prevent a tender offer or takeover attempt that a stockholder might consider to be in its best interests, including attempts that might result in a premium being paid over the market price for the shares held by stockholders. If we fail to comply with the terms of the License Agreement, our rights to those patents may be terminated, and we will be unable to conduct our business.

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. Based on our current development plans, we believe that our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements for at least the next eighteen months unless we halt research and development activities. Therefore, for the foreseeable future, we will have to fund all of our operations and capital expenditures from the net proceeds of future offerings. For our lead product candidate, REL-1017, we anticipate commencing in the second half of 2020 two Phase 3 trials in the adjunctive treatment of MDD, which we cannot assure you that we can complete, or we will need to halt our research and development activities. 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 will be unable to complete planned clinical trials or obtain approval of our product candidates from the FDA and other regulatory authorities. In addition, we could be forced to discontinue research and development activities, product development, reduce or forego 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 $119.9 million at December 31, 2019. The Company had cash, cash equivalents and short term investments of approximately $116.4 million at December 31, 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.

We had cash, cash equivalents and short term investments of approximately $116.4 million at December 31, 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 candidate is not expected to be commercialized for at least several years, if ever, and the revenues it will generate, if any, 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. 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.

We may be subject to litigation for a variety of claims, which could adversely affect our business, financial condition or results of operations.

In addition to product liability claims, we and our directors and officers may be subject to claims arising from our normal business activities. These may include claims, suits, and proceedings involving shareholder and fiduciary matters, intellectual property, labor and employment, wage and hour, commercial and other matters. For example, in 2014, we dismissed with prejudice a lawsuit we had brought against Najib Babul, our former President, which had sought to compel Dr. Babul to account for questionable expenditures of our funds. Dr. Babul subsequently brought a lawsuit against us, including claims for breach of contract, intentional infliction of emotional distress, defamation and wrongful use of civil process. We settled this litigation, agreeing, among other things, to pay Dr. Babul as a consulting fee a $500,000 initial payment and four subsequent payments of $250,000, the last installment of which is due on December 31, 2019.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

As of December 31, 2019, we had Federal, New York State and New York City net operating loss (NOL) carryforwards of approximately $62,010,000, $58,357,000 and $57,937,000, respectively, which begin expiring in 2027, 2032 and 2032, respectively. Under U.S. federal tax legislation enacted in 2017, informally titled the Tax Cuts and Jobs Act, or Tax Act, federal NOLs incurred in 2018 and in future years may be carried forward indefinitely, but the deductibility of such federal NOLs is limited to 80% of taxable income in the year . It is uncertain if and to what extent various states will conform to the Tax Act. Under Sections 382 and 383 of the U.S. Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change" (generally defined as a greater than 50 percentage-point cumulative change (by value) in the equity ownership of certain stockholders over a rolling three-year period), the corporation's ability to use its pre-change NOLs and other pre-change tax attributes to offset its post-change taxable income or taxes may be limited. We may also experience ownership changes as a result of stock offerings or as a result of subsequent shifts in our stock ownership, some of which are outside our control. We have not completed an analysis to determine whether any such limitations have been triggered. If any were determined to be triggered, our ability to use our current NOLs and other pre-change tax attributes to offset post-change taxable income or taxes would be subject to limitation. We will be unable to use our NOLs if we do not attain profitability sufficient to offset our available NOLs prior to their expiration.

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 currently only have 6 full time employees and are likely 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, research, 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.

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 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 us.

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.

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.

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.

Our business could be adversely affected by the effects of health epidemics, including the global COVID-19 pandemic.

In December 2019, a novel strain of COVID-19 was reported in China. Since then, COVID-19 has spread globally, to include Canada, the United States and several European countries. The spread of COVID-19 from China to other countries has resulted in the World Health Organization (WHO) declaring the outbreak of COVID-19 as a "pandemic," or a worldwide spread of a new disease, on March 11, 2020. Many countries around the world have imposed quarantines and restrictions on travel and mass gatherings to slow the spread of the virus and have closed non-essential businesses.

As local jurisdictions continue to put restrictions in place, our ability to continue to operate our business may also be limited. Such events may result in a period of business and manufacturing disruption, and in reduced operations, any of which could materially affect our business, financial condition and results of operations.

The spread of COVID-19, which has caused a broad impact globally, may materially affect us economically. While the potential economic impact brought by, and the duration of, COVID-19 may be difficult to assess or predict, a widespread pandemic could result in significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common shares.

The continued spread of COVID-19 globally could also adversely affect our planned clinical trial operations, including our ability to initiate the trials on the expected timelines and recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 if an outbreak occurs in their geography. Further, the COVID-19 outbreak could result in delays in our clinical trials due to prioritization of hospital resources toward the outbreak, restrictions in travel, potential unwillingness of patients to enroll in trials at this time, or the inability of patients to comply with clinical trial protocols if quarantines or travel restrictions impede patient movement or interrupt healthcare services. In addition, we rely on independent clinical investigators, contract research organizations and other third-party service providers to assist us in managing, monitoring and otherwise carrying out our preclinical studies and clinical trials, and the outbreak may affect their ability to devote sufficient time and resources to our programs or to travel to sites to perform work for us.

Additionally, COVID-19 may also result in delays in receiving approvals from local and foreign regulatory authorities, delays in necessary interactions with local and foreign regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees.

The global outbreak of COVID-19 continues to rapidly evolve. The ultimate long-term impact of COVID-19 is highly uncertain and cannot be predicted with confidence. In addition, since COVID-19 has become a pandemic, it could materially affect our operations globally, including at our headquarters in the New York City area and at our future clinical trial sites throughout the globe.

Our business could be adversely affected by health epidemics in regions where we have significant manufacturing and distribution facilities, concentrations of clinical trial sites or other business operations.

The ultimate impact of the COVID-19 outbreak or a similar health epidemic is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our supply chain, clinical trials, healthcare systems or the global economy as a whole. However, these effects could have a material impact on our operations, and, therefore, we will continue to monitor the COVID-19 situation closely and implement risk mitigation as needed.

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 studies in addition to those we plan to conduct, 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 successful clinical trials, our drug candidates will not be able to receive regulatory approval.

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.

Results from early clinical trials may not support moving a drug candidate to later-stage 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 d-methadone measure clinical symptoms, such as depression that are not biologically measurable. 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., immediate release oral, parenteral) may not be predictive of results from our future clinical trials. In addition, clinical trial results from the study of depression are inherently difficult to predict.

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.

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 candidate will depend on our ability to demonstrate with substantial clinical evidence through adequate well-controlled clinical trials, that the product candidate is 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. 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.

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. In that case, both the cost and the amount of time required to conduct a clinical trial could increase.

The DEA through its quota system limits the availability of the active ingredients in certain of our current drug candidates and, as a result, the Company's 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 certain controlled substance chemical compounds as Schedule I, II, III, IV or V substances, with Schedule I substances considered to present the highest risk of 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. Consequently, their handling (including manufacture, research, shipment, storage, sale and use) are subject to a high degree of federal and state oversight and regulation. For example, all Schedule II drug prescriptions other than electronic prescriptions must be signed by a physician, physically presented to a pharmacist and may not be refilled. A new prescription is necessary to receive additional amounts of the drug product. Furthermore, the amount of Schedule II substances that can be obtained for clinical trials and commercial distribution is limited by the DEA through its quota system. Quotas for these substances may not be sufficient to complete clinical trials or meet commercial demand. There is a risk that federal statutes and DEA regulations concerning applicable quotas may interfere with the supply of the drugs used in clinical trials for our product candidates, and, in the future, the ability to manufacture 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 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 manufacturing processes, labeling, packaging, distribution, post-approval monitoring and adverse event reporting, storage, import, export, advertising, promotion and record keeping for the drug will be subject to extensive and ongoing regulatory requirements. The FDA has significant post-market authority, including the authority to require labeling changes based on new safety information and to require post-market studies or clinical trials to evaluate safety risks related to the use of a product or to require withdrawal of the product from the market. The manufacturing facilities used to manufacture our product candidates will also be subject to periodic review and inspection by the FDA and other regulatory agencies, including for continued compliance with current good manufacturing practices (cGMPs) requirements. The discovery of any new or previously unknown problems with our third-party manufacturers, manufacturing processes or facilities may result in restrictions on the product, manufacturer or facility, including withdrawal of the product from the market. Any product promotion and advertising will also be subject to regulatory requirements and continuing regulatory review. The FDA imposes stringent restrictions on manufacturers' communications regarding use of their products. If we promote our product candidates in a manner inconsistent with FDA-approved labeling or otherwise not in compliance with FDA regulations, we may be subject to enforcement action. If we or our collaborators, manufacturers or service providers fail to comply with applicable continuing regulatory requirements in the United States or foreign jurisdictions in which we seek to market our products, we or they may be subject to, among other things, fines, warning or untitled letters, holds on clinical trials, suspension or withdrawal of regulatory approval, product recalls and seizures, administrative detention of products, refusal to permit the import or export of products, operating restrictions, injunction, civil penalties and criminal prosecution.

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.

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.

Fast Track Designation may not lead to a faster development or regulatory review or approval process.

We have obtained Fast Track Designation for d-methadone for the adjunctive treatment of MDD. Fast Track Designation is granted if a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition. Fast Track Designation does not guarantee a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw Fast Track Designation if it believes that the designation is no longer supported by data from our clinical development program.

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

The FDA has granted orphan drug designation for mepivacaine for postherpetic neuralgia (PHN) and painful HIV neuropathy. We have also received orphan designation for 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 drug exclusivity, which means that for seven years, the FDA may not approve any other applications to market the same drug for the same indication, except in limited circumstances. We may be unable to obtain orphan drug designations for any additional product candidates or orphan drug exclusivity for any of our product candidates, or our potential competitors may obtain orphan drug exclusivity for d-methadone or mepivacaine product candidates for the orphan indications we are pursuing before we do, in which case our product candidates may not be approved during 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 drug 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 marketing exclusivity under the Hatch-Waxman Amendments 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, if approved. The Hatch-Waxman Amendments provide marketing exclusivity to the first applicant to gain approval of an NDA under specific provisions of the Federal Food, Drug, and Cosmetic Act. For d-methadone, which we intend to elect to have not be considered the same active ingredient as methadone and therefore an NCE, we anticipate obtaining 5-year exclusivity. If FDA were to determine that we do not meet the requirements to make the election, we may not be able to obtain 5-year exclusivity for the product. In addition, under the statute, this election currently may only be made in an NDA submitted before October 1, 2022. If we do not submit an NDA before that date or if the statute is not amended to extend the election, we may not obtain 5-year exclusivity for d-methadone, if approved. For d-methadone, which is an NCE, we anticipate obtaining 5-year exclusivity for a product containing an active moiety that the FDA has not previously approved.

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 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, d-methadone has potential benefits in other therapeutic areas. If our drug development efforts in depression fail, 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. statutes and regulations, and the use of which may generate public controversy.

The active ingredients in d-methadone are listed by the DEA as controlled substances under the Controlled Substances Act of 1970. The DEA regulates certain drug substances in Schedule I, II, III, IV or V, with Schedule I substances considered to present the highest risk of substance abuse and Schedule V substances the lowest risk. These product candidates are also subject to DEA regulations relating to their handling (i.e., manufacturing, storage, distribution, prescribing and dispensing procedures).

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 Controlled Substances Act or DEA 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 opioid controlled substances. Although d-methadone is substantially devoid of opioid activity, the DEA may elect to designate it as a controlled substance falling under a DEA controlled substance Schedule, including Schedule II. 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 d-methadone, 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.

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. 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.

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

Our pharmaceutical excipients and other APIs 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 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 submission, 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.

Modifications to our products may require new NDA approvals.

After a product candidate receives FDA approval, expanded uses or uses in new indications of our products may require additional clinical trials and new regulatory approvals, including additional IND submissions before we can begin clinical development and supplemental NDA approval prior to marketing and sales. If we are required to conduct additional clinical studies, it would require additional expenditures and harm our operating results. Delays in obtaining required future approvals could adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth.

Moving from a powder dose formulation to a tablet formulation for future Phase 3 and Phase 2 REL-1017 trials could result in product development delays.

We are currently collaborating with Patheon/ThermoFisher to manufacture REL-1017 tablets for the clinical development program. We will propose to the FDA that we include a pharmacokinetic (PK) analysis of the tablets as part of the anticipated Phase 3 adjunctive therapy in MDD study expected to commence in the second half of 2020. If, however, the FDA requests that we run a separate PK bridging study prior to the initiation of our Phase 3 adjunctive therapy in MDD study, the start of the anticipated Phase 3 and Phase 2 MDD studies could be delayed to the first quarter of 2021 or beyond.

Delays in the commencement or completion of pharmaceutical development, manufacturing or clinical 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 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 APIs, 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 a during our cGMP 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;
- obtaining approval of the institutional review board (IRB) at each site selected for participation in our clinical trials;
- 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.

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.

Adverse safety outcomes could affect our ability to conduct our clinical trials or obtain approval of our product candidates.

Serious injury or death resulting from a failure of one of our drug candidates during current or future clinical trials could 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 submission of any NDAs to 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 required a boxed warning to be added to the Prescribing Information for 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. 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.

Our products may never achieve market acceptance.

Products that we may develop, if approved, 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 determine 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, if approved, 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.

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

Some of our product candidates, the controlled substance-based and maybe others, may 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, Axsome, 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.

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.

Risks Related to Our Intellectual Property

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.

Changes in U.S. patent law or the patent law of other countries or jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.

The United States has enacted and implemented wide-ranging patent reform legislation. The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on actions by Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we have licensed or that we might obtain in the future. Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we have licensed or that we may obtain in the future.

We may not be able to protect our intellectual property rights throughout the world, which could impair our business.

Filing, prosecuting, and defending patents covering our product candidates and any future product candidate throughout the world would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we may have or obtain patent protection, but where patent enforcement is not as strong as that in the United States. These unauthorized products may compete with our products in such jurisdictions and take away our market share where we do not have any issued or licensed patents and any future patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

If our future trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

We intend to use registered or unregistered trademarks or trade names to brand and market ourselves and our products. Our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. We may license our trademarks and trade names to third parties, such as distributors. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names. Our efforts to enforce or protect our proprietary rights related to trademarks, trade names, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our financial condition or results of operations.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative:

- others may be able to make product that is similar to our current and future product candidates we intend to commercialize that is not covered by the patents that we own or license and have the right to enforce;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our future patent applications will not lead to issued patents;
- issued patents that we own or license may not provide us with any competitive advantages, or may be held invalid or unenforceable as a result of legal challenges;
- our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights, and then use the information learned from such activities to develop competitive products for sale in our major commercial markets; and we may not develop additional proprietary technologies that are patentable.

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 marketing exclusivity under the Hatch-Waxman Amendments, the six month pediatric exclusivity, any 7- year Orphan Drug exclusivity, potential future formulation patents and up to ten years of data exclusivity in Europe.

Risks Related to Government Regulation

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 depend on our information technology systems and those of our third-party collaborators, service providers, contractors or consultants. Our internal computer systems, or those of our third-party collaborators, service providers, contractors or consultants, may fail or suffer security breaches, disruptions, or incidents, which could result in a material disruption of our development programs or loss of data or compromise the privacy, security, integrity or confidentiality of sensitive information related to our business and have a material adverse effect on our reputation, business, financial condition or results of operations.

In the ordinary course of our business, we collect, store and transmit large amounts of confidential information, including intellectual property, proprietary business information and personal information. Our internal technology systems and infrastructure, and those of our current or future third-party collaborators, service providers, contractors and consultants are vulnerable to damage from computer viruses, unauthorized access or use resulting from malware, natural disasters, terrorism, war and telecommunication and electrical failures, denial-of-service attacks, cyber-attacks or cyber-intrusions over the Internet, hacking, phishing and other social engineering attacks, persons inside our organizations (including employees or contractors), loss or theft, or persons with access to systems inside our organization. Attacks on information technology systems are increasing in their frequency, levels of persistence, sophistication and intensity, and they are being conducted by increasingly sophisticated and organized foreign governments, groups and individuals with a wide range of motives and expertise. In addition to extracting or accessing sensitive information, such attacks could include the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the security, confidentiality, integrity and availability of information. The prevalent use of mobile devices that access sensitive information also increases the risk of data security incidents which could lead to the loss of confidential information or other intellectual property. While to our knowledge we have not experienced any material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations or the operations of third-party collaborators, service providers, contractors and consultants, it could result in a material disruption of our development programs and significant reputational, financial, legal, regulatory, business or operational harm. The costs to us to mitigate, investigate and respond to potential security incidents, breaches, disruptions, network security problems, bugs, viruses, worms, malicious software programs and security vulnerabilities could be significant, and while we have implemented security measures to protect our data security and information technology systems, our efforts to address these problems may not be successful, and these problems could result in unexpected interruptions, delays, cessation of service and other harm to our business and our competitive position.

For example, the loss of clinical trial data from completed, ongoing or planned clinical trials for our product candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any real or perceived security breach affects our systems (or those of our third-party collaborators, service providers, contractors or consultants), or results in the loss of or accidental, unlawful or unauthorized access to, use of, release of, or other processing of personally identifiable information or damage to our data or applications or other data or applications relating to our technology or product candidates, or inappropriate disclosure of confidential or proprietary information, we could incur liabilities and the further development of our product candidates could be delayed. Such a breach may require notification to governmental agencies, the media or individuals pursuant to various foreign, domestic (federal and state) privacy and security laws, if applicable, including the U.S. Health Insurance Portability and Accountability Act of 1996 (HIPAA), as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH), and its implementing rules and regulations, as well as regulations promulgated by the Federal Trade Commission and state breach notification laws. In addition, our liability insurance may not be sufficient in type or amount to cover us against claims related to security breaches, cyberattacks and other related incidents.

Any failure or perceived failure by us or any third-party collaborators, service providers, contractors or consultants to comply with our privacy, confidentiality, data security or similar obligations, or any data security incidents or other security breaches that result in the accidental, unlawful or unauthorized access to, use of, release of, processing of, or transfer of sensitive information, including personally identifiable information, may result in negative publicity, harm to our reputation, governmental investigations, enforcement actions, regulatory fines, litigation or public statements against us, could cause third parties to lose trust in us or could result in claims by third parties, including those that assert that we have breached our privacy, confidentiality, data security or similar obligations, any of which could have a material adverse effect on our reputation, business, financial condition or results of operations. To the extent we maintain individually identifiable health information, we could be subject to fines and penalties (including civil and criminal) under HIPAA for any failure by us or our business associates to comply with HIPAA's requirements. Moreover, data security incidents and other security breaches can be difficult to detect, and any delay in identifying them may lead to increased harm. While we have implemented data security measures intended to protect our information, data, information technology systems, applications and infrastructure, there can be no assurance that such measures will successfully prevent service interruptions or data security incidents.

Failure to comply with existing or future laws and regulations related to privacy or data security could lead to government enforcement actions (which could include civil or criminal fines or penalties), private litigation, other liabilities, and/or adverse publicity. Compliance or the failure to comply with such laws could increase the costs of our products and services, could limit their use or adoption, and could otherwise negatively affect our operating results and business.

Regulation of data processing is evolving, as federal, state, and foreign governments continue to adopt new, or modify existing, laws and regulations addressing data privacy and security, and the collection, processing, storage, transfer, and use of data. We and our partners may be subject to current, new, or modified federal, state, and foreign data privacy and protection laws and regulations (e.g., laws and regulations that address data privacy and data security including, without limitation, health data). These new or proposed laws and regulations are subject to differing interpretations and may be inconsistent among jurisdictions, and guidance on implementation and compliance practices are often updated or otherwise revised, which adds to the complexity of processing personal data. These and other requirements could require us or our partners to incur additional costs to achieve compliance, limit our competitiveness, necessitate the acceptance of more onerous obligations in our contracts, restrict our ability to use, store, transfer, and process data, impact our or our partners' ability to process or use data in order to support the provision of our products or services, affect our or our partners' ability to offer our products and services in certain locations, or cause regulators to reject, limit or disrupt our clinical trial activities.

In the United States, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), that govern the collection, use, disclosure, and protection of health-related and other personal information could apply to our operations or the operations of our partners. Furthermore, in June 2018, California enacted the California Consumer Privacy Act of 2018, or CCPA, which takes effect on January 1, 2020. The CCPA gives California residents certain rights related to their personal information, including the right to access and require deletion of their personal information, the right to opt out of certain personal information sharing, and the right to detailed information about how their personal information is collected, used and shared. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. Although the CCPA includes exemptions for certain clinical trials data, the law may increase our compliance costs and potential liability with respect to other personal information we collect about California residents. The CCPA has prompted a wave of proposals for new federal and state privacy legislation that, if passed, could increase our potential liability, increase our compliance costs and adversely affect our business.

International data protection laws, including, without limitation, the General Data Protection Regulation ((EU) 2016/679)) (the "GDPR"), that took effect in May 2018, and member state data protection legislation, may also apply to health-related and other personal information obtained outside of the United States. These laws impose strict obligations on the ability to process health-related and other personal information of data subjects in the EU, including in relation to use, collection, analysis, and transfer of such personal information. These laws include several requirements relating to obtaining the consent of the individuals to whom the personal data relates, limitations on data processing, establishing a legal basis for processing, notification of data processing obligations or security incidents to appropriate data protection authorities or data subjects, the security and confidentiality of the personal data and various rights that data subjects may exercise.

The GDPR prohibits the transfer, without an appropriate legal basis, of personal data to countries outside of the European Economic Area, or EEA, such as the United States, which are not considered by the European Commission to provide an adequate level of data protection. Switzerland has adopted similar restrictions. Although there are legal mechanisms to allow for the transfer of personal data from the EEA and Switzerland to the United States, uncertainty about compliance with EU data protection laws remains and such mechanisms may not be available or applicable with respect to the personal data processing activities necessary to research, develop and market our products and services. For example, ongoing legal challenges in Europe to the mechanisms allowing companies to transfer personal data from the EEA to the United States could result in further limitations on the ability to transfer personal data across borders, particularly if governments are unable or unwilling to reach new or maintain existing agreements that support cross-border data transfers, such as the European Union-U.S. and Swiss-U.S. Privacy Shield framework. Additionally, other countries have passed or are considering passing laws requiring local data residency and/or restricting the international transfer of data.

Under the GDPR, regulators may impose substantial fines and penalties for non-compliance. Companies that violate the GDPR can face fines of up to the greater of 20 million Euros or 4% of their worldwide annual turnover (revenue). The GDPR has increased our responsibility and liability in relation to personal data that we process, requiring us to put in place additional mechanisms to ensure compliance with the GDPR and other EU and international data protection rules.

Failure to comply with U.S. and international data privacy and protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties, fines or sanctions), private litigation, and/or adverse publicity and could negatively affect our operating results and business. Moreover, patients about whom we or our partners obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations related to security or privacy, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business. Compliance with data protection laws may be time-consuming, require additional resources and could result in increased expenses, reduce overall demand for our products and services and make it more difficult to meet expectations of or commitments to customers or partners.

Any of these matters could materially adversely affect our business, financial condition, or operational results.

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 healthcare providers, payors, customers and others 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 research, 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;

- State and local 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 report certain information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and drug pricing; 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.

If our operations are found to be in violation of any of the federal and state laws described above or any other government laws that apply to us, we may be subject to significant civil, criminal, and administrative penalties, including, without limitation, damages, fines, imprisonment, exclusion from participation in government healthcare programs, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and the curtailment of restricting of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Healthcare legislative reform measures may have a negative impact on our business and results of operations.

The U.S. and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our future products profitably. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. For example, the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, or collectively the ACA, was passed in March 2010 and substantially changed the way healthcare is financed and continues to significantly impact the U.S. pharmaceutical industry. Since the ACA's enactment, there have been, and continue to be, Congressional, executive branch, judicial, and regulatory challenges to the ACA. In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted, and we expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products.

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 do not own or operate facilities for drug manufacturing, storage, distribution or quality testing. We currently rely, and may continue to rely, on third-party contract manufacturers to manufacture APIs, drug products and other components of our product candidates. Reliance on third-party manufacturers may expose us to different risks than if we were to manufacture product candidates ourselves.

The manufacturing process for a product candidate is subject to FDA and foreign regulatory authority review. We, and our suppliers and manufacturers, must meet applicable manufacturing requirements and undergo rigorous facility and process validation tests required by regulatory authorities in order to comply with regulatory standards, such as cGMPs. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the FDA and foreign regulatory authorities. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or comparable foreign regulatory authorities, we may not be able to rely on their manufacturing facilities for the manufacture of our product candidates. Moreover, we do not control the manufacturing process at our contract manufacturers and are completely dependent on them for compliance with current regulatory requirements. In the event that any of our manufacturers fails to comply with such requirements or to perform its obligations in relation to quality, timing or otherwise, or if our supply of components or other materials becomes limited or interrupted for other reasons, we may be forced to enter into an agreement with another third party, which we may not be able to do on reasonable terms, if at all. In some cases, the technical skills or technology required to manufacture our product candidates may be unique or proprietary to the original manufacturer and we may have difficulty transferring such to another third party. These factors would increase our reliance on such manufacturer or require us to obtain a license from such manufacturer in order to enable us, or to have another third party, manufacture our product candidates. If we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines; and we may be required to repeat some of the development program. The delays associated with the verification of a new manufacturer could negatively affect our ability to develop product candidates in a timely manner or within budget.

We expect to continue to rely on third-party manufacturers if we receive regulatory approval for any product candidate. To the extent that we have existing, or enter into future, manufacturing arrangements with third parties, we will depend on these third parties to perform their obligations in a timely manner consistent with contractual and regulatory requirements, including those related to quality control and assurance. Any manufacturing facilities used to produce our products will be subject to periodic review and inspection by the FDA and foreign regulatory authorities, including for continued compliance with cGMP requirements, quality control, quality assurance and corresponding maintenance of records and documents. If we are unable to obtain or maintain third-party manufacturing for product candidates, or to do so on commercially reasonable terms, we may not be able to develop and commercialize our product candidates successfully. Our or a third party's failure to execute on our manufacturing requirements, comply with cGMPs or maintain a compliance status acceptable to the FDA or foreign regulatory authorities could adversely affect our business in a number of ways, including:

- an inability to initiate or continue clinical trials of product candidates under development;
- delay in submitting regulatory applications, or receiving regulatory approvals, for product candidates;
- loss of the cooperation of existing or future collaborators;
- subjecting third-party manufacturing facilities to additional inspections by regulatory authorities;
- requirements to cease distribution or to recall batches of our product candidates; and
- in the event of approval to market and commercialize a product candidate, an inability to meet commercial demands for our products.

Additionally, our contract manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If our contract manufacturers were to encounter any of these difficulties, our ability to provide our product candidates to patients in preclinical and clinical trials, or to provide product for treatment of patients once approved, would be jeopardized.

We intend to rely on third parties to conduct our preclinical studies and 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 do not currently intend to conduct preclinical studies or clinical trials on our own, and instead will rely on third parties, such as contract research organizations (CROs), medical institutions, clinical investigators and contract laboratories, to assist us with our preclinical studies and clinical trials. Accordingly, we will have less control over the timing, quality and other aspects of preclinical studies and clinical trials than we would have had we conducted them on our own. These investigators, CROs and consultants will not be our employees and we will have limited control over the amount of time and resources that they dedicate to our programs. These third parties may have contractual relationships with other entities, some of which may be our competitors, which may draw time and resources from our programs. The third parties with which we may contract might not be diligent, careful or timely in conducting our preclinical studies or clinical trials, resulting in the preclinical studies or clinical trials being delayed or unsuccessful.

If we cannot contract with acceptable third parties on commercially reasonable terms, or at all, or if these third parties do not carry out their contractual duties, satisfy legal and regulatory requirements for the conduct of preclinical studies or clinical trials or meet expected deadlines, our clinical development programs could be delayed and otherwise adversely affected. In all events, we will be responsible for ensuring that each of our preclinical studies and clinical trials are conducted in accordance with the general investigational plan and protocols for the trial as well as applicable legal and regulatory requirements. The FDA generally requires preclinical studies to be conducted in accordance with good laboratory practices and clinical trials to be conducted in accordance with good clinical practices, including for designing, conducting, recording and reporting the results of preclinical studies and clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of clinical trial participants are protected. Our reliance on third parties that we do not control will not relieve us of these responsibilities and requirements. Any adverse development or delay in our preclinical studies or clinical trials as a result of our reliance on third parties could have a material and adverse effect on our business, financial condition, results of operations and prospects.

If 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.

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 listed on the Nasdaq Capital Market 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, as amended (the Securities Act). We have registered under separate registration statements in aggregate up to 10,894,658 shares of our common stock for sale into the public market by certain selling stockholders named therein. These shares represent a large number of shares of our common stock, and if sold in the market all at once or at about the same time, could depress the market price of our common stock during the period the registration statement remains effective and could also affect our ability to raise equity capital.

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.

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. In addition, as a smaller reporting company, our independent registered public accounting firm is not required to formally attest to the effectiveness of our internal control over financial reporting so long as we remain a smaller reporting company, which could increase the likelihood of undiscovered errors in our internal controls or reported financial statements as compared to issuers whose independent registered public accounting firms have provided such attestations.

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.

The Nevada Revised Statutes and our articles of incorporation and bylaws contain provisions that could discourage, delay or prevent a change in control of our Company, prevent attempts to replace or remove current management and reduce the market price of our stock.

Provisions in our articles of incorporation and bylaws may discourage, delay or prevent a merger or acquisition involving us that our stockholders may consider favorable. For example, our articles of incorporation authorize our board of directors to issue up to 200,000,000 shares of "blank check" preferred stock. As a result, without further stockholder approval, the board of directors has the authority to attach special rights, including voting and dividend rights, to this preferred stock. With these rights, preferred stockholders could make it more difficult for a third party to acquire us.

We are also subject to the anti-takeover provisions of the Nevada Revised Statutes (NRS). Depending on the number of residents in the state of Nevada who own our shares, we could be subject to the provisions of Sections 78.378 et seq. of the Nevada Revised Statutes, which, unless otherwise provided in the Company's articles of incorporation or by-laws, restricts the ability of an acquiring person to obtain a controlling interest of 20% or more of our voting shares. Our articles of incorporation and by-laws do not contain any provision which would currently keep the change of control restrictions of Section 78.378 from applying to us.

In addition, our articles of incorporation and amended and restated bylaws provide that our board of directors is classified into three classes of directors with staggered three-year terms. Only one class of directors will be elected at each annual meeting of stockholders, with the other classes continuing for the remainder of their respective three-year terms. A third party may be discouraged from making a tender offer or otherwise attempting to obtain control of us as it is more difficult and time consuming for stockholders to replace a majority of the directors on a classified board of directors.

Our bylaws provides that a Nevada court and the federal district courts of the United States will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Pursuant to our bylaws, to the fullest extent permitted by law, and unless we consent in writing to the selection of an alternative forum, the Eighth Judicial District Court of Clark County, Nevada, is the sole and exclusive forum for any stockholder (including a beneficial owner of stock) to bring (a) any derivative action or proceeding brought in the name or right of the Company or on our behalf, (b) any action asserting a claim of, or a claim based on, breach of any fiduciary duty owed by any current or former director, officer, employee, agent or stockholder of the Company to the Company or the Company's stockholders, (c) any action arising or asserting a claim arising pursuant to any provision of NRS Chapters 78 or 92A or any provision of the articles of incorporation or our bylaws or (d) any action asserting a claim against us or any current or former director, officer, employee or stockholder (including a beneficial owner of stock) governed by the internal affairs doctrine, including, without limitation, any action to interpret, apply, enforce or determine the validity of our articles of incorporation or bylaws. By its terms, to the fullest extent permitted by law, our forum selection provision applies to actions arising under the Securities Act or Exchange Act. (However, Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder, and the Company does not intend for its exclusive forum jurisdiction provision to apply to Exchange Act claims.) These choice of forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees. If a court were to find the choice of forum provision contained in our bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business.

Our common stock was formerly deemed a "penny stock," which imposes certain limitations on us.

Prior to our 1-for-4 reverse stock split on September 30, 2019, and the listing of our common stock on the Nasdaq Capital Market on October 10, 2019, our common stock was considered a "penny stock" under the Exchange Act. The penny stock rules generally apply to companies whose common stock is not listed on a 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 imposed certain investor suitability and other requirements on brokers who traded our stock. Although currently our common stock is not subject to such limitations, because we offered and sold a "penny stock" in the past, we are considered an "ineligible issuer" under rule 405 of the Securities Act and remain subject to certain limitations until three years after our last offering of penny stock, including limitations on our ability to use free writing prospectuses and on the ability of brokers to publish research reports on us.

You may have difficulty trading our common stock.

There is a limited trading market for our common stock. As a result, investors may find it difficult to dispose of shares of our common stock. Accordingly, investors may therefore bear the economic risk of an investment in our common stock, 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 Exchange Act or disseminate to the public any current financial or other information concerning us, as is required by Rule 144 as part of the conditions of its availability.

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 expired on December 31, 2019 and has been renewed for calendar year 2020. Included in this lease is additional office space on the 10th floor along with the existing space on the 5th floor for a total monthly cost of $13,610.

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. 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 NASDAQ, under the symbol "RLMD".

Lack of a Public Market for Common Stock

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

Until our 1 for 4 reverse stock split in September 2019, our stock was considered a penny stock.

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 December 31, 2019, 14,457,013 shares of common stock were issued and outstanding, which were held by 259 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. A Form S-3 registration statement covering all shares was filed with the SEC on October 18, 2019, and was declared effective by the SEC on October 31, 2019.

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. On March 6, 2020, at the annual shareholders meeting, our shareholders approved the increase in shares authorized to be granted under the Plan by 2,500,000 shares. With these grants and approvals, as of December 31, 2019, the Company had 1,537,340 awards available to be issued.

The following table summarizes our equity compensation plan information as of December 31, 2019.

Equity Compensation Plan Information

Plan Category	Number of securities to be issued upon exercise of outstanding options and stock appreciation rights	Weighted-average exercise price of outstanding options and stock appreciation rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
	(a)	(b)	(c)
Equity compensation plans approved by security holders	3,615,602	$ 19.96	1,537,340
Equity compensation plans not approved by security holders	-	-	-
Total	3,615,602	$ 19.96	1,537,340

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 six months ended December 31, 2019 and 2018 (unaudited), and for the years ended June 30, 2019 and 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 which includes d-methadone (dextromethadone, REL-1017), a NMDA receptor antagonist for treating depression and neuropathic pain (this is the Company's main product under development); 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 lead product candidate, d-methadone, is an NCE being developed as a rapidly acting, oral agent for the treatment of depression and other potential indications. We have previously completed Phase 1 single and multiple ascending dose studies and on October 15, 2019 we reported top-line data from study REL-1017-202, a double-blind, placebo-controlled Phase 2a clinical trial evaluating the safety, tolerability and efficacy of two doses of REL-1017, 25 mg once a day and 50 mg once a day, as an adjunctive treatment in patients with MDD.

The Company changed its fiscal year end to December 31 from June 30. This transition report is for the six-month transition period of July 1, 2019 through December 31, 2019. The information for the six months ended December 31, 2018 is presented for comparative purposes only and is unaudited.

We have not generated revenues and do not anticipate generating revenues for the foreseeable future. We had a net loss of approximately $8,196,600, $10,509,400, $17,318,100 and $8,960,900 for the six months ended December 31, 2019, the transition period, the six months ended December 31, 2018 (unaudited) and for the years ended June 30, 2019 and 2018, respectively. At December 31, 2019, we have an accumulated deficit of approximately $119,858,900.

Results of Operations

For the Six Months Ended December 31, 2019 vs Six Months Ended December 31, 2018 (unaudited)

Research and Development Expense

Total research and development expense for the six months ended December 31, 2019 was approximately $3,513,600, as compared to $2,678,900 for the same period of 2018, an increase of $834,700. The increase in research and development expense was primarily due to:

- Decrease in study costs of $715,800 associated with the execution of our Phase 2a study;
- Increase in manufacturing and drug storage costs of $677,300;
- Increase in pre-clinical and toxicology expenses of $17,800;
- Increase in salaries and stock based compensation expense of $408,800;
- Increase in research expenses of $446,600.

General and Administrative Expense

Total general and administrative expense for the six months ended December 31, 2019 was approximately $4,758,000, as compared to $3,211,300 for the same period of 2018, an increase of $1,546,700. The increase in general and administrative expenses was primarily due to:

- Increase in salaries and stock-based compensation of $2,114,100;
- Decrease in legal and settlement expense fees of $1,341,800;
- Increase in other G&A expenses of $198,100;
- Increase in non-litigation professional fees of $576,300.

Other Income (Expense)

The Company did not have any derivative liabilities during the six months ended December 31, 2019. The change in the fair value of derivative liabilities was a non-cash unrealized loss for the six months ended December 31, 2018 of $54,600.

The Company did not have any loss on extinguishment of debt for the six months ended December 31, 2019. The loss on extinguishment of debt, a non-cash item, of approximately $3,774,500 for the six months ended December 31, 2018, was due to a conversion of outstanding principal and accrued interest on convertible promissory notes into 2,682,917 shares of common stock.

Net interest income for the six month period ended December 31, 2019 was approximately $75,100 compared to net interest expense of $790,100 for the six month period ended December 31, 2018. The change of $865,200 consisted of decreased interest expense resulting from the extinguishment of the two-year convertible promissory notes on October 18, 2018 and interest income earned on the investment securities during December 2019.

Income Taxes

The Company did not provide for income taxes for the six months ended December 31, 2019 and December 31, 2018, since there was a loss and a full valuation allowance against all deferred tax assets.

Net Loss

The Company recorded a net loss of approximately $8,196,600 and $10,509,400, or $0.77 and $2.20 per common share, basic and diluted, during the six months ended December 31, 2019 and 2018, respectively, based on the factors described above.

For the years 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 salaries and stock based compensation expense of $153,500; and
- 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 was eliminated when the Company up-listed to NASDAQ.

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 June 30, 2019 and 2018 since there were losses for both years and a full valuation allowance against all deferred tax assets.

Net Loss

The Company recorded a net loss of approximately $17,318,100 and $8,960,900 or $2.74 and $2.86 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 $6,413,775 for the six months ended December 31, 2019 and has an accumulated deficit of $119,858,909 from inception through December 31, 2019.

Relmada has funded its past operations through equity raises and most recently in the six months ended December 31, 2019, the transition period, Relmada raised net proceeds from the sale of common stock of $109,447,482 and $4,447,038 through the exercise of warrants.

Management believes that due to the recent equity raises completed and exercises of outstanding warrants and the resulting cash position on its balance sheet, it has obtained sufficient funding to continue ongoing operations for at least 12 months from the issuance of the accompanying consolidated financial statements. Since December 31, 2019 and to date, the Company has received approximately $3,100,000 in warrant and option exercises, which resulted in the Company having approximately $116.4 million in cash, cash equivalents and short term investments at March 16, 2020. Based on its budgeted cash flow requirements, the Company believes these funds are sufficient to fund its ongoing operations for at least 12 months after the issuance of these consolidated financial statements. The Company expects that the cash burn rate for the 12 months ended December 31, 2020, will be approximately $21 million.

Given the positive results of the Company's Phase 2 clinical trial, and based on our current development plans, management believes that our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirement for at least the next 12 months. Beyond that point management will evaluate the size and scope of any subsequent trials that 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 at least 12 months from the issuance of these consolidated financial statements.

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

	For the Six Months Ended December 31, 2019	(Unaudited) For the Six Months Ended December 31, 2018	For the Year Ended June 30, 2019	For the Year Ended June 30, 2018
Cash used in operating activities	$ (6,413,775)	$ (4,818,845)	$ (10,497,854)	$ (6,002,078)
Cash used in investing activities	(80,164,823)	-	-	(12,391)
Cash provided by financing activities	113,640,563	5,006,653	17,475,465	6,542,900
Net increase in cash and cash equivalents	$ 27,061,965	$ 187,808	$ 6,977,611	$ 528,431

For the six months ended December 31, 2019, the transition period, cash used in operating activities was $6,413,775 primarily due to the net loss of approximately $8,196,600. This was offset by non-cash expenses which primarily consisted of stock-based compensation of $2,367,001. There were changes in operating assets and liabilities for the six months ended December 31, 2019 of approximately $586,400.

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 $1,505,500 and $700,100, respectively.

For the six months ended December 31, 2019, the transition period, cash used in investing activities was $80,164,823, primarily due to $84,849,198 of purchases of short term investments offset by $4,684,375 of sales of short term investments. For the year ended June 30, 2019, no cash was used in investing activities. For the year ended June 30, 2018, cash used in investing activities was $12,391 for the purchase of fixed assets.

Net cash provided by financing activities for the six months ended December 31, 2019, the transition period, was $113,640,563 due to proceeds from issuance of common stock of $109,447,482, proceeds from warrants exercised for common stock of $4,447,038 partially offset by payments of notes payable of $253,957.

Net cash provided by financing activities for the year ended June 30, 2019 was $17,475,465 primarily due to proceeds from issuance of common stock of $17,760,635 partially offset by payments of notes payable of $285,170.

Net cash provided by financing activities for the years ended June 30, 2018 was $6,542,900 primarily due to proceeds from promissory notes and warrants of $6,534,400 and an increase of notes payable of $8,500.

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:

	Total	Less than 1 year	1 - 2 years	3 - 5 years	More than 5 years
Office lease	$ 163,320	$ 163,320	$ -	$ -	$ -
Total obligations	$ 163,320	$ 163,320	$ -	$ -	$ -

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 December 31, 2019, 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 as of December 31, 2019 and for the six months then ended, the transition period, and as of June 30, 2019 and 2018 and for the years then ended and our unaudited financial statements for the six month ended December 31, 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 December 31, 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 December 31, 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 December 31, 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 March 26, 2020:

Name	Age	Position
Sergio Traversa	59	Chief Executive Officer, and Director
Maged Shenouda	55	Chief Financial Officer
Charles Ence	60	Chief Accounting and Compliance Officer
Thomas Wessel	64	Executive Vice President, Head of R&D
Charles J. Casamento	74	Chairman of the Board and Director
Paul Kelly	62	Director
Eric Schmidt	51	Director
John Glasspool	58	Director

Sergio Traversa 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 Chief Executive Officer of Medeor Inc., a spinoff pharmaceutical company from Cornell University. From January 2008 to January 2010, Mr. Traversa was a partner at Ardana Capital. Mr. 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, 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, Mr. 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. Mr. Traversa started his career as a sales representative at Farmitalia Carlo Erba, now part of Pfizer. Mr. Traversa served as a board member of Actinium Pharmaceuticals, Inc. Mr. 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 our Chief Executive Officer, Mr. Traversa is our most senior executive and as such provides our Board of Directors with the greatest insight into our business and the challenges and material risks it faces. Mr. 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 Mr. Traversa should serve as Chief Executive Officer and Director of the Company.

Maged Shenouda has been our Chief Financial Officer since January 2020. He was also our director from November 2015 to January 2020. During his time as a director with the Company Mr. Shenouda was a member of the Audit Committee and Compensation Committee, and Chairman of the Corporate Governance and Nominating Committee. Mr. Shenouda has over 25 years of biotechnology and equity research experience. From September 2017 to November 2019, Mr. Shenouda was the Chief Financial Officer of AzurRx Biopharma, Inc. where he also served as a Director from October 2015 to October 2019. 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.

Charles Ence was appointed as our Chief Accounting and Compliance Officer in January 2020. Prior to this he was our Chief Financial Officer from July 29, 2019 to January9, 2020. From October 2018 until June 2019, Mr. Ence was Corporate Controller of New Age Beverages Corp/Xing Beverages, LLC ("New Age") located in Denver, Colorado. From August 2003 until October 2018, Mr. Ence was Chief Financial Officer of New Age. 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.

Thomas C. Wessel, has been our Executive Vice President, Head of Research and Development since March 9, 2020. Dr. Wessel is a board-certified neurologist with extensive drug development experience, including medical lead for three CNS products approved in the United States: Razadyne®, Lunesta® and Ampyra®. Over the last decade, he served as Chief Medical Officer (CMO) for Acorda Therapeutics from November 2008 to September 2011, Flex Pharma from December 2014 to July 2018 and more recently at Asceneuron from November 2018 to October 2019. He was also a CMO consultant with Verge Genomics in San Francisco from December 2019 to March 2020. Dr. Wessel gained extensive experience in the development of CNS active isomers as Senior Vice President of Clinical Research at Sepracor from September 2007 to October 2008. He also worked on several development projects in neurology and psychiatry at Janssen Pharmaceutical (Johnson & Johnson) in Europe and the United States. Dr. Wessel received his M.D. from the Ludwig-Maximilians-University in Munich, Germany, and his Ph.D. in experimental neurobiology at the Max-Planck-Institute for Psychiatry in Martinsried, Germany. Dr. Wessel completed his residency in neurology at New York Hospital and Memorial Sloan-Kettering Cancer Center (Department of Neurology at Weill Cornell University Hospital) where he remained on the faculty for several years as an Instructor and Assistant Professor before joining the industry.

Board of Directors

Charles J. Casamento has been our Chairman of the Board since June 2017 and a director since July 2015. Mr. Casamento is a member of our Audit Committee, Compensation Committee, 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.

Earlier in his career, Mr. Casamento was Senior Vice President & General Manager for Pharmaceuticals and Biochemicals at Genzyme. 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.

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.

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. 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. Mr. Casamento brings over 35 years of biotechnology experience to our Board of Directors, having served in various senior 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. Casamento 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 M.B.A. 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.

Eric Schmidt has been a Director of the Company since December 19, 2019. Dr. Schmidt is also the Chairman of the Company's Audit Committee and a member of the Company's Corporate Governance and Nominating Committee. He has served as the Chief Financial Officer of Allogene Therapeutics, Inc. since June 2018. Prior to joining Allogene Therapeutics, Dr. Schmidt was a Managing Director and Senior Research Analyst at Cowen and Company, LLC. He joined Cowen as a Research Analyst in 1998 where he covered biotechnology stocks until June 2018. He was previously a Vice President and Research Analyst for UBS Securities. Before joining UBS in 1995, he co-founded Cambridge Biological Consultants, a scientific consulting and research firm. Dr. Schmidt obtained a Bachelor of Arts in Chemistry from the University of Pennsylvania and a Ph.D. in Biology from the Massachusetts Institute of Technology. That Dr. Schmidt brings over 25 years of biotechnology and financial 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 Dr. Schmidt should serve as a director.

John Glasspool has been a Director of the Company since December 19, 2019. Mr. Glasspool is also a member of the Company's Compensation Committee and Chairman of the Company's Corporate Governance and Nominating Committee. He has been CEO and member of the Board of Directors of Anthos Therapeutics since February 2019. He is also has been a member of the Board of Directors of Dalcor Corporation since May 2017, and a senior advisor to MIT since October 2016. From June 2017 to October 2018, he was a consultant for Roivant Sciences. From July 2015 to January 2017, Mr. Glasspool was the Executive Vice President, Head of Corporate Strategy and Customer Operations at Baxalta Incorporated, formerly Baxter BioScience. From August 2012 to June 2015, he was Vice President, Emerging Therapies and Market Development at Baxter Bioscience. Mr. Glasspool obtained a Bachelor of Arts degree from the University of Staffordshire and a degree in Business Administration from Oxford University. That Mr. Glasspool 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 Mr. Glasspool has developed significant management and leadership skills relating to the pharmaceutical industry led us to conclude that Mr. Glasspool 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 2019 Meeting)
Eric Schmidt	Class I	24 months
Charles J. Casamento	Class II	36 months
Sergio Traversa	Class II	36 months
Paul Kelly	Class III	12 months
John Glasspool	Class III	12 months

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

Director Independence

We believe that Charles J. Casamento, Paul Kelly, Eric Schmidt, and John Glasspool qualify as independent directors for NASDAQ Stock Market purposes. This means that our board of directors is composed of a majority of independent directors as required by NASDAQ Stock Market rules.

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 serves as our Chief Executive Officer and Charles J. Casamento 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 six months ended December 31, 2019, the Board of Directors held 12 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
Eric Schmidt*	John Glasspool*	Paul Kelly*
Charles J. Casamento	Charles J. Casamento	Charles J. Casamento
Paul Kelly	Eric Schmidt	John Glasspool

***** 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 NASDAQ Capital Market. Eric Schmidt 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 John Glasspool, Charles J. Casamento and Eric Schmidt. Mr. Glasspool 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 two times in 2019 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. Since June 30, 2019 no 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 for the six months ended December 31, 2019, for our Executive officers:

Name/Position	Salary	Bonus	Option Awards (a)	All other compensation (b)	Total
Sergio Traversa Chief Executive Officer and Director	$ 214,115	$ 250,000	$ 15,690,640	$ -	$ 16,154,755
Ottavio Vitolo, MD Senior Vice President, Head of R&D and Chief Medical Officer	$ 165,000	$ 132,000	$ 4,068,960	$ -	$ 4,365,960
Charles Ence Chief Financial Officer	$ 101,935	$ 50,000	$ 2,341,637	$ -	$ 2,493,572

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)	June 30, 2019	$ 367,500	$ 25,000	$ 843,862	$ -	$ 1,236,362
Chief Executive Officer and Director	June 30, 2018	$ 376,250	$ 46,000	$ 552,267	$ -	$ 974,517
Ottavio Vitolo, MD (2)	June 30, 2019	$ 330,000	$ -	$ 375,050	$ -	$ 705,050
Senior Vice President, Head of R&D and Chief Medical Officer	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. Dr. Vitolo left the Company on March 6, 2020.

(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)

On January 9, 2020, the Company and Mr. Traversa entered into an Amended and Restated Employment Agreement (the "Traversa Employment Agreement"). The parties entered into an Amended and Restated Employment Agreement on August 5, 2015 which is amended and restated pursuant to the Traversa Employment Agreement. Pursuant to the Traversa Employment Agreement, Mr. Traversa and the Company agreed to the following:

- Salary is $600,000 per year, and he may be entitled to a cash bonus in an amount to be determined by the board with a target of 50% of the base salary.

- Mr. Traversa may also be entitled to certain severance payments. Upon termination of Mr. Traversa's employment due to death, his estate also shall be entitled to receive a single lump sum payment equal to three (3) months base salary, payable within 30 days of his death. In the event of termination other than for cause or resignation for good reason Mr. Traversa will be entitled to severance equal to twenty four (24) months of compensation and health benefits. In the event of termination in connection with a change of control, Mr. Traversa will be entitled to severance equal to thirty (30) months of compensation and health benefits.

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

- Mr. Traversa is also eligible to participate in the Company's benefit plans that are generally provided for executive employees.

- Non-Solicitation. The Employment Agreement also contains a non-solicitation provision that, among other things, provides that during the term of employment and for a period of 24 months following the cessation of employment with the Company he 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

- 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 Maged Shenouda (Chief Financial Officer)

On January 9, 2020, the Company and Mr. Shenouda entered into an employment agreement (the "Shenouda Employment Agreement"). Pursuant to the Shenouda Employment Agreement, Mr. Shenouda and the Company agreed to the following:

- Salary is $395,000 per year, and he may be entitled to a cash bonus in an amount to be determined by the board with a target of 40% of the base salary.

- Mr. Shenouda's employment with the Company will be on an "at will" basis meaning that either Mr. Shenouda or the Company may terminate his employment at any time for any reason or no reason, upon written notification to the other party, without further obligation or liability, except as provided in the agreement.

  Mr. Shenouda may also be entitled to certain severance payments. Upon termination of Mr. Shenouda's employment due to death, his estate also shall be entitled to receive a single lump sum payment equal to three (3) months base salary, payable within 30 days of his death. In the event of termination other than for cause, resignation for good reason, or in connection with a change of control, Mr. Shenouda will be entitled to severance equal to six months of compensation and health benefits.

- During the term of the agreement, he may also be awarded grants under the Company's 2014 Stock Option and Equity Incentive Plan, as amended (the "Stock Plan"), subject to Board approval. Mr. Shenouda's options granted to him as a Director of the Company shall continue to vest in accordance with the terms of the Stock Plan, so long as he remains employed by the Company.

- Mr. Shenouda is also eligible to participate in the Company's benefit plans that are generally provided for executive employees.

- Non-Solicitation. The Employment Agreement also contains a non-solicitation provision that, among other things, provides that during the term of employment and for a period of 24 months following the cessation of employment with the Company he 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.

- The Company also entered in a standard indemnification agreement (the "Indemnification Agreement") with Mr. Shenouda where the Company agreed to indemnify him in certain situations for his role as Chief Financial Officer.

Compensatory Plan with Charles Ence (Chief Accounting and Compliance Officer)

On January 9, 2020, the Company and Mr. Ence entered into an employment agreement (the "Ence Employment Agreement"). Pursuant to the Ence Employment Agreement, Mr. Ence and the Company agreed to the following:

- Salary is $275,000 per year, and he may be entitled to a cash bonus in an amount to be determined by the board with a target of 40% of the base salary. Mr. Ence was also awarded a sign on bonus of $100,000.

- Mr. Ence's employment with the Company will be on an "at will" basis meaning that either Mr. Ence or the Company may terminate his employment at any time for any reason or no reason, upon written notification to the other party, without further obligation or liability, except as provided in the agreement.

  Mr. Ence may also be entitled to certain severance payments. Upon termination of Mr. Ence's employment due to death, his estate also shall be entitled to receive a single lump sum payment equal to three (3) months base salary, payable within 30 days of his death. In the event of termination other than for cause, resignation for good reason, or in connection with a change of control, Mr. Ence will be entitled to severance equal to six months of compensation and health benefits.

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

- Mr. Ence is also eligible to participate in the Company's benefit plans that are generally provided for executive employees.

- Non-Solicitation. The Employment Agreement also contains a non-solicitation provision that, among other things, provides that during the term of employment and for a period of 24 months following the cessation of employment with the Company he 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 Accounting and Compliance 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 Thomas Wessel (EVP, Head of Research & Development)

On March 8, 2020, the Company and Dr. Wessel entered into an employment agreement (the "Wessel Employment Agreement"). Pursuant to the Wessel Employment Agreement, Dr. Wessel and the Company agreed to the following:

- Salary is $475,000 per year, and a sign on bonus of $50,000, with a yearly target bonus of 40% of the base salary.

- Dr. Wessel's. employment with the Company will be on an "at will" basis meaning that either Dr. Wessel or the Company may terminate his employment at any time for any reason or no reason, upon written notification to the other party, without further obligation or liability, except as provided in the agreement.

Dr. Wessel may also be entitled to certain severance payments. In the event of termination other than for cause, Dr. Wessel will be entitled to severance equal to six months of compensation and health benefits.

- During the term of the agreement, he may also be awarded grants under the Company's 2014 Stock Option and Equity Incentive Plan, as amended (the "Stock Plan"), subject to Board approval. Dr. Wessel was granted an initial option grant of 350,000 shares which vest over a four year period pursuant to the terms of the Company's stock plan.

- Dr. Wessel is also eligible to participate in the Company's benefit plans that are generally provided for executive employees.

- Non-Solicitation. The Employment Agreement also contains a non-solicitation provision that, among other things, provides that during the term of employment and for a period of 24 months following the cessation of employment with the Company he 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. Dr. Wessel and the Company also entered into the Company's standard indemnification agreement where the Company agreed to indemnify Dr. Wessel in certain circumstances.

Director Compensation

Non-management Directors of the Company receive a quarterly cash retainer of $15,000 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 $57,000 per year for his role as chairman.

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

BOD Committee	Chairman	Member
Audit	$ 20,000	$ 9,000
Compensation	$ 14,500	$ 7,000
Corporate Governance and Nominating	$ 14,500	$ 7,000

The following table sets forth the compensation of our directors for the six months ended December 31, 2019:

Name	Fees Earned or Paid in Cash	Stock Awards	Option Awards (a)	All Other Compensation	Total
Charles J. Casamento (1)	$ 60,000	$ -	$ 4,508,367	$ -	$ 4,568,367
Maged Shenouda (2)	$ 33,500	$ -	$ 5,232,753	$	$ 5,266,253
Paul Kelly (2)	$ 33,500	$ -	$ 6,496,620	$ -	$ 6,530,120

(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.

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

Name	Year	Fees Earned or Paid in Cash	Stock Awards	Option Awards (a)	All Other Compensation	Total
Charles J. Casamento (1)	2019	$ 120,000	$ -	$ 421,931	$ -	$ 541,931
Charles J. Casamento	2018	$ 120,000	$ -	$ 276,134	$ -	$ 396,134
Maged Shenouda (2)	2019	$ 67,000	$ -	$ 421,931	$	$ 488,931
Maged Shenouda	2018	$ 67,000	$ -	$ 276,134	$ 65,918	$ 409,052
Paul Kelly (2)	2019	$ 67,000	$ -	$ 468,812	$ -	$ 535,812
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.Maged Shenouda was appointed the Company's CFO in January, 2020.

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 March 11, 2020. 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 March 5, 2020, 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 14,891,729 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**
Venrock Healthcare Capital Partners[(1)] 7 Bryant Park 23rd floor, New York, NY 10018	882,814	6.0%
Tang Capital Partners[(2)] 4747 Executive Drive, Suite 510, San Diego, CA 92121	780,847	5.2%
Sergio Traversa, PharmD, MBA[(3)] Director and Chief Executive Officer	372,912	2.5%
Paul Kelly[(4)] Director	325,906	2.2%
Charles J. Casamento[(5)] Chairman of the Board	118,195	*
Maged Shenouda[(6)] Chief Financial Officer	126,717	*
Thomas Wessel[(7)] EVP, Head of R&D	-	*
Charles Ence[(8)] Chief Accounting & Compliance Officer	28,750	*
Eric Schmidt[(9)] Director	112,500	*
John Glasspool[(10)] Director	12,500	*
All Directors and Executive Officers	1,097,480	7.4%

* Below 1% ownership.

(1) These shares are owned directly as follows: 81,745 shares are owned by Venrock Healthcare Capital Partners II, L.P., 33,131 shares are owned by VHCP Co-Investment Holdings II, LLC, 698,142 shares are owned by Venrock Healthcare Capital Partners III, L.P. and 69,796 shares are owned by VHCP Co-Investment Holdings III, LLC. VHCP Management II, LLC is the general partner of Venrock Healthcare Capital Partners II, L.P. and the manager of VHCP Co-Investment Holdings II, LLC. VHCP Management III, LLC is the general partner of Venrock Healthcare Capital Partners III, L.P. and the manager of VHCP Co-Investment Holdings III, LLC. Messrs. Shah and Koh are the voting members of VHCP Management II, LLC and VHCP Management III, LLC.

(2) Includes 780,847 shares as reported in Form 13G.

(3) Includes: 29,631 common shares; 33,898 vested options with an exercise price of $16.00; 33,288 vested options with an exercise price of $16.00; 11,250 vested options with an exercise price of $54.00; 119,531 vested options with an exercise price of $3.24; 70,313 vested options with an exercise price of $4.60; 53,126 vested options with an exercise price of $8.80; 21,875 vested options with an exercise price of $43.47; and Excludes: 92,969 unvested options with an exercise price of $3.24; 154,687 unvested options with an exercise price of $4.60; 371,874 unvested options with an exercise price of $8.80; 328,125 unvested options with an exercise price of $43.47.

(4) Includes: 127,121 common shares; 24,375 Investor Warrants at $6.00 per share; 25,000 Investor Warrants at $1.50 per share; 12,500 Investor Warrants at $9.00 per share; 6,441 vested options with an exercise price of $13.80; 63,281 vested options with an exercise price of $3.24; 39,063 vested options with an exercise price of $4.60; 18,750 vested options with an exercise price of $8.80; 9,375 vested options with an exercise price of $43.47; and Excludes: 49,219 unvested options with an exercise price of $3.24; 85,937 unvested options with an exercise price of $4.60; 131,250 unvested options with an exercise price of $8.80; 140,625 unvested options with an exercise price of $43.47.

(5) Includes: 62,534 common shares; 6,441 vested options with an exercise price of $13.80; 13,282 vested options with an exercise price of $3.24; 14,062 vested options with an exercise price of $4.60; 15,626 vested options with an exercise price of $8.80; 6,250 vested options with an exercise price of $43.47; and Excludes: 92,968 unvested options with an exercise price of $3.24; 98,438 unvested options with an exercise price of $4.60; 109,374 unvested options with an exercise price of $8.80; 93,750 unvested options with an exercise price of $43.47.

(6) Includes: 2,228 common shares; 6,441 vested options with an exercise price of $13.80; 59,766 vested options with an exercise price of $3.24; 35,156 vested options with an exercise price of $4.60; 15,626 vested options with an exercise price of $8.80; 7,500 vested options with an exercise price of $43.47; and Excludes: 46,484 unvested options with an exercise price of $3.24; 77,344 unvested options with an exercise price of $4.60; 109,374 unvested options with an exercise price of $8.80; 112,500 unvested options with an exercise price of $43.47.

(7) Excludes: 350,000 unvested options with an exercise price of $45.61.

(8) Includes: 25,000 vested options with an exercise price of $8.80; 3,750 vested options with an exercise price of $43.47; and Excludes: 56,250 unvested options with an exercise price of $43.47.

(9) Includes: 55,000 common shares; 32,500 Investor Warrants at $6.00 per share; 12,500 Investor Warrants at $9.00 per share; 12,500 vested options with an exercise price of $43.47; and Excludes: 187,500 unvested options with an exercise price of $43.47.

(10) Includes: 12,500 vested options with an exercise price of $43.47; and Excludes: 187,500 unvested options with an exercise price of $43.47.

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 1,652,942. 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 2,652,942. At December 31, 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 December 31, 2019, the Company had exceeded the maximum shares under the plan by 962,660. On December 19,2019 the Board unanimously approved he amendment to the Company's 2014 Stock Option and Equity Incentive Plan, as amended, subject to stockholder approval, to increase the number of shares of Common Stock authorized for issuance under the Plan by 2.5 million shares from 2,652,942 to 5,152,942.

Outstanding Equity Awards at Fiscal Year-End Table

OUTSTANDING EQUITY AWARDS AT DECEMBER 31, 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 December 31, 2019.

	Option Awards					Stock Award			
Name (a)	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 Unearned 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)	Equity Incentive Plan Awards: Number of 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	33,898	-	-	16.00	07/10/2022	-	-	-	-
Sergio Traversa	33,288	-	-	16.00	09/30/2023	-	-	-	-
Sergio Traversa	11,250		-	54.00	02/23/2025	-	-	-	-
Sergio Traversa	106,250	106,250	-	3.24	10/20/2027	-	-	-	-
Sergio Traversa	56,250	168,750	-	4.60	12/20/2028	-	-	-	-
Sergio Traversa	26,563	398,437	-	8.80	07/29/2029	-	-	-	-
Sergio Traversa	-	350,000	-	43.47	12/19/2029	-	-	-	-
Ottavio Vitolo	28,125	46,875		3.52	04/02/2028	-	-	-	-
Ottavio Vitolo	37,500	-		3.20	06/27/2027	-	-	-	-
Ottavio Vitolo	25,000	75,000		4.60	12/20/2028	-	-	-	-
Ottavio Vitolo	2,344	35,156		8.80	07/29/2029	-	-	-	-
Ottavio Vitolo	-	105,000		43.47	12/19/2029	-	-	-	-
Charles Ence	-	25,000		8.80	7/29/2029	-	-	-	-
Charles Ence	-	60,000		43.47	12/19/2029	-	-	-	-
	360,468	1,370,468							

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, 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

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 1,652,942. 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 2,652,942. In December 2019, the board approved an amendment to the Plan (the 2019 Plan Amendment) that increased the number of shares under the plan to 5,152,942. This increase was ratified by shareholders at the March 6, 2020 annual meeting.

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

The following is a summary of each transaction or series of similar transactions since June 30, 2017 or any currently proposed transaction, to which we were or are a party in which:

- the amount involved exceeded or exceeds $120,000 or one percent of our total assets at June 30, 2018; and
- any of our directors or executive officers or any beneficial owners of 5% of any class of our voting capital stock or and affiliate or immediate family member thereof, had or will have a direct or indirect material interest, other than compensation and other arrangements that are described under the section titled "Executive Compensation" or that were approved by our compensation committee.

Beneficial ownership is determined in accordance with the rules of the SEC and generally includes voting or investment power with respect to such securities.

Related Party Transactions

License Agreement

See "Business—Intellectual Property Portfolio and Market Exclusivity—D-Methadone License Agreement" regarding our Intellectual Property Assignment Agreement and License Agreement with Dr. Charles E. Inturrisi and Dr. Paolo Manfredi, as it relates to our Chief Executive Officer, Sergio Traversa.

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 December 31, 2019, the transition period, June 30, 2019 and 2018, are set forth in the table below:

Fee Category	For the Six Months Ended December 31, 2019	For the Year Ended June 30, 2019	For the Year Ended June 30, 2018
Audit fees (1)			
GBH CPAs PC	$ -	$ -	$ 54,000
Marcum LLP	168,500	137,000	57,000
Audit-related fees (2)	-	-	-
Tax fees	-	-	-
All other fees (4)	-	-	-
Total fees	$ 168,500	$ 137,000	$ 111,000

(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 six months ended December 31, 2019, the transition period, and 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.
(INDEX TO FINANCIAL STATEMENTS)

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 December 31, 2019, June 30, 2019 and June 30, 2018, the related consolidated statements of operations, stockholders' equity (deficit) and cash flows for the six months ended December 31, 2019 and 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 December 31, 2019, June 30, 2019 and June 30, 2018, and the results of its operations and its cash flows for the six months ended December 31, 2019 and each of the two years in the period ended June 30, 2019, 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 llp

Marcum llp

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

Houston, Texas
March 26, 2020

Relmada Therapeutics, Inc.
Consolidated Balance Sheets

	As of December 31, 2019	As of June 30, 2019	As of June 30, 2018
Assets			
Current assets:			
Cash and cash equivalents	$ 36,278,519	$ 9,216,554	$ 2,238,943
Short-term investments	80,164,823	-	-
Other receivable	-	176,980	7,617
Lease payments receivable – short term	73,091	70,102	64,486
Prepaid expenses	423,863	520,745	426,921
Total current assets	116,940,296	9,984,381	2,737,967
Fixed assets, net of accumulated depreciation	5,010	7,210	12,080
Other assets	25,000	25,000	24,788
Lease payments receivable – long term	165,834	203,142	273,244
Total assets	$ 117,136,140	$ 10,219,733	$ 3,048,079
Liabilities and Stockholders' Equity (Deficit)			
Current liabilities:			
Accounts payable	$ 522,663	$ 924,359	$ 765,439
Accrued expenses	824,936	1,317,855	659,455
Notes payable	110,247	364,204	285,170
Derivative Liabilities	-	-	4,194,634
Total current liabilities	1,457,846	2,606,418	5,904,698
Promissory notes payable, net of discount of $0, $0, and $4,548,543	-	-	2,656,457
Total liabilities	1,457,846	2,606,418	8,561,155
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, 50,000,000 shares authorized, 14,457,013, 9,744,643 and 3,137,468 shares issued and outstanding, respectively	14,457	9,744	3,137
Additional paid-in capital	235,522,746	119,265,938	88,828,094
Accumulated deficit	(119,858,909)	(111,662,367)	(94,344,307)
Total stockholders' equity (deficit)	115,678,294	7,613,315	(5,513,076)
Total liabilities and stockholders' equity (deficit)	$ 117,136,140	$ 10,219,733	$ 3,048,079

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

Relmada Therapeutics, Inc.
Consolidated Statements of Operations

	Six months ended December 31, 2019	(Unaudited) Six months ended December 31, 2018	Year ended June 30, 2019	Year ended June 30, 2018
Operating expenses:				
Research and development	$ 3,513,606	$ 2,678,900	$ 7,024,747	$ 2,942,625
General and administrative	4,757,999	3,211,314	5,703,173	3,974,850
Total operating expenses	8,271,605	5,890,214	12,727,920	6,917,475
Loss from operations	(8,271,605)	(5,890,214)	(12,727,920)	(6,917,475)
Other income (expenses):				
Change in fair value of derivative liabilities	-	(54,634)	(54,634)	(708,901)
Interest income (expense), net	75,063	(790,087)	(761,038)	(1,336,826)
Other	-	-	-	2,350
Loss on extinguishment of debt	-	(3,774,468)	(3,774,468)	-
Total other income (expenses)	75,063	(4,619,189)	(4,590,140)	(2,043,377)
Net loss	$ (8,196,542)	$ (10,509,403)	$ (17,318,060)	$ (8,960,852)
Net loss per common share – basic and diluted	$ (0.77)	$ (2.20)	$ (2.74)	$ (2.86)
Weighted average number of common shares outstanding – basic and diluted	10,577,866	4,766,724	6,311,769	3,136,336

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

Relmada Therapeutics, Inc.
Consolidated Statements of Stockholders' Equity (Deficit)

	Common Stock		Additional Paid-in	Accumulated	
	Shares	Par Value	Capital	Deficit	Total
Balance – June 30, 2017	3,132,093	$ 3,132	$ 86,840,607	$ (85,383,455)	$ 1,460,284
Issuance of restricted common stock	938	1	3	-	4
Issuance of common stock for cashless exercises of warrants from consultants and Series A Preferred Stock warrant holder	4,437	4	(4)	-	-
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	3,137,468	3,137	88,828,094	(94,344,307)	(5,513,076)
Cumulative effect of Write-off of Derivative Liabilities under ASU 2017-11	-	-	59,397	-	59,397
Adjusted Balance at June 30, 2018	3,137,468	3,137	88,887,491	(94,344,307)	(5,453,679)
Stock-based compensation expense	-	-	1,213,996	-	1,213,996
Conversion of notes and accrued interest	2,682,917	2,683	11,802,150	-	11,804,833
Equity units issued for cash, net	3,975,115	3,975	17,756,660	-	17,760,635
Shares relinquished by former officer	(75,848)	(76)	(394,334)	-	(394,410)
Issuance of common stock for cashless exercises of warrants from consultants and Series A Preferred Stock warrant holder	24,991	25	(25)	-	-
Net loss	-	-	-	(17,318,060)	(17,318,060)
Balance – June 30, 2019	9,744,643	9,744	119,265,938	(111,662,367)	7,613,315
Stock-based compensation expense	-	-	2,367,001	-	2,367,001
Equity units issued for cash, net	3,951,299	3,951	109,443,531	-	109,447,482
Warrants exercised	656,943	657	4,446,381	-	4,447,038
Cashless exercise of warrants	42,644	43	(43)	-	-
Cashless exercise of options	61,484	62	(62)	-	-
Net loss	-	-	-	(8,196,542)	(8,196,542)
Balance – December 31, 2019	14,457,013	$ 14,457	$ 235,522,746	$ (119,858,909)	$ 115,678,294

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

Relmada Therapeutics, Inc.
Consolidated Statements of Stockholders' Equity (Deficit) (Unaudited)

	Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Capital	Deficit	Deficit
Balance - June 30, 2018	3,137,468	$ 3,137	$ 88,828,094	$ (94,344,307)	$ (5,513,076)
Cumulative effect of write-off of derivative liability for adoption of ASU 2017-11	-	-	59,397	-	59,397
Adjusted Balance - June 30, 2018	3,137,468	$ 3,137	$ 88,887,491	$ (94,344,307)	$ (5,453,679)
Stock based compensation	-	-	415,845	-	415,845
Conversion of Notes and accrued interest	2,682,917	2,683	11,802,150	-	11,804,833
Equity units issued for cash	1,620,668	1,621	5,175,464	-	5,177,085
Net loss	-	-	-	(10,509,403)	(10,509,403)
Balance - December 31, 2018 (unaudited)	7,441,053	$ 7,441	$ 106,280,950	$ (104,853,710)	$ 1,434,681

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

Relmada Therapeutics, Inc.
Consolidated Statements of Cash Flows

	Six months ended December 31, 2019	(Unaudited) Six months ended December 31, 2018	Year ended June 30, 2019	Year ended June 30, 2018
Cash flows from operating activities				
Net loss	$ (8,196,542)	$ (10,509,403)	$ (17,318,060)	$ (8,960,852)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation expense	2,200	2,707	4,870	2,627
Stock-based compensation	2,367,001	415,844	1,213,996	517,999
Amortization of deferred financing costs	-	661,167	661,168	1,029,183
Change in fair value of derivative liabilities	-	54,636	54,634	708,901
Fair value of shares relinquished	-	(394,410)	(394,410)	-
Loss on promissory note extinguishment	-	3,774,468	3,774,468	-
Changes in operating assets and liabilities:				
Prepaid expenses and other assets	96,882	(110,744)	270,167	42,741
Other receivable	176,980	7,617	(169,363)	224,980
Other assets	-	5,880	-	-
Lease payment receivable	34,319	31,570	64,486	59,319
Accounts payable	(401,696)	(406,549)	158,920	157,392
Accrued expenses	(492,919)	1,648,372	1,181,270	215,632
Net cash used in operating activities	(6,413,775)	(4,818,845)	(10,497,854)	(6,002,078)
Cash flows from investing activities				
Purchase of investments	(84,849,198)	-	-	-
Sale of investments	4,684,375	-	-	-
Purchase of fixed assets	-	-	-	(12,391)
Net cash used in investing activities	(80,164,823)	-	-	(12,391)
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	109,447,482	5,177,085	17,760,635	-
Proceeds from warrants exercised for common stock	4,447,038	-	-	-
Payment/proceeds on notes payable	(253,957)	(170,432)	(285,170)	8,500
Net cash provided by financing activities	113,640,563	5,006,653	17,475,465	6,542,900
Net increase in cash and cash equivalents	27,061,965	187,808	6,977,611	528,431
Cash and cash equivalents at beginning of the period	9,216,554	2,238,943	2,238,943	1,710,512
Cash and cash equivalents at end of the period	$ 36,278,519	$ 2,426,751	$ 9,216,554	$ 2,238,943

Relmada Therapeutics, Inc.
Consolidated Statements of Cash Flows (continued)

	Six months ended December 31, 2019	(Unaudited) Six months ended December 31, 2018	Year ended June 30, 2019	Year ended June 30, 2018
Supplemental disclosure of cash flows information:				
Cash paid during the period for:				
Income taxes	$ -	$ -	$ -	$ -
Interest	$ 4,610	$ 1,509	$ 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	$ 43	$ -	$ 100	$ 18
Cashless exercise of options for common stock	$ 62	$ -	$ -	$ -
Issuance of restricted stock for services	$ -	$ -	$ -	$ 4
Write off for derivative liability due to adoption of ASU 2017-11	$ -	$ 59,397	$ 59,397	$ -
Conversion of promissory notes and accrued interest to common stock	$ -	$ 8,030,365	$ 8,030,365	$ -

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

NOTE 1 - BUSINESS

Relmada Therapeutics Inc. (Relmada, the Company) (a Nevada corporation) 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 (NCE) that potentially addresses areas of high unmet medical need in the treatment of central nervous system (CNS) diseases and other disorders.

On October 7, 2019, our application to list our common stock on the NASDAQ Capital Market was approved. On October 10, 2019, our common stock began trading on Nasdaq under our existing symbol, "RLMD."

On December 19, 2019, the Board of Directors of the Company approved a change to its end of fiscal year from June 30 to December 31. The change in fiscal year will become effective for the Company's 2020 fiscal year, which will begin January 1, 2020 and end December 31, 2020. As a result, the Company is filing this transition report on Form 10-KT for the six-month period from July 1, 2019 through December 31, 2019 within the time period prescribed by the Securities and Exchange Commission.

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.

On September 26, 2019, the Company's Board of Directors approved a 1-to-4 reverse split of the Common Stock, which was effective on the NASDAQ Capital Market on September 30, 2019. As a result of the reverse stock split, every 4 shares of issued and outstanding common stock were converted into 1 share of issued and outstanding common stock, with all fractional shares rounded up to the nearest whole share, and the Company's authorized share of common stock were reduced from 200,000,000 to 50,000,000 shares. All share and per share amounts have been retroactively restated to reflect this reverse stock split.

Change in Fiscal Year

The Company changed its fiscal year end to December 31 from June 30. This transition report is for the six-month transition period of July 1, 2019 through December 31, 2019. The information for the six months ended December 31, 2018 is presented for comparative purposes only and is unaudited.

Liquidity

As shown in the accompanying financial statements, the Company incurred negative operating cash flows of $6,413,775 for the transition period ended December 31, 2019 and has an accumulated deficit of $119,858,909 from inception through December 31, 2019.

Relmada has funded its past operations through equity raises and most recently in the six months ended December 31, 2019, the transition period, Relmada raised net proceeds from the sale of common stock of $109,447,482 and $4,447,038 through the exercise of warrants.

Management believes that due to the recent equity raises completed and exercises of outstanding warrants and the current cash position on its balance sheet, it has obtained sufficient funding to continue ongoing operations for at least 12 months from the issuance of the accompanying consolidated financial statements. Since December 31, 2019 and to date, the Company has received approximately $3,100,000 in warrant and option exercises, which resulted in the Company having approximately $116.4 million in cash, cash equivalents, and short term investments at March 16, 2020. Based on its budgeted cash flow requirements, the Company believes these funds are sufficient to fund its ongoing operations for at least 12 months after the issuance of these consolidated financial statements. Regardless of the results of any ongoing clinical trial, the Company has control over its expenditures and has the ability to adjust spending accordingly based on the budgeted cash flow requirements developed and the excess cash on hand.

Management believes that their existing cash and cash equivalents will enable them to fund operating expenses and capital expenditure requirement for at least the next 12 months. Beyond that point management will evaluate the size and scope of any subsequent trials that 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 at least 12 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 stock-based compensation expenses, the valuation of derivative liabilities 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 $36,278,519 at December 31, 2019 at these institutions exceed federally insured limits.

Short-term Investments

The Company's investments consist entirely of mutual funds. The securities are measured at fair value based on the net asset value ("NAV"). The Company has adopted FASB ASU 2016-01, Financial Instruments, for the six months ended December 31, 2019 which requires substantially all equity investments in nonconsolidated entities to be measured at fair value with recurring changes recognized in earnings, except for those accounted for using equity method accounting. Changes in fair value of the securities are recorded as part of other income on the consolidated statement of operations. Short term investment activity is presented in the investing activities section on the consolidated statement of cash flows.

Short-term investments at December 31, 2019 consisted of mutual funds with a fair value of $80,164,823.

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.

Leases

The Company recognizes their leases with a term of greater than a year on the balance sheet by recording right-of-use assets and lease liabilities. Leases can be classified as either operating leases or finance leases. Operating leases will result in straight-line lease expense, while finance leases will result in front-loaded expense. The Company's lease consists of an operating leases for office space. The Company does not recognize a lease liability or right-of-use asset on the balance sheet for short-term leases. Instead, the Company recognizes short-term lease payments as an expense on a straight-line basis over the lease term. A short-term lease is defined as a lease that, at the commencement date, has a lease term of 12 months or less and does not include an option to purchase the underlying asset that the lessee is reasonably certain to exercise.

Fair Value of Financial Instruments

The Company's financial instruments primarily include cash, short term investments derivative liabilities and accounts payable. Due to the short-term nature of cash 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. 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).

The Company's short-term investment instruments of $80,164,823 at December 31, 2019 are classified using Level 1 inputs within the fair value hierarchy because they are valued using NAV. Unrealized gains and losses are recorded in the consolidated statement of operations under other income. The Company recorded an unrealized gain of $974, included in other income for the period ended December 31, 2019.

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 as of June 30, 2018 were all converted to equity during the year ended June 30, 2019. As of June 30, 2019 and December 31, 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 December 31, 2019, 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 December 31, 2019, 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 forward.

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.

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.

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 losses in each period.

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):

	Six Months ended December 31, 2019	(Unaudited) Six Months ended December 31, 2018	Year ended June 30, 2019	Year ended June 30, 2018
Common stock warrants	3,646,872	3,743,898	4,429,982	2,453,753
Common stock options	3,615,602	1,435,810	1,473,314	767,216
Total	7,262,474	5,179,708	5,903,296	3,220,969

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. The adoption of this standard had no impact on the Company's consolidated financial statements due to the Company's leases being for periods of one year or less.

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.

In December 2019, the FASB issued ASU 2019-12, "*Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*" which is intended to simplify various aspects related to accounting for income taxes. ASU 2019-12 removes certain exceptions to the general principles in Topic 740 and also clarifies and amends existing guidance to improve consistent application. This guidance is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020, with early adoption permitted. We do not expect the adoption of ASU 2019-12 to have a material impact on our 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):

	December 31, 2019	June 30, 2019	June 30, 2018
Insurance	$ 223,600	$ 451,500	$ 345,700
Research and Development	139,200	-	20,800
Legal	11,000	7,500	10,000
Rent	-	-	9,200
Other	50,100	61,800	41,200
Total	$ 423,900	$ 520,800	$ 426,900

NOTE 4 - FIXED ASSETS

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

	Useful lives	December 31, 2019	June 30, 2019	June 30, 2018
Computer and software	3 years	$ 16,700	$ 16,700	$ 16,700
Less: accumulated depreciation		(11,700)	(9,500)	(4,600)
Fixed assets, net		$ 5,000	$ 7,200	$ 12,100

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 December 31, 2019, June 30, 2019 and June 30, 2018, the balance of unearned interest income was approximately $32,100, $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 December 31, 2019 are as follows:

2020	$ 90,348
2021	90,348
2022	90,348
Total	$ 271,044

NOTE 5 - ACCRUED EXPENSES

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

	December 31, 2019	June 30, 2019	June 30, 2018
Research and development	$ 134,500	$ 563,400	$ 10,400
Professional fees	172,900	98,400	173,600
Accrued bonus	50,000	-	-
Accrued vacation	124,600	96,700	48,000
Legal Settlement	250,000	500,000	-
Interest on promissory notes	-	-	371,600
Other	92,900	59,400	55,900
Total	$ 824,900	$ 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 December 31, 2019 and June 30, 2019 and 2018, the note payable outstanding balances were approximately $110,200, $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 643,643 warrants expired in the year ended June 30, 2019.

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 July 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.

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 December 31, 2019 and 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
	$ -	$ -	$ 4,194,634	$ 4,194,634

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:

	Six Months ended		Year ended	
	December 31, 2019	(Unaudited) December 31, 2018	June 30, 2019	June 30, 2018
Beginning balance	$ -	$ 4,194,634	$ 4,194,634	$ 175,853
Adoption of ASU 2017-11 – warrants	-	(59,397)	(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	54,634	708,901
Extinguishment of derivative liabilities on conversion of promissory notes.	-	(4,189,871)	(4,189,871)	-
Ending balance	$ -	$ -	$ -	$ 4,194,634

The Company had no financial liabilities classified as level 3 during the six months ended December 31, 2019 and year ended June 30, 2019.

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 2,682,917 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.

NOTE 9 - STOCKHOLDERS' EQUITY

Common Stock

During the six months ended December 31, 2019 and the years ended June 30, 2019 and 2018, the Company issued 42,644, 24,991, and 4,437 shares of common stock for cashless exercise of 88,751, 25,004, and 4,443 warrants, respectively.

During the six months ended December 31, 2019, the Company issued 61,484 shares of common stock for cashless exercise of 67,578 options.

During the six months ended December 31, 2019, the Company closed on a private placement of 3,833,334 shares of common stock. The price per share was $30.00 to the public (with a price to the underwriters of $28.00 per share). The net proceeds from the closing was $108,621,733. Approximately, $478,000 of legal and professional fees were incurred in relation to the closing. The Company also closed on a private placement of 117,965 shares for $7.00 per share and net proceeds of $825,749 during the 3rd calendar quarter of 2019.

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 2.60 or 2.00 of a share of common stock) was $3.60, $5.60 or $6.00. The Company issued an aggregate of 3,975,115 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.

Date of closing	Common Stock Issued	Warrants issued	Unit Price	Net proceeds	Warrant exercise price	Warrant coverage
October 12, 2018	501,027	325,668	$ 3.60	$ 1,630,991	$ 6.00	.65
October 18, 2018	410,084	266,555	$ 3.60	$ 1,287,007	$ 6.00	.65
November 2, 2018	374,864	243,662	$ 3.60	$ 1,215,242	$ 6.00	.65
December 5, 2018	334,694	217,550	$ 3.60	$ 1,083,307	$ 6.00	.65
February 12, 2019	201,389	130,903	$ 3.60	$ 725,000	$ 6.00	.65
March 27, 2019	178,572	89,286	$ 5.60	$ 1,000,000	$ 9.00	.50
May 14, 2019	569,083	284,541	$ 6.00	$ 3,168,865	$ 9.00	.50
June 14, 2019	612,914	306,456	$ 6.00	$ 3,274,331	$ 9.00	.50
June 20, 2019	720,799	360,399	$ 6.00	$ 4,059,050	$ 9.00	.50
June 28, 2019	71,689	35,845	$ 6.00	$ 395,863	$ 9.00	.50
Total	**3,975,115**	**2,260,865**		**$ 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 2,682,917 shares of common stock.

During the six months ended December 31, 2019, and years ended June 30, 2019 and 2018, the Company issued 0, 0 and 938 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 357,396 warrants to the placement agent in connection with the closings. The agent warrants have an exercise price between $3.96 and $9.00, 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 19, 2019, the Company granted employees options to purchase a total of 1,295,000 shares of common stock. The options have a ten-year term and have an exercise price of $43.47 and vest over 4 years. The options have an aggregate fair value of $46,904,043 calculated using the Black-Scholes option-pricing model. Variables used in the Black-Scholes option-pricing model include: (1) discount rate of 1.79% (2) expected life of 6.25 years, (3) expected volatility of 108.2%, and (4) zero expected dividends.

On December 19, 2019, the Company granted a consultant options to purchase a total of 10,000 shares of common stock. The options have a ten-year term and have an exercise price of $43.47 and vest immediately. The options have an aggregate fair value of $338,992 calculated using the Black-Scholes option-pricing model. Variables used in the Black-Scholes option-pricing model include: (1) discount rate of 1.73% (2) expected life of 5 years, (3) expected volatility of 107.4%, and (4) zero expected dividends.

On April 1, 2019, the Company granted various employees options to purchase a total of 37,500 shares of common stock. The options have a ten-year term and have an exercise price of $7.04 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.

On December 20, 2018, the Company granted various employees options to purchase a total of 675,000 shares of common stock. The options have a ten-year term and have an exercise price of $4.60 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.

During the year ended June 30, 2018, the Company granted employees options to purchase a total of 662,500 shares of common stock. The options have a ten-year term and have an exercise price ranging from $3.20 to $3.52 per share. 612,500 options vest at a rate of 6.25% each quarter over 4 years. 50,000 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 probably of the clinical trial event occurring. The fair value of the options on the grant date ranges from $2.60 to $2.84 per share using the Black-Scholes Option pricing model.

A summary of the changes in options outstanding for the periods ended December 31, 2019, 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	139,997	$ 25.64	6.7	$ -
Granted	662,500	3.28	9.3	511,000
Forfeited	(35,277)	37.00	-	-
Outstanding and expected to vest at June 30, 2018	767,220	$ 5.80	8.8	$ 511,000
Granted	712,500	4.73	9.5	-
Forfeited	(6,406)	-	-	-
Outstanding and expected to vest at June 30, 2019	1,473,314	$ 5.18	8.6	$ 4,668,153
Granted	2,205,000	29.32	9.8	-
Exercised	(62,712)	-	-	$ -
Outstanding and expected to vest at December 31, 2019	3,615,602	$ 19.96	9.2	$ 74,837,043
Options exercisable at December 31, 2019	632,301	$ 7.83	7.7	$ 19,924,698

At December 31, 2019, the Company has unrecognized stock-based compensation expense of approximately $54,814,000 related to unvested stock options over the weighted average remaining service period of 3.86 years. The weighted average fair value of options granted during the six months ended December 31, 2019 and 2018, and the years ended June 30, 2019 and 2018 was approximately $29.32, $4.60 (unaudited), $3.84 and $2.64 per share, respectively, on the date of grant using the Black-Scholes option pricing model with the following assumptions:

	Six Months Ended December 31, 2019	(Unaudited) Six Months Ended December 31, 2018	Year ended June 30, 2019	Year ended June 30, 2018
Risk free interest rate	1.73 to 1.79%	2.69%	2.37 to 2.69%	2.14 to 2.61%
Dividend yield	0%	0%	0%	0%
Volatility	107.4-108.2%	102.3%	101.5-102.3%	99.9-101.6%
Expected term (in years)	5 to 6.25	6.25	6.25	6.25

Stock-based compensation – restricted common stock

A summary of the changes in outstanding restricted stocks during the periods ended December 31, 2019, 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	2,188	$ 61.00
Issued	(938)	$ 61.00
Forfeited	(1,250)	$ 61.00
Outstanding and vested at June 30, 2018	-	$ -
Issued	-	$ -
Forfeited	-	$ -
Outstanding and vested at June 30, 2019	-	$ -
Issued	-	$ -
Forfeited	-	$ -
Outstanding and vested at December 31, 2019	-	$ -

As of December 31, 2019, June 30, 2019 and 2018, all restricted stock shares are issued.

Warrants

A summary of the changes in outstanding warrants during the periods ended December 31, 2019, June 30, 2019 and 2018 is as follows:

	Number of Shares	Weighted Average Exercise Price Per Share
Outstanding and vested at June 30, 2017	971,718	$ 30.85
Issued	1,486,482	$ 6.00
Exercised	(4,443)	$ 0.004
Outstanding and vested at June 30, 2018	2,453,757	$ 15.845
Issued	2,691,123	$ 7.10
Exercised	(25,004)	$ 0.004
Forfeited/Expired	(689,894)	$ 18.94
Outstanding and vested at June 30, 2019	4,429,982	$ 7.12
Issued	21,250	$ 10.25
Exercised	(740,694)	$ 7.80
Forfeited/Expired	(63,666)	$ 13.89
Outstanding and vested at December 31, 2019	3,646,872	$ 6.83

Included in the warrants outstanding at June 30, 2018 are 643,643 warrants that expired in the year ended June 30, 2019. These warrants had an exercise price that was subject to downward adjustment on the sale of equity at prices below their original exercise price.

On October 8, 2019, the Company granted 15,000 warrants to a contractor with exercise price of $10.85, non-cancellable term and immediate vesting. The warrants have an aggregated fair value of $121,252 that was calculated using the Black-Scholes option-pricing model. Variables used in the Black-Scholes option-pricing model include: (1) discount rate of 1.36% (2) expected life of 5 years, (3) expected volatility of 100%, and (4) zero expected dividends.

On August 1, 2019, the Company granted 6,250 warrants to a contractor with exercise price of $8.80, a 10-year term and immediate vesting. The warrants have an aggregated fair value of $41,386 that was calculated using the Black-Scholes option-pricing model. Variables used in the Black-Scholes option-pricing model include: (1) discount rate of 1.68% (2) expected life of 5 years, (3) expected volatility of 101.1%, and (4) zero expected dividends.

On March 9, 2019, the Company granted 17,857 warrants to a consultant with exercise price of $7.00, 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.

On January 1, 2019, the Company granted 30,000 warrants to a contractor with exercise price of $4.60, 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.

On December 20, 2018, the Company granted 25,000 warrants to a contractor with exercise price of $4.60, 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.

During the year ended June 30, 2019, the Company issued an aggregate of 2,260,860 warrants to investors in connection with private placements, with a fair value of approximately $11,420,300. The exercise price ranges from $6.00 to $9.00, 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 84,650 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 $3.00 to $6.60 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 1,200,833 and 201,000 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 $6.00 to $6.60. The warrants are non-cancellable, vest upon issuance or over the service period and expire the seventh anniversary of the date of issuance

At December 31, 2019, the Company had $129,000 of unrecognized stock based compensation expense related to outstanding warrants. At December 31, 2019, the aggregate intrinsic value of warrants vested and outstanding was $115,731,488. During the six months ended December 31, 2019, and the years ended June 30, 2019 and June 30, 2018, the Company recorded approximately $0, $0 and $50,000 of expenses, respectively, 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 (rounded to nearest $00):

	Six Months Ended December 31, 2019	(Unaudited) Six Months Ended December 31, 2018	Year ended June 30, 2019	Year ended June 30, 2018
Research and development	$ 174,500	$ 29,500	$ 215,900	$ 62,500
General and administrative	2,192,500	386,300	998,100	455,500
Total	$ 2,367,000	$ 415,800	$ 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 at the time. Mr. Seth had 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 provided 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 six months ended December 31, 2019.

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:

	December 31, 2019	June 30, 2019	June 30, 2018
Deferred tax assets:			
Federal net operating loss	$ 13,022,000	$ 13,555,000	$ 11,123,000
State net operating loss	7,912,000	8,252,000	6,678,000
Research and development tax credits	1,499,000	1,230,000	1,081,000
Capitalized R&D	3,168,000	-	-
Nonqualified Stock Options	172,000	-	-
Accruals	133,000	206,000	13,000
Other	45,000	46,000	37,000
Less: valuation allowance	(25,951,000)	(23,289,000)	(18,932,000)
Total	$ -	$ -	$ -

The Company has maintained a full valuation allowance against its deferred tax assets at December 31, 2019, 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 six months ended December 31, 2019, and the years ended June 30, 2019 and 2018, by approximately $2,662,000, $4,357,000, and $(235,000), respectively. Deferred tax asset for net operating loss carryforwards at December 31, 2019 was adjusted with the corresponding offset to valuation allowance.

At December 31, 2019, the Company had federal, New York State and New York City net operating loss (NOL) carryforwards of approximately $62,010,000, $58,357,000 and $57,937,000, respectively, which begin expiring in 2027, 2032 and 2032 respectively. Approximately $16,540,000 federal NOL can be carried forward indefinitely but it is limited to 80% of future taxable income. The Company also has federal research and development tax credit carryforwards of approximately $1,499,000 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 December 31, 2019.

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

	Six Months Ended December 31, 2019	(Unaudited) Six Months Ended December 31, 2018	Year Ended June 30, 2019	Year Ended June 30, 2018
Statutory federal income tax rate	21%	21%	21%	27.5%
State (net of federal benefit)	11.96%	8.4%	9.5%	6%
Non-deductible expenses	(5.75)%	(8.5)%	(6.3)%	(6.0)%
Impact of Tax Cuts and Jobs Act	-%	-%	-%	(71.6)%
Other	5.27%	1.7%	1%	-%
Change in valuation allowance	(32.48)%	(22.6)%	(25.2)%	44.1%
Effective income tax rate	0%	0%	0%	0%

The Company does not have any uncertain tax positions at December 31, 2019, 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.

NOTE 12 - COMMITMENTS AND CONTINGENCIES

License Agreements

Wonpung

On August 20, 2007, the Company entered into a License Development and Commercialization Agreement with Wonpung Mulsan Co, a shareholder of the Company. Wonpung 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.

Third Party Licensor

Based upon a prior acquisition, the Company assumed an obligation to pay a third party (Dr. Charles E. Inturrisi and Dr. Paolo Manfredi - see below): (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 December 31, 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

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 was for one year. The lease agreement expired on December 31, 2019 and has been renewed for calendar year 2020. As the Company's leases consist of one lease for their corporate headquarters, which is for a period of 12 months or less. The Company has elected the practical expedient and recognizes rent expense evenly over the 12 months.

The Company incurred rent expense of approximately $47,100, 68,000, $114,800, and $95,500 for the six months ended December 31, 2019 and December 31, 2018 (unaudited) and years ended June 30, 2019 and 2018, respectively.

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

From January 1st through March 16, 2020, 480,361 warrants with an average exercise price of $6.30 were exercised, for net proceeds of $3,028,414.

In February 2020, 2,434 options were exercised at an exercise price of $30.00, for net proceeds of $73,020.

In January 2020, Maged Shenouda retired from the Board of Directors and was appointed to be the Chief Financial Officer of Relmada.

In January 2020, Charles Ence was appointed to be the Chief Accounting and Compliance Officer of Relmada and his pre-existing consulting contract was terminated.

In March 2020, the company hired three individuals and granted 600,000 options pursuant to the employee stock option plan, which vest over 4 years and have a range of exercise price from $28.00 to $45.61.

The Company's lease agreement at 880 Third Avenue expired on December 31, 2019 and has been renewed for calendar year 2020. Included in this lease is additional office space on the 10th floor along with the existing space on the 5th floor for a total monthly cost of $13,610.

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
1.1	Underwriting Agreement, dated December 3, 2019, by and among Relmada Therapeutics, Inc. and Jefferies LLC and SVB Leerink LLC, as representatives of the several underwriters named therein (incorporated by reference to Exhibit 1.1 of Relmada's Form 8-K filed with the SEC on December 6, 2019).
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-Q 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).
	(v) Certificate of Change of Relmada Therapeutics, Inc. dated September 26, 2019 (incorporated by reference to Exhibit 3.1 of Relmada's Form 8-K filed with the SEC on September 27, 2019).
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).

Exhibit Number	Description
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).
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	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).
10.16	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).
10.17	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).
10.18	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).
10.19	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).
10.20	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).
10.21	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).
10.22	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).
10.23	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).
10.24	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).
10.25	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).
10.26	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).

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).
10.46	Form of Share Purchase Agreement, dated September 23, 2019 and September 26, 2019, among Relmada Therapeutics, Inc. and certain accredited investors named therein (incorporated by reference to Exhibit 10.4 of Relmada's Form 10-Q filed with the SEC on November 13, 2019).
10.47	Form of Registration Rights Agreement, dated September 23, 2019 and September 26, 2019, among Relmada Therapeutics, Inc. and certain accredited investors named therein (incorporated by reference to Exhibit 10.5 of Relmada's Form 10-Q filed with the SEC on November 13, 2019).
10.48	Amended and Restated Unit Purchase Agreement dated November 27, 2019, between Relmada Therapeutics, Inc., and certain accredited investors (incorporated by reference to Exhibit 10.1 of Relmada's Form 8-K filed with the SEC on December 3, 2019).
10.49	Amendment No.1 To License Agreement dated December 2, 2019, to the License Agreement dated January 16, 2018 between Relmada Therapeutics, Inc., and 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 December 3, 2019).
10.50	Director Agreement, effective December 19, 2019, by and between Eric Schmidt and Relmada Therapeutics, Inc. (incorporated by reference to Exhibit 10.1 of Relmada's Form 8-K filed with the SEC on December 26, 2019).
10.51	Indemnity Agreement, effective December 19, 2019, by and between Eric Schmidt and Relmada Therapeutics, Inc. (incorporated by reference to Exhibit 10.2 of Relmada's Form 8-K filed with the SEC on December 26, 2019).
10.52	Director Agreement, effective December 19, 2019, by and between John Glasspool and Relmada Therapeutics, Inc. (incorporated by reference to Exhibit 10.3 of Relmada's Form 8-K filed with the SEC on December 26, 2019).
10.53	Indemnity Agreement, effective December 19, 2019, by and between John Glasspool and Relmada Therapeutics, Inc. (incorporated by reference to Exhibit 10.4 of Relmada's Form 8-K filed with the SEC on December 26, 2019).
10.54	Employment Agreement, dated January 9, 2020, by and between Maged Shenouda and Relmada Therapeutics, Inc. (incorporated by reference to Exhibit 10.1 of Relmada's Form 8-K filed with the SEC on January 10, 2020).
10.55	Employment Agreement, dated January 9, 2020, by and between Charles Ence and Relmada Therapeutics, Inc. (incorporated by reference to Exhibit 10.2 of Relmada's Form 8-K filed with the SEC on January 10, 2020).
10.56	Amended and Restated Employment Agreement, dated January 9, 2020, by and between Sergio Traversa and Relmada Therapeutics, Inc. (incorporated by reference to Exhibit 10.3 of Relmada's Form 8-K filed with the SEC on January 10, 2020).
10.57	Amendment No. 5 to Stock Option and Equity incentive Plan (incorporated by reference to Exhibit 10.1 of Relmada's Form 8-K filed with the SEC on March 9, 2020).
10.58	Employment Agreement, dated March 7, 2020, by and between Thomas Wessel and Relmada Therapeutics, Inc. (incorporated by reference to Exhibit 10.1 of Relmada's Form 8-K filed with the SEC on March 12, 2020).
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).
23.1	Consent of Marcum LLP
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: March 26, 2020

RELMADA THERAPEUTICS, INC.

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

By: /s/ Maged Shenouda
Maged Shenouda
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.

Signature	Title	Date
/s/ Sergio Traversa Sergio Traversa	Chief Executive Officer, and Director	March 26, 2020
/s/ Maged Shenouda Maged Shenouda	Chief Financial Officer	March 26, 2020
/s/ Charles J. Casamento Charles J. Casamento	Chairman of the Board	March 26, 2020
/s/ Paul Kelly Paul Kelly	Director	March 26, 2020
/s/ Eric Schmidt Eric Schmidt	Director	March 26, 2020
/s/ John Glasspool John Glasspool	Director	March 26, 2020

Exhibit 23.1

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM'S CONSENT

We consent to the incorporation by reference in the Registration Statements of Relmada Therapeutics, Inc. on Form S-3**(**File No. 333-234262) and on Form S-3 (Post-Effective Amendment No. 1 to Forms S-1 [Files No. 333-229258 and 333-233228]) of our report dated March 25, 2020**,** with respect to our audits of the consolidated financial statements of Relmada Therapeutics, Inc. as of December 31, 2019, June 30, 2019 and June 30, 2018 and for the six months ended December 31, 2019 and the years ended June 30, 2019 and 2018, which report is included in this Annual Report on Form 10-KT of Relmada Therapeutics, Inc. for the six months ended December 31, 2019.

/s/ Marcum llp

Marcum llp
Houston, Texas
March 26, 2020

Exhibit 31.1

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 December 31, 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: March 26, 2020

Exhibit 31.2

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, Maged Shenouda, certify that:

1. I have reviewed this report on Form 10-K of Relmada Therapeutics, Inc. for the year ended December 31, 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/ Maged Shenouda
Maged Shenouda
Chief Financial Officer
(Principal Financial and Accounting Officer)

Date: March 26, 2020

Exhibit 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

In connection with the Annual Report of Relmada Therapeutics, Inc. a Nevada corporation (the "Company"), on Form 10-K for the year ended December 31, 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: March 26, 2020

Exhibit 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**

In connection with the Annual Report of Relmada Therapeutics, Inc. a Nevada corporation (the "Company"), on Form 10-K for the year ended December 31, 2019 as filed with the Securities and Exchange Commission (the "Report"), I, Maged Shenouda, 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/ Maged Shenouda

Maged Shenouda
Chief Financial Officer
(Principal Financial and Accounting Officer)

Date: March 26, 2020