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 fiscal year ended December 31, 2020

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

Securities registered pursuant to section 12(g) of the Act:
None

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 filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

Indicate by check mark whether the registrant has submitted electronically 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, 2020 (the last business day of the registrant's most recently completed second fiscal quarter), the aggregate market value of the registrant's common stock held by non-affiliates of the registrant was $694,982,670 based on the closing price as reported on the NASDAQ.

As of March 15, 2021, there were 16,745,930 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 esmethadone (d-methadone, dextromethadone, REL-1017), an N-methyl-D-aspartate (NMDA) receptor antagonist. esmethadone 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 became effective for the Company's 2020 fiscal year, which began January 1, 2020 and ended December 31, 2020. Accordingly the Company filed the 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, esmethadone, 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.

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).

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 2 clinical study were of the same nature as those observed in the Phase 1 clinical studies in esmethadone, and importantly there was no evidence of either treatment induced psychotomimetic and dissociative AEs or withdrawal signs and symptoms upon treatment discontinuation.

Phase 3 Program

On December 20, 2020 we announced that the first patient had been enrolled in the first Phase 3 clinical trial (RELIANCE I) for the Company's lead product candidate, REL-1017, as an adjunctive treatment for major depressive disorder (MDD).

Key points of the Phase 3 program agreed upon in discussions with FDA include:

- The Phase 3 program will consist of two sister, two-arm, placebo-controlled clinical trials. Each trial will be conducted in 55 clinical sites in the United States and will include approximately 400 MDD patients with inadequate response to standard antidepressants in their current depression episode. Patients will add either a 25 mg oral dose of REL-1017 once per day or placebo to their ongoing antidepressant treatment.

- The primary endpoint to be evaluated will be the change from baseline on the Montgomery and Asberg Depression Rating Scale (MADRS) score at day-28 for REL-1017 compared to placebo. Success on this endpoint with the collection of sufficient safety data would support the use of REL-1017 for chronic treatment, if approved.

- The change from baseline and the 7-day MADRS score will serve as a key secondary endpoint and will provide data on the rapid onset of treatment effect; statistically significant separation between REL-1017 and the control group was achieved by day 4 in the Phase 2 proof-of-principle trial completed in 2019.

- The Company expects to initiate the second Phase 3 trial, RELIANCE II, in the first half of 2021. Patients who complete RELIANCE I and RELIANCE II will be eligible to rollover into the long-term, open-label study, which is also expected to include subjects who had not previously participated in a REL-1017 clinical trial.

Key Upcoming Anticipated Milestones

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

- Start of RELIANCE II, the second pivotal Phase 3 adjunctive MDD trial in the first half of 2021.

- Start of Phase 2 monotherapy MDD trial in the first half of 2021.

- Results of oxycodone human abuse potential study in the second quarter of 2021.

- Results of IV ketamine human abuse potential study in the fourth quarter of 2021.

- Results of RELIANCE I and RELIANCE II adjunctive MDD trials in the first half of 2022.

Our Development Program

Esmethadone (d-Methadone, dextromethadone, REL-1017) as a treatment for MDD

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.

Esmethadone Overview and Mechanism of Action

Esmethadone'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, esmethadone 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, esmethadone 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, esmethadone, 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, esmethadone could show benefits in several different CNS indications.

Esmethadone (d-methadone, dextromethadone, REL-1017) in other indications

In addition to developing esmethadone as an adjunctive treatment of MDD, we are planning to evaluate the utility of esmethadone 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.

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 prospective 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 $59,456,400 for the year ended December 31, 2020, $8,196,500 for the six months ended December 31, 2019, and $17,318,100 for the year ended June 30, 2019, respectively. At December 31, 2020, we have an accumulated deficit of approximately $179,315,300.

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, including recognized experts in the fields of depression, and business advisors with significant industry and regulatory experience to lead and execute the development and commercialization of esmethadone.

We plan to further develop esmethadone as our priority program. As the drug esmethadone is an NCE, the regulatory pathway, under the Food and Drug Administration Amendment Act Section 505(u) provision, required to support an 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 notable 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 over 50 issued patents and pending patent applications related to REL-1017 for multiple uses, including psychological and neurological conditions. We have also secured an Orphan Drug Designation from the FDA for d-methadone for "the treatment of postherpetic neuralgia', which, if pursed and upon potential NDA approval, would carry 7-year FDA Orphan Drug marketing exclusivity. In the European Union, some of our actual and prospective 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, REL-1017 will be eligible for market exclusivity to run concurrently with the term of the patent for 5 years in the U.S. (Hatch Waxman Act) plus additional 6 month of pediatric exclusivity and up to 10 years of in the E.U. We believe an extensive intellectual property estate of US and foreign patents and applications, will protect our technology and products once our patent applications for our products are approved.

Esmethadone License Agreement

As a result of a prior acquisition, the Company assumed an obligation to pay third parties (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, 2020, 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 esmethadone 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 esmethadone. 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.

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 esmethadone, (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 esmethadone 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, 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. If the parties cannot agree to terms of a license agreement then the Company shall be able to engage in discussions with other potential licensors. As of March 2021, no discussions are active between the Company and Wonpung.

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.

Key Strengths

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

- Compelling lead product opportunity, esmethadone currently in Phase 3 trial for the adjunctive treatment of MDD.
- Successful Phase 1 safety studies of esmethadone 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 esmethadone have also been designated as Orphan Drugs by the FDA, thereby providing seven years of market exclusivity at launch.

Competition

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, we currently have no product 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.

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.

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 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.

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.

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.

Generic Competition

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 (a Paragraph IV certification). The ANDA applicant may also elect to submit a section viii statement certifying that its proposed ANDA label doe s 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 or certifies that the listed patents will not be infringed by the new product, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired. If the ANDA applicant has provided a Paragraph IV certification, the NDA and patent holders may then initiate a patent infringement lawsuit in response. The filing of a patent infringement lawsuit within 45 days of the receipt of a such 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. ***Exclusivity***

Upon NDA approval of a new chemical entity (NCE) such as esmethadone, 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.

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 active ingredients in esmethadone are listed by the United States Drug Enforcement Administration, or DEA, as controlled substances under the U.S. Controlled Substances Act of 1970, or CSA. The Controlled Substances Act and its implementing regulations establish a closed chain of distribution for entities handling controlled substances. The CSA and regulations enforced by the 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.

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. 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.

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.

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.

Insurance Coverage and Reimbursement

Significant uncertainty exists as to the insurance 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.

Available Information

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

Human Capital

As of December 31, 2020, we had a total of 14 employees. We understand people are our greatest asset and that our innovation and operational excellence are ultimately noted in our human capital. Our success depends in large part on our ability to recruit, develop and retain a qualified, productive, and engaged workforce.

Inclusion & Diversity

Inclusion and diversity is a focus of our corporate human capital strategy. By embracing inclusion and diversity, we enhance our work environment and drive business success. We endeavor to create a culture of inclusion in which our employees feel empowered to bring their full, authentic selves to work and pursue their professional goals in a setting of equality. Fostering such a culture welcomes different perspectives and generates innovation and growth. We honor the diversity of our employees—in gender, race/ethnicity, age, gender identity, sexual orientation, socio-economic status, language, nationality, abilities and life experiences. As of December 31, 2020, our employee population was approximately 64% female.

Total Rewards and Employee Engagement

We maintain a competitive compensation and benefits package including incentive compensation tied to both company and individual performance, and retirement benefits. Our performance-based compensation strategy is designed to recognize and reward employees for their contribution to our success, and we strive to provide strong, equitable incentives for performance. Compensation is comprised of two elements: base compensation, which is determined based upon a number of factors, including size, scope and impact of the employee's role, the market value associated with the employee's role, leadership skills, length of service and individual performance; and an annual bonus, which is a cash award determined based on a combination of individual and company performance during the period to which the bonus relates. We seek to determine compensation on the basis of merit and without regard to demographic characteristics. During 2020, we employed a third-party consultant to assist us in evaluating our pay practices. In conducting this exercise, we found no meaningful difference in compensation based upon gender, race or any other defining characteristic examined.

COVID-19 Response

We moved swiftly in our response to the COVID-19 pandemic to promote the safety of our associates and best serve our members and communities. In March of 2020, we transitioned the out workforce to remote work environments, while maintaining service operations. We continued to pay employees who missed work for COVID-19 related reasons and avoided role reductions as a direct result of COVID-19.

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.

Summary of Risks

This section provides a summary of the risks that may impact our performance in the future. For details of our various risk factors and their impacts, see "Risk Factors Discussion."

Our risk factors are organized into the following categories: 1) Risks related to our business, 2) Risks related to clinical and regulatory matters, 3) Risks related to our intellectual property, 4) Risks related to government regulations, 5) Risks related to our reliance on third parties, and 6) Risks related to our common stock,

Risks related to our business

Business risks include risks associated with our products and regulatory approval, licensing agreements, historical losses, managing growth, acquisitions and the COVID-19 pandemic. In general, the risks related to our business can cause variability in the future profits of the Company.

Risks related to Clinical and Regulatory Matters

Clinical and regulatory matters include risks associated with clinical trials and the future ability to commercially market the product. In order for any of our products to be commercialized and produce future profits, successful trials need to be completed with supporting data to receive regulatory approval. Failing to complete the trial will significantly increase our cost of doing business. In addition, the active ingredient in our products is a controlled substance which can affect the supply available for clinical trials, as well as commercial sales. A limited supply could increase the time needed to complete clinical trials and overall costs including product liability claims. We could also face potential fines or reputational risk if we do not comply. Developments from competitors and the ability to obtain market exclusivity could also negatively impact future profits.

Risks related to our intellectual property

Our products depend upon securing and protecting critical intellectual property. Patent positions are highly uncertain and involve complex legal and factual questions. Infringing upon a patents or trade secrets could force us to cease or alter our product development efforts or obtain a license to continue to develop or sale our products. These risks could not only impact the future profits of the company but also create adverse publicity for us.

Risks related to government regulations

We are required to comply with various federal and state pharmaceutical and healthcare laws and regulations, and to maintain secure systems to protect sensitive confidential information. Complying with the various regulations can increase our cost of doing business. We could also face potential fines or reputational risk if we do not comply. Litigation or investigations can increase costs, negatively affect our operating results and create adverse publicity for us.

Risks related to our reliance on third parties

The Company relies on third parties to conduct preclinical and clinical studies, as well as to manufacture our product candidates. Third parties' failure to perform the trials as contractually require could impact our ability to obtain regulatory approval. If manufacturers fail to meet our requirements and strict regulatory requirements, our product development and commercialization efforts may be materially harmed.

Risks related to our common stock

Common stocks risks includes risks associated with the limited market for our common stock, a potential issuance of a substantial number of additional shares, stock price volatility, and reporting requirements of federal securities laws. The net effect of these risks can include reductions in future profits, additional operating expenses, inability to meet liquidity needs, inability to access capital and increased cost of capital.

Risk Factors Discussion

Risk Related to Our Business

Our business depends on the success of esmethadone (d-methadone, dextromethadone, REL-1017), our only product candidate currently under clinical development, which has recently entered into a pivotal clinical trial for the adjunctive treatment of MDD. 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 esmethadone (d-methadone, dextromethadone, REL-1017) for the adjunctive treatment of patients with MDD. Currently, esmethadone 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 setback of a lead candidate. Successful continued development and ultimate regulatory approval of esmethadone 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 esmethadone. If we cannot successfully develop, obtain regulatory approval for and commercialize esmethadone, we may not be able to continue our operations. The future regulatory and commercial success of esmethadone is subject to a number of risks, including the following:

- we may not be able to obtain adequate evidence from clinical trials of efficacy and safety for esmethadone for the adjunctive treatment of MDD, monotherapy for MDD or other indications;
- we may not be able to demonstrate that the benefits of esmethadone for the adjunctive treatment of MDD, monotherapy for MDD or other indications outweigh the risks;
- in our clinical trials for esmethadone, enrollment may be slower than anticipated and 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 esmethadone, 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 esmethadone;
- 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 2 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 esmethadone for the adjunctive treatment of MDD, monotherapy for MDD or any other indication;
- we may not have sufficient financial and other resources to complete the necessary clinical trials for esmethadone, including, but not limited to, the clinical trials needed to obtain drug approval;
- if approved for the adjunctive treatment of MDD or as a monotherapy for MDD, esmethadone will likely compete with products that may reach approval prior to esmethadone, 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.

Esmethadone 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 esmethadone, 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 esmethadone 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. Owing in part to the complexity of biological pathways, esmethadone 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 2 clinical study has involved a small population of subjects with MDD, 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 esmethadone 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 esmethadone, 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 esmethadone. If we or any of our future development collaborators are unable to develop, or obtain regulatory approval for, or, if approved, successfully commercialize esmethadone, 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 esmethadone 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 esmethadone, 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 esmethadone 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 esmethadone in neurological and other uses, to develop and commercialize esmethadone 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 esmethadone 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 esmethadone, 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 esmethadone, (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 esmethadone 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 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 $179.3 million at December 31, 2020. The Company had cash, cash equivalents and short term investments of approximately $117.1 million at December 31, 2020. 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.

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

As of December 31, 2020, we had Federal, New York State and New York City net operating loss (NOL) carryforwards of approximately $72,507,000, $68,854,000 and $68,470,000, 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 14 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.

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.

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.

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 the United States. The spread of COVID-19 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, travel restrictions, limitations on gatherings, closures of businesses and other social distancing measures.

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 COVID-19 pandemic and efforts to contain the outbreak have led to economic disruption, including declines in interest rates, extreme volatility in financial markets, fluctuations in foreign currency exchange rates, reduced economic activity and a sharp increase in unemployment claims. While the potential economic impact brought by COVID-19 may be difficult to assess or predict, a more protracted 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 is 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 esmethadone 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 our clinical trials conducted to date 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 (if applicable). 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. Esmethadone is the single isomer of methadone, a Schedule II compound, and its handling (including manufacture, research, shipment, storage, sale and use) is subject to a high degree of federal and state oversight and regulation. 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 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 esmethadone 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.

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

We have obtained Fast Track Designation for esmethadone 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 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 esmethadone, 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 esmethadone, if approved. For esmethadone, 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 esmethadone, this may not protect us from direct competition. A competitor(s) with a generic version of our products may be able to obtain approval of its 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, esmethadone 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 esmethadone 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.

Esmethadone is subject to extensive regulation by the DEA. Although esmethadone is substantially devoid of opioid activity, and psychotomimetic effects, the DEA may elect to designate it as a controlled substance falling under a DEA controlled substance Schedule. Additionally, esmethadone 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 esmethadone, 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.

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.

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 esmethadone 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 esmethadone we will likely have to conduct a specific study to evaluate the effects of esmethadone 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 esmethadone. An adverse safety outcome from such study could result in a similar bolded warning on the label of esmethadone or in a decision not to approve esmethadone, either one of which could have serious consequences for our continued operation.

Esmethadone may require Risk Evaluation and Mitigation Strategies (REMS).

Esmethadone, 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 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, and Axsome Therapeutics among others.

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.

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.

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.

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.

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.

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.

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.

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.

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.

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 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, or in the future, 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 are not 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.

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.

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;
- 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.

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, and renewed in 2020 the Company leased the space for a total monthly cost of $13,610. For 2021, the lease agreement was renewed at an average monthly rent rate of approximately $8,730.

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

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

ITEM 3. LEGAL PROCEEDINGS

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

Lawsuit Brought by Current Employee

On July 15, 2020, an employee of the Company filed a Complaint alleging unequal pay based on gender and other employment-based claims. The Company intends to defend the lawsuit, it is currently in discovery and the ultimate outcome is not known.

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".

Holders

As of December 31, 2020, 16,332,939 shares of common stock were issued and outstanding, which were held by 178 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.

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, 2020, the Company had 1,247,205 awards available to be issued.

The following table summarizes our equity compensation plan information as of December 31, 2020:

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	3,905,737	$ 24.32	1,247,205
Equity compensation plans not approved by security holders	-	-	-
Total	3,905,737	$ 24.32	1,247,205

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

The information and financial data discussed below is derived from the consolidated financial statements of Relmada for the year ended December 31, 2020, year ended December 31, 2019 (unaudited), six months ended December 31, 2019 and year ended June 30, 2019. 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 late-stage, publicly traded biotechnology company developing (New Chemical Entities) NCEs to address areas of high unmet medical need in the treatment of CNS diseases - primarily depression. The Company's lead product Esmethadone, 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 2 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. On Dec. 7, the Company announced that the first patient had been enrolled in the first Phase 3 clinical trial (RELIANCE I) of REL-1017, as an adjunctive treatment for major depressive disorder (MDD).

Key points of the REL-017 Phase 3 program agreed upon in discussions with FDA include:

- The Phase 3 program will consist of two sister, two-arm, placebo-controlled clinical trials. Each trial will be conducted in 55 clinical sites in the United States and will include approximately 400 MDD patients with inadequate response to standard antidepressants in their current depression episode. Patients will add either a 25 mg oral dose of REL-1017 once per day or placebo to their ongoing antidepressant treatment.

- The primary endpoint to be evaluated will be the change from baseline on the Montgomery and Asberg Depression Rating Scale (MADRS) score at day-28 for REL-1017 compared to placebo. Success on this endpoint with the collection of sufficient safety data would support the use of REL-1017 for chronic treatment, if approved.

- The change from baseline and the 7-day MADRS score will serve as a key secondary endpoint and will provide data on the rapid onset of treatment effect; statistically significant separation between REL-1017 and the control group was achieved by day 4 in the Phase 2 proof-of-principle trial completed in 2019.

- The Company expects to initiate the second Phase 3 trial, RELIANCE II, in the first half of 2021. Patients who complete RELIANCE I and RELIANCE II will be eligible to rollover into the long-term, open-label study, which is also expected to include subjects who had not previously participated in a REL-1017 clinical trial.

The Company changed its fiscal year end to December 31 from June 30. This transition report was for the six-month transition period of July 1, 2019 through December 31, 2019. The information for the year ended December 31, 2019 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 $59,456,400, $15,005,200, $8,196,500, and $17,318,100 for the years ended December 31, 2020, December 31, 2019 (unaudited), six months ended December 31, 2019, and for the year ended June 30, 2019, respectively. At December 31, 2020, we have an accumulated deficit of approximately $179,315,300.

Results of Operations

For the Year Ended December 31, 2020 vs the Year Ended December 31, 2019 (unaudited)

Research and Development Expense

Total research and development expense for the year ended December 31, 2020 was approximately $35,972,700, as compared to $7,859,500 for the same period of 2019, an increase of $28,113,200. The increase in research and development expense was primarily due to:

- Increase in study costs of $15,238,700 associated with the execution of our Phase 2 and Phase 3 studies;

- Increase in manufacturing and drug storage costs of $989,700;

- Increase in pre-clinical and toxicology expenses of $1,881,900;

- Increase in compensation expense of $2,376,000 related to the hiring of six additional research and development employees and their related bonuses;

- Increase in stock-based compensation expense of $3,677,600 of stock-based compensation expense related to the hiring of six additional research and development employees and the related options granted to them, as well as the separation agreement with Ottavio Vitolo of approximately $1,500,000;

- Increase in other research expenses of $3,949,400 primarily associated to the additional consultants contracted with to assist in the execution of our Phase 3 studies.

General and Administrative Expense

Total general and administrative expense for the year ended December 31, 2020 was approximately $24,865,900, as compared to $7,249,900 for the same period of 2019, an increase of $17,616,000. The increase in general and administrative expenses was primarily due to:

- Increase in compensation expense of $2,753,800 related to the hiring of four additional general and administrative employees and their related bonuses;
- Increased in stock-based compensation expense of $13,934,400 primarily related to options granted to employees and the board of directors during 2020;
- Increase in other G&A expenses of $927,800.

Interest Income and Expense, Net

Interest income and realized and unrealized gains and losses in investments was approximately $1,382,300 and $104,100 for the years ended December 31, 2020 and 2019, respectively. The increase of $1,278,200 resulted from the increase in investments during 2020 compared to 2019.

Income Taxes

The Company did not provide for income taxes for the year ended December 31, 2020 and December 31, 2019, 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 $59,456,400 and $15,005,200 or $3.81 and $1.62 per common share, basic and diluted, during the years ended December 31, 2020 and 2019, respectively, based on the factors described above.

Liquidity

As shown in the accompanying financial statements, the Company incurred negative operating cash flows of $27,808,801 for the year ended December 31, 2020 and has an accumulated deficit of $179,315,303 from inception through December 31, 2020.

Relmada has funded its past operations through equity raises and most recently in the year ended December 31, 2020, Relmada raised net proceeds from the sale of common stock of $19,791,644 and $8,056,416 through the exercise of warrants, and $735,514 through the exercise of options.

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 filing of this annual report. Since December 31, 2020 and to date, the Company has received approximately $1,909,200 in warrant and option exercises, which resulted in the Company having approximately $105.3 million in cash, cash equivalents and short term investments at March 15, 2021. 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 filing of this annual report. The Company expects that the cash burn rate for the 12 months ended December 31, 2021, will range between $75 and $100 million.

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

	For the Year Ended December 31, 2020	(Unaudited) For the Year Ended December 31, 2019	For the Six Months Ended December 31, 2019	For the Year Ended June 30, 2019
Cash used in operating activities	$ (27,808,801)	$ (12,092,784)	$ (6,413,775)	$ (10,497,854)
Cash used in investing activities	(34,447,648)	(80,164,823)	(80,164,823)	-
Cash provided by financing activities	28,473,327	126,109,375	113,640,563	17,475,465
Net increase/(decrease) in cash and cash equivalents	$ (33,783,122)	$ 33,851,768	$ 27,061,965	$ 6,977,611

For the year ended December 31, 2020, cash used in operating activities was $27,808,801 primarily due to the net loss of $59,456,394. This was offset by non-cash expenses which primarily consisted of stock-based compensation of $20,777,272. There were realized losses and unrealized gains on short term investments of $156,213 and $139,267, respectively. In addition, there were changes in operating assets and liabilities for the year ended December 31, 2020 of $10,849,623.

For the unaudited year ended December 31, 2019, cash used in operating activities was $12,092,784 primarily due to the net loss of $15,005,199. This was offset by non-cash expenses which primarily consisted of stock-based compensation and loss on fair value of shares relinquished of $3,165,153 and $394,410, respectively. There were changes in operating assets and liabilities for the year ended December 31, 2020 of $137,309.

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 $8,196,542. 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 $586,434.

For the year ended June 30, 2019 cash used in operating activities was $10,497,854 primarily due to the net loss of $17,318,060. This was offset by non-cash expenses which primarily consisted of stock-based compensation of $1,213,996, the change in the fair value of derivative liabilities of $54,634, loss on fair value of shares relinquished of $394,410, loss on extinguishment of promissory note of $3,774,468 and amortization of deferred financing costs of $661,168. There were changes in operating assets and liabilities for the years ended June 30, 2019 of $1,505,480.

For the year ended December 31, 2020, cash used in investing activities was $34,447,648, due to $182,051,630 of purchases of short term investments offset by $147,603,982 of sales of short term investments.

For the unaudited year ended December 31, 2019, cash used in investing activities was $80,164,823, due to $84,849,198 of purchases of short term investments offset by $4,684,375 of sales of short term investments.

For the six months ended December 31, 2019, cash used in investing activities was $80,164,823, 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.

Net cash provided by financing activities for the six months ended December 31, 2020, was $28,473,327 due to proceeds from issuance of common stock of $19,791,644, proceeds from warrants exercised for common stock of $8,056,416, proceeds from options exercised for common stock of $735,514 partially offset by payments of notes payable of $110,247.

Net cash provided by financing activities for the unaudited year ended December 31, 2019, was $126,109,375 due to proceeds from issuance of common stock of $122,031,032, proceeds from warrants exercised for common stock of $4,447,038 partially offset by payments of notes payable of $368,695.

Net cash provided by financing activities for the six months ended December 31, 2019, 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 due to proceeds from issuance of common stock of $17,760,635 partially offset by payments of notes payable of $285,170.

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	$ 104,760	$ 104,760	$ -	$ -	$ -
Total obligations	$ 104,760	$ 104,760	$ -	$ -	$ -

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.

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, 2020 and 2019, and June 30, 2019, 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.

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, 2020 and for the year then ended, as of December 31, 2019 and for the six months then ended, as of June 30, 2019 and for the year then ended and our unaudited financial statements for the year ended December 31, 2019 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, 2020, 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, 2020. 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, 2020.

ITEM 9B. OTHER INFORMATION

On March 19, 2021, our Board of Directors unanimously approved, subject to stockholder approval, the Company's 2021 Equity Incentive Plan (the "2021 Plan"), pursuant to which awards covering up to 1,500,000 shares of our common stock will be available for issuance.

The purpose of the 2021 Plan is to (a) enable the Company and its affiliates to attract and retain the types of employees, directors and consultants who will contribute to the Company's long range success; (b) provide incentives that align the interests of employees, consultants and directors with those of the stockholders of the Company; and (c) promote the success of the Company's business, thus enhancing the value of the Company for the benefit of its stockholders.

Administration. The 2021 Plan will be administered by a committee (the "Committee"), or in the Board's sole discretion by the Board. In case no Committee has been appointed, the Board may appoint one or more members of the Board appointed by the Board to administer the 2021 Plan in accordance with the terms of the 2021 Plan. The Board has appointed the Compensation Committee of the Board to administer the 2021 Plan.

Shares Available for Awards. Subject to adjustment in certain circumstances in accordance with the terms of the 2021 Plan, we will reserve for issuance under the 2021 Plan no more than 1,500,000 shares of common stock (subject to adjustment in certain circumstances as provided in the Plan). Shares of Common Stock available for distribution under the 2021 Plan may consist, in whole or in part, of authorized and unissued shares, treasury shares or shares reacquired by the Company in any manner. Shares of Common Stock subject to an award that expires or is canceled, forfeited, or terminated without issuance of the full number of shares of Common Stock to which the award related, as well as any shares of common stock subject to an award that are (a) tendered in payment of an option, (b) delivered or withheld by the company to satisfy any tax withholding obligation, or (c) covered by a stock-settled stock appreciation right or other awards that were not issued upon the settlement of the award, shall be added back to the shares of common stock available for issuance of awards or delivery under the 2021 Plan.

Available Awards. Awards that may be granted under the 2021 plan include: (a) incentive stock options, (b) non-qualified stock options, (c) stock appreciation rights, (d) restricted awards, (e) performance share awards, (f) cash awards, and (g) other equity-based awards.

Recipients of Grants. Incentive stock options may be granted only to employees. Awards other than incentive stock options may be granted to employees, consultants and directors and those individuals whom the Committee or the Board determines are reasonably expected to become employees, consultants and directors following the grant date. Our principal executive officer, principal financial officer and other named executive officers are eligible to participate in and receive awards under the 2021 Plan.

Term. The 2021 Plan has a term of ten years.

This summary of the 2021 Plan is qualified in its entirety by the full text of the 2021 Plan, which is filed as Exhibit 10.61 to this Report and is incorporated by reference herein.

The 2021 Plan will be submitted for the approval of our stockholders at our 2020 Annual Meeting of Stockholders. If the proposal is not approved by the stockholders, the 2021 Plan will not be effective.

PART III

The information required for the Items contained in Part III are incorporated herein by reference from our definitive proxy statement for our 2021 Annual Meeting of Stockholders (the "Proxy Statement"), which will be filed with the SEC no later than 120 days after December 31, 2020.

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS, AND CORPORATE GOVERNANCE

ITEM 11. EXECUTIVE COMPENSATION

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

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

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

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)

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders 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, 2020, December 31, 2019 and June 30, 2019, , the related consolidated statements of operations, stockholders' equity and cash flows for the year ended December 31, 2020, the six months ended December 31, 2019 and the year 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, 2020, December 31, 2019, and June 30, 2019, and the results of its operations and its cash flows for year ended December 31, 2020, the six months ended December 31, 2019 and the year 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.

Critical Audit Matters

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Valuation and accounting for stock-based compensation

Description of the Matter

As described in Notes 8 and 11 to the financial statements, the Company awarded a total of 1,000,000 options to employees and 250,000 warrants to nonemployees during 2020. The Company also entered into Separation and Severance Agreements with two employees during the year ended December 31, 2020 and agreed to accelerate the vesting period of their options. The Company recognized an aggregate stock-based compensation of $20.8 million during the year ended December 31, 2020, which includes the above instruments.

Auditing management's valuation and accounting for stock-based compensation required subjective judgement to analyze the terms within the stock-based agreements to determine that we concurred with management's valuation and calculations.

How We Addressed the Matter in Our Audit

Our audit procedures included, amongst others:

- We tested the option and warrant agreements to determine whether management appropriately evaluated such agreements on the date of grant.
- We reviewed the vesting terms of the option and warrant agreements to determine the stock-based compensation is recorded in the proper period.
- We reviewed the terms of the Separation and Severance Agreements to determine that any modifications related to the options thereto were appropriately recorded.
- We tested the underlying expenses and other information that served as the basis for valuation and tested inputs and terms used in the valuation to determine completeness and accuracy.
- We evaluated the reasonableness of the valuation method and assumptions used by management to calculate the values on the date of grant by developing an independent estimate of the volatility by utilizing third party historical data of closing prices.

/s/ Marcum LLP

Marcum LLP

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

Houston, Texas
March 24, 2021

Relmada Therapeutics, Inc.
Consolidated Balance Sheets

	As of December 31, 2020	As of December 31, 2019	As of June 30, 2019
Assets			
Current assets:			
Cash and cash equivalents	$ 2,495,397	$ 36,278,519	$ 9,216,554
Short-term investments	114,595,525	80,164,823	-
Other receivable	-	-	176,980
Lease payments receivable – short term	79,457	73,091	70,102
Prepaid expenses	903,190	423,863	520,745
Total current assets	118,073,569	116,940,296	9,984,381
Fixed assets, net of accumulated depreciation	1,258	5,010	7,210
Other assets	25,000	25,000	25,000
Lease payments receivable – long term	86,377	165,834	203,142
Total assets	$ 118,186,204	$ 117,136,140	$ 10,219,733
Liabilities and Stockholders' Equity			
Current liabilities:			
Accounts payable	$ 8,346,475	$ 522,663	$ 924,359
Accrued expenses	4,256,983	824,936	1,317,855
Notes payable	-	110,247	364,204
Total current liabilities	12,603,458	1,457,846	2,606,418
Total liabilities	12,603,458	1,457,846	2,606,418
Stockholders' Equity:			
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, 16,332,939, 14,457,013 and 9,744,643 shares issued and outstanding, respectively	16,333	14,457	9,744
Additional paid-in capital	284,881,716	235,522,746	119,265,938
Accumulated deficit	(179,315,303)	(119,858,909)	(111,662,367)
Total stockholders' equity	105,582,746	115,678,294	7,613,315
Total liabilities and stockholders' equity	$ 118,186,204	$ 117,136,140	$ 10,219,733

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

Relmada Therapeutics, Inc.
Consolidated Statements of Operations

	Year Ended December 31, 2020	(Unaudited) Year ended December 31, 2019	Six months ended December 31, 2019	Year ended June 30, 2019
Operating expenses:				
Research and development	$ 35,972,731	$ 7,859,453	$ 3,513,606	$ 7,024,747
General and administrative	24,865,942	7,249,858	4,757,999	5,703,173
Total operating expenses	60,838,673	15,109,311	8,271,605	12,727,920
Loss from operations	(60,838,673)	(15,109,311)	(8,271,605)	(12,727,920)
Other income (expenses):				
Change in fair value of derivative liabilities	-	-	-	(54,634)
Interest income (expense), net	1,399,225	104,112	75,063	(761,038)
Realized loss on short-term investments	(156,213)	-	-	-
Unrealized gain on short-term investments	139,267	-	-	-
Loss on extinguishment of debt	-	-	-	(3,774,468)
Total other income (expenses), net	1,382,279	104,112	75,063	(4,590,140)
Net loss	$ (59,456,394)	$ (15,005,199)	$ (8,196,542)	$ (17,318,060)
Net loss per common share – basic and diluted	$ (3.81)	$ (1.62)	$ (0.77)	$ (2.74)
Weighted average number of common shares outstanding – basic and diluted	15,594,228	9,241,219	10,577,866	6,311,769

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 at 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
Stock-based compensation expense	-	-	20,777,272	-	20,777,272
Equity offering, net	427,700	428	19,791,216	-	19,791,644
Warrants exercised	1,159,989	1,160	8,055,256	-	8,056,416
Cashless exercise of warrants	42,475	42	(42)	-	-
Options exercised	155,558	156	735,358	-	735,514
Cashless exercise of options	90,204	90	(90)	-	-
Net loss	-	-	-	(59,456,394)	(59,456,394)
Balance – December 31, 2020	16,332,939	$ 16,333	$ 284,881,716	$ (179,315,303)	$ 105,582,746

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

Relmada Therapeutics, Inc.
Consolidated Statements of Cash Flows

	Year ended December 31, 2020	(Unaudited) Year ended December 31, 2019	Six months ended December 31, 2019	Year ended June 30, 2019
Cash flows from operating activities				
Net loss	$ (59,456,394)	$ (15,005,199)	$ (8,196,542)	$ (17,318,060)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation expense	3,752	4,363	2,200	4,870
Stock-based compensation	20,777,272	3,165,153	2,367,001	1,213,996
Realized loss on short-term investments	156,213	-	-	-
Unrealized gain on short-term investments	(139,267)	-	-	-
Amortization of deferred financing costs	-	-	-	661,168
Change in fair value of derivative liabilities	-	-	-	54,634
Fair value of shares relinquished	-	(394,410)	-	(394,410)
Loss on promissory note extinguishment	-	-	-	3,774,468
Changes in operating assets and liabilities:				
Prepaid expenses and other assets	(479,327)	471,912	96,882	270,167
Other receivable	-	-	176,980	(169,363)
Lease payment receivable	73,091	67,235	34,319	64,486
Accounts payable	7,823,812	163,773	(401,696)	158,920
Accrued expenses	3,432,047	(565,611)	(492,919)	1,181,270
Net cash used in operating activities	(27,808,801)	(12,092,784)	(6,413,775)	(10,497,854)
Cash flows from investing activities				
Purchase of investments	(182,051,630)	(84,849,198)	(84,849,198)	-
Sale of investments	147,603,982	4,684,375	4,684,375	-
Net cash used in investing activities	(34,447,648)	(80,164,823)	(80,164,823)	-
Cash flows from financing activities				
Proceeds from issuance of common stock, net of fees	19,791,644	122,031,032	109,447,482	17,760,635
Proceeds from warrants exercised for common stock	8,056,416	4,447,038	4,447,038	-
Proceeds from options exercised for common stock	735,514	-	-	-
Principal payment of notes payable	(110,247)	(368,695)	(253,957)	(285,170)
Net cash provided by financing activities	28,473,327	126,109,375	113,640,563	17,475,465
Net increase/(decrease) in cash and cash equivalents	(33,783,122)	33,851,768	27,061,965	6,977,611
Cash and cash equivalents at beginning of the period	36,278,519	2,426,751	9,216,554	2,238,943
Cash and cash equivalents at end of the period	$ 2,495,397	$ 36,278,519	$ 36,278,519	$ 9,216,554

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

	Year ended December 31, 2020	(Unaudited) Year ended December 31, 2019	Six months ended December 31, 2019	Year ended June 30, 2019
Supplemental disclosure of cash flows information:				
Cash paid during the period for:				
Income taxes	$ -	$ -	$ -	$ -
Interest	$ 2,415	$ 9,034	$ 4,610	$ 5,933
Non-cash investing and financing transactions:				
Notes payable issued in connection with director and officer insurance policies	$ -	$ 364,204	$ -	$ 364,204
Cashless exercise of warrants for common stock	$ 42	$ 68	$ 43	$ 25
Cashless exercise of options for common stock	$ 90	$ 62	$ 62	$ -
Write off for derivative liability due to adoption of ASU 2017-11	$ -	$ -	$ -	$ 59,397
Conversion of promissory notes and accrued interest to common stock	$ -	$ -	$ -	$ 8,030,365

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

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 esmethadone (d-methadone, dextromethadone, REL-1017), an N-methyl-D-aspartate (NMDA) receptor antagonist. esmethadone 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 was effective for the Company's 2020 fiscal year.

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. The information for the year ended December 31, 2019 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 $27,808,801 for the year ended December 31, 2020 and has an accumulated deficit of $179,315,303 from inception through December 31, 2020.

Relmada has funded its past operations through equity raises and most recently in the year ended December 31, 2020, Relmada raised net proceeds from the sale of common stock of $19,791,644, $8,056,416 through the exercise of warrants and $735,514 through the exercise of options.

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 this annual report. Since December 31, 2020 and to date, the Company has received approximately $1,909,200 in warrant and option exercises, which resulted in the Company having approximately $105.3 million in cash, cash equivalents, and short term investments at March 15, 2021. 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 requirements for at least the next 12 months from the issuance of these consolidated financial statements. 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 $2,495,397 at December 31, 2020 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 year ended December 31, 2020 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, 2020 consisted of mutual funds with a fair value of $114,595,525.

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 $114,595,525 at December 31, 2020 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 as unrealized gain on short-term investments. The Company recorded an unrealized gain of $139,267, included in other income for the period ended December 31, 2020.

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.

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, 2020 and 2019 and June 30, 2019, 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, 2020 and 2019, and June 30, 2019. The open tax years, subject to potential examination by the applicable taxing authority, for the Company are from June 30, 2018 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):

	Year ended December 31, 2020	(Unaudited) Year ended December 31, 2019	Six Months ended December 31, 2019	Year ended June 30, 2019
Common stock warrants	2,670,633	3,646,872	3,646,872	4,429,982
Common stock options	3,905,737	3,615,602	3,615,602	1,473,314
Total	6,576,370	7,262,474	7,262,474	5,903,296

Recent Accounting Pronouncements

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.

In August 2018, FASB issued ASU 2018-13, *Fair Value Measurement – Disclosure Framework (Topic 820).* The updated guidance improves the disclosure requirements on fair value measurements, primarily associated with Level 3 fair value measurements and is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. Early adoption is permitted upon issuance of the standard disclosures modified or removed with a delay of adoption of the additional disclosures until their effective date. The Company adopted this standard effective January 1, 2020 and the standard did not have a significant impact on the Company's financial statements.

In November 2018, FASB issued ASU 2018-18 – *Collaborative Arrangements (Topic 808): Clarifying the Interaction between Topic 808 and Topic 606*, which, among other things, provides guidance on how to assess whether certain collaborative arrangement transactions should be accounted for under Topic 606. The amendments in the ASU are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019, with early adoption permitted. The Company adopted this standard on January 1, 2020 and the standard did not have a significant impact on the Company's financial statements.

NOTE 3 - PREPAID EXPENSES

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

	December 31, 2020	December 31, 2019	June 30, 2019
Insurance	$ 527,600	$ 223,600	$ 451,500
Research and Development	291,800	139,200	-
Legal	11,000	11,000	7,500
Other	72,800	50,100	61,800
Total	$ 903,200	$ 423,900	$ 520,800

NOTE 4 - FIXED ASSETS

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

	Useful lives	December 31, 2020	December 31, 2019	June 30, 2019
Computer and software	3 years	$ 16,700	$ 16,700	$ 16,700
Less: accumulated depreciation		(15,400)	(11,700)	(9,500)
Fixed assets, net		$ 1,300	$ 5,000	$ 7,200

NOTE 5 - ACCRUED EXPENSES

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

	December 31, 2020	December 31, 2019	June 30, 2019
Research and development	$ 2,183,800	$ 134,500	$ 563,400
Professional fees	150,900	172,900	98,400
Accrued bonus	1,444,900	50,000	-
Accrued vacation	351,200	124,600	96,700
Legal Settlement	-	250,000	500,000
Other	126,200	92,900	59,400
Total	$ 4,257,000	$ 824,900	$ 1,317,900

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 matured 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, 2020 and 2019 and June 30, 2019, the note payable outstanding balances were approximately $0, $110,200, and $364,200, 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.

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, 2020 and 2019 and June 30, 2019.

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:

	Year ended		Six months ended	Year ended
	December 31, 2020	(Unaudited) December 31, 2019	December 31, 2019	June 30, 2019
Beginning balance	$ -	$ -	$ -	$ 4,194,634
Adoption of ASU 2017-11 – warrants	-	-	-	(59,397)
Fair value of derivative liabilities for redemption feature of promissory notes payable	-	-	-	-
Change in fair value of derivative liabilities	-	-	-	54,634
Extinguishment of derivative liabilities on conversion of promissory notes.	-	-	-	(4,189,871)
Ending balance	$ -	$ -	$ -	$ -

The Company had no financial liabilities classified as level 3 during the year ended December 31, 2020 and the six months ended December 31, 2019.

NOTE 8 - STOCKHOLDERS' EQUITY

Common Stock

During the year ended December 31, 2020 and the six months ended December 31, 2019 and year ended June 30, 2019, the Company issued 42,475, 42,644, and 24,991 shares of common stock for cashless exercise of 60,513, 88,751, and 25,004 warrants, respectively. During the year ended December 31, 2020 and the six months ended December 31, 2019 and year ended June 30, 2019, the Company issued 1,159,989, 656,943, and nil shares of common stock for the exercise of warrants for proceeds of $8,056,416, $4,447,038 and $nil, respectively.

During the year ended December 31, 2020, the Company issued 90,204 shares of common stock for cashless exercise of 98,370 options. During the year ended December 31, 2020, the Company issued 155,558 shares of common stock for the exercise of options for proceeds of $735,514.

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

On May 15, 2020, the Company entered into an Open Market Sale Agreement with Jefferies LLC, as sales agent ("Jefferies"), pursuant to which the Company may offer and sell, from time to time, through Jefferies, shares of the Company's common stock, having an aggregate offering price of up to $75,000,000. The Company is not obligated to sell any shares under the agreement. During the year ended December 31, 2020 the Company issued shares of common stock for net cash proceeds of $19,791,644 under the agreement.

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 year ended December 31, 2020, the six months ended December 31, 2019, and years ended June 30, 2019, there were no common stock shares issued 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

In December 2014, the Board of Directors adopted and the shareholders approved Relmada's 2014 Stock Option and Equity Incentive 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. The Plan allowed for the granting of 5,152,942 options or stock awards.

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, 2020, 1,247,205 shares were available for future grants under the Plan.

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.

During the year ended December 31, 2020, the Company awarded a total of 1,000,000 options to employees with exercise prices ranging from $28.00- $45.61 and a 10-year term vesting over 4-year period. The options have an aggregate fair value of $32.4 million calculated using the Black-Scholes option-pricing model. Variables used in the Black-Scholes option-pricing model include: (1) discount rate of 0.36%-0.83% (2) expected life of 6.25 years, (3) expected volatility of 101%-108%, and (4) zero expected dividends.

During the year ended December 31, 2020, the Company recognized additional compensation expense of approximately $1,500,000 related to acceleration of vesting and a nominal amount related to the modification of certain options in connection with the separation and settlement agreement with Dr. Ottavio Vitolo (see note 11).

During the year ended December 31, 2020, the Company recognized compensation expense of approximately $484,000 related to the extended period of time to allow for some options to vest under the separation and settlement agreement with Dr. Thomas Wessel. This was considered a Type III modification and as a result the total expense of $1.8 million previously recognized was reversed as the options would not have vested prior to the modification (see note 11).

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.

A summary of the changes in options outstanding for the periods ended December 31, 2020 and 2019, and June 30, 2019 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, 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
Granted	1,000,000	39.50	9.3	-
Exercised	(253,927)	-	-	-
Forfeited	(455,938)	-	-	-
Outstanding and expected to vest at December 31, 2020	3,905,737	$ 24.32	8.4	$ 48,952,339
Options exercisable at December 31, 2020	1,241,359	$ 16.73	7.7	$ 22,960,117

At December 31, 2020, the Company has unrecognized stock-based compensation expense of approximately $53,502,000 related to unvested stock options over the weighted average remaining service period of 3.04 years. The weighted average fair value of options granted during the years ended December 31, 2020 and 2019, the six months ended December 31, 2019 and the year ended June 30, 2019 was approximately $32.45, $24.00 (unaudited), $24.31 and $3.84 per share, respectively, on the date of grant using the Black-Scholes option pricing model with the following assumptions:

	Years Ended December 31, 2020	(Unaudited) Years Ended December 31, 2019	Six Months ended December 31, 2019	Year ended June 30, 2019
Risk free interest rate	0.36 to 0.83%	1.73 to 2.37%	1.73 to 1.79%	2.37 to 2.69%
Dividend yield	0%	0%	0%	0%
Volatility	101-108%	101.5-108%	107.4-108.2%	101.5-102.3%
Expected term (in years)	6.25	5 to 6.25	5 to 6.25	6.25

Warrants

A summary of the changes in outstanding warrants during the year ended December 31, 2020 and six months ended December 31. 2019, and year ended June 30, 2019 is as follows:

	Number of Shares	Weighted Average Exercise Price Per Share
Outstanding 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 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 at December 31, 2019	3,646,872	$ 6.83
Issued	250,000	$ 33.32
Exercised	(1,211,199)	$ 7.27
Forfeited/Expired	(15,040)	$ 16.80
Outstanding at December 31, 2020	2,670,633	$ 9.11
Warrants exercisable at December 31, 2020	2,646,257	$ 9.16

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 December 16, 2020, the Company granted 20,000 warrants to a consultant with an exercise price of $34.87, a 5-year term and vesting over 4 years. The warrants have an aggregated fair value of $479 thousand using the Black-Scholes option-pricing model. Variables used in the Black-Scholes option-pricing model include: (1) discount rate of 0.37% (2) expected life of 3.75 years, (3) expected volatility of 105%, and (4) zero expected dividends

On December 16, 2020, the Company granted 108,000 warrants to consultants with an exercise price of $34.87, a 5-year term and vesting based on future events. The warrants have an aggregated fair value of $2.86 million that was calculated using the Black-Scholes option-pricing model. Variables used in the Black-Scholes option-pricing model include: (1) discount rate of 0.37% (2) expected life of 5 years, (3) expected volatility of 105%, and (4) zero expected dividends

On April 27, 2020, the Company granted 2,000 warrants to a consultant with an exercise price of $37.67, a 5-year term and immediate vesting. The warrants have an aggregated fair value of $48 thousand that was calculated using the Black-Scholes option-pricing model. Variables used in the Black-Scholes option-pricing model include: (1) discount rate of 0.27% (2) expected life of 2.5 years, (3) expected volatility of 116%, and (4) zero expected dividends.

On April 1, 2020, the Company granted 120,000 warrants to consultants with an exercise price of $31.59, a 5-year term and immediate vesting. The warrants have an aggregated fair value of $2.5 million that was calculated using the Black-Scholes option-pricing model. Variables used in the Black-Scholes option-pricing model include: (1) discount rate of 0.26% (2) expected life of 2.5 years, (3) expected volatility of 118%, and (4) zero expected dividends.

On October 8, 2019, the Company granted 15,000 warrants to a contractor with an 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 an 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 an 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 an 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 an 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.

At December 31, 2020, the Company had $3.4 million of unrecognized stock-based compensation expense related to outstanding warrants. At December 31, 2020, the aggregate intrinsic value of warrants vested and outstanding was $61.2 million.

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):

	Year Ended December 31, 2020	(Unaudited) Year Ended December 31, 2019	Six Months ended December 31, 2019	Year ended June 30, 2019
Research and development	$ 4,038,500	$ 360,900	$ 174,500	$ 215,900
General and administrative	16,738,800	2,804,300	2,192,500	998,100
Total	$ 20,777,300	$ 3,165,200	$ 2,367,000	$ 1,214,000

NOTE 9 - 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.

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, 2020	December 31, 2019	June 30, 2019
Deferred tax assets:			
Federal net operating loss	$ 15,227,000	$ 13,022,000	$ 13,555,000
State net operating loss	9,361,000	7,912,000	8,252,000
Research and development tax credits	3,407,000	1,499,000	1,230,000
Capitalized R&D	14,387,000	3,168,000	-
Nonqualified Stock Options	7,352,000	172,000	-
Accruals	645,000	133,000	206,000
Other	41,000	45,000	46,000
Less: valuation allowance	(50,420,000)	(25,951,000)	(23,289,000)
Total	$ -	$ -	$ -

On March 27, 2020, the Coronavirus Aid Relief and Economic Security ("CARES") Act was signed into law. The Act contains several new or changed income tax provisions, including but not limited to the following: increased limitation threshold for determining deductible interest expense, class life changes to qualified improvements (in general, from 39 years to 15 years) and the ability to carry back net operating losses ("NOLs") incurred from tax years 2018 through 2020 up to the five preceding tax years. Most of these provisions are either not applicable or have no material effect on the Company.

The Company has maintained a full valuation allowance against its deferred tax assets at December 31, 2020 and 2019, and June 30, 2019. 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 year ended December 31, 2020, the six months December 31, 2019 and the year ended June 30, 2019, by approximately $24,469,000, $2,662,000, and $4,357,000, respectively. Deferred tax asset for net operating loss carryforwards at December 31, 2020 was adjusted with the corresponding offset to valuation allowance.

At December 31, 2020, the Company had federal, New York State and New York City net operating loss (NOL) carryforwards of approximately $72,507,000, $68,854,000 and $68,470,000 respectively, which begin expiring in 2027, 2032 and 2032 respectively. Approximately $27,037,000 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 $3,407,000 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, 2020.

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

	Year Ended December 31, 2020	(Unaudited) Year Ended December 31, 2019	Six Months Ended December 31, 2019	Year Ended June 30, 2019
Statutory federal income tax rate	21.00%	21.00%	21%	21%
State (net of federal benefit)	15.50%	16.21%	11.96%	9.5%
Non-deductible expenses	0.42%	(4.24)%	(5.75)%	(6.3)%
R&D Credit	3.21%	3.02%	-%	-%
Other	1.01%	1.08%	5.27%	1%
Change in valuation allowance	(41.15)%	(37.07)%	(32.48)%	(25.2)%
Effective income tax rate	0%	0%	0%	0%

The Company does not have any uncertain tax positions at December 31, 2020, December 31, 2019 and June 30, 2019 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 10 - 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, 2020, 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 esmethadone 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 esmethadone 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 and Subleases

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 was renewed for calendar years 2020 and 2021. 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 $165,900, 93,900, $47,100, and $114,800 for the year ended December 31, 2020 and December 31, 2019 (unaudited), the six months ended December 31, 2019 and year ended June 30, 2019, respectively.

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, 2020 and 2019, and June 30, 2019, the balance of unearned interest income was approximately $14,900, $32,100 and 43,000, respectively.

The future minimum lease payments to be received under the lease for each year as of December 31, 2020 are as follows:

2021	$	90,348
2022		90,348
Total	$	180,696

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.

Lawsuit Brought by Current Employee

On July 15, 2020, an employee of the Company filed a Complaint alleging unequal pay based on gender and other employment-based claims. The Company intends to defend the lawsuit vigorously, it is currently in discovery and the ultimate outcome is not known.

NOTE 11 - RELATED PARTY TRANSACTIONS

Effective March 6, 2020, Dr. Vitolo entered into a Separation and Severance Agreement with the Company. Pursuant to the terms of the agreement, the Company agreed to pay Dr. Vitolo severance of $200,000 in accordance with his employment contract. In addition, Dr. Vitolo's options granted under the Company's 2014 Stock Option and Equity Incentive Plan continued to vest until September 6, 2020. Dr. Vitolo shall have until March 6, 2021 to exercise his vested options and he shall be allowed to use a cashless exercise provision to exercise his vested options. The agreement also contains customary confidentiality, release, and non-disparagement provisions, and the Company agreed to pay accrued and unpaid salary, vacation time and attorney's fees totaling approximately $45,000.

Effective December 31, 2020, Dr. Wessel entered into a Separation and Severance Agreement with the Company. Pursuant to the terms of the agreement, the Company agreed to pay Dr. Wessel severance of $237,500 in accordance with his employment contract. In addition, Dr. Wessel's options granted under the Company's 2014 Stock Option and Equity Incentive Plan continued to vest until June 30, 2021. Dr. Wessel shall have until December 31, 2021 to exercise his vested options and he shall be allowed to use a cashless exercise provision to exercise his vested options. The agreement also contains customary confidentiality, release, and non-disparagement provisions, and the Company agreed to pay accrued vacation time totaling approximately $28,940.

NOTE 12 - OTHER POSTRETIREMENT BENEFIT PLAN

Relmada participates in a multiemployer 401(k) plan that permits eligible employees to contribute funds on a pretax basis subject to maximum allowed under federal tax provisions. The Company matches 100% of the first 3% of employee contributions, plus 50% of employee contributions that exceed 3% but do not exceed 5%.

The employees choose an amount from various investment options for both their contributions and the Company's matching contribution. The Company's contribution expense was $90,692, $20,081, $10,261, and $18,853 for the year ended December 31, 2020 and December 31, 2019 (unaudited), the six months ended December 31, 2019 and year ended June 30, 2019, respectively.

NOTE 13 - SUBSEQUENT EVENTS

From January 1st through March 15, 2021, 271,366 warrants with an average exercise price of $5.31 were exercised, for net proceeds of $1,441,382.

From January 1st through March 15, 2021, 141,625 options with an average exercise price of $3.30 were exercised, for net proceeds of $467,772.

On January 7, 2021, the Company awarded a total of 1,490,000 options to employees and board of directors at an exercise price of $33.43 and a 10-year term vesting over a four-year period. The grants to the employees are 50% based on a four year vesting term and the other 50% are based on milestones achieved.

On January 7, 2021, the Company awarded Drs. Manfredi and Pappagallo, Acting CSO and Acting CMO, respectively, 200,000 warrants each, with an exercise price of $33.43 per share and a duration of 10 years from 1/7/2021. Half of each award shall vest 6.25% per quarter starting 4/7/21. The other half of each award shall vest 25% on 1/7/22, then 6.25% per quarter, and shall be subject to the same forfeiture for contingencies as the management options.

On February 3, 2021, the Company awarded a total of 25,000 options to a new employee with an exercise price of $34.47 and a 10-year term vesting over a four-year period.

The Company's lease agreement at 880 Third Avenue expired on December 31, 2020 and has been renewed for calendar year 2021. Included in this lease is additional office space on the 10th floor along with the existing space on the 5th floor for an average monthly cost of approximately $8,730.

Exhibits

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

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

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

Exhibit Number	Description
2.1	Share Exchange Agreement, dated May 20, 2014, by and among Camp Nine, Inc., Relmada Therapeutics, Inc., and the stockholders of Relmada Therapeutics, Inc. (incorporated by reference to Exhibit 2.1 of Relmada's Form 8-K filed with the SEC on May 27, 2014).
3.1	(i) Articles of Incorporation of Camp Nine, Inc. (incorporated by reference to Exhibit 3.1 of Relmada's Registration Statement on Form S-1 filed with the SEC on November 13, 2012).
	(ii) Certificate of Designation dated May 13, 2014 (incorporated by reference to Exhibit 4.1 to Relmada's Report on Form 8-K filed with the SEC on May 19, 2014).
	(iii) Nevada Certificate of Amendment to Articles of Incorporation of Camp Nine, Inc., effective May 30, 2014 (incorporated by reference to Exhibit 3.1 of Relmada's Form 8-K filed with the SEC on June 2, 2014).
	(iv) Nevada Certificate of Amendment to Articles of Incorporation of Camp Nine, Inc., effective July 8, 2014 (incorporated by reference to Exhibit 3.1 of Relmada's Form 8-K filed with the SEC on July 14, 2014).
3.2	(i) Amended and Restated Certificate of Incorporation of Relmada Therapeutics, Inc. (incorporated by reference to Exhibit 3.2(i) of Relmada's Form 8-K filed with the SEC on May 27, 2014).
	(ii) Amendment effective April 19, 2013 to Certificate of Incorporation of Relmada Therapeutics, Inc. (incorporated by reference to Exhibit 3.2(ii) of Relmada's Form 8-K filed with the SEC on May 27, 2014).
	(iii) Certificate of Amendment to Articles of Incorporation of Relmada Therapeutics, Inc. (incorporated by reference to Exhibit 3.1 of Relmada's Form 10-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).

Exhibit Number	Description
4.5	Form of Convertible Promissory Note (incorporated by reference to Exhibit 4.1 of Relmada's Form 10-Q filed with the SEC on February 12, 2018).
4.6	Form of Warrant to Purchase Common Stock (incorporated by reference to Exhibit 4.2 of Relmada's Form 10-Q filed with the SEC on February 12, 2018).
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).
4.9	Description of Securities (incorporated by reference to the description of the Company's common stock, par value $0.001 per share, under the heading "Description of Securities We May Offer—Authorized Capital Stock; Issued and Outstanding Capital Stock," "—Common Stock," "—Forum for Adjudication of Disputes, "—Anti-takeover Effects of Our Articles of Incorporation and By-laws, and "—Anti-takeover Effects of Nevada Law" in the Company's Registration Statement on Form S-3 (File No. 333-245054), filed with the Securities and Exchange Commission on August 12, 2020)
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).
10.6	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).
10.11	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)
10.13	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)
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).

Exhibit Number	Description
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).
10.27	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).

Exhibit Number	Description
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).
10.43	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).
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).

Exhibit Number	Description
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).
10.59	Severance and Separation Agreement, dated April 1, 2020, by and between Ottavio Vitolo and Relmada Therapeutics, Inc. (incorporated by reference to Exhibit 10.6 of Relmada's Form 10-Q filed with the SEC on May 15, 2020).
10.60	Open Market Sale Agreement℠ dated as of May 15, 2020 by and between Relmada Therapeutics, Inc. and Jefferies LLC. (incorporated by reference to Exhibit 10.7 of Relmada's Form 10-Q filed with the SEC on May 15, 2020).
10.61*	Relmada Therapeutics, Inc., 2021 Equity Incentive Plan
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 24, 2021

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 24, 2021
/s/ Maged Shenouda Maged Shenouda	Chief Financial Officer	March 24, 2021
/s/ Charles J. Casamento Charles J. Casamento	Chairman of the Board	March 24, 2021
/s/ Paul Kelly Paul Kelly	Director	March 24, 2021
/s/ Eric Schmidt Eric Schmidt	Director	March 24, 2021
/s/ John Glasspool John Glasspool	Director	March 24, 2021

Exhibit 10.61

RELMADA THERAPEUTICS, INC.

2021 EQUITY INCENTIVE PLAN

As adopted by the Board of Directors of Relmada Therapeutics, Inc., on March 19, 2021.

As approved by the shareholders of Relmada Therapeutics, Inc., on _____, 2021.

1. Purpose; Eligibility.

1.1 General Purpose. The name of this plan is the Relmada Therapeutics, Inc. 2021 Equity Incentive Plan (the "**Plan**"). The purposes of the Plan are to (a) enable Relmada Therapeutics, Inc., a Nevada corporation (the "**Company**"), and any Affiliate to attract and retain the types of Employees, Consultants and Directors who will contribute to the Company's long range success; (b) provide incentives that align the interests of Employees, Consultants and Directors with those of the shareholders of the Company; and (c) promote the success of the Company's business.

1.2 Eligible Award Recipients. The persons eligible to receive Awards are the Employees, Consultants and Directors of the Company and its Affiliates and such other individuals designated by the Committee who are reasonably expected to become Employees, Consultants and Directors after the receipt of Awards.

1.3 Available Awards. Awards that may be granted under the Plan include: (a) Incentive Stock Options, (b) Non-qualified Stock Options, (c) Stock Appreciation Rights, (d) Restricted Awards, (e) Performance Share Awards, (f) Cash Awards, and (g) Other Equity-Based Awards.

2. Definitions.

"**Affiliate**" means a corporation or other entity that, directly or through one or more intermediaries, controls, is controlled by or is under common control with, the Company.

"**Applicable Laws**" means the requirements related to or implicated by the administration of the Plan under applicable state corporate law, United States federal and state securities laws, the Code, any stock exchange or quotation system on which the shares of Common Stock are listed or quoted, and the applicable laws of any foreign country or jurisdiction where Awards are granted under the Plan.

"**Award**" means any right granted under the Plan, including an Incentive Stock Option, a Non-qualified Stock Option, a Stock Appreciation Right, a Restricted Award, a Performance Share Award, a Cash Award, or an Other Equity-Based Award.

"**Award Agreement**" means a written agreement, contract, certificate or other instrument or document evidencing the terms and conditions of an individual Award granted under the Plan which may, in the discretion of the Company, be transmitted electronically to any Participant. Each Award Agreement shall be subject to the terms and conditions of the Plan.

"**Beneficial Owner**" has the meaning assigned to such term in Rule 13d-3 and Rule 13d-5 under the Exchange Act, except that in calculating the beneficial ownership of any particular Person, such Person shall be deemed to have beneficial ownership of all securities that such Person has the right to acquire by conversion or exercise of other securities, whether such right is currently exercisable or is exercisable only after the passage of time. The terms "Beneficially Owns" and "Beneficially Owned" have a corresponding meaning.

"**Board**" means the Board of Directors of the Company, as constituted at any time.

"**Cash Award**" means an Award denominated in cash that is granted under Section 10 of the Plan.

"**Cause**" means:

With respect to any Employee or Consultant, unless the applicable Award Agreement states otherwise:

(a) If the Employee or Consultant is a party to an employment or service agreement with the Company or its Affiliates and such agreement provides for a definition of Cause, the definition contained therein; or

(b) If no such agreement exists, or if such agreement does not define Cause: (i) the commission of, or plea of guilty or no contest to, a felony or a crime involving moral turpitude or the commission of any other act involving willful malfeasance or material fiduciary breach with respect to the Company or an Affiliate; (ii) conduct that brings or is reasonably likely to bring the Company or an Affiliate negative publicity or into public disgrace, embarrassment, or disrepute; (iii) gross negligence or willful misconduct with respect to the Company or an Affiliate; (iv) material violation of state or federal securities laws; or (v) material violation of the Company's written policies or codes of conduct, including written policies related to discrimination, harassment, performance of illegal or unethical activities, and ethical misconduct.

With respect to any Director, unless the applicable Award Agreement states otherwise, a determination by a majority of the disinterested Board members that the Director has engaged in any of the following:

(a) malfeasance in office;

(b) gross misconduct or neglect;

(c) false or fraudulent misrepresentation inducing the director's appointment;

(d) willful conversion of corporate funds; or

(e) repeated failure to participate in Board meetings on a regular basis despite having received proper notice of the meetings in advance.

The Committee, in its absolute discretion, shall determine the effect of all matters and questions relating to whether a Participant has been discharged for Cause.

"**Change in Control**" means:

(a) if the Award is not subject to Section 409A of the Code:

(i) The direct or indirect sale, transfer, conveyance or other disposition (other than by way of merger or consolidation), in one or a series of related transactions, of all or substantially all of the properties or assets of the Company and its subsidiaries, taken as a whole, to any Person that is not a subsidiary of the Company;

(ii) The Incumbent Directors cease for any reason to constitute at least a majority of the Board;

(iii) The date which is 10 business days prior to the consummation of a complete liquidation or dissolution of the Company;

(iv) The acquisition by any Person of Beneficial Ownership of more than 50% (on a fully diluted basis) of either (i) the then outstanding shares of Common Stock of the Company, taking into account as outstanding for this purpose such Common Stock issuable upon the exercise of options or warrants, the conversion of convertible stock or debt, and the exercise of any similar right to acquire such Common Stock (the "**Outstanding Company Common Stock**") or (ii) the combined voting power of the then outstanding voting securities of the Company entitled to vote generally in the election of directors (the "**Outstanding Company Voting Securities**"); *provided, however*, that for purposes of this Plan, the following acquisitions shall not constitute a Change in Control: (A) any acquisition by the Company or any Affiliate, (B) any acquisition by any employee benefit plan sponsored or maintained by the Company or any subsidiary, (C) any acquisition which complies with clauses, (i), (ii) and (iii) of subsection (e) of this definition or (D) in respect of an Award held by a particular Participant, any acquisition by the Participant or any group of persons including the Participant (or any entity controlled by the Participant or any group of persons including the Participant); or

(v) The consummation of a reorganization, merger, consolidation, statutory share exchange or similar form of corporate transaction involving the Company that requires the approval of the Company's shareholders, whether for such transaction or the issuance of securities in the transaction (a "**Business Combination**"), unless immediately following such Business Combination: (i) more than 50% of the total voting power of (A) the entity resulting from such Business Combination (the "**Surviving Company**"), or (B) if applicable, the ultimate parent entity that directly or indirectly has beneficial ownership of sufficient voting securities eligible to elect a majority of the members of the board of directors (or the analogous governing body) of the Surviving Company (the "**Parent Company**"), is represented by the Outstanding Company Voting Securities that were outstanding immediately prior to such Business Combination (or, if applicable, is represented by shares into which the Outstanding Company Voting Securities were converted pursuant to such Business Combination), and such voting power among the holders thereof is in substantially the same proportion as the voting power of the Outstanding Company Voting Securities among the holders thereof immediately prior to the Business Combination; (ii) no Person (other than any employee benefit plan sponsored or maintained by the Surviving Company or the Parent Company) is or becomes the Beneficial Owner, directly or indirectly, of 50% or more of the total voting power of the outstanding voting securities eligible to elect members of the board of directors of the Parent Company (or the analogous governing body) (or, if there is no Parent Company, the Surviving Company); and (iii) at least a majority of the members of the board of directors (or the analogous governing body) of the Parent Company (or, if there is no Parent Company, the Surviving Company) following the consummation of the Business Combination were Board members at the time of the Board's approval of the execution of the initial agreement providing for such Business Combination; or

(b) if the Award is subject to Section 409A of the Code:

(i) One Person (or more than one Person acting as a group) acquires ownership of stock of the Company that, together with the stock held by such person or group, constitutes more than 50% of the total fair market value or total voting power of the stock of the Company; *provided, that*, a Change in Control shall not occur if any Person (or more than one Person acting as a group) owns more than 50% of the total fair market value or total voting power of the Company's stock and acquires additional stock;

(ii) One person (or more than one person acting as a group) acquires (or has acquired during the twelve-month period ending on the date of the most recent acquisition) ownership of the Company's stock possessing 30% or more of the total voting power of the stock of such corporation;

(iii) A majority of the members of the Board are replaced during any twelve-month period by directors whose appointment or election is not endorsed by a majority of the Board before the date of appointment or election; or

(iv) One person (or more than one person acting as a group), acquires (or has acquired during the twelve-month period ending on the date of the most recent acquisition) assets from the Company that have a total gross fair market value equal to or more than 40% of the total gross fair market value of all of the assets of the Company immediately before such acquisition(s).

"**Code**" means the Internal Revenue Code of 1986, as it may be amended from time to time. Any reference to a section of the Code shall be deemed to include a reference to any regulations promulgated thereunder.

"**Committee**" means a committee of one or more members of the Board appointed by the Board to administer the Plan in accordance with Section 3.3 and Section 3.4.

"**Common Stock**" means the common stock, $0.001 par value per share, of the Company, or such other securities of the Company as may be designated by the Committee from time to time in substitution thereof.

"**Consultant**" means any individual or entity which performs bona fide services to the Company or an Affiliate, other than as an Employee or Director, and who may be offered securities registerable pursuant to a registration statement on Form S-8 under the Securities Act.

"**Continuous Service**" means that the Participant's service with the Company or an Affiliate, whether as an Employee, Consultant or Director, is not interrupted or terminated. The Participant's Continuous Service shall not be deemed to have terminated merely because of a change in the capacity in which the Participant renders service to the Company or an Affiliate as an Employee, Consultant or Director or a change in the entity for which the Participant renders such service, *provided that* there is no interruption or termination of the Participant's Continuous Service; *provided further that* if any Award is subject to Section 409A of the Code, this sentence shall only be given effect to the extent consistent with Section 409A of the Code. For example, a change in status from an Employee of the Company to a Director of an Affiliate will not constitute an interruption of Continuous Service. The Committee or its delegate, in its sole discretion, may determine whether Continuous Service shall be considered interrupted in the case of any leave of absence approved by that party, including sick leave, military leave or any other personal or family leave of absence. The Committee or its delegate, in its sole discretion, may determine whether a Company transaction, such as a sale or spin-off of a division or subsidiary that employs a Participant, shall be deemed to result in a termination of Continuous Service for purposes of affected Awards, and such decision shall be final, conclusive and binding.

"**Deferred Stock Units (DSUs)**" has the meaning set forth in Section 8.1(b) hereof.

"**Director**" means a member of the Board.

"**Disability**" means, unless the applicable Award Agreement says otherwise, that the Participant is unable to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment; *provided, however,* for purposes of determining the term of an Incentive Stock Option pursuant to Section 6.10 hereof, the term Disability shall have the meaning ascribed to it under Section 22(e)(3) of the Code. The determination of whether an individual has a Disability shall be determined under procedures established by the Committee. Except in situations where the Committee is determining Disability for purposes of the term of an Incentive Stock Option pursuant to Section 6.10 hereof within the meaning of Section 22(e)(3) of the Code, the Committee may rely on any determination that a Participant is disabled for purposes of benefits under any long-term disability plan maintained by the Company or any Affiliate in which a Participant participates.

"**Disqualifying Disposition**" has the meaning set forth in Section 17.12.

"**Effective Date**" shall mean the date as of which this Plan is adopted by the Board.

"**Employee**" means any person, including an Officer or Director, employed by the Company or an Affiliate; *provided, that,* for purposes of determining eligibility to receive Incentive Stock Options, an Employee shall mean an employee of the Company or a parent or subsidiary corporation within the meaning of Section 424 of the Code. Mere service as a Director or payment of a director's fee by the Company or an Affiliate shall not be sufficient to constitute "employment" by the Company or an Affiliate.

"**Exchange Act**" means the Securities Exchange Act of 1934, as amended.

"**Fair Market Value**" means, as of any date, the value of the Common Stock as determined below. If the Common Stock is listed on any established stock exchange or a national market system, including without limitation, the New York Stock Exchange or the Nasdaq Stock Market, the Fair Market Value shall be the closing price of a share of Common Stock (or if no sales were reported the closing price on the date immediately preceding such date) as quoted on such exchange or system on the day of determination, as reported in the *Wall Street Journal*. In the absence of an established market for the Common Stock, the Fair Market Value shall be determined in good faith by the Committee and such determination shall be conclusive and binding on all persons.

"**Fiscal Year**" means the Company's fiscal year.

"**Free Standing Rights**" has the meaning set forth in Section 7.

"**Good Reason**" means, unless the applicable Award Agreement states otherwise:

(a) If an Employee or Consultant is a party to an employment or service agreement with the Company or its Affiliates and such agreement provides for a definition of Good Reason, the definition contained therein; or

(b) If no such agreement exists or if such agreement does not define Good Reason, the occurrence of one or more of the following without the Participant's express written consent, which circumstances are not remedied by the Company within thirty (30) days of its receipt of a written notice from the Participant describing the applicable circumstances (which notice must be provided by the Participant within ninety (90) days of the Participant's knowledge of the applicable circumstances):

(i) any material, adverse change in the Participant's duties, responsibilities, authority, title, status or reporting structure;

(ii) a material reduction in the Participant's base salary or bonus opportunity; or

(iii) a geographical relocation of the Participant's principal office location by more than fifty (50) miles.

"**Grant Date**" means the date on which the Committee adopts a resolution, or takes other appropriate action, expressly granting an Award to a Participant that specifies the key terms and conditions of the Award or, if a later date is set forth in such resolution, then such date as is set forth in such resolution.

"**Incentive Stock Option**" means an Option that is designated by the Committee as an incentive stock option within the meaning of Section 422 of the Code and that meets the requirements set out in the Plan.

"**Incumbent Directors**" means individuals who, on the Effective Date, constitute the Board, *provided that* any individual becoming a Director subsequent to the Effective Date whose election or nomination for election to the Board was approved by a vote of at least two-thirds of the Incumbent Directors then on the Board (either by a specific vote or by approval of the proxy statement of the Company in which such person is named as a nominee for Director without objection to such nomination) shall be an Incumbent Director. No individual initially elected or nominated as a director of the Company as a result of an actual or threatened election contest with respect to Directors or as a result of any other actual or threatened solicitation of proxies by or on behalf of any person other than the Board shall be an Incumbent Director.

"**Non-Employee Director**" means a Director who is a "non-employee director" within the meaning of Rule 16b-3.

"**Non-qualified Stock Option**" means an Option that by its terms does not qualify or is not intended to qualify as an Incentive Stock Option.

"**Officer**" means a person who is an officer of the Company within the meaning of Section 16 of the Exchange Act and the rules and regulations promulgated thereunder.

"**Option**" means an Incentive Stock Option or a Non-qualified Stock Option granted pursuant to the Plan.

"**Optionholder**" means a person to whom an Option is granted pursuant to the Plan or, if applicable, such other person who holds an outstanding Option.

"**Option Exercise Price**" means the price at which a share of Common Stock may be purchased upon the exercise of an Option.

"Other Equity-Based Award" means an Award that is not an Option, Stock Appreciation Right, Restricted Stock, Restricted Stock Unit, or Performance Share Award that is granted under Section 10 and is payable by delivery of Common Stock and/or which is measured by reference to the value of Common Stock.

"**Participant**" means an eligible person to whom an Award is granted pursuant to the Plan or, if applicable, such other person who holds an outstanding Award.

"**Performance Goals**" means, for a Performance Period, the one or more goals established by the Committee for the Performance Period based upon business criteria or other performance measures determined by the Committee in its discretion.

"**Performance Period**" means the one or more periods of time, as the Committee may select, over which the attainment of one or more Performance Goals will be measured for the purpose of determining a Participant's right to and the payment of a Performance Share Award or a Cash Award.

"**Performance Share Award**" means any Award granted pursuant to Section 9 hereof.

"**Performance Share**" means the grant of a right to receive a number of actual shares of Common Stock or share units based upon the performance of the Company during a Performance Period, as determined by the Committee.

"**Permitted Transferee**" means:

(a) a member of the Optionholder's immediate family (child, stepchild, grandchild, parent, stepparent, grandparent, spouse, former spouse, sibling, niece, nephew, mother-in-law, father-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law, including adoptive relationships), any person sharing the Optionholder's household (other than a tenant or employee), a trust in which these persons have more than 50% of the beneficial interest, a foundation in which these persons (or the Optionholder) control the management of assets, and any other entity in which these persons (or the Optionholder) own more than 50% of the voting interests; and

(b) such other transferees as may be permitted by the Committee in its sole discretion.

"Person" means a person as defined in Section 13(d)(3) of the Exchange Act.

"**Plan**" means this Relmada Therapeutics, Inc. 2021 Equity Incentive Plan, as amended and/or amended and restated from time to time.

"**Related Rights**" has the meaning set forth in Section 7.

"**Restricted Award**" means any Award granted pursuant to Section 8.

"**Restricted Period**" has the meaning set forth in Section 8.

"**Rule 16b-3**" means Rule 16b-3 promulgated under the Exchange Act or any successor to Rule 16b-3, as in effect from time to time.

"**Securities Act**" means the Securities Act of 1933, as amended.

"**Stock Appreciation Right**" means the right pursuant to an Award granted under Section 7 to receive, upon exercise, an amount payable in cash or shares equal to the number of shares subject to the Stock Appreciation Right that is being exercised multiplied by the excess of (a) the Fair Market Value of a share of Common Stock on the date the Award is exercised, over (b) the exercise price specified in the Stock Appreciation Right Award Agreement.

"Substitute Award" has the meaning set forth in Section 4.5.

"**Ten Percent Shareholder**" means a person who owns (or is deemed to own pursuant to Section 424(d) of the Code) stock possessing more than 10% of the total combined voting power of all classes of stock of the Company or of any of its Affiliates.

"Total Share Reserve" has the meaning set forth in Section 4.1.

3. Administration.

3.1 Authority of Committee. The Plan shall be administered by the Committee or, in the Board's sole discretion, by the Board. Subject to the terms of the Plan, the Committee's charter and Applicable Laws, and in addition to other express powers and authorization conferred by the Plan, the Committee shall have the authority:

(a) to construe and interpret the Plan and apply its provisions;

(b) to promulgate, amend, and rescind rules and regulations relating to the administration of the Plan;

(c) to authorize any person to execute, on behalf of the Company, any instrument required to carry out the purposes of the Plan;

(d) to delegate its authority to one or more Officers of the Company with respect to Awards that do not involve "insiders" within the meaning of Section 16 of the Exchange Act;

(e) to determine when Awards are to be granted under the Plan and the applicable Grant Date;

(f) from time to time to select, subject to the limitations set forth in this Plan, those eligible Award recipients to whom Awards shall be granted;

(g) to determine the number of shares of Common Stock to be made subject to each Award;

(h) to determine whether each Option is to be an Incentive Stock Option or a Non-qualified Stock Option;

(i) to prescribe the terms and conditions of each Award, including, without limitation, the exercise price and medium of payment and vesting provisions, and to specify the provisions of the Award Agreement relating to such grant;

(j) to determine the target number of Performance Shares to be granted pursuant to a Performance Share Award, the performance measures that will be used to establish the Performance Goals, the Performance Period(s) and the number of Performance Shares earned by a Participant;

(k) to amend any outstanding Awards, including for the purpose of modifying the time or manner of vesting, or the term of any outstanding Award; *provided, however*, that if any such amendment impairs a Participant's rights or increases a Participant's obligations under his or her Award or creates or increases a Participant's federal income tax liability with respect to an Award, such amendment shall also be subject to the Participant's consent;

(l) to determine the duration and purpose of leaves of absences which may be granted to a Participant without constituting termination of their employment for purposes of the Plan, which periods shall be no shorter than the periods generally applicable to Employees under the Company's employment policies;

(m) to make decisions with respect to outstanding Awards that may become necessary upon a change in corporate control or an event that triggers anti-dilution adjustments;

(n) to interpret, administer, reconcile any inconsistency in, correct any defect in and/or supply any omission in the Plan and any instrument or agreement relating to, or Award granted under, the Plan; and

(o) to exercise discretion to make any and all other determinations which it determines to be necessary or advisable for the administration of the Plan.

Except in connection with a corporate transaction involving the Company (including, without limitation, any stock dividend, stock split, extraordinary cash dividend, recapitalization, reorganization, merger, consolidation, split-up, spin-off, combination, or exchange of shares), the terms of outstanding Awards may not be amended to reduce the exercise price of outstanding Options or Stock Appreciation Rights or cancel outstanding Options or Stock Appreciation Rights in exchange for cash, other Awards or Options or Stock Appreciation Rights with an exercise price that is less than the exercise price of the original Options or Stock Appreciation Rights without stockholder approval.

3.2 Committee Decisions Final. All decisions made by the Committee pursuant to the provisions of the Plan shall be final and binding on the Company and the Participants, unless such decisions are determined by a court having jurisdiction to be arbitrary and capricious.

3.3 Delegation. The Committee or, if no Committee has been appointed, the Board may delegate administration of the Plan to a committee or committees of one or more members of the Board, and the term "**Committee**" shall apply to any person or persons to whom such authority has been delegated. The Committee shall have the power to delegate to a subcommittee any of the administrative powers the Committee is authorized to exercise (and references in this Plan to the Board or the Committee shall thereafter be to the committee or subcommittee), subject, however, to such resolutions, not inconsistent with the provisions of the Plan, as may be adopted from time to time by the Board. The Board may abolish the Committee at any time and revest in the Board the administration of the Plan. The members of the Committee shall be appointed by and serve at the pleasure of the Board. From time to time, the Board may increase or decrease the size of the Committee, add additional members to, remove members (with or without cause) from, appoint new members in substitution therefor, and fill vacancies, however caused, in the Committee. The Committee shall act pursuant to a vote of the majority of its members or, in the case of a Committee comprised of only two members, the unanimous consent of its members, whether present or not, or by the written consent of the majority of its members and minutes shall be kept of all of its meetings and copies thereof shall be provided to the Board. Subject to the limitations prescribed by the Plan and the Board, the Committee may establish and follow such rules and regulations for the conduct of its business as it may determine to be advisable.

3.4 Committee Composition. Except as otherwise determined by the Board, the Committee shall consist solely of two or more Non-Employee Directors. The Board shall have discretion to determine whether or not it intends to comply with the exemption requirements of Rule 16b-3. However, if the Board intends to satisfy such exemption requirements, with respect to any insider subject to Section 16 of the Exchange Act, the Committee shall be a compensation committee of the Board that at all times consists solely of two or more Non-Employee Directors. Within the scope of such authority, the Board or the Committee may delegate to a committee of one or more members of the Board who are not Non-Employee Directors the authority to grant Awards to eligible persons who are not then subject to Section 16 of the Exchange Act. Nothing herein shall create an inference that an Award is not validly granted under the Plan in the event Awards are granted under the Plan by a compensation committee of the Board that does not at all times consist solely of two or more Non-Employee Directors.

3.5 Indemnification. In addition to such other rights of indemnification as they may have as Directors or members of the Committee, and to the extent allowed by Applicable Laws, the Committee shall be indemnified by the Company against the reasonable expenses, including attorney's fees, actually incurred in connection with any action, suit or proceeding or in connection with any appeal therein, to which the Committee may be party by reason of any action taken or failure to act under or in connection with the Plan or any Award granted under the Plan, and against all amounts paid by the Committee in settlement thereof (*provided, however*, that the settlement has been approved by the Company, which approval shall not be unreasonably withheld) or paid by the Committee in satisfaction of a judgment in any such action, suit or proceeding, except in relation to matters as to which it shall be adjudged in such action, suit or proceeding that such Committee did not act in good faith and in a manner which such person reasonably believed to be in the best interests of the Company, or in the case of a criminal proceeding, had no reason to believe that the conduct complained of was unlawful; *provided, however*, that within 60 days after the institution of any such action, suit or proceeding, such Committee shall, in writing, offer the Company the opportunity at its own expense to handle and defend such action, suit or proceeding.

4. Shares Subject to the Plan.

4.1 Subject to adjustment in accordance with Section 14, no more than 1,500,000 shares of Common Stock shall be available for the grant of Awards under the Plan (the "**Total Share Reserve**"). During the terms of the Awards, the Company shall keep available at all times the number of shares of Common Stock required to satisfy such Awards.

4.2 Shares of Common Stock available for distribution under the Plan may consist, in whole or in part, of authorized and unissued shares, treasury shares or shares reacquired by the Company in any manner.

4.3 Subject to adjustment in accordance with Section 14, no more than 1,500,000 shares of Common Stock may be issued in the aggregate pursuant to the exercise of Incentive Stock Options (the **"ISO Limit"**).

4.4 Any shares of Common Stock subject to an Award that expires or is canceled, forfeited, or terminated without issuance of the full number of shares of Common Stock to which the Award related shall again be available for issuance of Awards or delivery under the Plan. Any shares of Common Stock subject to an Award under the Plan that are (a) tendered in payment of an Option, (b) delivered or withheld by the Company to satisfy any tax withholding obligation, or (c) covered by a stock-settled Stock Appreciation Right or other Awards that were not issued upon the settlement of the Award shall be added back to the shares of Common Stock available for issuance of Awards or delivery under the Plan and, to the extent permitted under Section 422 of the Code and the regulations promulgated thereunder, to the shares of Common Stock that may be issued as Incentive Stock Options.

4.5 Awards may, in the sole discretion of the Committee, be granted under the Plan in assumption of, or in substitution for, outstanding awards previously granted by an entity acquired by the Company or with which the Company combines ("**Substitute Awards**"). Substitute Awards shall not be counted against the Total Share Reserve; *provided, that*, Substitute Awards issued in connection with the assumption of, or in substitution for, outstanding options intended to qualify as Incentive Stock Options shall be counted against the ISO limit. Subject to applicable stock exchange requirements, available shares under a shareholder-approved plan of an entity directly or indirectly acquired by the Company or with which the Company combines (as appropriately adjusted to reflect such acquisition or transaction) may be used for Awards under the Plan and shall not count toward the Total Share Limit.

5. Eligibility.

5.1 Eligibility for Specific Awards. Incentive Stock Options may be granted only to Employees. Awards other than Incentive Stock Options may be granted to Employees, Consultants and Directors and those individuals whom the Committee determines are reasonably expected to become Employees, Consultants and Directors following the Grant Date.

5.2 Ten Percent Shareholders. A Ten Percent Shareholder shall not be granted an Incentive Stock Option unless the Option Exercise Price is at least 110% of the Fair Market Value of the Common Stock on the Grant Date and the Option is not exercisable after the expiration of five years from the Grant Date.

6. Options. Each Option granted under the Plan shall be evidenced by an Award Agreement. Each Option so granted shall be subject to the conditions set forth in this Section 6, and to such other conditions not inconsistent with the Plan as may be reflected in the applicable Award Agreement. All Options shall be separately designated Incentive Stock Options or Non-qualified Stock Options at the time of grant, and, if certificates are issued, a separate certificate or certificates will be issued for shares of Common Stock purchased on exercise of each type of Option. Notwithstanding the foregoing, the Company shall have no liability to any Participant or any other person if an Option designated as an Incentive Stock Option fails to qualify as such at any time or if an Option is determined to constitute "nonqualified deferred compensation" within the meaning of Section 409A of the Code and the terms of such Option do not satisfy the requirements of Section 409A of the Code. The provisions of separate Options need not be identical, but each Option shall include (through incorporation of provisions hereof by reference in the Option or otherwise) the substance of each of the following provisions:

6.1 Term. Subject to the provisions of Section 5.2 regarding Ten Percent Shareholders, no Incentive Stock Option shall be exercisable after the expiration of 10 years from the Grant Date. The term of a Non-qualified Stock Option granted under the Plan shall be determined by the Committee; *provided, however*, no Non-qualified Stock Option shall be exercisable after the expiration of 10 years from the Grant Date.

6.2 Exercise Price of an Incentive Stock Option. Subject to the provisions of Section 5.2 regarding Ten Percent Shareholders, the Option Exercise Price of each Incentive Stock Option shall be not less than 100% of the Fair Market Value of the Common Stock subject to the Option on the Grant Date. Notwithstanding the foregoing, an Incentive Stock Option may be granted with an Option Exercise Price lower than that set forth in the preceding sentence if such Option is granted pursuant to an assumption or substitution for another option in a manner satisfying the provisions of Section 424(a) of the Code.

6.3 Exercise Price of a Non-qualified Stock Option. The Option Exercise Price of each Non-qualified Stock Option shall be not less than 100% of the Fair Market Value of the Common Stock subject to the Option on the Grant Date. Notwithstanding the foregoing, a Non-qualified Stock Option may be granted with an Option Exercise Price lower than that set forth in the preceding sentence if such Option is granted pursuant to an assumption or substitution for another option in a manner satisfying the provisions of Section 409A of the Code.

6.4 Consideration. The Option Exercise Price of Common Stock acquired pursuant to an Option shall be paid, to the extent permitted by applicable statutes and regulations, either (a) in cash or by certified or bank check at the time the Option is exercised or (b) in the discretion of the Committee, upon such terms as the Committee shall approve, the Option Exercise Price may be paid: (i) by delivery to the Company of other Common Stock, duly endorsed for transfer to the Company, with a Fair Market Value on the date of delivery equal to the Option Exercise Price (or portion thereof) due for the number of shares being acquired, or by means of attestation whereby the Participant identifies for delivery specific shares of Common Stock that have an aggregate Fair Market Value on the date of attestation equal to the Option Exercise Price (or portion thereof) and receives a number of shares of Common Stock equal to the difference between the number of shares thereby purchased and the number of identified attestation shares of Common Stock; (ii) a "cashless" exercise program established with a broker; (iii) by reduction in the number of shares of Common Stock otherwise deliverable upon exercise of such Option with a Fair Market Value equal to the aggregate Option Exercise Price at the time of exercise; (iv) by any combination of the foregoing methods; or (v) in any other form of legal consideration that may be acceptable to the Committee. Unless otherwise specifically provided in the Option, the exercise price of Common Stock acquired pursuant to an Option that is paid by delivery (or attestation) to the Company of other Common Stock acquired, directly or indirectly from the Company, shall be paid only by shares of the Common Stock of the Company that have been held for more than six months (or such longer or shorter period of time required to avoid a charge to earnings for financial accounting purposes). Notwithstanding the foregoing, during any period for which the Common Stock is publicly traded (i.e., the Common Stock is listed on any established stock exchange or a national market system) an exercise by a Director or Officer that involves or may involve a direct or indirect extension of credit or arrangement of an extension of credit by the Company, directly or indirectly, in violation of Section 402(a) of the Sarbanes-Oxley Act of 2002 shall be prohibited with respect to any Award under this Plan.

6.5 Transferability of an Incentive Stock Option. An Incentive Stock Option shall not be transferable except by will or by the laws of descent and distribution and shall be exercisable during the lifetime of the Optionholder only by the Optionholder. Notwithstanding the foregoing, the Optionholder may, by delivering written notice to the Company, in a form satisfactory to the Company, designate a third party who, in the event of the death of the Optionholder, shall thereafter be entitled to exercise the Option.

6.6 Transferability of a Non-qualified Stock Option. A Non-qualified Stock Option may, in the sole discretion of the Committee, be transferable to a Permitted Transferee, upon written approval by the Committee to the extent provided in the Award Agreement. If the Non-qualified Stock Option does not provide for transferability, then the Non-qualified Stock Option shall not be transferable except by will or by the laws of descent and distribution and shall be exercisable during the lifetime of the Optionholder only by the Optionholder. Notwithstanding the foregoing, the Optionholder may, by delivering written notice to the Company, in a form satisfactory to the Company, designate a third party who, in the event of the death of the Optionholder, shall thereafter be entitled to exercise the Option.

6.7 Vesting of Options. Each Option may, but need not, vest and therefore become exercisable in periodic installments that may, but need not, be equal. The Option may be subject to such other terms and conditions on the time or times when it may be exercised (which may be based on performance or other criteria) as the Committee may deem appropriate. The vesting provisions of individual Options may vary. No Option may be exercised for a fraction of a share of Common Stock. The Committee may, but shall not be required to, provide for an acceleration of vesting and exercisability in the terms of any Award Agreement upon the occurrence of a specified event.

6.8 Termination of Continuous Service. Unless otherwise provided in an Award Agreement or in an employment agreement the terms of which have been approved by the Committee, in the event an Optionholder's Continuous Service terminates (other than upon the Optionholder's death or Disability), the Optionholder may exercise his or her Option (to the extent that the Optionholder was entitled to exercise such Option as of the date of termination) but only within such period of time ending on the earlier of (a) the date three months following the termination of the Optionholder's Continuous Service or (b) the expiration of the term of the Option as set forth in the Award Agreement; *provided that*, if the termination of Continuous Service is by the Company for Cause, all outstanding Options (whether or not vested) shall immediately terminate and cease to be exercisable. If, after termination, the Optionholder does not exercise his or her Option within the time specified in the Award Agreement, the Option shall terminate.

6.9 Extension of Termination Date. An Optionholder's Award Agreement may also provide that if the exercise of the Option following the termination of the Optionholder's Continuous Service for any reason would be prohibited at any time because the issuance of shares of Common Stock would violate the registration requirements under the Securities Act or any other state or federal securities law or the rules of any securities exchange or interdealer quotation system, then the Option shall terminate on the earlier of (a) the expiration of the term of the Option in accordance with Section 6.1 or (b) the expiration of a period after termination of the Participant's Continuous Service that is three months after the end of the period during which the exercise of the Option would be in violation of such registration or other securities law requirements.

6.10 Disability of Optionholder. Unless otherwise provided in an Award Agreement, in the event that an Optionholder's Continuous Service terminates as a result of the Optionholder's Disability, the Optionholder may exercise his or her Option (to the extent that the Optionholder was entitled to exercise such Option as of the date of termination), but only within such period of time ending on the earlier of (a) the date 12 months following such termination or (b) the expiration of the term of the Option as set forth in the Award Agreement. If, after termination, the Optionholder does not exercise his or her Option within the time specified herein or in the Award Agreement, the Option shall terminate.

6.11 Death of Optionholder. Unless otherwise provided in an Award Agreement, in the event an Optionholder's Continuous Service terminates as a result of the Optionholder's death, then the Option may be exercised (to the extent the Optionholder was entitled to exercise such Option as of the date of death) by the Optionholder's estate, by a person who acquired the right to exercise the Option by bequest or inheritance or by a person designated to exercise the Option upon the Optionholder's death, but only within the period ending on the earlier of (a) the date 12 months following the date of death or (b) the expiration of the term of such Option as set forth in the Award Agreement. If, after the Optionholder's death, the Option is not exercised within the time specified herein or in the Award Agreement, the Option shall terminate.

6.12 Incentive Stock Option $100,000 Limitation. To the extent that the aggregate Fair Market Value (determined at the time of grant) of Common Stock with respect to which Incentive Stock Options are exercisable for the first time by any Optionholder during any calendar year (under all plans of the Company and its Affiliates) exceeds $100,000, the Options or portions thereof which exceed such limit (according to the order in which they were granted) shall be treated as Non-qualified Stock Options.

7. Stock Appreciation Rights. Each Stock Appreciation Right granted under the Plan shall be evidenced by an Award Agreement. Each Stock Appreciation Right so granted shall be subject to the conditions set forth in this Section 7, and to such other conditions not inconsistent with the Plan as may be reflected in the applicable Award Agreement. Stock Appreciation Rights may be granted alone ("**Free Standing Rights**") or in tandem with an Option granted under the Plan ("**Related Rights**").

7.1 Grant Requirements for Related Rights. Any Related Right that relates to a Non-qualified Stock Option may be granted at the same time the Option is granted or at any time thereafter but before the exercise or expiration of the Option. Any Related Right that relates to an Incentive Stock Option must be granted at the same time the Incentive Stock Option is granted.

7.2 Term. The term of a Stock Appreciation Right granted under the Plan shall be determined by the Committee; *provided, however*, no Stock Appreciation Right shall be exercisable later than the tenth (10^{th}) anniversary of the Grant Date.

7.3 Vesting of SARs. Each Stock Appreciation Right may, but need not, vest and therefore become exercisable in periodic installments that may, but need not, be equal. The Stock Appreciation Right may be subject to such other terms and conditions on the time or times when it may be exercised as the Committee may deem appropriate. The vesting provisions of individual Stock Appreciation Rights may vary. No Stock Appreciation Right may be exercised for a fraction of a share of Common Stock. The Committee may, but shall not be required to, provide for an acceleration of vesting and exercisability in the terms of any Stock Appreciation Right upon the occurrence of a specified event.

7.4 Exercise and Payment. Upon exercise of a Stock Appreciation Right, the holder shall be entitled to receive from the Company an amount equal to the number of shares of Common Stock subject to the Stock Appreciation Right that is being exercised multiplied by the excess of (i) the Fair Market Value of a share of Common Stock on the date the Award is exercised, over (ii) the exercise price specified in the Stock Appreciation Right or related Option. Payment with respect to the exercise of a Stock Appreciation Right shall be made on the date of exercise. Payment shall be made in the form of shares of Common Stock (with or without restrictions as to substantial risk of forfeiture and transferability, as determined by the Committee in its sole discretion), cash or a combination thereof, as determined by the Committee.

7.5 Exercise Price. The exercise price of a Free Standing Right shall be determined by the Committee, but shall not be less than 100% of the Fair Market Value of one share of Common Stock on the Grant Date of such Stock Appreciation Right. A Related Right granted simultaneously with or subsequent to the grant of an Option and in conjunction therewith or in the alternative thereto shall have the same exercise price as the related Option, shall be transferable only upon the same terms and conditions as the related Option, and shall be exercisable only to the same extent as the related Option; *provided, however*, that a Stock Appreciation Right, by its terms, shall be exercisable only when the Fair Market Value per share of Common Stock subject to the Stock Appreciation Right and related Option exceeds the exercise price per share thereof and no Stock Appreciation Rights may be granted in tandem with an Option unless the Committee determines that the requirements of Section 7.1 are satisfied.

7.6 Reduction in the Underlying Option Shares. Upon any exercise of a Related Right, the number of shares of Common Stock for which any related Option shall be exercisable shall be reduced by the number of shares for which the Stock Appreciation Right has been exercised. The number of shares of Common Stock for which a Related Right shall be exercisable shall be reduced upon any exercise of any related Option by the number of shares of Common Stock for which such Option has been exercised.

8. Restricted Awards. A Restricted Award is an Award of actual shares of Common Stock ("**Restricted Stock**") or hypothetical Common Stock units ("**Restricted Stock Units**") having a value equal to the Fair Market Value of an identical number of shares of Common Stock, which may, but need not, provide that such Restricted Award may not be sold, assigned, transferred or otherwise disposed of, pledged or hypothecated as collateral for a loan or as security for the performance of any obligation or for any other purpose for such period (the "**Restricted Period**") as the Committee shall determine. Each Restricted Award granted under the Plan shall be evidenced by an Award Agreement. Each Restricted Award so granted shall be subject to the conditions set forth in this Section 8, and to such other conditions not inconsistent with the Plan as may be reflected in the applicable Award Agreement.

8.1 Restricted Stock and Restricted Stock Units.

(a) Each Participant granted Restricted Stock shall execute and deliver to the Company an Award Agreement with respect to the Restricted Stock setting forth the restrictions and other terms and conditions applicable to such Restricted Stock. If the Committee determines that the Restricted Stock shall be held by the Company or in escrow rather than delivered to the Participant pending the release of the applicable restrictions, the Committee may require the Participant to additionally execute and deliver to the Company (A) an escrow agreement satisfactory to the Committee, if applicable and (B) the appropriate blank stock power with respect to the Restricted Stock covered by such agreement. If a Participant fails to execute an agreement evidencing an Award of Restricted Stock and, if applicable, an escrow agreement and stock power, the Award shall be null and void. Subject to the restrictions set forth in the Award, the Participant generally shall have the rights and privileges of a shareholder as to such Restricted Stock, including the right to vote such Restricted Stock and the right to receive dividends; *provided that*, any cash dividends and stock dividends with respect to the Restricted Stock shall be withheld by the Company for the Participant's account, and interest may be credited on the amount of the cash dividends withheld at a rate and subject to such terms as determined by the Committee. The cash dividends or stock dividends so withheld by the Committee and attributable to any particular share of Restricted Stock (and earnings thereon, if applicable) shall be distributed to the Participant in cash or, at the discretion of the Committee, in shares of Common Stock having a Fair Market Value equal to the amount of such dividends, if applicable, upon the release of restrictions on such share and, if such share is forfeited, the Participant shall have no right to such dividends.

(b) The terms and conditions of a grant of Restricted Stock Units shall be reflected in an Award Agreement. No shares of Common Stock shall be issued at the time a Restricted Stock Unit is granted, and the Company will not be required to set aside funds for the payment of any such Award. A Participant shall have no voting rights with respect to any Restricted Stock Units granted hereunder. The Committee may also grant Restricted Stock Units with a deferral feature, whereby settlement is deferred beyond the vesting date until the occurrence of a future payment date or event set forth in an Award Agreement ("**Deferred Stock Units**"). At the discretion of the Committee, each Restricted Stock Unit or Deferred Stock Unit (representing one share of Common Stock) may be credited with an amount equal to the cash and stock dividends paid by the Company in respect of one share of Common Stock ("**Dividend Equivalents**"). Dividend Equivalents shall be withheld by the Company and credited to the Participant's account, and interest may be credited on the amount of cash Dividend Equivalents credited to the Participant's account at a rate and subject to such terms as determined by the Committee. Dividend Equivalents credited to a Participant's account and attributable to any particular Restricted Stock Unit or Deferred Stock Unit (and earnings thereon, if applicable) shall be distributed in cash or, at the discretion of the Committee, in shares of Common Stock having a Fair Market Value equal to the amount of such Dividend Equivalents and earnings, if applicable, to the Participant upon settlement of such Restricted Stock Unit or Deferred Stock Unit and, if such Restricted Stock Unit or Deferred Stock Unit is forfeited, the Participant shall have no right to such Dividend Equivalents. Dividend Equivalents may, if so determined by the Committee, be deemed re-invested in additional Restricted Stock Units or Deferred Stock Units based on the Fair Market Value of a share of Common Stock on the applicable dividend payment date and rounded down to the nearest whole share.

8.2 Restrictions.

(a) Restricted Stock awarded to a Participant shall be subject to the following restrictions until the expiration of the Restricted Period, and to such other terms and conditions as may be set forth in the applicable Award Agreement: (A) if an escrow arrangement is used, the Participant shall not be entitled to delivery of the stock certificate; (B) the shares shall be subject to the restrictions on transferability set forth in the Award Agreement; (C) the shares shall be subject to forfeiture to the extent provided in the applicable Award Agreement; and (D) to the extent such shares are forfeited, the stock certificates shall be returned to the Company, and all rights of the Participant to such shares and as a shareholder with respect to such shares shall terminate without further obligation on the part of the Company.

(b) Restricted Stock Units and Deferred Stock Units awarded to any Participant shall be subject to (A) forfeiture until the expiration of the Restricted Period, and satisfaction of any applicable Performance Goals during such period, to the extent provided in the applicable Award Agreement, and to the extent such Restricted Stock Units or Deferred Stock Units are forfeited, all rights of the Participant to such Restricted Stock Units or Deferred Stock Units shall terminate without further obligation on the part of the Company and (B) such other terms and conditions as may be set forth in the applicable Award Agreement.

(c) The Committee shall have the authority to remove any or all of the restrictions on the Restricted Stock, Restricted Stock Units and Deferred Stock Units whenever it may determine that, by reason of changes in Applicable Laws or other changes in circumstances arising after the date the Restricted Stock or Restricted Stock Units or Deferred Stock Units are granted, such action is appropriate.

8.3 Restricted Period. With respect to Restricted Awards, the Restricted Period shall commence on the Grant Date and end at the time or times set forth on a schedule established by the Committee in the applicable Award Agreement. No Restricted Award may be granted or settled for a fraction of a share of Common Stock. The Committee may, but shall not be required to, provide for an acceleration of vesting in the terms of any Award Agreement upon the occurrence of a specified event.

8.4 Delivery of Restricted Stock and Settlement of Restricted Stock Units. Upon the expiration of the Restricted Period with respect to any shares of Restricted Stock, the restrictions set forth in Section 8.2 and the applicable Award Agreement shall be of no further force or effect with respect to such shares, except as set forth in the applicable Award Agreement. If an escrow arrangement is used, upon such expiration, the Company shall deliver to the Participant, or his or her beneficiary, without charge, the stock certificate evidencing the shares of Restricted Stock which have not then been forfeited and with respect to which the Restricted Period has expired (to the nearest full share) and any cash dividends or stock dividends credited to the Participant's account with respect to such Restricted Stock and the interest thereon, if any. Upon the expiration of the Restricted Period with respect to any outstanding Restricted Stock Units, or at the expiration of the deferral period with respect to any outstanding Deferred Stock Units, the Company shall deliver to the Participant, or his or her beneficiary, without charge, one share of Common Stock for each such outstanding vested Restricted Stock Unit or Deferred Stock Unit ("**Vested Unit**") and cash equal to any Dividend Equivalents credited with respect to each such Vested Unit in accordance with Section 8.1(b) hereof and the interest thereon or, at the discretion of the Committee, in shares of Common Stock having a Fair Market Value equal to such Dividend Equivalents and the interest thereon, if any; *provided, however*, that, if explicitly provided in the applicable Award Agreement, the Committee may, in its sole discretion, elect to pay cash or part cash and part Common Stock in lieu of delivering only shares of Common Stock for Vested Units. If a cash payment is made in lieu of delivering shares of Common Stock, the amount of such payment shall be equal to the Fair Market Value of the Common Stock as of the date on which the Restricted Period lapsed in the case of Restricted Stock Units, or the delivery date in the case of Deferred Stock Units, with respect to each Vested Unit.

8.5 Stock Restrictions. Each certificate representing Restricted Stock awarded under the Plan shall bear a legend in such form as the Company deems appropriate.

9. Performance Share Awards. Each Performance Share Award granted under the Plan shall be evidenced by an Award Agreement. Each Performance Share Award so granted shall be subject to the conditions set forth in this Section 9, and to such other conditions not inconsistent with the Plan as may be reflected in the applicable Award Agreement. The Committee shall have the discretion to determine: (i) the number of shares of Common Stock or stock-denominated units subject to a Performance Share Award granted to any Participant; (ii) the Performance Period applicable to any Award; (iii) the conditions that must be satisfied for a Participant to earn an Award; and (iv) the other terms, conditions and restrictions of the Award.

9.1 Earning Performance Share Awards. The number of Performance Shares earned by a Participant will depend on the extent to which the performance goals established by the Committee are attained within the applicable Performance Period, as determined by the Committee.

10. Other Equity-Based Awards and Cash Awards. The Committee may grant Other Equity-Based Awards, either alone or in tandem with other Awards, in such amounts and subject to such conditions as the Committee shall determine in its sole discretion. Each Equity-Based Award shall be evidenced by an Award Agreement and shall be subject to such conditions, not inconsistent with the Plan, as may be reflected in the applicable Award Agreement. The Committee may grant Cash Awards in such amounts and subject to such Performance Goals, other vesting conditions, and such other terms as the Committee determines in its discretion. Cash Awards shall be evidenced in such form as the Committee may determine.

11. Securities Law Compliance. Each Award Agreement shall provide that no shares of Common Stock shall be purchased or sold thereunder unless and until (a) any then applicable requirements of state or federal laws and regulatory agencies have been fully complied with to the satisfaction of the Company and its counsel and (b) if required to do so by the Company, the Participant has executed and delivered to the Company a letter of investment intent in such form and containing such provisions as the Committee may require. The Company shall use reasonable efforts to seek to obtain from each regulatory commission or agency having jurisdiction over the Plan such authority as may be required to grant Awards and to issue and sell shares of Common Stock upon exercise of the Awards; *provided, however*, that this undertaking shall not require the Company to register under the Securities Act the Plan, any Award or any Common Stock issued or issuable pursuant to any such Award. If, after reasonable efforts, the Company is unable to obtain from any such regulatory commission or agency the authority which counsel for the Company deems necessary for the lawful issuance and sale of Common Stock under the Plan, the Company shall be relieved from any liability for failure to issue and sell Common Stock upon exercise of such Awards unless and until such authority is obtained.

12. Use of Proceeds from Stock. Proceeds from the sale of Common Stock pursuant to Awards, or upon exercise thereof, shall constitute general funds of the Company.

13. Miscellaneous.

13.1 Acceleration of Exercisability and Vesting. The Committee shall have the power to accelerate the time at which an Award may first be exercised or the time during which an Award or any part thereof will vest in accordance with the Plan, notwithstanding the provisions in the Award stating the time at which it may first be exercised or the time during which it will vest.

13.2 Shareholder Rights. Except as provided in the Plan, no Participant shall be deemed to be the holder of, or to have any of the rights of a holder with respect to, any shares of Common Stock subject to such Award unless and until such Participant has satisfied all requirements for exercise of the Award pursuant to its terms and no adjustment shall be made for, nor shall any Participant be entitled to receive, any dividends (ordinary or extraordinary, whether in cash, securities or other property) or distributions of other rights for which the record date is prior to the date the certificate representing Common Stock issuable pursuant to an Award is actually issued, except as provided in Section 14 hereof.

13.3 No Employment or Other Service Rights. Nothing in the Plan or any instrument executed or Award granted pursuant thereto shall confer upon any Participant any right to continue to serve the Company or an Affiliate in the capacity in effect at the time the Award was granted or shall affect the right of the Company or an Affiliate to terminate (a) the employment of an Employee with or without notice and with or without Cause or (b) the service of a Director pursuant to the By-laws of the Company or an Affiliate, and any applicable provisions of the corporate law of the state in which the Company or the Affiliate is incorporated, as the case may be.

13.4 Transfer; Approved Leave of Absence. For purposes of the Plan, no termination of employment by an Employee shall be deemed to result from either (a) a transfer of employment to the Company from an Affiliate or from the Company to an Affiliate, or from one Affiliate to another, or (b) an approved leave of absence for military service or sickness, or for any other purpose approved by the Company, if the Employee's right to reemployment is guaranteed either by a statute or by contract or under the policy pursuant to which the leave of absence was granted or if the Committee otherwise so provides in writing, in either case, except to the extent inconsistent with Section 409A of the Code if the applicable Award is subject thereto.

13.5 Withholding Obligations. To the extent provided by the terms of an Award Agreement and subject to the discretion of the Committee, the Participant may satisfy any federal, state or local tax withholding obligation relating to the exercise or acquisition of Common Stock under an Award by any of the following means (in addition to the Company's right to withhold from any compensation paid to the Participant by the Company) or by a combination of such means: (a) tendering a cash payment; (b) authorizing the Company to withhold shares of Common Stock from the shares of Common Stock otherwise issuable to the Participant as a result of the exercise or acquisition of Common Stock under the Award, *provided, however*, that no shares of Common Stock are withheld with a value exceeding the maximum amount of tax required to be withheld by law (or such lesser amount as may be necessary to avoid classification of the Stock Award as a liability for financial accounting purposes); or (c) delivering to the Company previously owned and unencumbered shares of Common Stock of the Company.

14. Adjustments upon Changes in Stock. In the event of changes in the outstanding Common Stock or in the capital structure of the Company by reason of any stock or extraordinary cash dividend, stock split, reverse stock split, an extraordinary corporate transaction such as any recapitalization, reorganization, merger, consolidation, combination, exchange, or other relevant change in capitalization occurring after the Grant Date of any Award, Awards granted under the Plan and any Award Agreements, the exercise price of Options and Stock Appreciation Rights, the Performance Goals to which Performance Share Awards and Cash Awards are subject, the maximum number of shares of Common Stock subject to all Awards stated in Section 4 will be equitably adjusted or substituted, as to the number, price or kind of a share of Common Stock or other consideration subject to such Awards to the extent necessary to preserve the economic intent of such Award. In the case of adjustments made pursuant to this Section 14, unless the Committee specifically determines that such adjustment is in the best interests of the Company or its Affiliates, the Committee shall, in the case of Incentive Stock Options, ensure that any adjustments under this Section 14 will not constitute a modification, extension or renewal of the Incentive Stock Options within the meaning of Section 424(h)(3) of the Code and in the case of Non-qualified Stock Options, ensure that any adjustments under this Section 14 will not constitute a modification of such Non-qualified Stock Options within the meaning of Section 409A of the Code. Any adjustments made under this Section 14 shall be made in a manner which does not adversely affect the exemption provided pursuant to Rule 16b-3 under the Exchange Act. The Company shall give each Participant notice of an adjustment hereunder and, upon notice, such adjustment shall be conclusive and binding for all purposes.

15. Effect of Change in Control.

15.1 Unless otherwise provided in an Award Agreement, notwithstanding any provision of the Plan to the contrary:

(a) In the event of a Change in Control, all outstanding Options and Stock Appreciation Rights shall become immediately exercisable with respect to 100% of the shares subject to such Options or Stock Appreciation Rights, and/or the Restricted Period shall expire immediately with respect to 100% of the outstanding shares of Restricted Stock or Restricted Stock Units.

(b) With respect to Performance Share Awards and Cash Awards, in the event of a Change in Control, all Performance Goals or other vesting criteria will be deemed achieved at 100% of target levels and all other terms and conditions will be deemed met.

15.2 In addition, in the event of a Change in Control, the Committee may in its discretion and upon at least 10 days' advance notice to the affected persons, cancel any outstanding Awards and pay to the holders thereof, in cash or stock, or any combination thereof, the value of such Awards based upon the price per share of Common Stock received or to be received by other shareholders of the Company in the event. In the case of any Option or Stock Appreciation Right with an exercise price (or SAR Exercise Price in the case of a Stock Appreciation Right) that equals or exceeds the price paid for a share of Common Stock in connection with the Change in Control, the Committee may cancel the Option or Stock Appreciation Right without the payment of consideration therefor.

15.3 The obligations of the Company under the Plan shall be binding upon any successor corporation or organization resulting from the merger, consolidation or other reorganization of the Company, or upon any successor corporation or organization succeeding to all or substantially all of the assets and business of the Company and its Affiliates, taken as a whole.

16. Amendment of the Plan and Awards.

16.1 Amendment of Plan. The Board at any time, and from time to time, may amend or terminate the Plan. However, except as provided in Section 14 relating to adjustments upon changes in Common Stock and Section 16.3, no amendment shall be effective unless approved by the shareholders of the Company to the extent shareholder approval is necessary to satisfy any Applicable Laws. At the time of such amendment, the Board shall determine, upon advice from counsel, whether such amendment will be contingent on shareholder approval.

16.2 Shareholder Approval. The Board may, in its sole discretion, submit any other amendment to the Plan for shareholder approval.

16.3 Contemplated Amendments. It is expressly contemplated that the Board may amend the Plan in any respect the Board deems necessary or advisable to provide eligible Employees, Consultants and Directors with the maximum benefits provided or to be provided under the provisions of the Code and the regulations promulgated thereunder relating to Incentive Stock Options or to the nonqualified deferred compensation provisions of Section 409A of the Code and/or to bring the Plan and/or Awards granted under it into compliance therewith.

16.4 No Impairment of Rights. Rights under any Award granted before amendment of the Plan shall not be impaired by any amendment of the Plan unless (a) the Company requests the consent of the Participant and (b) the Participant consents in writing.

16.5 Amendment of Awards. The Committee at any time, and from time to time, may amend the terms of any one or more Awards; *provided, however*, that the Committee may not affect any amendment which would otherwise constitute an impairment of the rights under any Award unless (a) the Company requests the consent of the Participant and (b) the Participant consents in writing.

17. General Provisions.

17.1 Forfeiture Events. The Committee may specify in an Award Agreement that the Participant's rights, payments and benefits with respect to an Award shall be subject to reduction, cancellation, forfeiture or recoupment upon the occurrence of certain events, in addition to applicable vesting conditions of an Award. Such events may include, without limitation, breach of non-competition, non-solicitation, confidentiality, or other restrictive covenants that are contained in the Award Agreement or otherwise applicable to the Participant, a termination of the Participant's Continuous Service for Cause, or other conduct by the Participant that is detrimental to the business or reputation of the Company and/or its Affiliates.

17.2 Clawback. Notwithstanding any other provisions in this Plan, the Company may cancel any Award, require reimbursement of any Award by a Participant, and effect any other right of recoupment of equity or other compensation provided under the Plan in accordance with any Company policies that may be adopted and/or modified from time to time (**"Clawback Policy"**). In addition, a Participant may be required to repay to the Company previously paid compensation, whether provided pursuant to the Plan or an Award Agreement, in accordance with the Clawback Policy. By accepting an Award, the Participant is agreeing to be bound by the Clawback Policy, as in effect or as may be adopted and/or modified from time to time by the Company in its discretion (including, without limitation, to comply with applicable law or stock exchange listing requirements).

17.3 Other Compensation Arrangements. Nothing contained in this Plan shall prevent the Board from adopting other or additional compensation arrangements, subject to shareholder approval if such approval is required; and such arrangements may be either generally applicable or applicable only in specific cases.

17.4 Sub-Plans. The Committee may from time to time establish sub-plans under the Plan for purposes of satisfying securities, tax or other laws of various jurisdictions in which the Company intends to grant Awards. Any sub-plans shall contain such limitations and other terms and conditions as the Committee determines are necessary or desirable. All sub-plans shall be deemed a part of the Plan, but each sub-plan shall apply only to the Participants in the jurisdiction for which the sub-plan was designed.

17.5 Deferral of Awards. The Committee may establish one or more programs under the Plan to permit selected Participants the opportunity to elect to defer receipt of consideration upon exercise of an Award, satisfaction of performance criteria, or other event that absent the election would entitle the Participant to payment or receipt of shares of Common Stock or other consideration under an Award. The Committee may establish the election procedures, the timing of such elections, the mechanisms for payments of, and accrual of interest or other earnings, if any, on amounts, shares or other consideration so deferred, and such other terms, conditions, rules and procedures that the Committee deems advisable for the administration of any such deferral program. Any such deferral program must comply with Section 409A.

17.6 Unfunded Plan. The Plan shall be unfunded. Neither the Company, the Board nor the Committee shall be required to establish any special or separate fund or to segregate any assets to assure the performance of its obligations under the Plan.

17.7 Recapitalizations. Each Award Agreement shall contain provisions required to reflect the provisions of Section 14.

17.8 Delivery. Upon exercise of a right granted under this Plan, the Company shall issue Common Stock or pay any amounts due within a reasonable period of time thereafter. Subject to any statutory or regulatory obligations the Company may otherwise have, for purposes of this Plan, 30 days shall be considered a reasonable period of time.

17.9 No Fractional Shares. No fractional shares of Common Stock shall be issued or delivered pursuant to the Plan. The Committee shall determine whether cash, additional Awards or other securities or property shall be issued or paid in lieu of fractional shares of Common Stock or whether any fractional shares should be rounded, forfeited or otherwise eliminated.

17.10 Other Provisions. The Award Agreements authorized under the Plan may contain such other provisions not inconsistent with this Plan, including, without limitation, restrictions upon the exercise of Awards, as the Committee may deem advisable.

17.11 Section 409A. The Plan is intended to comply with Section 409A of the Code to the extent subject thereto, and, accordingly, to the maximum extent permitted, the Plan shall be interpreted and administered to be in compliance therewith. Any payments described in the Plan that are due within the "short-term deferral period" as defined in Section 409A of the Code shall not be treated as deferred compensation unless Applicable Laws require otherwise. Notwithstanding anything to the contrary in the Plan, to the extent required to avoid accelerated taxation and tax penalties under Section 409A of the Code, amounts that would otherwise be payable and benefits that would otherwise be provided pursuant to the Plan during the six (6) month period immediately following the Participant's termination of Continuous Service shall instead be paid on the first payroll date after the six-month anniversary of the Participant's separation from service (or the Participant's death, if earlier). Notwithstanding the foregoing, neither the Company nor the Committee shall have any obligation to take any action to prevent the assessment of any additional tax or penalty on any Participant under Section 409A of the Code and neither the Company nor the Committee will have any liability to any Participant for such tax or penalty.

17.12 Disqualifying Dispositions. Any Participant who shall make a "disposition" (as defined in Section 424 of the Code) of all or any portion of shares of Common Stock acquired upon exercise of an Incentive Stock Option within two years from the Grant Date of such Incentive Stock Option or within one year after the issuance of the shares of Common Stock acquired upon exercise of such Incentive Stock Option (a "**Disqualifying Disposition**") shall be required to immediately advise the Company in writing as to the occurrence of the sale and the price realized upon the sale of such shares of Common Stock.

17.13 Section 16. It is the intent of the Company that the Plan satisfy, and be interpreted in a manner that satisfies, the applicable requirements of Rule 16b-3 as promulgated under Section 16 of the Exchange Act so that Participants will be entitled to the benefit of Rule 16b-3, or any other rule promulgated under Section 16 of the Exchange Act, and will not be subject to short-swing liability under Section 16 of the Exchange Act. Accordingly, if the operation of any provision of the Plan would conflict with the intent expressed in this Section 17.13, such provision to the extent possible shall be interpreted and/or deemed amended so as to avoid such conflict.

17.14 Beneficiary Designation. Each Participant under the Plan may from time to time name any beneficiary or beneficiaries by whom any right under the Plan is to be exercised in case of such Participant's death. Each designation will revoke all prior designations by the same Participant, shall be in a form reasonably prescribed by the Committee and shall be effective only when filed by the Participant in writing with the Company during the Participant's lifetime.

17.15 Expenses. The costs of administering the Plan shall be paid by the Company.

17.16 Severability. If any of the provisions of the Plan or any Award Agreement is held to be invalid, illegal or unenforceable, whether in whole or in part, such provision shall be deemed modified to the extent, but only to the extent, of such invalidity, illegality or unenforceability and the remaining provisions shall not be affected thereby.

17.17 Headings. The headings in the Plan are for purposes of convenience only and are not intended to define or limit the construction of the provisions hereof.

17.18 Non-Uniform Treatment. The Committee's determinations under the Plan need not be uniform and may be made by it selectively among persons who are eligible to receive, or actually receive, Awards. Without limiting the generality of the foregoing, the Committee shall be entitled to make non-uniform and selective determinations, amendments and adjustments, and to enter into non-uniform and selective Award Agreements.

18. Effective Date of Plan. The Plan shall become effective as of the Effective Date, but no Award shall be exercised (or, in the case of a stock Award, shall be granted) unless and until the Plan has been approved by the shareholders of the Company, which approval shall be within twelve (12) months before or after the date the Plan is adopted by the Board.

19. Termination or Suspension of the Plan. The Plan shall terminate automatically on the tenth (10^{th}) anniversary of the Effective Date. No Award shall be granted pursuant to the Plan after such date, but (subject to Sections 5.2, 6.1 and 7.2) Awards theretofore granted may extend beyond that date. The Board may suspend or terminate the Plan at any earlier date pursuant to Section 16.1 hereof. No Awards may be granted under the Plan while the Plan is suspended or after it is terminated.

20. Choice of Law. The law of the State of Nevada shall govern all questions concerning the construction, validity and interpretation of this Plan, without regard to such state's conflict of law rules.

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. 333-245054), 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 24, 2021, with respect to our audits of the consolidated financial statements of Relmada Therapeutics, Inc. as of December 31, 2020, December 31, 2019 and June 30, 2019 and for the year ended December 31, 2020, the six months ended December 31, 2019 and the year ended June 30, 2019, which report is included in this Annual Report on Form 10-K of Relmada Therapeutics, Inc. for the year ended December 31, 2020.

/s/ Marcum LLP

Marcum LLP
Houston, Texas
March 24, 2021

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, 2020.

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 24, 2021

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, 2020.

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 24, 2021

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, 2020 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 24, 2021

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, 2020 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 24, 2021