

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

FORM 10-K

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

For the fiscal year ended June 30, 2015

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number: 333-\_\_\_\_\_

**Relmada Therapeutics, Inc.**

(Exact name of registrant as specified in its charter)

**Nevada**

(State or other jurisdiction of  
incorporation or organization)

**45-5401931**

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

**757 Third Avenue, Suite 2018**

**New York, NY 10017**

(Address of principal executive offices)(Zip Code)

**(212) 376-5776**

(Registrant's telephone number, including area code)

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

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

Indicate by checkmark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company.

Large accelerated filer  Accelerated filer   
Non-accelerated filer  Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes  No

The aggregate market value of voting stock held by non-affiliates of the registrant as of December 31, 2014, the last business day of the registrant's most recently completed second fiscal quarter, based on the closing price of the common stock on the OTCQB on December 31, 2014 was \$127,028,464.

As of September 11, 2015, there are 10,814,913 shares of common stock, \$0.001 par value per share outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None

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## CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

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

## PART I

### ITEM 1. BUSINESS

#### Business Overview

Relmada Therapeutics, Inc. (“Relmada” or the “Company”) is a clinical stage biopharmaceutical company focused on developing a pipeline of drug candidates to treat chronic pain. Chronic pain is often defined as any pain lasting more than 12 weeks. Whereas acute pain is a normal sensation that alerts us to possible injury, chronic pain persists – often for months or even longer. Chronic pain may arise from an initial injury, such as back sprain, or there may be an ongoing cause, such as an illness. Sometimes there is no clear cause. According to the National Institutes of Health, approximately 100 million people in the U.S. are living with chronic pain.

We intend to realize our business objectives by implementing two core strategies to address unmet medical needs in the treatment of chronic pain: a) developing improved versions of proven drug candidates; and b) developing new chemical entities. This two tiered approach is expected to reduce overall clinical development investment, time, and risks. Our drug candidates are designed to improve the overall benefits and use of a drug for patients by improving the metabolism, distribution, pharmacokinetics, pharmacodynamics, half-life and/or bioavailability of drugs.

#### d-Methadone (dextromethadone, REL-1017)

Our most-advanced new chemical entity, d-Methadone (dextromethadone, REL-1017), is a novel, N-methyl-D-aspartate (NMDA) receptor antagonist being developed for the treatment of neuropathic pain. As a single isomer of racemic methadone, d-Methadone has been shown to possess NMDA antagonist properties with virtually no opioid activity at the expected therapeutic doses. The activation of NMDA receptors has been associated with neuropathic pain and it is expected that d-Methadone will have a role in pain management by blocking this activity. In contrast, racemic methadone is a long-acting narcotic producing typical opioid side effects used in the treatment of various pain states and as a substitution therapy in opioid addiction. In November 2014, Health Canada approved a Clinical Trial Application (“CTA”) to conduct the first Phase I study with d-Methadone. This is a Single Ascending Dose (“SAD”) study that will be followed by a Multiple Ascending Dose (“MAD”) study, both in healthy volunteers. The two studies are designed to assess the safety, tolerability and pharmacokinetics of d-Methadone in healthy subjects. The SAD study includes single escalating oral doses of d-Methadone to determine the maximum tolerated dose. In the MAD study, healthy subjects are to receive daily oral doses of d-Methadone for several days to assess its safety, pharmacokinetics and tolerability. In March 2015, d-Methadone demonstrated a safe profile with no dose limiting side effects after four cohorts were exposed to increasing higher doses. In April 2015, the Company received clearance from Health Canada to continue with dose escalation and explore higher doses of d-Methadone. In June 2015, the Company successfully completed the SAD study and subsequently received a No Objection Letter (NOL) from Health Canada to conduct the MAD clinical study in August 2015. The data from these studies will inform the design of a subsequent Phase II proof of concept study.

Ketamine hydrochloride (ketamine), an NMDA receptor antagonist, is an U.S. Food and Drug Administration (“FDA”) FDA-approved, rapid-acting general anesthetic that also produces strong analgesia in neuropathic pain states. The NMDA receptor is an excitatory glutamatergic receptor present at spinal and supraspinal sites and involved in the afferent transmission of nociceptive signals. In chronic pain states prolonged nociceptive stimulation causes activation and upregulation of the NMDA receptor at dorsal horn synapses resulting in enhanced and amplified trafficking of pain signals to the brain (central sensitization). This phenomenon is an important factor in the process of perseverance of pain. There is now ample evidence that NMDA receptor antagonists that block the NMDA receptor, such as ketamine, are able to halt the excessive barrage of nociceptive input to the brain and are therefore potential alternatives to existing treatments of chronic pain syndromes. The potential for widespread therapeutic use of ketamine is severely limited by its potential for abuse, dissociative and psychosis-like side effects. Orally-available d-Methadone is among the new generation of pain medications with potential to deliver ketamine-like palliative effects, without ketamine’s side effects.

#### LevoCap ER (REL-1015)

Our most-advanced novel version of a proven drug product, LevoCap ER (REL-1015), is an extended release, abuse deterrent, proprietary formulation of the opioid analgesic levorphanol, which is pharmacologically differentiated from morphine, oxycodone, and other strong opioids for the management of pain severe enough to require daily, around-the-clock and long-term opioid treatment. In particular, levorphanol binds to all three opioid receptor subtypes involved in analgesia (mu, kappa, and delta), the N-methyl-D-aspartate (NMDA) receptor and the norepinephrine and serotonin uptake pumps, whereas morphine is relatively selective for mu sites. The dual mechanism of action of levorphanol, combining opioid receptor agonism with noradrenaline reuptake inhibition in the same molecule makes levorphanol a useful analgesic to treat chronic and neuropathic pain in addition to providing pain relief in patients resistant to other strong opioids. Levorphanol is a strong opioid first synthesized decades ago and is considered equal in potency to hydromorphone, oxycodone, fentanyl, and methadone. In clinical studies, it has demonstrated a remarkably broad spectrum of analgesic activity against many different types of pain including neuropathic pain, post-surgical pain, and chronic pain in patients refractory to other opioids. We continue to scale up manufacturing and prepare for Phase III development program and are planning to submit a request to the FDA to discuss the final regulatory and clinical plan for this product. In preparation for pivotal trial(s) that we plan to perform under US IND, we are selecting the final formulation and are planning to generate the necessary GMP batches.

## **BuTab (REL-1028)**

Our second-most-advanced novel version of a proven drug product, BuTab (REL-1028), represents novel formulations of oral, modified release buprenorphine being developed for both chronic pain and opioid dependence indications. Buprenorphine is a partial opioid agonist that has been widely used by the sublingual and transdermal routes of administration, but was believed to be ineffective by the oral route. We have completed a preclinical program to better define the pharmacokinetic profile of BuTab and to assess the time course of systemic absorption of buprenorphine using several different oral modified release formulations of buprenorphine in dogs, compared to an intravenous administration. Based on the results of this work, we have obtained approval from Health Canada to initiate a Phase I pharmacokinetic study in healthy volunteers in the second quarter of 2015. This trial is ongoing.

### *Chronic Pain Indication*

The first buprenorphine formulation for the treatment of chronic pain was approved in 2010. Purdue Pharmaceuticals received FDA approval for Butrans® (buprenorphine transdermal system) in July. Butrans® is indicated for the management of moderate to severe chronic pain and delivers buprenorphine transdermally (through the skin) over a period of seven days. The approval of Butrans® signaled the interest and approvability of new formulations of buprenorphine. It is our view that a traditional oral tablet that is ingested and absorbed through the intestine will make it a preferred formulation for a significant number of patients with chronic pain conditions. Butrans® was launched in early 2011. Sales of Butrans® in 2014 totaled over \$192 million and continue to steadily grow. Other formulations of buprenorphine are in development for the treatment of pain.

In August 2014, the U.S. Drug Enforcement Administration (DEA) published in the Federal Register their final ruling moving hydrocodone combination products (such as Vicodin, Lortab, Norco, etc.) from Schedule III to the more-restrictive Schedule II, as recommended by the Assistant Secretary for Health of the U.S. Department of Health and Human Services (HHS) and as supported by the DEA's own evaluation of relevant data. As a result of the ruling, hydrocodone containing products are now classified in the same category (Schedule II) as morphine and oxycodone. As a result of the change to Schedule II, access to these products will be more restricted. Among other changes, written prescriptions will be required and refills will not be permitted. The ruling also conveyed findings that hydrocodone combination products have a higher risk of abuse and addiction compared to Schedule III products. The ruling went into full effect in October 2014.

Buprenorphine is one of the few remaining Schedule III opioids and has a lower risk of abuse and addiction compared to Schedule II opioids and thus will have fewer restrictions on dispensing. BuTab has the opportunity to provide a Schedule III option for the treatment of chronic pain and thus helping to replace the void left from the hydrocodone combination products. We believe the actions taken to restrict the use of hydrocodone combination products may markedly increase the utility and appeal of BuTab as it could address an important unmet medical need for Schedule III options.

In December 2014, BioDelivery Sciences and Endo Pharmaceuticals, Inc. announced the NDA submission for BELBUCA™ for moderate to severe chronic pain, which was accepted by FDA in February 2015. BELBUCA™ is subject to a ten month FDA review, which could result in an approval in the fourth quarter of 2015 and allow for product launch in early 2016.

### *Opioid Addiction Indication*

Maintenance treatment with buprenorphine reduces the typical cravings and withdrawal symptoms associated with coming off opioid prescription painkillers and heroin. This allows the individual suffering from an addiction to opioids –along with counseling and support – to work toward recovery. On average, treatment lasts a couple months, reflecting relatively high dropout rates, but a significant number of people remain on buprenorphine treatment chronically, with nearly one-quarter of patients still on therapy after nine months.

The total market for buprenorphine containing products for opioid dependence approached \$1.8 billion in 2014. The market has grown significantly as a result of the rapidly escalating problem of prescription opioid misuse and abuse, a recent resurgence of heroin use, the growing number of physicians treating opioid dependence, and the inclusion of addiction treatment as an essential benefit in the Affordable Care Act.

The products currently marketed for this indication include Suboxone®, a sublingual film formulation of buprenorphine and naloxone, a sublingual tablet, Zubsolv®, and generic formulations of buprenorphine/naloxone tablets. Suboxone® film, the market leader, achieved sales of nearly \$1.2 billion in the U.S. in 2014. While maintaining its dominance as the market leader in the U.S., Suboxone® film experienced a decline in sales and share due to increased use of generics and the availability of newer formulation of buprenorphine/naloxone. In December 2014, Reckitt Benckiser Group PLC, the manufacturer of Suboxone® sublingual tablets and films, announced that they completed the spin-off of that company's pharmaceutical business (including the Suboxone® brand) under the name Indivior PLC in order to allow the consumer goods group to focus on its consumer health and hygiene products. The Indivior business will focus on addiction treatment and closely related areas including opioid overdose, cocaine overdose and alcohol dependence. In September 2012, Reckitt Benckiser announced that it had notified the FDA that they would be voluntarily discontinuing the distribution of Suboxone® tablets in the U.S. and subsequently halted further shipments in March 2013. The decision made by Reckitt Benckiser was reportedly due to accumulating data demonstrating significantly lower rates of accidental pediatric exposure with Suboxone® films compared with their tablet formulation due to the child-resistant, unit-dose packaging of the film versus a multi-dose bottle for the tablets. Additionally, Reckitt Benckiser filed a Citizens Petition to request that the FDA require all manufacturers of buprenorphine-containing products for the treatment of opioid dependence to implement public health safeguards including child-resistant, unit-dose packaging to reduce the risk of pediatric exposure. FDA subsequently rejected the Citizens Petition in February 2013, which allowed for the approval of the first generic formulations of Suboxone® tablets.



The actions taken by Reckitt Benckiser as well as patient preference for a film formulation of Suboxone® resulted in significant conversion of the Suboxone® market to the branded film formulation. In 2013, the sublingual film formulation of Suboxone® accounted for over 95% of total Suboxone® prescription sales.

Generic buprenorphine/naloxone tablet formulations were launched in early 2013 by Actavis and Amneal Pharmaceuticals and were followed by additional entrants including a generic formulation from Teva. The remaining prescription volume for Suboxone® tablets was rapidly converted to generics; however, the impact of generic buprenorphine/naloxone tablets on Suboxone® film sales has been somewhat limited to date. In 2014, generic buprenorphine/naloxone tablets accounted for 18% of total buprenorphine/naloxone sales. It is anticipated that additional generics may enter the market, though the timing is unclear.

In June 2014, BioDelivery Sciences received FDA approval for BUNAVAIL® for the maintenance treatment of opioid dependence. BUNAVAIL® contains the partial opioid agonist buprenorphine with naloxone, an opioid antagonist, included as an abuse deterrent. When used as directed, the naloxone is swallowed and minimally absorbed; however, if misused (ie, dissolved and injected), the naloxone rapidly precipitates withdrawal symptoms.

In terms of additional competition, Phase 3 trials were completed for Probuphine, a subcutaneous depot delivery system containing buprenorphine from Titan Pharmaceuticals. Results of clinical studies demonstrated efficacy and safety, and Probuphine was submitted for FDA review in October 2012. Probuphine was anticipated to address the needs of the subset of patients undergoing treatment for opioid dependence who are unable to maintain compliance with alternative formulations or those who may be at high risk for diversion. In December 2012, Titan announced the signing of a license agreement with Braeburn Pharmaceuticals Sprl. The license grants Braeburn exclusive commercialization rights in the United States and Canada. In April 2013, the FDA issued a Complete Response Letter for Probuphine and requested additional data regarding its efficacy. An additional Phase 3 study assessing the efficacy and safety of Probuphine was initiated in April 2014. In June 2015, Titan announced that the Phase 3 study of Probuphine for opioid addiction met the primary endpoint, allowing for a resubmission of their NDA in late 2015 and potentially securing approval for the product in the first half of 2016. Given the need for surgical implantation and removal, Probuphine is not expected to be a significant competitive threat to BuTab.

A sublingual tablet, referred to as Zubsolv® or OX219, was approved by FDA in July 2013 and subsequently launched in September 2013. Zubsolv® is a sublingual formulation of buprenorphine/naloxone using Orexo's proprietary sublingual drug delivery technology. Orexo is a specialty pharmaceutical company with headquarters in Sweden. Orexo is developing treatments using their proprietary sublingual drug delivery technology, which includes the marketed product Abstral® that delivers fentanyl for the treatment of breakthrough cancer pain. In July 2013 Orexo announced the establishment of a commercial partnership with Publicis Healthcare Solutions. In May 2014, Orexo announced a new partnership with InVentiv Health for Zubsolv in the U.S.

The sales efforts for Zubsolv® are supported by a contract sales organization (Inventive Health) and the product is being marketed predominantly based on its claims of improved taste and faster dissolve time compared to Suboxone®. Sales for Zubsolv® in 2014 totaled approximately \$52 million in the U.S and a prescription market share of just over 3%.

While limited information is available, other formulations of buprenorphine may also be in early stages of development for the treatment of opioid dependence, including an oral capsule (NTC-510) from Nanotherapeutics, Inc. Three Phase 1 studies have been completed to date (two Phase 1a single dose pharmacokinetic studies and one Phase 1b, multidose pharmacokinetic study). It has been demonstrated that NTC-510 administered orally achieves appropriate serum buprenorphine concentrations for analgesia and could potentially be dosed once daily. Also in development is a sublingual spray formulation of buprenorphine/naloxone from Insys which completed a Phase 1 study and buprenorphine hemiadipate (RBP-6300) from Indivior, an oral abuse-deterrent formulation of buprenorphine prodrug using Capsugel drug delivery technology.

While we anticipate that the market for buprenorphine/naloxone products for the treatment of opioid dependence will get increasingly more competitive, we believe BuTab would have significant appeal given its traditional oral route of administration. We also believe that the increased number of companies promoting the use of buprenorphine containing-products for opioid dependence has the potential to create greater awareness and help to further expand what is already a significant and growing market.

## **MepiGel (REL-1021)**

Our third-most-advanced novel version of a proven drug product, MepiGel (REL-1021), is a proprietary topical dosage form of the local anesthetic mepivacaine for the treatment of painful peripheral neuropathies, such as painful diabetic neuropathy, postherpetic neuralgia and painful HIV-associated neuropathy. Mepivacaine is an anesthetic (numbing medicine) that blocks the nerve impulses that send pain signals to the brain. It is chemically related to bupivacaine but pharmacologically related to lidocaine. Mepivacaine is currently indicated for infiltration, nerve block and epidural anesthesia. Relmada has received two FDA Orphan Drug Designations for mepivacaine, one each for “the treatment of painful HIV-associated neuropathy” and for “the management of postherpetic neuralgia,” or PHN. We have selected the formulations to be advanced into clinical studies for MepiGel after the evaluation of results from in vitro and ex vivo studies comparing various topical prototypes of mepivacaine that were conducted by MedPharm Ltd, a specialist formulation development company recognized internationally for its expertise in topical and transdermal products. Relmada is planning single and multiple dose Phase I studies in healthy subjects with the selected MepiGel formulations. The data from these studies will inform the design of a subsequent Phase 2 proof of concept study in patients suffering from neuropathic pain.

Along with antidepressants, antiepileptic drugs (AEDs) are often used as a first-line therapy for PHN. The most commonly prescribed AEDs for PHN are gabapentin and pregabalin (Lyrica). The choice between them is mostly influenced by physicians’ preference for the more-favorable dosing attributes (less-frequent daily dosing, faster titration) of pregabalin in balance with price and accessibility. AEDs are commonly associated with side effects including somnolence, dizziness, and weight gain. If first-line AED or antidepressant monotherapy fails to provide acceptable pain relief, physicians initiate combination therapy. If AED/antidepressant combination therapy is not effective, physicians typically add a dual-acting opioid such as tramadol. For more-severe pain, physicians may add or switch to tapentadol ER (Nucynta ER). If pain persists with the addition of tramadol or tapentadol, physicians often switch to a more potent opioid analgesic (e.g., oxycodone) while maintaining AED and/or antidepressant therapy. Although some experts acknowledge that strong opioids can be quite effective for PHN, they generally reserve this drug class for refractory cases and/or those with high pain intensity. For some PHN patients, particularly those experiencing highly localized pain, physicians may prescribe the lidocaine 5% patch (Lidoderm). Pain specialists generally consider that lidocaine is particularly beneficial for localized pain, and many physicians prefer it to oral agents because it does not cause systemic side effects and is easy to administer. In many cases, the patch is used in combination with an oral first-line AED and/or antidepressant therapy.

Accorda Therapeutics is developing a concentrated (20%) topical liquid formulation of capsaicin (NP-1998 [formerly NGX-1998]) for the treatment of neuropathic pain. The product was formerly in development by NeurogesX, which licensed all U.S. rights as well as those of its 8% capsaicin patch (Qutenza) to Accorda in July 2013. Accorda is planning to launch a Phase 3 clinical trial of NP-1998 in painful HIV (human immunodeficiency virus) peripheral neuropathy as the first potential indication for NP-1998. The company is also exploring the potential for additional indications, including painful diabetic neuropathy. In 2011, NeurogesX completed a Phase 2 trial in post herpetic neuralgia and results from the trial confirmed efficacy and safety. Teva and Xenon Pharmaceuticals are developing TV-45070 (formerly XEN402), a subtype selective ion channel inhibitor. TV-45070 has potentially broad application in nociceptive pain, including inflammatory pain, and neuropathic pain indications. TV-45070 is partnered with Teva in a milestone, royalty and co-promotion partnership. Using a topical (ointment) formulation of TV-45070, Teva has initiated a 300-patient Phase 2b clinical trial in osteoarthritis, or OA, of the knee. In July 2015, it was reported that TV-45070 4% and 8% did not demonstrate statistically significant difference from placebo in efficacy endpoints in Phase 2b study in pain due to osteoarthritis of the knee. Teva is also developing topical TV-45070 in neuropathic pain indications, and is currently planning a Phase 2b clinical trial in patients with postherpetic neuralgia.

## **Research and Development Expenses**

A significant portion of our operating expenses is related to research and development and we intend to maintain our strong commitment to research and development. Research and development expense for year ended June 30, 2015, for the six months ended June 30, 2014 and for the year ended December 31, 2013 was approximately \$7,872,400, \$840,000 and \$5,248,700, respectively.



## **Overview of the 505(b)(2) Regulatory Pathway**

The majority of our drug development pipeline is based on the application of drug delivery technologies and/or new dosage forms/indications to existing drugs for the creation of novel products. We then seek proprietary protection and FDA approval, and subsequently plan to commercialize these products ourselves or through partners. We believe that research and development efforts focused on novel dose forms of FDA approved drugs is less risky than attempting to discover new drugs, sometimes called new chemical entities (known as NCEs).

An important part of our strategy is the utilization of FDA's 505(b)(2) NDA process for approval. The 505(b)(2) new drug application (NDA) is one of three U.S. Food and Drug Administration (FDA) drug approval pathways and represents an appealing regulatory strategy for many companies. The pathway was created by the Hatch-Waxman Amendments of 1984, with 505(b)(2) referring to a section of the Federal Food, Drug, and Cosmetic Act. The provisions of 505(b)(2) were created, in part, to help avoid unnecessary duplication of studies already performed on a previously approved ("reference" or "listed") drug; the section gives the FDA express permission to rely on data not developed by the NDA applicant.

A 505(b)(2) NDA contains full safety and effectiveness reports but allows at least some of the information required for NDA approval, such as safety and efficacy information on the active ingredient, to come from studies not conducted by or for the applicant. This can result in a much less expensive and much faster route to approval, compared with a traditional development path [such as 505(b)(1)], while creating new, differentiated products with tremendous commercial value.

## **Overview of Orphan Drug Status**

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

## **Our Corporate History and Background**

We are a clinical stage biopharmaceutical company focused on developing a pipeline of drug candidates to treat chronic pain.

Relmada Therapeutics, Inc. ("RTI"), which was previously a private company commenced operations in May 2004, entered into a Merger Agreement with Medeor Inc. ("Medeor") on December 31, 2013. This transaction occurred by the exchange of Medeor's shares, for RTI's common stock. Following the transaction, the corporate existence of Medeor ceased and RTI continued as the surviving corporation (the "Merger"). In connection with the Merger, each share of common stock of Medeor was converted into the right to receive a pro rata share of RTI's common stock based upon an exchange ratio. Medeor was developing d-Methadone.

In May 2014, RTI completed a Share Exchange with Camp Nine, Inc., a publicly traded Nevada corporation that was formed in May 2012. In July 2014, we changed the name of Camp Nine, Inc. to Relmada Therapeutics, Inc. At the Share Exchange, RTI shareholders exchanged 10 shares of RTI common stock for one share of our common stock. As a result of the Share Exchange, RTI's shareholders acquired the majority of our issued and outstanding capital stock and RTI became our subsidiary.

The Share Exchange was accounted for as a "reverse merger" rather than a business combination, wherein Relmada is considered the acquirer for accounting and financial reporting purposes. The statement of operations reflects the activities of RTI from the commencement of its operations since inception. Unless the context suggests otherwise, when we refer in this Report to business and financial information for periods prior to the consummation of the Share Exchange, we are referring to the business and financial information of RTI.

During the six months ended June 30, 2014, we changed our year end to June 30 and increased its authorized common stock to 500,000,000 shares and its authorized preferred stock to 200,000,000 shares of which 3,500,000 is designated for Class A preferred stock. On August 12, 2015, the Company completed a one-for-five reverse stock split in preparation for our proposed up-listing to NASDAQ Capital Markets reducing the authorized common share to 100,000,000 common shares. This Annual Report reflects a retroactive adjustment for the reverse stock split.

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

We have not generated revenues and do not anticipate generating revenues for the foreseeable future. We had net loss of approximately \$20,803,600, \$21,336,000 and \$19,871, 900 for the year ended June 30, 2015, for the six months ended June 30, 2014 and for the year ended the year ended December 31, 2013, respectively. At June 30, 2015, we have an accumulated deficit of approximately \$76,122,200.

### **Business Strategy**

Our strategy is to leverage our considerable industry experience, understanding of pain 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 pain.

We plan to further develop our novel, proprietary drug products via the 505(b)(2) development pathway and also to gain exclusivity under the Hatch-Waxman Act for new indications and also orphan drug designation in certain indications. We plan to also generate intellectual property (IP) that will further protect our products from competition. As the drug d-Methadone is not an already approved product by the FDA, the regulatory pathway to approval will be the more traditional NDA development, which may consist of conducting a full clinical development program. We will continue to prioritize our product development activities after taking into account the resources we have available, market dynamics and potential for adding value. We will continue to outsource development of our products, while retaining scientific, operational and financial oversight and control.

We intend to seek and execute licensing and/or co-development agreements with companies capable of supporting the final stage development of the Company's products and their subsequent commercialization in the U.S. and international markets. We may also develop our own internal sales and marketing capabilities to commercialize some or all of our products to selected specialty medical segments in the U.S. while out-licensing sales and marketing for the international market.

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

## Market Opportunity

The pain market is well established, with many pharmaceutical companies marketing innovative products as well as generic versions of older, non-patent protected products. In 2014, according to data from IMS Health, there were 328 million pain prescriptions representing \$13 billion in annual sales in the U.S.

Analgesics continue to be among the most widely prescribed medications and there is little to suggest that their preeminence will change in the near future, given the prominent role of pain in many diseases. Survey data indicate substantial patient dissatisfaction with current pain management modalities. According to the Chronic Pain in America Study published in 1999 by AAPM, APS, and Jansen and the Voice of Chronic Pain Survey by the American Pain Foundation in May 2006; only 55% of patients with chronic pain feel their pain is “under control” and only 23% believe their pain medications are “very effective.” According to IMS Health, the U.S. opioid market was worth approximately \$8.3B in 2013, with ER (Extended Release) opioids accounting for approximately \$4.8B in sales. Significant market value has been maintained in the presence of low-cost high-volume generics over the last two decades through the introduction of new products that were approved via the 505(b)(2) FDA approval route. These products are branded and differentiated formulations such as fixed dose combinations, extended-release products, transdermal patches, etc. and thus provide both market exclusivity and the possibility of a high price point. Per Decision Resources, the cost of therapy for branded ER opioids is approximately \$11.00 per day versus generics which cost \$3.00 per day. Our ER opioids LevoCap ER and BuTab are pharmacologically differentiated from commercially available immediate release (IR) opioids, including OxyContin®, Embeda®, Opana® ER, Duragesic®, Avinza®, Kadian®, Remoxy® & Exalgo®. Many patients with neuropathic pain have suboptimal relief with monotherapy and treatment is frequently multimodal, involving use of two or more drugs from different pharmacologic classes. Our topical local anaesthetic mepivacaine and oral d-Methadone are anticipated to be used for the treatment of painful peripheral neuropathies. According to Decision Resources, the market for neuropathic pain drugs is expected to grow to \$9.7B by 2018 in the U.S. According to GlobalData, the U.S. neuropathic pain market consists of approximately 4.7M patients and is expected to grow to more than 6.1M patients in 2018. d-Methadone is anticipated to compete with the current available therapies for neuropathic pain, including Cymbalta® which had \$5.1B in worldwide 2013 sales, according to Eli Lilly 2013 annual report Lyrica® which had \$4.6B in worldwide 2013 sales, according to Pfizer 2013 annual report and lidocaine patch which had \$1.28B in U.S. 2014 sales, according to IMS Health including generics.

Our orphan designated topical MepiGel is anticipated to compete with topical lidocaine patch with \$1.28B according to ISM which includes generic drugs in U.S. 2014 sales and may also be used in combination with oral therapies for neuropathic pain. MepiGel is developed for the relief of pain associated with post-herpetic neuralgia which is the same indication as that of the topical Lidocaine patch. Hence, we believe that MepiGel is anticipated to compete with the Lidocaine patch. Lidocaine patch is the only topical local anaesthetic approved for the treatment of neuropathic pain. Lidocaine patch provides only modest pain relief in patients with postherpetic neuralgia. According to the March 2010 issue of UK National Institute of Health and Clinical Excellence (NICE) clinical guideline on neuropathic pain, there is a “lack of evidence for the efficacy of topical lidocaine for treating neuropathic pain” and topical lidocaine should be considered as “third line” treatment for neuropathic pain.

### **Intellectual Property Portfolio and Market Exclusivity**

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

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

**Levorphanol:** These patent applications cover the Levorphanol product.

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

Patent application 12/597,702 filed 4/28/08, Multimodal Abuse Resistant and Extended Release Opioid Formulations. Currently claims are allowed. Issued fee paid.

Patent application 13/320,9889 filed 2/26/10, Extended Release Oral Pharmaceutical Compositions of 3-Hydroxy-N-Methylmorphinan and Method of Use. Currently pending.

U.S. Patent No. 9,125,833 was issued by the U.S. Patent and Trademark Office (USPTO) on September 8, 2015 for its patent application entitled, "Multimodal abuse resistant and extended release opioid formulations." The issued patent covers the SECUREL technology platform and Relmada's lead product candidate, LevoCap ER (REL-1015, levorphanol extended-release, abuse deterrent capsules) as well as providing additional coverage for multiple opioid molecules that are prone to abuse.

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

Patent No. 6,008,258 filed 1/21/98, d-Methadone, a Nonopioid Analgesic, Patent granted.

Patent application 13/803,375 filed 3/14/13, d-Methadone for the Treatment of Psychiatric Symptoms. Currently pending.

**Buprenorphine:** This patent application covers the buprenorphine product.

Patent application 12/988,209 filed 3/9/09, Oral Pharmaceutical Compositions of Buprenorphine and Method of Use. Currently pending.

**Mepivacaine:** This patent application covers the Mepivacaine product.

Patent application PCT/US2011/032,381 filed 4/13/11, Dermal Pharmaceutical Composition of 1-Methyl-2',6'-Pipicoloxylidide and Method of Use. Currently pending.

## Key Strengths

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

- A multiple product portfolio with a balanced risk reward profile: We have four products at various stages of development, and each has its own development risk profile and indication. Accordingly, management believes that we are well positioned to become a competitive player in a large unsatisfied market.
- Products are differentiated and address significant unmet needs: All four lead development programs are well differentiated value added pain drugs that address significant unmet medical needs. Pain management remains a critical area of unmet medical need. Increasingly, patients, advocacy groups, pain related professional organizations and the media are highlighting the limitations of pain management and are demanding changes in the medical system. Neuropathic pain in particular is a large and unsatisfied segment where d-Methadone could play an important role. In addition, the abuse potential of leading pain medications such as the OxyContin franchise, Vicodin, etc. has been reported extensively. Our LevoCap ER dosage form is designed to deter the manipulation for intravenous, intranasal or inhalational use, and for oral ingestion to provide high peak concentrations to opioid addicts and recreational drug users.
- Scientific support of leading experts: Our scientific advisory board includes clinicians and scientists who are affiliated with a number of highly regarded medical institutions. The board consists of individuals who have served as executives of leading national and international societies in pain, rheumatology and the FDA.
- Efficient development strategy: The 505(b) (2) pathway lowers the risk of drug development. Our strategy of combining proven drug candidates with novel delivery methods and pharmaceutical compositions reduces clinical development time and costs and lowers regulatory risks, while delivering valuable products in areas of high unmet need to the market place. Abuse resistant and once a day formulations improve the commercial potential of opioids, addressing the risk of opioid abuse and opioid diversion by making the dosage form tamper resistant, thereby frustrating attempts at physical manipulation of the dosage.
- Substantial IP portfolio and market protection: Upon the approval of our filed patent applications for our products we will have secured an intellectual property portfolio comprised of several patents. In addition, some of our drugs have also been designated as Orphan Drugs by the FDA, thereby providing seven years of market exclusivity at launch.
- Experienced management: We combine business expertise with what we believe is an internationally recognized research team. We believe our highly experienced drug development leadership provides us with a significant competitive advantage in designing highly efficient clinical programs with predictable regulatory outcomes.

## Competition Overview

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

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

The pain market has peculiar characteristics with regards to competition. While there are several products in development both in the narcotic and neuropathic pain space, the market history has shown that a new entry in the therapeutic area does not necessarily cannibalize existing products, but instead expands the market. The reasons behind this behavior can be found in the “opioid rotation” phenomena. As there is considerable variability in the efficacy and side effect response of patients to opioid analgesics, many patients rotate from one opioid to another, offering growth opportunity to new entries. In the case of the neuropathic pain indication, it is mostly the limited efficacy of the existing therapies that creates a strong demand for new entries, a model also supported by the considerable off-label use of opioids, tricyclic antidepressant and NSAIDS in neuropathic pain.

Because of the large opportunity, the current competitive landscape includes a significant number of pharmaceutical companies such as Pfizer, Johnson & Johnson, Eli Lilly, Endo Pharmaceutical Holding, Purdue Pharma, Mallinckrodt, DepoMed, and Teva Pharmaceutical.

In addition to the marketed drugs, we expect competition from product candidates that are or will be in development by the companies mentioned above and others. We are aware that several companies not mentioned before are working on new delivery forms of pain products and abuse deterrent formulations, including Acura Pharmaceutical, BioDelivery Science, Collegium Pharmaceutical, Egalet A/S, Elite Pharmaceutical, Inspirin Delivery Technologies, and Intellipharmaceutics International.

## Government Regulation

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

In the United States, the FDA regulates such products under the Federal Food, Drug and Cosmetic Act (FDCA), as amended and regulations pursuant to the FDCA.

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

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

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

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

We are also subject to United States regulation under the Controlled Substances Act (“CSA”). Drug Enforcement Administration regulations require Scheduled II controlled substances to be manufactured in the United States if the products are to be marketed in the United States. Our only products that contain Schedule II controlled substances are LevoCap-ER and d-Methadone. We are in the process of transferring all third party manufacturing of these products to the United States, and we intend to comply with this CSA requirement.

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

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



Relmada believes that a two tiered approach can reduce overall clinical development risks. Our approach consists of: (1) developing improved versions of proven drug candidates and filings under 505(b)(2) which may require an abbreviated clinical development program; and (2) developing a drug in treating conditions that have not been approved by the FDA, and filings under the traditional NDA which would require a full clinical development program. In general, drugs for the 505(b)(2) filing possess less risks as compared to drugs filed under the traditional NDA route. As with all drugs filed with the FDA, there is no guarantee of approval.

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

### **U.S. Food and Drug Administration Regulation**

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

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

### **Corporate Information**

Our principal executive office is located at 757 Third Avenue, Suite 2018, New York, NY 10017 and our telephone number is (212) 376-5776. Our website address is [www.relmada.com](http://www.relmada.com). The information contained in, or that can be accessed through, our website is not part of, and is not incorporated in, this Annual Report. The information contained therein or connected thereto shall be deemed to be incorporated into this 10-K which it forms a part.

### **Employees**

As of September 11, 2015, we have eleven (11) full-time employees and no part-time employees. None of these employees are covered by a collective bargaining agreement, and we believe our relationship with our employees is good. We also engage consultants on an as-needed basis to supplement existing staff.

### **Available Information**

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



## ITEM 1A.RISK FACTORS

### RISK FACTORS

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

#### **Risk Related to Our Business**

##### ***Our product candidates are in early stages of clinical testing.***

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

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

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

##### ***International commercialization of our product candidates faces significant obstacles.***

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

##### ***We need to raise additional capital to operate our business.***

We are a company focused on product development and have not generated any product revenues to date. Until, and if, we receive approval from the FDA and other regulatory authorities for our product candidates, we cannot sell our drugs and will not have product revenues. Therefore, for the foreseeable future, we will have to fund all of our operations and capital expenditures from the net proceeds of future offerings and grants. We believe with our cash and cash equivalents on hand at June 30, 2015 of approximately \$22,470,000 we can fund our operations until the end of calendar year 2016. Our actual capital requirements will depend on many factors. If we experience unanticipated cash requirements, we may need to seek additional sources of financing, which may not be available on favorable terms, if at all. If we do not succeed in raising additional funds on acceptable terms, we may be unable to complete planned nonclinical studies and clinical trials or obtain approval of our product candidates from the FDA and other regulatory authorities. In addition, we could be forced to discontinue product development, reduce or forego sales and marketing efforts and attractive business opportunities, or discontinue operations.

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

We have incurred substantial losses since our inception, and we may not achieve profitability for the foreseeable future, if at all. We have incurred an accumulated loss of approximately \$76,122,200, which includes non-cash expenses of approximately \$47,565,700. The Company has cash and cash equivalents of approximately \$22,470,000 at June 30, 2015. 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 nonclinical 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 nonclinical studies and early stage clinical trials of our principal product candidates. These operations provide a limited basis for you to assess our ability to commercialize our product candidates and the advisability of investing in our common stock.

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

We will need to continue to seek capital from time to time to continue for the development beyond of our product that are in Phase I and II clinical trials. We also may acquire and develop other product candidates. Our first product is not expected to be commercialized until at least 2018 and the revenues it will generate may not be sufficient to fund our ongoing operations. The Company believes that with current cash on hand it will be able to fund the Company's operations until end of calendar year 2016. Accordingly, we believe that we will need to raise substantial additional capital to fund our continuing operations and the development and commercialization of our product candidates in the second half of 2015. Our business or operations may change in a manner that would consume available funds more rapidly than anticipated and substantial additional funding may be required to maintain operations, fund expansion, develop new or enhanced products, acquire complementary products, business or technologies or otherwise respond to competitive pressures and opportunities, such as a change in the regulatory environment or a change in preferred pain treatment modalities. In addition, we may need to accelerate the growth of our sales capabilities and distribution beyond what is currently envisioned and this would require additional capital. However, we may not be able to secure funding when we need it or on favorable terms. If we cannot raise adequate funds to satisfy our capital requirements, we will have to delay, scale-back or eliminate our research and development activities, clinical studies or future operations. We may also be required to obtain funds through arrangements with collaborators, which arrangements may require us to relinquish rights to certain technologies or products that we otherwise would not consider relinquishing, including rights to future product candidates or certain major geographic markets. We may further have to license our technology to others. This could result in sharing revenues which we might otherwise retain for ourselves. Any of these actions may harm our business, financial condition and results of operations.

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

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

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

## **Risks Related to Clinical and Regulatory Matters**

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

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

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

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

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

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

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

Results from Phase I clinical programs may not support moving a drug candidate to Phase II or Phase III clinical trials. Phase III 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 III 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 other drug candidates for treatment of pain measure clinical symptoms, such as pain and physical dependence that are not biologically measurable. The success in clinical trials and our other drug candidates designed to reduce risks of unintended use depends on reaching statistically significant changes in patients' symptoms based on clinician-rated scales. Due in part to a lack of consensus on standardized processes for assessing clinical outcomes, these scores may or may not be reliable, useful or acceptable to regulatory agencies.

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The FDA's and other regulatory agencies' decision to approve our analgesic product candidates will depend on our ability to demonstrate with substantial clinical evidence through well-controlled clinical trials, that the product candidates are effective, as measured statistically by comparing the overall improvement in pain in actively-treated patients against improvement in pain in the control group (usually a placebo control). However, there is a possibility that our data may fail to show a statistically significant difference from the placebo-control or the active control. Alternatively, there is a possibility that our data may be statistically significant, but that the actual clinical benefit of the product candidates may not be considered to be clinically significant, clinically relevant or clinically meaningful. Consequently, we believe that the FDA may consider additional data, such as a "responder" analysis, secondary efficacy endpoints and even safety when evaluating whether our product can be approved. We believe that the FDA views "responders" as patients who experience at least a 30% reduction in overall pain. We cannot predict whether the regulatory agencies will find that our clinical trial results provide compelling "responder" or other secondary endpoint data. Even if we believe that the data from our trials will support marketing approval in the United States or in Europe, we cannot predict whether the agencies will agree with our analysis and approve our applications.

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

Although our primary strategic interest is in the area of pain management, a number of our products have potential efficacy in other therapeutic areas such as addiction. If our drug development efforts in pain management fail, or if the competitive landscape or investment climate for analgesic 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 pain. We have very limited drug development experience in other therapeutic areas and we may be unsuccessful in making this change from a pain management company to a company with a focus in areas other than pain or a company with a focus in multiple therapeutic areas including pain.

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

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

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

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

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

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

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

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

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

The DEA limits the availability and production of all scheduled substances, including our product candidates, 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 III development program, and we will need significantly greater amounts to implement our commercialization plans if the FDA approves our proposed formulations. Any delay or refusal by the DEA in establishing the procurement quota or a reduction in our quota for scheduled controlled substances or a failure to increase it over time as we anticipate could delay or stop the clinical development or commercial sale of some of our products or product candidates. This could have a material adverse effect on our business, results of operations, financial condition and prospects.

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

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

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

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

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

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

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



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

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

***Modifications to our products may require new NDA approvals.***

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

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

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

We are currently preparing to conduct several Phase I/II clinical trials for our drug candidates and in the future expect to submit NDAs to the FDA for approval of these products. The FDA may not approve or clear these products for the indications that are necessary or desirable for successful commercialization. Indeed, the FDA may refuse our requests for NDA market approval of new products, new intended uses or indications to existing or future products. Failure to receive approval for our new products would have an adverse effect on our ability to expand our business.

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

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

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

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

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

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

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

- recruiting and enrolling patients to participate in a clinical trial;
- obtaining regulatory approval to commence a clinical trial;

- reaching agreement on acceptable terms with prospective clinical research organizations and trial sites;

- manufacturing sufficient quantities of a product candidate;
- investigator fraud, including data fabrication by clinical trial personnel;
- diversion of controlled substances by clinical trial personnel; and

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

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

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

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

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

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

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

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

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

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

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

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



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

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

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

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

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

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

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

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

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

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

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

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

***Future products may never achieve market acceptance.***

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

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

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

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

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

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

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

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

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

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

***Our revenue stream will depend upon third party reimbursement.***

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

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

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

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

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

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

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





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

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

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

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

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

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

***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 Purdue Pharma, Pfizer, Eli Lilly, Endo, Astra Zeneca, among others.

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

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



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

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

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

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

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

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

***Our business depends upon securing and protecting critical intellectual property.***

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

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

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

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

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

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

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

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

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

**Levorphanol:** These patent applications cover the Levorphanol product.

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

Patent application 12/597,702 filed 4/28/08, Multimodal Abuse Resistant and Extended Release Opioid Formulations. Currently claims are allowed. Issued fee paid.

Patent application 13/320,9889 filed 2/26/10, Extended Release Oral Pharmaceutical Compositions of 3-Hydroxy-N-Methylmorphinan and Method of Use. Currently pending.

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

Patent No. 6,008,258 filed 1/21/98, d-Methadone, a Nonopioid Analgesic, Patent granted.

Patent application 13/803,375 filed 3/14/13, d-Methadone for the Treatment of Psychiatric Symptoms. Currently pending.

U.S. Patent No. 9,125,833 was issued by the U.S. Patent and Trademark Office (USPTO) on September 8, 2015 for its patent application entitled, "Multimodal abuse resistant and extended release opioid formulations." The issued patent covers the SECUREL technology platform and Relmada's lead product candidate, LevoCap ER (REL-1015, levorphanol extended-release, abuse deterrent capsules) as well as providing additional coverage for multiple opioid molecules that are prone to abuse.

**Buprenorphine:** This patent application covers the buprenorphine product.

Patent application 12/988,209 filed 3/9/09, Oral Pharmaceutical Compositions of Buprenorphine and Method of Use. Currently pending.

**Mepivacaine:** This patent application covers the Mepivacaine product.

Patent application PCT/US2011/032,381 filed 4/13/11, Dermal Pharmaceutical Composition of 1-Methyl-2',6'

-Pipicoloxylidide and Method of Use. Currently pending.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

***We may not successfully manage our growth.***

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



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

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

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

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

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

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

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

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

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

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

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

Government agencies, professional and medical societies, and other groups may establish usage guidelines that apply to our

Law enforcement concerns over diversion of opioids and social issues around abuse of opioids may make the regulatory approval process and commercialization of our drug candidates very difficult.

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

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

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

***Business interruptions could limit our ability to operate our business.***

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

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

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

**Risks Related to Ownership of Our Common Stock**

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

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

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

If our stockholders sell substantial amounts of our common stock in the public market, the market price of our common stock could fall. These sales also may make it more difficult for us to sell equity or equity-related securities in the future at a time and price that we deem reasonable or appropriate. Stockholders who have been issued shares in the Reverse Merger will be able to sell their shares pursuant to Rule 144 under the Securities Act of 1933, beginning one year after the stockholders acquired their shares, subject to limitations imposed by the lock-up agreements.

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

We are a public reporting company and, accordingly, subject to the information and reporting requirements of the Exchange Act and other federal securities laws, including compliance with the Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act"). The costs of preparing and filing annual and quarterly reports, proxy statements and other information with the SEC and furnishing audited reports to stockholders would cause our expenses to be higher than they would be if we remained privately held and did not consummate the Reverse Merger. In addition, we will incur substantial expenses in connection with the preparation of the registration statement and related documents required under the terms of our May and June 2014 offerings.

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.

***The issuing of our press release, dated July 1, 2014, which was not in compliance with Rule 134 of the Securities Act of 1933, as amended (the "Securities Act") and potentially Section 5(b) of the Securities Act, could subject us to rescission rights by investors that are participating in the offering***

On July 1, 2014, we filed a press release announcing the filing of registration statement on Form S-1, of which this Annual Report is a part. The press release was not in compliance with the provisions of Rule 134 of the Securities Act. The SEC has regulations concerning the ability of an issuer to make public announcements during a registered public offering of its securities. Rule 134 of the Securities Act is a safe harbor which permits an issuer to make a public announcement during the waiting period (the period after filing the registration statement). As a result, investors in this offering may potentially be entitled to bring suit against the Company for not being in compliance with the Securities Act, and such investor may be able to obtain rescission rights. The potential costs, risks and liabilities associated with such potential lawsuits, rights of rescission and/or regulatory actions cannot be accurately assessed at this time, but in the event such lawsuits, rescission offerings and/or regulatory actions are instituted, our Company believes that such actions will not have a material financial effect on our Company. Also, our Company's inability to resolve any potential violation of Section 5 of the Securities Act to the satisfaction of the SEC could result in a delay or prohibition in obtaining the effectiveness of any future registration statements, which could hinder or impair the ability to obtain future financing.

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

The Sarbanes-Oxley Act and new rules subsequently implemented by the SEC have required changes in corporate governance practices of public companies. As a public company, we expect these new rules and regulations to increase our compliance costs in 2012 and beyond and to make certain activities more time consuming and costly. As a public company, we also expect that these new rules and regulations may make it more difficult and expensive for us to obtain director and officer liability insurance in the future and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified persons to serve on our board of directors or as executive officers.

***Our stock price may be volatile.***

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

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

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

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

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

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

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

## ITEM 1B.UNRESOLVED STAFF COMMENTS

Not applicable

## ITEM 2. PROPERTIES

We do not own any property. As of June 30, 2015, we have a commitment of \$30,600 at our previous corporate office location. We temporarily moved our corporate office location and have a commitment of approximately \$41,600 through September 30, 2015 at 757 Third Avenue, Suite 2018, New York, NY 10017. In June 2015, we entered into a seven year and three months lease at 275 Madison Avenue, Suite 702, New York, NY 10016 for our corporate office location, with an annual rental rate commencing at approximately \$312,700 per year for the period to commencing in October 2015 through September 2019. The annual rent will increase to approximately \$341,600 commencing in October 2019 through the end of the lease term. We also lease an office at Village Square Professional Building Two, 686 DeKalb Pike, Suite 202, Blue Bell, PA 19422 for approximately \$3,100, expiring September, 2017. We entered into a sublease agreement through September 2016 whereby a tenant will be reimbursing us \$2,350 for rent per month.

## 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 or operating results.

**Lawsuit Brought by Former Officer:** In 2014, Relmada was dismissed with prejudice of its lawsuit against Najib Babul, which had sought to compel Mr. Babul, Relmada's former President and sole stockholder, to account for questionable expenditures of Relmada funds made while Babul controlled the Company. Relmada's decision to surrender 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 the subsidiary, Relmada Delaware, for shares in the Company.

Subsequently, Babul has brought a second lawsuit against Relmada, making claims for breach of contract, defamation, intentional infliction of emotional distress, and wrongful use of civil process. The Company has moved to dismiss Babul's claims, brought in the United States District Court for the Eastern District of Pennsylvania. Management also believes that, if the litigation is permitted to proceed, it will have good defenses to all of Babul's claims. However, litigation is an inherently uncertain process, and there can be no assurance that the Company will succeed in its defense. Management believes that the outcome of the Babul litigation, even if unfavorable, would not materially affect the Company's operations or financial position.

## ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

## PART II

## ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

### Market Information

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

The following table shows, for the for the year ended June 30, 2015 and for the six months ended June 30, 2014 indicates the high and low closing prices per share of our common stock as reported by the OTCQB quotation service. These closing prices represent prices quoted by broker-dealers on the OTCQB quotation service. The quotations reflect inter-dealer prices, without retail mark-up, mark-down or commissions, and may not represent actual transactions. The table below does not give effect to the reverse stock split of one-for-five that occurred on August 12, 2015.

For the Year Ended June 30, 2015	High	Low
Three months ended June 30, 2015	\$ 2.89	\$ 1.51
Three months ended March 31, 2015	\$ 3.72	\$ 2.50
Three months ended December 31, 2014	\$ 3.58	\$ 2.54
Three months ended September 30, 2014	\$ 3.19	\$ 1.50
For the Six Months Ended June 30, 2014	High	Low
Three months ended June 30, 2014	\$ 3.00	\$ 0.01
Three months ended March 31, 2014	\$ -	\$ -

- Did not trade

### **Lack of a Public Market for Common Stock**

Prior to our share exchange there was no public market for our common stock. We completed a share exchange on May 20, 2014 as described in the business section of this 10-K. In addition, on August 5, 2014, FIRNA approved our symbol change from CMPE to RLMD. This became effective on August 6, 2014. Due the reverse stock split that occurred on August 12, 2015, our stock symbol temporarily changed from RLMD to RLMD and reverted back to RLMD. There is no assurance that our shares will continue to be traded on the bulletin board, or if traded, that a public market will materialize.

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

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

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

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

### **Holders**

As of June 30, 2015, 10,778,243 shares of common stock were issued and outstanding, which were held by 597 holders of record. These stockholders held their stock either individually or in nominee or "street" names through various brokerage firms. There are 71,672 shares of Class A convertible preferred stock outstanding held by three holders of record. Our transfer agent is:

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

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



## **Registration Rights**

In connection with Relmada's May 2014 private placement offering that closed on May 15, 2014, we were obligated to file within 45 days of the final closing of the offering a registration statement registering for resale all shares of common stock of Relmada issued as part of the units and all common shares of Relmada issuable upon exercise of the A warrants and B warrants issued in the offering. Also, in connection with our May 2014 private placement offering that closed on June 10, 2014, we were obligated to file within 45 days of the final closing of the offering a registration statement registering for resale all shares of common stock of the Company issued as part of the units and all common shares of the Company issuable upon exercise of the A warrants and B warrants issued in the offering. We were also obligated to include in the registration statement: (i) Relmada's Series A preferred stock that converted into Common Stock at the Share Exchange, (ii) Relmada Notes that converted into Common Stock at the Share Exchange, (iii) underlying Common Stock included with the Series A Preferred Warrants and Notes Warrants; and (iv) underlying common stock in connection with warrants issued to the placement agent in the Relmada's Series A Preferred financing, Notes financing and May 2014 offering. On June 27, 2014, we filed a registration statement that included these holders in the selling stockholders table. This registration statement was declared effective by the Securities and Exchange Commission on December 30, 2014.

## **Dividends**

We plan to retain any earnings for the foreseeable future for our operations. We have never paid any dividends on our preferred 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. In addition, our credit facility restricts our ability to pay dividends.

## **Securities Authorized for Issuance under Equity Compensation Plans**

Relmada has a 2014 Option and Equity Incentive Plan, as amended (the "Plan") in which its directors, officers, employees and consultants shall be eligible to participate. The Plan allows for the granting of common stock awards, stock appreciation rights, and incentive and nonqualified stock options to purchase shares of the Company. As of June 30, 2015, the Company has 740,138 awards available to be issued.

The following table summarizes our equity compensation plan information as of June 30, 2015.

#### Equity Compensation Plan Information

Plan Category	Number of securities to be issued upon exercise of outstanding options and stock appreciation rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	871,630	\$ 8.12	740,138
Equity compensation plans not approved by security holders			
<b>Total</b>	<b>871,630</b>	<b>\$ 8.12</b>	<b>740,138</b>

#### ITEM 6. SELECTED FINANCIAL DATA

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

Our public float was greater than \$75 million as of December 31, 2014, the last business day of our second quarter of fiscal year 2015 and accordingly we became an accelerated filer at the end of fiscal year 2015. In accordance with Item 10(f)(2)(i) of Regulation S-K, we will transition from the scaled disclosure requirements available to smaller reporting companies to the disclosure requirements applicable to accelerated filers beginning with our quarterly report on Form 10-Q for our first quarter of fiscal year 2016.

#### 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 twelve months ended June 30, 2015, for the six months ended June 30, 2014 and the twelve months ended December 31, 2013. The Results of Operations for the Transition Period is a comparison of our twelve months June 30, 2015 to June 30, 2014 and the six months ended June 30, 2014 to June 30, 2013 as presented in footnote 10 to the financial statements, consolidated "Transition Period Comparable Information Unaudited". 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**

We are a clinical stage biopharmaceutical company focused on developing a pipeline of drug candidates to treat chronic pain.

Relmada Therapeutics, Inc. ("RTI"), which was previously a private company commenced operations in May 2004, entered into a Merger Agreement with Medeor Inc. ("Medeor") on December 31, 2013. This transaction occurred by the exchange of Medeor's shares, for RTI's common stock. Following the transaction, the corporate existence of Medeor ceased and RTI continued as the surviving corporation (the "Merger"). In connection with the Merger, each share of common stock of Medeor was converted into the right to receive a pro rata share of RTI's common stock based upon an exchange ratio. Medeor was developing d-Methadone.

In May 2014, RTI completed a Share Exchange with Camp Nine, Inc., a publicly traded Nevada corporation that was formed in May 2012. In July 2014, we changed the name of Camp Nine, Inc. to Relmada Therapeutics, Inc. At the Share Exchange, RTI shareholders exchanged 10 shares of RTI common stock for one share of our common stock. As a result of the Share Exchange, RTI's shareholders acquired the majority of our issued and outstanding capital stock and RTI became our subsidiary.

The Share Exchange was accounted for as a "reverse merger" rather than a business combination, wherein Relmada is considered the acquirer for accounting and financial reporting purposes. The statement of operations reflects the activities of RTI from the commencement of its operations since inception. Unless the context suggests otherwise, when we refer in this Report to business and financial information for periods prior to the consummation of the Share Exchange, we are referring to the business and financial information of RTI.

During the six months ended June 30, 2014, we changed our year end to June 30 and increased its authorized common stock to 500,000,000 shares and its authorized preferred stock to 200,000,000 shares of which 3,500,000 is designated for Class A preferred stock. On August 12, 2015, the Company completed a one-for-five reverse stock split in preparation for our proposed up-listing to NASDAQ Capital Markets reducing the authorized common share to 100,000,000 common shares. This Annual Report reflects a retroactive adjustment for the reverse stock split.

We have not generated revenues and do not anticipate generating revenues for the foreseeable future. We had net loss of approximately \$20,803,600, \$21,336,000 and \$19,871,900 for the year ended June 30, 2015, for the six months ended June 30, 2014 and for the year ended the year ended December 31, 2013, respectively. At June 30, 2015, we have an accumulated deficit of approximately \$76,122,200.

We intend to realize our business objectives by implementing two core strategies to address unmet medical needs in the treatment of chronic pain: a) developing improved versions of proven drug candidates; and b) developing new chemical entities. This two tiered approach is expected to reduce overall clinical development investment, time, and risks. Our drug candidates are designed to improve the overall benefits and use of a drug for patients by improving the metabolism, distribution, pharmacokinetics, pharmacodynamics, half-life and/or bioavailability of drugs.

#### **d-Methadone (dextromethadone, REL-1017)**

Our most-advanced new chemical entity, d-Methadone (dextromethadone, REL-1017), is a novel, N-methyl-D-aspartate (NMDA) receptor antagonist being developed for the treatment of neuropathic pain. As a single isomer of racemic methadone, d-Methadone has been shown to possess NMDA antagonist properties with virtually no opioid activity at the expected therapeutic doses. The activation of NMDA receptors has been associated with neuropathic pain and it is expected that d-Methadone will have a role in pain management by blocking this activity. In contrast, racemic methadone is a long-acting narcotic producing typical opioid side effects used in the treatment of various pain states and as a substitution therapy in opioid addiction. In November 2014, Health Canada approved a Clinical Trial Application (“CTA”) to conduct the first Phase I study with d-Methadone. This is a Single Ascending Dose (“SAD”) study that will be followed by a Multiple Ascending Dose (“MAD”) study, both in healthy volunteers. The two studies are designed to assess the safety, tolerability and pharmacokinetics of d-Methadone in healthy subjects. The SAD study includes single escalating oral doses of d-Methadone to determine the maximum tolerated dose. In the MAD study, healthy subjects are to receive daily oral doses of d-Methadone for several days to assess its safety, pharmacokinetics and tolerability. In March 2015, d-Methadone demonstrated a safe profile with no dose limiting side effects after four cohorts were exposed to increasing higher doses. In April 2015, the Company received clearance from Health Canada to continue with dose escalation and explore higher doses of d-Methadone. In June 2015, the Company successfully completed the SAD study and subsequently received a No Objection Letter (NOL) from Health Canada to conduct the MAD clinical study in August 2015. The data from these studies will inform the design of a subsequent Phase II proof of concept study.

#### **LevoCap ER (REL-1015)**

Our most-advanced novel version of a proven drug product, LevoCap ER (REL-1015), is an extended release, abuse deterrent, and proprietary formulation of the opioid analgesic levorphanol, which is pharmacologically differentiated from morphine, oxycodone, and other strong opioids for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment. In particular, levorphanol binds to all three opioid receptor subtypes involved in analgesia ( $\mu$ ,  $\kappa$ , and  $\delta$ ), the N-methyl-D-aspartate (NMDA) receptor and the norepinephrine and serotonin uptake pumps, whereas morphine is relatively selective for  $\mu$  sites. Due to the selectivity of morphine for  $\mu$  receptors compared to levorphanol's ability to interact more potently with other relevant receptor subtypes, levorphanol could achieve analgesia in patients resistant to other strong opioids. Levorphanol is a strong opioid first synthesized decades ago and is considered equal in potency to hydromorphone, oxycodone, fentanyl, and methadone. In clinical studies, it has demonstrated a remarkably broad spectrum of analgesic activity against many different types of pain including neuropathic pain, post-surgical pain, and chronic pain in patients refractory to other opioids. We continue to scale up manufacturing and prepare for Phase III development program and are planning to submit a request to the FDA to discuss the final regulatory and clinical plan for this product. In preparation for pivotal trial(s) that we plan to perform under US IND, we are selecting the final formulation and are planning to generate the necessary GMP batches.

#### **BuTab (REL-1028)**

Our second-most-advanced novel version of a proven drug product, BuTab (REL-1028), represents novel formulations of oral, modified release buprenorphine being developed for both chronic pain and opioid dependence indications. Buprenorphine has been widely used by the sublingual and transdermal routes of administration, but was believed to be ineffective by the oral route. We have completed a preclinical program to better define the pharmacokinetic profile of BuTab and to assess the time course of systemic absorption of buprenorphine using several different oral modified release formulations of buprenorphine in dogs, compared to an intravenous administration. Based on the results of this work, we have obtained approval from Health Canada to initiate a Phase I pharmacokinetic study in healthy volunteers in the second quarter of 2015. This trial is ongoing.

## **MepiGel (REL-1021)**

Our third-most-advanced novel version of a proven drug product, MepiGel (REL-1021), is a proprietary topical dosage form of the local anesthetic mepivacaine for the treatment of painful peripheral neuropathies, such as painful diabetic neuropathy, postherpetic neuralgia and painful HIV-associated neuropathy. Mepivacaine is an anesthetic (numbing medicine) that blocks the nerve impulses that send pain signals to the brain. It is chemically related to bupivacaine but pharmacologically related to lidocaine. Mepivacaine is currently indicated for infiltration, nerve block and epidural anesthesia. Relmada has received two FDA Orphan Drug Designations for mepivacaine, one each for “the treatment of painful HIV-associated neuropathy” and for “the management of postherpetic neuralgia,” or PHN. We have selected the formulations to be advanced into clinical studies for MepiGel after the evaluation of results from in vitro and ex vivo studies comparing various topical prototypes of mepivacaine that were conducted by MedPharm Ltd, a specialist formulation development company recognized internationally for its expertise in topical and transdermal products. Relmada is planning single and multiple dose Phase I studies in healthy subjects with the selected MepiGel formulations. The data from these studies will inform the design of a subsequent Phase 2 proof of concept study in patients suffering from neuropathic pain.

## **Results of Operations**

### **For the twelve months ended June 30, 2015 versus June 30, 2014**

#### **Research and Development Expense**

Research and development expense for the twelve months ended June 30, 2015 was approximately \$7,872,400 compared to \$5,380,100 for the twelve months ended June 30, 2014, a difference of \$2,492,300. The increase was attributable to increased clinical activities during the twelve months ended June 30, 2015 as compared to the comparable period. During the twelve months ended June 30, 2014, research and development expenses included a non-cash expense of \$3,750,000 related to the merger with Medeor that occurred on December 31, 2013. This transaction occurred in connection with the exchange of Medeor's shares for the issuance of the Company's common stock at fair market value. Following the transaction, Medeor ceased and the Company continued as the surviving corporation.

#### **General and Administrative Expense**

General and administrative expense for the twelve months ended June 30, 2015 was approximately \$9,226,900 compared to \$13,103,800 for the twelve months ended June 30, 2014, a difference of \$3,876,900. The decrease was primarily attributed to stock-based compensation expense, a non-cash charge of \$8,835,700. In addition, there were higher expenses for the twelve months ended June 30, 2015 that were comprised primarily of professional, consulting fees and salaries of approximately \$3,229,000.

#### **Change in Fair Value of Derivative Liabilities**

The change in the fair value of derivative liabilities was an unrealized loss of approximately \$3,710,300 for the twelve months ended June 30, 2015, as compared to an unrealized loss of approximately \$8,971,300 for the comparable period in 2014. For the twelve months ended June 30, 2015 and 2014, derivative liabilities included warrants issued with the May 2014 and June 2014 offerings. The derivative liability will decrease when warrants are exercised, expire or when the anti-dilution feature is eliminated. The anti-dilution feature is eliminated when the Company is up-listed to a National Exchange (NYSE or NASDAQ). The derivative liabilities are affected by factors that are subject to significant fluctuations and are not under the Company's control. Therefore, the resulting effect upon our net income or loss is subject to significant fluctuations and will continue to be subject to significant fluctuations until the derivatives are reduced to zero, expire or are exercised. The accounting guidance applicable to these warrants requires the Company (assuming all other inputs to the pricing model remain constant) to record a non-cash loss when the Company's stock price is rising and to record non-cash income when the Company's stock price is decreasing.

**Interest Expense**

Interest expense for the twelve months ended June 30, 2015 was \$4,900 compared to the twelve months ended June 30, 2014 was approximately \$614,300, a difference of \$609,400. The difference primarily consisted of approximately \$186,700 resulting from a beneficial conversion feature that existed with the September 2013 notes payable at the issuance date that was recorded upon going public. The Company recorded approximately \$422,700 in interest expense, debt discount and debt issuance cost in connection subordinated notes sold which included warrants.

**Income Taxes**

The Company did not provide for income taxes for the twelve months ended June 30, 2015 and 2014 since there was a loss.

**Loss per Common Share**

The Company recorded a net loss of approximately \$20,803,600 and \$28,068,000 or \$2.09 and \$18.89 per common share, basic and diluted, for the twelve months ended June 30, 2015 and 2014, respectively, based on the factors described above.

**For the Six Months Ended June 30, 2014 versus June 30, 2013****Research and Development Expense**

Research and development expense for the six months ended June 30, 2014 was approximately \$840,000 compared to \$708,600, for the six month ended June 30, 2013. This increase of \$131,400 was attributable to increased clinical activities during the six months ended June 30, 2014 as compared to the comparable period.

**General and Administrative Expense**

General and administrative expense for the six months ended June 30, 2014 was approximately \$12,106,900 compared to \$528,400, for the six month ended June 30, 2013, a difference of \$11,578,500. The increase was primarily attributed to stock-based compensation expense, a non-cash charge of \$10,184,800. In addition, there were increases in professional fees, consulting fees of \$1,060,000 and financial advisory fees paid to a related party of approximately \$273,300.

### **Change in Fair Value of Derivative Liabilities**

The change in the fair value of derivative liabilities was an unrealized loss of approximately \$7,955,000 for the six months ended June 30, 2014, as compared to an unrealized loss of approximately \$11,861,300 for the comparable period in 2013. For the six months ended June 30, 2014 and 2013, derivative liabilities included warrants issued with units sold with the Series A preferred stock offerings and notes offerings. The derivative liability will decrease when warrants are exercised, expire or when the anti-dilution feature is eliminated. The anti-dilution feature was eliminated when the Company went public through the Share Exchange. The derivative liabilities are affected by factors that are subject to significant fluctuations and are not under the Company's control. Therefore, the resulting effect upon our net income or loss is subject to significant fluctuations and will continue to be subject to significant fluctuations until the derivatives are reduced to zero, expire or are exercised. The accounting guidance applicable to these warrants requires the Company (assuming all other inputs to the pricing model remain constant) to record a non-cash loss when the Company's stock price is rising and to record non-cash income when the Company's stock price is decreasing.

### **Interest Expense**

Interest expense for the six months ended June 30, 2014 was approximately \$435,600 compared to \$41,700 for the six months ended June 30, 2013, a difference of \$393,900. The difference primarily consisted of approximately \$186,700 resulting from a beneficial conversion feature that existed with the September 2013 notes payable at the issuance date that was recorded upon going public. The Company recorded approximately \$207,200 in interest expense, debt discount and debt issuance cost in connection subordinated notes sold which included warrants.

### **Income Taxes**

The Company did not provide for income taxes for the six months June 30, 2014 and 2013 since there was a loss.

### **Loss per Common Share**

The Company recorded a net loss of approximately \$21,336,000 and \$13,139,900, or \$8.65 and \$27.35 per common share, basic and diluted, during the six months ended June 30, 2014 and 2013 respectively, based on the factors described above.

### **Liquidity**

To date, we have financed our operations primarily through issuance of common stock and warrants and subordinated debt (converted to common stock). Since our inception, we have not generated any product revenue and do not anticipate generating any revenues for the foreseeable future. We have incurred losses from inception to June 30, 2015 of approximately \$76,122,200 that includes non-cash charges of approximately \$47,565,700. We have generated negative cash flows from operations since inception. We expect to incur increasing expenses over the next several years developing our products.

We will need to raise additional funds in order to continue our clinical trials. Insufficient funds may cause us to delay, reduce the scope of or eliminate one or more of our development programs. For the year ended June 30, 2016, the Company has commitments totaling \$4,515,600. We anticipate that with our cash and cash equivalents on hand at June 30, 2015, of approximately \$22,470,000, the Company can fund future operations until the end of calendar year 2016. Our future capital needs and the adequacy of our available funds will depend on many factors, including the cost of clinical studies and other actions needed to obtain regulatory approval of our products in development. If additional funds are required, we may raise such funds from time to time through public or private sales of equity or debt securities or from bank or other loans or through strategic research and development, or licensing. Financing may not be available on acceptable terms, or at all, and our failure to raise capital when needed could materially adversely impact our growth plans and our financial condition or results of operations. Additional equity financing, if available, may be dilutive to our shareholders.



## Effects of Inflation

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

## Contractual Obligations

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

	<u>Total</u>	<u>Less than 1 year</u>	<u>1 - 2 years</u>	<u>3 - 5 years</u>	<u>More than 5 years</u>
Office lease	\$ 2,553,500	\$ 266,800	\$ 694,500	\$ 1,039,600	\$ 552,600
Research and development contracts	3,985,000	3,985,000	-	-	-
Note payable	263,800	263,800	-	-	-
Total obligations	<u>\$ 6,802,300</u>	<u>\$ 4,515,600</u>	<u>\$ 694,500</u>	<u>\$ 1,039,600</u>	<u>\$ 552,600</u>

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

	<u>For the Years Ended June 30, 2015</u>	<u>For the Six Months Ended 2014</u>	<u>For the Year Ended December 31, 2013</u>
Cash used in operating activities	\$ (16,226,728)	\$ (2,164,254)	\$ (2,237,529)
Cash used in investing activities	(23,326)	(3,673)	(8,871)
Cash provided by financing activities	13,155,663	24,209,828	3,996,028
Net (decrease) increase in cash and cash equivalents	\$ (3,094,391)	\$ 22,041,901	\$ 1,749,628

For the year ended June 30, 2015, the six months ended June 30, 2014 and the year ended December 31, 2013, cash used in operating activities was approximately \$16,226,700, \$2,164,300 and \$2,237,500 primarily due to the net loss for each respective period, of approximately \$20,803,600, \$21,336,000 and \$19,871,900, respectively. This was offset by non-cash expenses which primarily consisted of stock-based compensation, common stock issued for services, the change in the fair value of derivative liabilities, amortization of debt discount and deferred financing cost and depreciation, for the year ended June 30, 2015, the six months ended months ended June 30, 2014 and for the year ended December 31, 2013 of approximately \$5,696,900, \$18,691,700 and \$17,215,500, respectively. There were changes in operating assets and liabilities for the year ended June 30, 2015, the six months ended June 30, 2014 and the year ended December 31, 2013 of approximately (\$1,120,000), \$480,100 and \$418,900, respectively.

For the year ended June 30, 2015 cash provided by financing activities was approximately \$13,155,700. The Company received net proceeds of approximately \$13,423,800 from the exercise of A warrants from those who invested in the May and June 2014 equity offerings. The Company paid principal note payments of approximately 293,600 for financing of director and officer insurance policies. For the six months ended June 30, 2014, cash provided by financing activities was approximately \$24,209,800 resulting from the net proceeds from the May and June 2014 equity offerings of common stock and A warrants and B warrants of approximately \$22,229,300 and from an investment from the principal shareholders of Camp Nine, Inc. of \$2,000,000. For the year ended December 31, 2013, cash provided by financing activities was approximately \$3,996,000 which was from the net proceeds from the sale of Series A preferred stock and warrants of approximately \$3,494,400 and from the net proceeds of issuance of subordinated promissory notes of approximately \$501,600.

## **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 stock-based compensation expense, valuation of derivative financial liabilities, and income taxes and valuation of income taxes.

## **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. Compensation expense for warrants granted to non-employees is determined by the fair value of the consideration received or the fair value of the equity instruments issued, whichever is more reliably measured, and is recognized over the service period. The expense is subsequently adjusted to fair value at the end of each reporting period until such warrants vest, and the fair value of such instruments, as adjusted, is expensed over the related vesting period. Adjustments to fair value at each reporting date may result in income or expense, depending upon the estimate of fair value and the amount of expense recorded prior to the adjustment. The Company reviews its agreements and the future performance obligation with respect to the unvested warrants for its vendors or consultants. When appropriate, the Company will expense the unvested warrants at the time when management deems the service obligation for future services has ceased.

## **Income Taxes**

The Company accounts for income taxes using the asset and liability method. Accordingly, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in the tax rate is recognized in income or expense in the period that the change is effective. Tax benefits are recognized when it is probable that the deduction will be sustained. A valuation allowance is established when it is more likely than not that all or a portion of a deferred tax asset will either expire before the Company is able to realize the benefit, or that future deductibility is uncertain. As of June 30, 2015 and 2014, the Company recorded a valuation allowance to the full extent of our net deferred tax assets since the likelihood of realization of the benefit does not meet the more likely than not threshold.

## Derivatives

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

## Fair Value of Financial Instruments

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

- Level 1 Inputs – Unadjusted quoted prices in active markets for identical assets or liabilities that the reporting entity has the ability to access at the measurement date.
- Level 2 Inputs – Inputs other than quoted prices included in Level 1 that are observable for the asset or liability, either directly or indirectly. These might include quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active, inputs other than quoted prices that are observable for the asset or liability (such as interest rates, volatilities, prepayment speeds, credit risks, etc.) or inputs that are derived principally from or corroborated by market data by correlation or other means.
- Level 3 Inputs – Unobservable inputs for determining the fair values of assets or liabilities that reflect an entity's own assumptions about the assumptions that market participants would use in pricing the assets or liabilities.

## Opportunities, Challenges and Risks

The market for drugs for pain treatment is large and in need of new solutions. Where successful, pain products can generate hundreds of millions of dollars in annual sales. A number of large pharmaceutical and biotechnology companies regularly acquire products in development, with preference given to products in Phase II or later clinical trials. These deals are typically structured to include an upfront payment that ranges from several million dollars to tens of millions of dollars or more, and additional milestone payments tied to development, regulatory and sales milestones. Our goal is to develop products up to the point where our resources are sufficient to sustain the costs, and subsequently partner them with larger companies to share further development expenses and leverage their sales and marketing infrastructure. We plan to retain the marketing or co-marketing rights for selected specialty medical areas in the U.S.

We believe our future success will be heavily dependent upon our ability to successfully conduct clinical trials and nonclinical development of our drug candidates. This will in turn depend on our ability to hire competent employees, continue our close collaboration with our suppliers and our Scientific Advisory Board. It is possible that despite our best efforts our clinical trials results may not meet regulatory requirements for approval. If our efforts are successful, we will be able to partner our development stage products on commercially favorable terms only if they enjoy appropriate market exclusivity. For that reason we intend to continue our efforts to maintain existing and generate new intellectual property. Intellectual property is a key factor in the success of our business.

To achieve the goals discussed above we intend to continue to invest in research and development at likely increasing rates thus incurring further losses until one or more of our products is/are sufficiently developed to partner them to large pharmaceutical and biotechnology companies.

## 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 covers \$250,000 for substantially all depository accounts.

## **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 warrant investments 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 June 30, 2015 and 2014, for the year ended June 30, 2015, for the six months ended June 30, 2014 and for the year ended December 31, 2013 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 our 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 our Chief Financial Officer have concluded that, at June 30, 2015, 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 have concluded, based on their evaluation as of the end of the period covered by this Report that our disclosure controls and procedures were sufficiently effective to provide reasonable assurance that the objectives of our disclosure control system were met.

### **Changes in Internal Control Over Financial Reporting**

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

### **Management's Report on Internal Control Over Financial Reporting**

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

- (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of our company,

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

Because of its inherent limitations, internal control over financial reporting may not prevent or detect errors or misstatements in our consolidated financial statements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree or compliance with the policies or procedures may deteriorate. Management assessed the effectiveness of our internal control over financial reporting at June 30, 2015. In making these assessments, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission COSO. Based on our assessments and those criteria, management determined that we maintained effective internal control over financial reporting at June 30, 2015.

## ITEM 9B. OTHER INFORMATION

None.

## PART III

### ITEM 10. DIRECTORS, EXECUTIVE OFFICERS, AND CORPORATE GOVERNANCE

The following sets forth information about our directors and executive officers as of September 11, 2015:

Name	Age	Position
Sergio Traversa, PharmD, MBA	55	Chief Executive Officer and Director
Douglas Beck, CPA	54	Chief Financial Officer
Charles J. Casamento	70	Director
Sandesh Seth, MS, MBA	51	Chairman of the Board
Shreeram Agharkar, Ph.D.	68	Director
Nabil Yazgi, MD	61	Director

**Sergio Traversa, PharmD, MBA** has been our Chief Executive Officer and director since April 2012. Previously, from January 2010 to April 2012 he was the CEO of Medeor Inc., a spinoff pharmaceutical company from Cornell University. From January 2008 to January 2010 Dr. Traversa was a partner at Ardana Capital. Dr. Traversa has over twenty-five years of experience in the healthcare sector in the United States and Europe, ranging from management positions in the pharmaceutical industry to investing and strategic advisory roles. He has held financial analyst, portfolio management and strategic advisory positions at large U.S. investment firms specializing in healthcare, including Mehta, Isaly and Mehta Partners, ING Barings, Merlin BioMed and Rx Capital. Dr. Traversa was a founding partner of Ardana Capital, a pharmaceutical and biotechnology investment advisory firm. In Europe, he held the position of Area Manager for Southern Europe of Therakos Inc., a cancer and immunology division of Johnson & Johnson. Prior to Therakos, Dr. Traversa was at Eli Lilly, where he served as Marketing Manager of the Hospital Business Unit. He was also a member of the CNS (Central Nervous System) team at Eli Lilly, where he participated in the launch of Prozac and the early development of Zyprexa and Cymbalta. Dr. Traversa started his career as a sales representative at Farmitalia Carlo Erba, the largest pharmaceutical company in Italy, now part of Pfizer. Mr. Traversa is also a board member of Actinium Pharmaceuticals, Inc. and previously served as interim CEO and CFO of Actinium. Dr. Traversa holds a Laurea degree in Pharmacy from the University of Turin (Italy) and an MBA in Finance and International Business from the New York University Leonard Stern School of Business. As Chief Executive Officer of the Company, Dr. Traversa is the most senior executive of the Company and as such provides our Board of Directors with the greatest insight into the Company's business and the challenges and material risks it faces. Dr. Traversa has more than 28 years of healthcare industry experience and is especially qualified to understand the risks and leadership challenges facing a growing pharmaceutical company from a senior management and financial expertise perspective led us to conclude that Dr. Traversa should serve as Chief Executive Officer and Director of the Company.

**Douglas Beck, CPA** has been our Chief Financial Officer since December 2013. Mr. Beck brings extensive previous experience in corporate management as chief financial officer of public companies, including two biopharmaceutical companies. From May 2011 to February 2013 Mr. Beck served as CFO at iBio Inc. (NYSE AMEX:IBIO). Previously, in 2005 he was appointed CFO of Lev Pharmaceuticals, Inc. also a publicly traded company where he headed financial planning, financial reporting and accounting. At Lev, he was part of the executive team and was instrumental in the successful sale of the company to ViroPharma Incorporated for \$618 million in cash and stock. He was employed at various times as an independent consultant. Mr. Beck serves on the SEC Practice Committee and the Chief Financial Officers Committee for the New York State Society of CPAs. Mr. Beck holds a B.S. from the Fairleigh Dickinson University.

## Board of Directors

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

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

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

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

**Sandesh Seth, MS, MBA**, has been our Director since October 2012 and served as our Lead Director since January 2014. Mr. Seth was appointed as the Chairman of the Board in July 2015. Mr. Seth was the Head of Healthcare Investment Banking at Laidlaw & Company (UK) Ltd until July 2015. He has over 20 years of experience which includes prior investment banking at Cowen & Co., equity research at Bear Stearns and Commonwealth Associates and in the pharmaceutical industry at Pfizer, Warner-Lambert, and SmithKline Beecham in strategic planning, business development and R&D project management respectively. Mr. Seth's financial services experience includes 100+ completed transactions in which \$5B+ in capital was raised. Transactions included venture investments, private placements, IPOs, FOs, PIPEs, and Convertible and High-Yield Debt. Mr. Seth was also involved with various strategic initiatives such as mergers and acquisitions, leveraged and management buy-outs, and licensing and joint ventures, including the \$100B merger of Pfizer and Warner-Lambert and the \$20B merger of Pharmacia & Upjohn with Monsanto. Mr. Seth is also the Executive Chairman and Chairman of the Board of Actinium Pharmaceuticals, Inc. Mr. Seth has an MBA in Finance from New York University; an M.S. in the Pharmaceutical Sciences from the University of Oklahoma Health Center and a B.Sc. in Chemistry from Bombay University. He has published several scientific articles and was awarded the University Regents Award for Research Excellence at the University of Oklahoma. Mr. Seth was designated as Regulatory Affairs Certified (R.A.C.) by the Regulatory Affairs Professionals Society which signifies proficiency with United States FDA regulations. He also holds the following Securities Industry Licenses: Series 7, 79 and 63. That Mr. Seth has served in various business executive-level positions over the course of his career, has significant investment banking experience, has developed significant management and leadership skills and is well accustomed to interfacing with investors, analysts, auditors, C-level executives, and outside advisors, led us to conclude that Mr. Seth should serve as a director.

**Shreeram N. Agharkar, PhD**, has been our director since February 2014 and has been a member of our Audit Committee and Chairman of our Compensation Committee since July 2015. Mr. Agharkar is the former Vice President, Deputy Head, Global Chemistry, Manufacturing & Control (GCMC) and Scientific Affairs at Sanofi, where he represented Global CMC development on several corporate R&D committees, provided CMC related scientific and strategic advice to R&D teams, reviewed and approved for Global registration scientific content of all CMC dossiers, co-chaired alliance partnership projects and Chaired GCMC portfolio reviews. He joined Sanofi from Aventis as a result of their merger. At Aventis he served as Vice President and Head of Global Pharmaceutical Development. Prior to this, he served as Executive Director of Pharmaceuticals R&D for Bristol-Myers Squibb Company. Earlier in his career, Dr. Agharkar served as the Senior Section Leader of Sterile Products Formulation R&D for Schering-Plough and as a Research Pharmacist for Parenteral Products Formulation R&D at Abbott Labs. Dr. Agharkar has 40 years of experience in the pharmaceutical industry and has served in various key positions building extensive experience in all aspects of biopharmaceutical product development, R&D, CMC functions, and management functions. Under his leadership and direction, over 30 pharmaceutical products were developed and approved. He is a former member of the American Association of Pharmaceutical Scientists the Parenteral Drug Association the Drug Information Association of and the PhRMA's Pharmaceutical Development Committee. Dr. Agharkar has a B.S., Tech. Pharm./Chem. from Bombay University, India, a M.S., in Pharmaceutics from Columbia University in New York and a PhD. in Pharmaceutics from the University of Kansas. That Dr. Agharkar brings over 40 years of pharmaceutical experience to our Board, having served in various pharmaceutical executive-level positions over the course of his career, and that Dr. Agharkar has developed significant management and leadership skills relating to the pharmaceutical industry led us to conclude that Dr. Agharkar should serve as a director.

**Nabil M. Yazgi, MD** has been our director since February 2014 and is a member of our Audit Committee and Compensation Committee since July 2015. Dr. Yazgi received his Medical Degree from University of Damascus, Syria in 1985. He moved to the United States and completed a Medical Residency Program at Atlantic City Medical Center from 1981 through 1984. He completed EEG and EMG Competence Studies. He then completed a Neurology Residency at the Medical College of Virginia from 1985 through 1987 earning status of Chief Resident. His studies included two months of Neuroradiology (CAT, Myelogram and Angiography Training). Dr. Yazgi earned his Board Certification in Neurology and Psychiatry in December 1991. His professional memberships include American Academy of Neurology and the Neurological Association of New Jersey. Dr. Yazgi has practiced General Neurology in Wayne, New Jersey for 25 years. He is associated with St. Joseph Medical Center, Wayne NJ. Dr. Yazgi practices Pain Management performing Epidural Injections and Trigger Point Injections. That Dr. Yazgi brings over 25 years of clinical experience in pain treatment to our Board, is well accustomed to interfacing with patients, and physicians led us to conclude that Dr. Yazgi should serve as a director.

#### ***Term of Office***

Directors are appointed until removed from office in accordance with our bylaws. Our officers are appointed by our Board and hold office until removed by our Board.

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

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

<b>Director</b>	<b>Class</b>	<b>Term (from 2014 Annual Meeting)</b>
Shreeram Agharkar	Class I	12 months
Nabil Yazgi	Class I	12 months
Charles J. Casamento*	Class II	24 months
Sergio Traversa	Class II	24 months
Sandesh Seth	Class III	36 months

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

\* Mr. Casamento was appointed to the board in July 2015

#### ***Director Independence***

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

- a director who is, or during the past three years was, employed by the company, other than prior employment as an interim executive officer (provided the interim employment did not last longer than one year);
- a director who accepted or has an immediate family member who accepted any compensation from the company in excess of \$120,000 during any period of twelve consecutive months within the three years preceding the determination of independence, other than the following:
  - (i) compensation for board or board committee service,





- (ii) compensation paid to an immediate family member who is an employee (other than an executive officer) of the company,
  - (iii) compensation received for former service as an interim executive officer (provided the interim employment did not last longer than one year) (See Commentary .08), or
  - (iv) benefits under a tax-qualified retirement plan, or non-discretionary compensation
- a director who is an immediate family member of an individual who is, or at any time during the past three years was, employed by the company as an executive officer;
  - a director who is, or has an immediate family member who is, a partner in, or a controlling shareholder or an executive officer of, any organization to which the company made, or from which the company received, payments (other than those arising solely from investments in the company's securities or payments under non-discretionary charitable contribution matching programs) that exceed 5% of the organization's gross revenues for that year, or \$200,000, whichever is more, in any of the most recent three fiscal years;
  - a director who is, or has an immediate family member who is, employed as an executive officer of another entity where at any time during the most recent three fiscal years any of the issuer's executive officers serve on the compensation committee of such other entity; or
  - a director who is, or has an immediate family member who is, a current partner of the company's outside auditor, or was a partner or employee of the company's outside auditor who worked on the company's audit at any time during any of the past three years.

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

#### **Committees of the Board of Directors**

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

<b>Audit Committee</b>	<b>Compensation Committee</b>
Charles J. Casamento*	Shreeram Agharkar*
Shreeram Agharkar	Nabil Yazgi
Nabil Yazgi	Sandesh Seth (advisor)

\* Indicates committee chair

#### ***Audit Committee***

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

#### ***Compensation Committee***

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

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



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

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

### **Family Relationships**

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

### **Involvement in Certain Legal Proceedings**

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

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

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

### **Shareholder Communications**

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

### **Whistle Blowing Policy**

We have adopted a Company Whistle Blowing Policy, for which a copy will be provided to any person requesting same without charge. To request a copy of our Whistle Blowing Policy please make written request to our CFO, at Relmada Therapeutics, Inc. 757 Third Avenue, Suite 2018, New York, NY 10017. We believe our Whistle Blowing Policy is reasonably designed to provide an environment where our employees and consultants may raise concerns about any and all dishonest, fraudulent or unacceptable behavior, which, if disclosed, could reasonably be expected to raise concerns regarding the integrity, ethics or bona fides of the Company.

### **Compliance with Section 16(a) of the Exchange Act**

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

The Executive Officers did not file their respective Form 4 within two business days of receiving each of their stock option grant on February 23, 2015. The stock grants for the Executive Officers were filed on March 5, 2015.



## ITEM 11.EXECUTIVE COMPENSATION

### EXECUTIVE COMPENSATION

The following table provides information regarding the compensation earned during the year ended June 30, 2015, the six months ended June 30, 2014 and for the year ended December 31, 2013 for our Executive officers:

<u>Name/Position</u>	<u>Year</u>	<u>Salary</u>	<u>Bonus</u>	<u>Option Awards (4)</u>	<u>Total</u>
Sergio Traversa, CEO and Board of Director	June 30, 2015	\$ 333,490	\$ 103,950	\$ 408,585	\$ 846,025
	June 30, 2014	132,501	50,000	-	182,051
	December 31, 2013	222,503	75,000	359,051	656,554
Eliseo Salinas, MD, MSc, Former President and Chief Scientific Officer	June 30, 2015	\$ 441,319	\$ 131,541	\$ 408,585	\$ 981,485
	June 30, 2014	167,468	50,000	937,631	1,151,109
Douglas Beck, CPA Chief Financial Officer	June 30, 2015	\$ 200,000	\$ 20,000	\$ 45,398	\$ 265,398
	June 30, 2014	100,000	40,000	-	140,000
	December 2013(2)	16,667	-	181,391	198,058

- (1) Hired as CEO on April 18, 2012 and in May 2014 Mr. Traversa's base salary was increased from \$250,000 to \$300,000 per year. Subsequently, the board of directors increased Mr. Traversa's base salary by \$30,000 and \$9,900 in July 2014 and February 2015, respectively. Mr. Traversa was awarded a \$50,000 and \$75,000 bonus for obtaining certain milestones pursuant to his employment agreement with the company. Mr. Traversa was awarded a discretionary bonus of \$103,950 based upon his calendar 2014 year performance.
- (2) Hired as CFO on December 2, 2013. Does not include \$16,667 that was paid as a consultant in November 2013. In May 2014, Mr. Beck was awarded a total bonus of \$40,000 during the six months ended June 30, 2014 for obtaining certain milestones pursuant to his offer letter with the Company. Mr. Beck was awarded a bonus of \$20,000 during the year ended June 30, 2015 based upon his calendar 2014 year performance.
- (3) Hired as President and Chief Scientific Officer on February 24, 2014. Mr. Salinas was awarded a \$50,000 bonus for obtaining certain milestones pursuant to his offer letter with the company. Mr. Salinas was awarded a discretionary bonus of \$131,541 during the year ended June 30, 2015, based upon his calendar year performance. Mr. Salinas voluntarily resigned on May 20, 2015.
- (4) This column shows the grant date fair value of awards computed in accordance with stock-based compensation accounting rules under Accounting Standards Codification Topic 718.

#### Employment Agreements

##### Compensatory Plan with Sergio Traversa (Principal Executive Officer)

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

##### Salary

- The initial base annual salary is \$339,900. Upon the six month anniversary of the effective date, the board will review the base salary, with the help of an independent compensation consultant, to adjust the base salary so as to be competitively aligned to a range between the 25th (twenty-fifth) and 75th (seventy-fifth) percentile of the relevant market data of CEO positions of similarly situated publicly traded Biotech companies.

##### Bonus

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

### Options

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

### Termination

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

### Non-Solicitation

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

### Indemnification

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

### Compensatory Plan with Douglas Beck (Principal Financial and Accounting Officer)

On August 5, 2015, the Company and Douglas Beck entered into an amended and restated agreement to employ Mr. Beck as the Company's Chief Financial Officer. The term of the agreement is one year. The employment term shall be automatically extended for successive one-year periods thereafter, unless, no later than 60 days prior to the expiration of the initial employment term, or any successive one-year renewal term, either party hereto shall provide to the other party hereto written notice of its or his desire not to extend the Employment Term. Mr. Beck's employment with the Company will be on an "at will" basis, meaning that either Mr. Beck or the Company may terminate your employment at any time for any reason or no reason, without further obligation or liability, except as provided in the Employment Agreement.

#### Salary

- The initial base annual salary is \$200,000. Annually, the board will review Mr. Beck's base salary, with the help of an independent compensation consultant, to adjust his base salary so as to be competitively aligned to a range between the 25th (twenty-fifth) and 75th (seventy-fifth) percentile of the relevant market data of CFO positions of similarly situated publicly traded Biotech companies.

#### Bonus

- Mr. Beck shall be entitled to participate in an executive bonus program, which shall be established by the board pursuant to which the board shall award bonuses to Mr. Beck, based upon the achievement of written individual and corporate objectives such as the board shall determine. Upon the attainment of such performance objectives, in addition to base salary, Mr. Beck shall be entitled to a cash bonus in an amount to be determined by the board with a target of thirty-five percent (35%) of the base salary.

#### Options

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

#### Termination

- Termination for death or disability or cause. In the event that employment is terminated because of death or disability, the Company's only obligation to Mr. Beck shall be to pay earned, but unpaid, base salary (as of the date of termination) and provide to Mr. Beck, if eligible, with the option to elect health coverage under the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("COBRA"); provided that upon termination of employment due to death, Mr. Beck's estate also shall be entitled to receive a single lump sum payment equal to three (3) months of base salary, payable within 30 days of your death. Upon termination of employment for cause (as defined in the Employment Agreement) Mr. Beck shall be paid any accrued and unpaid base salary and benefits through the date of termination and shall have no further rights to any compensation or any other benefits under the agreement or otherwise.
- Termination of Employment Other Than for Cause or Resignation for Good Reason (Not in Connection with a Change in Control). If the Company terminates employment other than for cause or if you resign for Good Reason (as defined in the Employment Agreement), Mr. Beck shall be entitled to (i) a single lump sum payment equal to 6 months of base salary (at the rate in effect as of the date of termination), (ii) continued health benefits for the 12-month period beginning on the date of termination, and (iii) all outstanding equity awards granted under the Company's equity compensation plans shall become immediately vested and exercisable (as applicable) as of the date of such termination and the performance goals with respect to such outstanding performance awards, if any, will be deemed satisfied at "target".

- **Change in Control.** If the Company terminates employment other than for cause or if Mr. Beck resigns for Good Reason (as defined in the Employment Agreement), in any case during the 12-month period beginning on the date of a Change in Control (as defined in the 2014 Equity Incentive Plan, as amended), Mr. Beck shall be entitled to (i) a single lump sum payment equal to 12 months of his compensation (at the rate in effect as of the date of termination), (ii) continued health benefits for the 12-month period beginning on the date of termination, (iii) all outstanding equity awards granted to Mr. Beck under the Company's equity compensation plans shall become immediately vested and exercisable (as applicable) as of the date of such termination and the performance goals with respect to such outstanding performance awards, if any, will be deemed satisfied at "target".

Non-Solicitation

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

Indemnification

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

**Director Compensation**

Historically non-management Directors of the Company do not receive any cash compensation. Commencing March 1, 2014, non-management Directors of the Company began to receive a quarterly cash retainer of \$7,500 per calendar quarter for their service on the Board of Directors. They also receive reimbursement for out-of-pocket expenses and certain directors have received stock option grants for shares of Company Common Stock as described below.

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

<b>BOD Committee</b>	<b>Chairman</b>	<b>Member</b>
Audit	\$ 15,000	\$ 6,000
Compensation	\$ 10,000	\$ 5,000



The following table sets forth the compensation of our directors for the year ended June 30, 2015 and for six month ended June 30, 2014:

<b>Name</b>	<b>Year</b>	<b>Fees Earned or Paid in Cash</b>	<b>Stock Awards</b>	<b>Option Awards (1)</b>	<b>All Other Compensation</b>	<b>Total</b>
Shreeram Agharkar, Ph.D. (2)	2015	\$ 34,988	\$ -	\$ -	\$ -	\$ 34,988
Shreeram Agharkar, Ph.D. (3)	2014	\$ 12,100	\$ -	\$ 45,405	\$ -	\$ 57,405
Sandesh Seth, MS, MBA	2015	\$ 30,000	\$ -	\$ -	\$ -	\$ 30,000
Sandesh Seth, MS, MBA	2014	\$ 10,000	\$ -	\$ 45,405	\$ -	\$ 55,405
Nabil M. Yazgi, MD	2015	\$ 30,000	\$ -	\$ -	\$ -	\$ 30,000
Nabil M. Yazgi, MD	2014	\$ 10,000	\$ -	\$ 45,405	\$ -	\$ 55,405

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

(2) Includes \$2,100 of consulting fees and \$30,000 of director fees.

(3) Includes \$2,100 of consulting fees and \$10,000 of director fees.

The following distinguished individuals serve on our Scientific Advisory Board.

**Gavril Pasternak, MD, PhD** holds the Anne Burnett Tandy Chair in Neurology at Memorial Sloan-Kettering Cancer Center and is a Laboratory Head in the Molecular Pharmacology and Chemistry Program within the Sloan-Kettering Institute. After receiving his M.D. and Ph.D. degrees from the Johns Hopkins University he completed his clinical training in Neurology at Johns Hopkins Hospital and then joined the faculty at Memorial Sloan-Kettering in 1979. He is a Fellow of the American Academy of Neurology and a Fellow of the American Neurological Association. His research has focused on opioid receptors and their mechanisms of action. He has published over 400 articles. Much of his work has addressed the reasons underlying the subtle, but distinct differences among opioid analgesics. These studies revealed the existence of multiple mu opioid receptor subtypes generated from alternative splicing of a single gene. He demonstrated the importance of different sets of mu receptor subtypes in the actions of various opioid analgesics and identified a set of subtypes that offer a unique target for the development of analgesics lacking opioid side-effects.

He is a recipient of a Senior Scientist Award and a MERIT Award from the National Institute on Drug Abuse and has served on their Board of Scientific Counselors. He is a member of the Johns Hopkins Society of Scholars and has been awarded the Millennium Prize from the Norwegian University of Science and Technology, the John J. Bonica Award from the Eastern Pain Association, the Julius Axelrod Award of the American Society of Pharmacology and Experimental Therapeutics, the S. Weir Mitchell Award from the American Academy of Neurology and the Louise and Allston Boyer Young Investigator Award for Clinical Investigation from MSKCC.

**Eric C. Strain, MD** is a Professor in the Department of Psychiatry and Behavioral Sciences at Johns Hopkins University School of Medicine, and is also the Director of the Johns Hopkins Center for Substance Abuse Treatment and Research. He maintains an active research program in substance abuse related issues, provides clinical care to patients, teaches medical students and residents, and provides administrative supervision in the maintenance of current substance abuse programs and the development of new substance abuse initiatives at Johns Hopkins. In addition to his responsibilities at Johns Hopkins, Dr. Strain chairs the NIH RPIA-N study section, is the Editor in Chief for the journal *Drug and Alcohol Dependence*, and is on the editorial board for several other journals. He edited, with Maxine Stitzer, the books *Methadone Treatment for Opioid Dependence* and *The Treatment of Opioid Dependence*, and with Pedro Ruiz edited the fifth edition of Lowinson and Ruiz's *Substance Abuse: A Comprehensive Textbook*. He was the lead in developing the first buprenorphine curriculum, which was subsequently used as the primary resource to train physicians in the use of this medication for the treatment of opioid dependence. He was Chair of the Food and Drug Administration's Drug Abuse Advisory Committee, and the American Psychiatric Association's Council on Addiction Psychiatry. He has served on the boards of The College on Problems of Drug Dependence (for which he is currently the President), the American Academy of Addiction Psychiatry, and Baltimore Substance Abuse Systems. He also has served on various committees for the National Institute on Drug Abuse, the National Institute on Alcohol Abuse and Alcoholism, and the federal Center for Substance Abuse Treatment, and is a frequent reviewer for scientific journals in the area of substance abuse. Dr. Strain is the recipient of several competitive grant awards from the National Institute of Health, and has published extensively on substance abuse-related matters. His research areas have included topics such as the optimal mechanisms for treating patients with substance abuse disorders, including opioid and cocaine dependence, the relationship between substance abuse and other psychiatric disorders, the abuse liability of novel medications, and the development of new pharmacotherapies for substance abuse treatment (including opioids and alcohol). His studies have included medications such as buprenorphine, methadone and LAAM, pharmacotherapies for alcohol dependence, and non-pharmacologic treatments for substance abuse disorders.

**Andrew Rice, MD, FRCA** is Professor of Pain Research at Imperial College and a Honorary Consultant in Pain Medicine at Chelsea and Westminster Hospital, providing a service for patients with neuropathic pain. He qualified in medicine at St. Mary's Hospital Medical School in 1982 and received his research doctorate from St. Thomas' Hospital Medical School (UMDS) in 1991. He completed his specialist training in Oxford before coming to Imperial College in 1995. Dr. Rice is Administrative Director of the London Pain Consortium ([www.lpc.ac.uk](http://www.lpc.ac.uk)), which is currently funded by a Wellcome Trust Strategic Award. He is a Work package Leader and Steering Committee member in the European Union and EFPIA-funded "Innovative Medicines Initiative" collaboration "EUROPAIN".

His research is devoted to elucidating basic and clinical aspects of neuropathic pain. Particular areas of interest include:

- Revealing the pharmacology of cannabinoid analgesia and pursuing strategies for improving the therapeutic index of cannabinoids.
- Developing models of herpes zoster-associated pain and HIV GP120 and antiretroviral-induced neuropathies. Using these models to reveal pain mechanisms in these diseases.
- Investigating the neurobiology of the relationship between neuropathic pain and co-morbidities such as anxiety, depression and circadian rhythm disturbance.
- Identification and exploitation of novel mechanistic and drug targets in neuropathic pain using functional genomics.
- Identification of sources of experimental bias in animal models.
- A program of clinical pheno-/geno-typing studies which seeks to identify risk factors for developing neuropathic pain.
- Conducting meta-analyses of the clinical evidence for therapies in neuropathic pain

He executes a number of responsibilities relating to education and training. For example, he leads the Faculty of Medicine program for medical students who undertake a PhD (MB BS/PhD) and is Site Tutor for Postgraduate Research Students at Chelsea and Westminster. At the Royal College of Anaesthetists, he served on the Founding Board of the Faculty of Pain Medicine and was a Regional Advisor for the Faculty until 2009.

Dr. Rice serves on the Editorial boards of: Pain, PLoS Medicine and the European Neurological Journal and is lead editor of the Textbook of Clinical Pain Management, published by Hodder. He is Secretary of the International Association for the Study of Pain, Special Interest Group on Neuropathic Pain (NeuPSIG) – [www.neupsig.org](http://www.neupsig.org). He has served on the British Pain Society Council. Dr. Rice was the Michael Cousins lecturer at the Australian and New Zealand College of Anaesthetists in 2009; Covino Lecturer at Harvard University in 2008; a plenary lecturer at the 10th World Congress of Pain in 2002 and the Patrick D. Wall Professor at the Royal College of Anaesthetists in 1998.

**Robert H. Dworkin, PhD** received his B.A. in 1971 from the University of Pennsylvania and his Ph.D. in 1977 from Harvard University. He is currently Professor of Anesthesiology, Neurology, Oncology, and Psychiatry, Professor of Neurology in the Center for Human Experimental Therapeutics, and Director of the Anesthesiology Clinical Research Center at the University of Rochester School of Medicine and Dentistry.

Dr. Dworkin is Director of the Analgesic, Anesthetic, and Addiction Clinical Trial Translations, Innovations, Opportunities, and Networks (ACTTION) public-private partnership with the US Food and Drug Administration (FDA); Co-chair of the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT); a member of the US Centers for Disease Control and Prevention (CDC) Zoster Working Group; and a Special Government Employee of the FDA Center for Drug Evaluation and Research. He is a member of the Editorial Boards of Pain, Journal of Pain, Mayo Clinic Proceedings, and Current Pain and Headache Reports, and has previously served as a consultant to and member of the FDA Anesthetic and Life Support Drugs Advisory Committee and as a member of the CDC Measles, Mumps, Rubella, and Varicella Working Group. In 2005, he received the American Pain Society's Wilbert E. Fordyce Clinical Investigator Award, which "recognizes individual excellence and achievements in clinical pain scholarship and is presented to a pain professional whose total career research achievements have contributed significantly to clinical practice," and in 2011, he received the Eastern Pain Association's John J. Bonica Award for his "many contributions to the study, prevention, and treatment of chronic pain."

The primary focus of Dr. Dworkin's current research involves methodologic aspects of analgesic clinical trials, especially identifying factors that might increase the assay sensitivity of a trial to detect differences between an active and a control or comparison treatment. With research funding from the FDA and other sources, he and colleagues are currently examining in acute and chronic pain trials the relationships between study methodologic features and study outcomes, as well as comparing the responsiveness to treatment effects of different primary and secondary outcome measures. The overall objective of these efforts — which are being conducted under the auspices of the ACTTION public-private partnership — is to identify approaches to improving the efficiency and informativeness of clinical trials of pain treatments and provide the foundation for an evidence-based approach to analgesic clinical trial design. In addition, Dr. Dworkin has for many years conducted studies of risk factors for the development of different types of chronic pain, which have been funded by the National Institutes of Health, the Department of Defense, and various pharmaceutical companies. One of the major results of this research has been that patients with greater acute pain are more likely to develop chronic pain, which suggests that attenuating acute pain might prevent chronic pain.

Dr. Dworkin has served as a consultant to over 100 pharmaceutical and device companies in the development and evaluation of analgesic and antiviral treatments. As Director of the Anesthesiology Clinical Research Center, he has served as principal investigator for a large number of clinical trials of analgesic treatments. These studies have examined treatments for various types of chronic pain—including neuropathic pain conditions, low back pain, cancer pain, fibromyalgia, and osteoarthritis—as well as treatments for acute pain in herpes zoster and for acute post-surgical pain.

**Michael E. Thase, MD** joined the faculty of the Perelman School of Medicine at the University of Pennsylvania in 2007 as Professor of Psychiatry after more than 27 years at the University of Pittsburgh Medical Center and the Western Psychiatric Institute and Clinic. Dr. Thase's research focuses on the assessment and treatment of mood disorders, including studies of the differential therapeutics of both depression and bipolar affective disorder.

A 1979 graduate of the Ohio State University College of Medicine, Dr. Thase is a Distinguished Fellow of the American Psychiatric Association, a Founding Fellow of the Academy of Cognitive Therapy, a member of the Board of Directors of the American Society of Clinical Psychopharmacology, and Vice Chairman of the Scientific Advisory Board of the National Depression and Bipolar Support Alliance. Dr. Thase has been elected to the membership of the American College of Psychiatrists and the American College of Neuropsychopharmacology. Dr. Thase has authored or co-authored more than 500 scientific articles and book chapters, as well as 15 books.

## ITEM 12 SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table shows the pro forma beneficial ownership of our common stock as of September 11, 2015. The table shows the common stock holdings of (i) each person known to us to be the beneficial owner of at least five percent (5%) of our common stock; (ii) each director; (iii) each executive officer; and (iv) all directors and executive officers as a group.

Beneficial ownership is determined in accordance with the rules of the SEC, and generally includes voting power and/or investment power with respect to the securities held. Shares of common stock subject to options and warrants currently exercisable or exercisable within 60 days as September 11, 2015, are deemed outstanding and beneficially owned by the person holding such options or warrants for purposes of computing the number of shares and percentage beneficially owned by such person, but are not deemed outstanding for purposes of computing the percentage beneficially owned by any other person. Except as indicated in the footnotes to this table, the persons or entities named have sole voting and investment power with respect to all shares of our common stock shown as beneficially owned by them.

The percentages in the table below are based on 10,886,586 outstanding shares of common stock and Class A convertible Preferred stock. Unless otherwise indicated, the principal mailing address of each of the persons below is c/o Relmada Therapeutics, Inc., 757 Third Avenue, Suite 2018, New York, NY 10017. The Company's executive office is located at 757 Third Avenue, Suite 2018 Avenue, New York, NY 10017.

<b>5 % Stockholders</b>	<b>Number of Common Shares Beneficially Owned</b>	<b>Percentage Ownership</b>
Southern Biotech, Inc. (1) 555 South Federal Highway #450 Boca Raton, FL 33432	981,968	9.0%
Sergio Traversa, PharmD, MBA Director and Chief Executive Officer (2)	299,286	2.8%
Douglas Beck, CPA, Chief Financial Officer (3)	29,868	*
Charles J. Casamento (4) Director	0	*
Shreeram Agharkar, Ph.D. (5) Director	3,650	*
Sandesh Seth, MS, MBA (6) Lead Director	102,649	0.9%
Nabil M. Yazgi, MD (7) Director	43,650	N/A
All Directors and Executive Officers	479,104	4.3%

\* Below 1% ownership.

(1) The beneficial owner of the common shares are held by Barry Honig on behalf of Southern Biotech, Inc.

- (2) Excludes unvested options of 68,999 that have an exercise price of \$4.00 per share. The options vest 25% at the date of grant and the remaining 75% of the options shall vest in equal quarterly increments over the next four (4) years. As of September 11, 2015, 199,744 options were vested that have an exercise price of \$4.00 per share. Excludes unvested options of 39,375 that have an exercise price of \$13.50 per share. The options vest shall vest in equal quarterly increments over the next four (4) years. As of September 11, 2015, options there were 5,625 vested that have an exercise price of \$13.50 per share. Includes 68,781 common shares that were received from the Medeor transactions. Includes 30,760 common shares that were granted pursuant to his employment contract.
- (3) Excludes unvested options to purchase 37,597 shares of common stock at an exercise price of \$4.00 per share. The vesting schedule is according to Relmada's 2014 Stock and Equity Incentive Option Plan, as amended, wherein 25% of the options shall vest upon the optionee's first anniversary of employment with the Company. The remaining 75% of the options shall thereafter vest each quarter over the next three years. It includes options to purchase 29,242 common shares of stock at \$4.00 per share. Excludes options to purchase 4,375 shares of common stock at an exercise price of \$13.50 per share. 25% of the options shall vest quarterly over four years. It includes options to purchase 625 common shares of stock at \$13.50 per share.
- (4) Excludes unvested options to purchase 25,625 shares of common stock at an exercise price of \$8.45 per share. The vesting schedule is according to Relmada's 2014 Stock and Equity Incentive Option Plan, as amended, wherein 25% of the options shall vest upon the optionee's first anniversary of employment with the Company. The remaining 75% of the options shall thereafter vest each quarter over the next three years.
- (5) Excludes unvested options to purchase 6,084 shares of common stock at an exercise price of \$7.50 per share. The vesting schedule is according to Relmada's 2014 Stock and Equity Incentive Option Plan, as amended, wherein 25% of the options shall vest upon the first anniversary of the grant date. The remaining 75% of the options shall thereafter vest each quarter over the next three years. It includes options to purchase 3,650 common shares of stock at \$7.50 per share.
- (6) Excludes unvested options to purchase 6,084 shares of common stock at an exercise price of \$7.50 per share. The vesting schedule is according to the Company ESOP wherein 25% of the options shall vest upon the first anniversary of the grant date. The remaining 75% of the options shall thereafter vest each quarter over the next three years. It includes options to purchase 3,650 common shares of stock at \$7.50 per share. Also includes warrants to purchase 39,418 shares of stock that has an exercise price of \$4.00 per shares that was issued by (i) the Placement Agent or its affiliates in connection with the following offering consummated by Relmada: an offering that closed on September 30, 2013 (the "2013 Offering"), (ii) Medeor merger that closed on December 31, 2013, and (iii) May 2014 and June 2014 equity offering ("the "2014 Offering"). Includes warrants to purchase 7,931 to purchase common stock from the Medeor transaction that closed on December 31, 2013 that has an exercise price of \$5.50 per share. Includes warrants to purchase 51,650 shares of common stock from the May and June 2014 equity offering that has an exercise price of \$7.50 per share. Excludes warrants issued to affiliates of Mr. Seth to purchase an aggregate of 592,707 shares of Common Stock of the Company at par value per share, exercisable on a cashless basis as the warrants are not exercisable upon less than 90 days' notice. The holder may waive the 90 day exercise notice requirement by giving 65 days prior notice of such waiver.
- (7) Excludes unvested options to purchase 6,084 shares of common stock at an exercise price of \$7.50 per share. The vesting schedule is according to Relmada's 2014 Stock and Equity Incentive Option Plan, as amended, wherein 25% of the options shall vest upon the first anniversary of the grant date. The remaining 75% of the options shall thereafter vest each quarter over the next three years. It includes options to purchase 3,650 common shares of stock at \$7.50 per share. Includes 25,000 Series A preferred shares that were purchased in the Series A offering and were converted to common stock. Includes 6,000 common shares that were purchased in the May 2014 offering of common stock and 6,000 common stock that was exercised from A warrants from the May 2014 offering. In addition, B warrants includes 3,000 shares of common stock at an exercise price of \$11.25.

### Equity Compensation Plan Information

The Company has established the 2014 Stock and Equity Incentive Option Plan, as amended (the "Plan"), which allows for the granting of common stock awards, stock appreciation rights, and incentive and nonqualified stock options to purchase shares of the Company's common stock to designated employees, non-employee directors, and consultants and advisors. In August 2015, the board approved an amendment to the Plan (the "Plan Amendment"). Among other things, the Plan Amendment updates the definition of "change of control" and provides for accelerated vesting of all awards granted under the plan in the event of a change of control of the Company. At June 30, 2015, no stock appreciation rights have been issued. Stock options are exercisable generally for a period of 10 years from the date of grant and generally vest over four years. As of June 30, 2015, 740,138 shares were available for future grants under the Plan.

## Outstanding Equity Awards at Fiscal Year-End Table

### OUTSTANDING EQUITY AWARDS AT JUNE 30, 2015

The following table sets forth all unexercised options and unvested restricted stock that have been awarded to our named executives by the Company and were outstanding as of June 30, 2015.

Name	Option Awards				Stock Awards				Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights That Have Not Vested
	Number of Securities Underlying Unexercised Options (#) (Exercisable) (b)	Number of Securities Underlying Unexercised Options (#) (Unexercisable) (c)	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Options (#) (d)	Option Exercise Price(\$)(e)	Option Expiration Date (f)	Number of Shares or Units of Stock That Have Not Vested (g)	Market Value of Units of Stock That Have Not Vested(\$)(h)	Equity Incentive Plan Awards: Number of Unearned Shares, Units or Other Rights That Have Not Vested (i)	Equity Incentive Plan Awards: Market or Payout Value of Unearned Shares, Units or Other Rights That Have Not Vested (\$)(j)
Sergio Traversa	103,813	31,779	-	4.00	07/11/2022	-	-	-	-
Sergio Traversa	76,977	56,173	-	4.00	09/30/2023	-	-	-	-
Sergio Traversa	2,813	42,187	-	13.50	02/23/2025	-	-	-	-
Douglas Beck, CPA	25,065	41,775	-	4.00	12/02/2023	-	-	-	-
Douglas Beck, CPA	313	4,687	-	13.50	02/23/2023	-	-	-	-

### Indemnification of Directors and Officers

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

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

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

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

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

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

### **Equity Compensation Plan Information**

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

### **Acquisition of Medeor**

On October 24, 2013, Relmada entered into an engagement agreement which was amended December 19, 2013 with its Placement Agent, of which Mr. Seth, a director of the Company, was the former Head of Healthcare Investment Banking, to advise on the merger of Medeor Inc. ("Medeor") In consideration for its services, the Placement Agent was eligible to receive (a) a cash success fee equal to \$200,000 less \$50,000 for Fairness Opinion, and (b) a \$50,000 activation fee. The Placement Agent or its designees also received five-year warrants to purchase 400,000 shares of Relmada common stock. As a result of the Share Exchange, these warrants were exchanged for a five-year warrant to purchase 40,000 shares of the Company's common stock at a price of \$5.50 per share. In April 2012, Relmada entered into a license agreement with Medeor and issued 3,578 shares of stock for the license agreement. On December 31, 2013, Relmada entered into a Merger Agreement with Medeor. This transaction occurred by the exchange of Medeor's shares, for Relmada's common stock. Following the transaction, the corporate existence of Medeor ceased and Relmada continued as the surviving corporation under Delaware law (the "Merger"). In connection with the Merger, each share of common stock of Medeor was converted into the right to receive a pro rata share of Relmada's common stock based upon an exchange ratio.

As a result of this transaction, Medeor stockholders, which included Sergio Traversa, CEO of the Company, Cornell University, and several other persons, obtained equity ownership in the Company. As of December 31, 2013, Relmada issued 500,000 shares of common stock in exchange for all the outstanding stock of Medeor whose only asset was a research and development project. As a result of the transactions with Medeor, our CEO received 68,781 shares of common stock of Relmada.

### **Placement Agent**

On December 6, 2011, Relmada entered into an engagement agreement with the Placement Agent for its Series A preferred stock and notes offering (collectively the "Financings"), of which Mr. Seth, a director of the Company was the former Head of Healthcare Investment Banking. The agreement was amended April 12, 2012 and February 25, 2013. Pursuant to the agreement, the Placement Agent was engaged on an exclusive basis for the Financings and as a financial advisor for assisting Relmada with the restructuring of its capitalization and negotiating the conversion of its outstanding debt obligations to enable a successful financing (the "Notes Conversion"). In consideration for its services, the Placement Agent received (a) an activation fee of \$25,000 and a re-activation fee of \$15,000, (b) a cash fee equal to 7% of the Notes Conversion and 10% of the gross proceeds raised in the Financings, and (c) non-accountable expense reimbursement equal to 2% of the gross proceeds raised. In connection with the Series A preferred stock private placement, the Placement Agent or its designees also received seven-year warrants to purchase 250,000 shares of Relmada common stock at a price of \$4.00 per share. As a result of the Share Exchange, these warrants were exchanged for a five-year warrant to purchase 250,000 shares of the Company's common stock at a price of \$4.00 per share. In connection with the notes offering private placement, the Placement Agent or its designees also received seven-year warrants to purchase 281,250 shares of Relmada common stock at a price of \$4.00 per share. As a result of the Share Exchange, these warrants were exchanged for a seven-year warrant to purchase 28,125 shares of the Company's common stock at a price of \$4.00 per share.

On February 18, 2014, Relmada entered into an engagement agreement with the Placement Agent for Relmada's May 2014 Offering, of which Mr. Seth, a director of the Company was the former Head of Healthcare Investment Banking. We agreed to pay Placement Agent a cash commission in the amount of ten percent (10%) of the gross proceeds of the Offering received from investors at a Closing as well as a non-accountable expense reimbursement equal to two percent (2%) of the gross proceeds of the Offering received from investors at a Closing. The Placement Agent or its designees also received five-year warrants to purchase 501,703 shares of Relmada common stock at a price of \$7.50 per share. As a result of the Share Exchange, these warrants were exchanged for a five-year warrant to purchase 501,703 shares of the Company's common stock at a price of \$7.50 per share. The Placement Agent shall also be entitled to the compensation set forth above as well for any cash exercise of Warrants within six (6) months of the final closing of the Offering as well as a five percent (5%) solicitation fee for any Warrants exercised as a result of any redemption of any Warrants. If the Company elects to call the warrants, the Placement Agent shall receive a warrant solicitation fee equal to 5% of the funds solicited by the Placement Agent upon exercise of the

warrants.



On May 19, 2014, Camp Nine entered into an engagement agreement with the Placement Agent for Camp Nine’s May 2014 Offering, of which Mr. Seth, a director of the Company was the former Head of Healthcare Investment Banking. We agreed to pay Placement Agent a cash commission in the amount of ten percent (10%) of the gross proceeds of the Offering received from investors at a Closing as well as a non-accountable expense reimbursement equal to two percent (2%) of the gross proceeds of the Offering received from investors at a Closing. The Placement Agent or its designees also received five-year warrants to purchase 356,486 shares of Camp Nine common stock at a price of \$7.50 per share. The Placement Agent shall also be entitled to the compensation set forth above as well for any cash exercise of Warrants within six (6) months of the final closing of the Offering as well as a five percent (5%) solicitation fee for any Warrants exercised as a result of any redemption of any Warrants. If the Company elects to call the warrants, the Placement Agent shall receive a warrant solicitation fee equal to 5% of the funds solicited by the Placement Agent upon exercise of the warrants. The Placement Agent receives a financial advisory fee of \$25,000 that commenced at the last closing on June 10, 2014. The Company extended the financial advisory agreement until it expired in May 2015.

#### Advisory Firm

On October 17, 2012 the Company entered into an advisory agreement with Jamess Capital Group, LLC (formerly known as Amerasia Capital Group, LLC), a consulting firm affiliated with Mr. Seth, a Director of the Company (“Advisory Firm”) to provide non-investment banking services related to: a) recruiting key level personnel of the Company and negotiating their contracts; b) advising Relmada on prioritizing its product development programs per strategic objectives and assisting with qualifying and retaining key consultants to assist with product development activities for its key pipeline drugs levorphanol and D-Methadone and if required other products as well; c) assessing the state of Relmada’s financial records per US GAAP requirements, and; d) assisting with the selection and oversight of appropriate financial, accounting and auditing professionals to prepare the financial records and reporting of the Company to public company standards; and advising Relmada on the structure and composition of its Board of Directors in order to qualify for a public listing and assisting with the recruiting and contract negotiations for at least two Board Members. The Advisory Firm was due a monthly fee of \$12,500 and the agreement was terminated as of June 30, 2015. The Advisory firm earned fully vested warrants to purchase common 1,731,157 shares of stock at an exercise price of \$0.001 that expires in May 2021. The Advisory Firm was also eligible to be reimbursed upon the submission of proper documentation for ordinary and necessary out-of-pocket expenses not to exceed \$5,000 per month. Jamess Capital Group, LLC has not requested to be reimbursed for any expenses. This agreement was terminated effective June 30, 2015.

On August 4, 2015, the Company also entered into an Advisory and Consulting Agreement (the “Consulting Agreement”) with Sandesh Seth, the Company’s Chairman of the Board. The effective date of the Consulting Agreement is June 30, 2015. Mr. Seth has substantial experience in, among other matters, business development, corporate planning, corporate finance, strategic planning, investor relations and public relations, and an expansive network of connections spanning the biopharmaceutical industry, accounting, legal and corporate communications professions. Mr. Seth will provide advisory and consulting services to assist the Company with strategic advisory services, assist in prioritizing product development programs per strategic objectives, assist in recruiting of key personnel and directors, corporate planning, business development activities, corporate finance advice, and assist in investor and public relations services. In consideration for the services to be provided, the Company agrees to pay Mr. Seth \$12,500 per month.

#### ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

##### Audit Fees

The aggregate fees billed to us by our principal independent public accountant for services rendered during the year ended June 30, 2015, for the six months ended June 30, 2014 and for the year ended December 31, 2013, are set forth in the table below:

Fee Category	For the Year Ended June 30, 2015	For the Six Months Ended June 30, 2014	For the Year Ended December 31, 2013
Audit fees (1)	\$ 112,900	\$ 47,500	\$ 49,500
Audit-related fees (2)	-	-	-
Tax fees	-	-	-
All other fees (4)	-	-	-
<b>Total fees</b>	<b>\$ 112,900</b>	<b>\$ 47,500</b>	<b>\$ 49,500</b>

- (1) Audit fees consist of fees incurred for professional services rendered for the audit of consolidated financial statements, for reviews of our interim consolidated financial statements included in our quarterly reports on Forms 10-Q and for services that are normally provided in connection with statutory or regulatory filings or engagements. Includes professional services performed for filing of the Company’s registration statement on Form S-1 and for the Company’s equity offerings.

- (2) Audit-related fees consist of fees billed for professional services that are reasonably related to the performance of the audit or review of our consolidated financial statements, but are not reported under "Audit fees."
- (3) Tax fees consist of fees billed for professional services relating to tax compliance, tax planning, and tax advice.
- (4) All other fees consist of fees billed for all other services.

*Audit Committee's Pre-Approval Practice*

We currently do not have an audit committee. Our board of directors selected GBH CPAs, PC as our independent registered public accounting firm for purposes of auditing our financial statements for the year ended June 30, 2015, the six months ended June 30, 2014 and for the year ended December 31, 2013. In accordance with board of director's practice, GBH CPAs, PC services were pre-approved to perform these audit services for us prior to its engagement.

**PART IV**

**ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES**

**Financial Statement Schedules**

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

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

**RELMADA THERAPEUTICS, INC.**  
**Audited Financial Statements**

As of June 30, 2015 and June 30, 2014,  
for the year ended June 30, 2015, for the six months ended June 30, 2014 and for the year ended December 31, 2013

**RELMADA THERAPEUTICS, INC.**  
**(INDEX TO FINANCIAL STATEMENTS)**

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**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM  
ON INTERNAL CONTROL OVER FINANCIAL REPORTING**

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

We have audited Relmada Therapeutics, Inc.'s internal control over financial reporting as of June 30, 2015, based on criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Relmada Therapeutics, Inc.'s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying 10-K. Our responsibility is to express an opinion on Relmada Therapeutics Inc.'s internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed 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. A company's 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 the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. 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 of compliance with the policies or procedures may deteriorate.

In our opinion, Relmada Therapeutics, Inc. maintained, in all material respects, effective internal control over financial reporting as of June 30, 2015, based on criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Relmada Therapeutics, Inc. as of June 30, 2015 and 2014 and the related consolidated statements of operations, stockholders' equity (deficit), and cash flows for the year ended June 30, 2015, for the six months ended June 30, 2014, and for the year ended December 31, 2013, and our report dated September 11, 2015, expressed an unqualified opinion.

/s/ GBH CPAs, PC

GBH CPAs, PC  
[www.gbhcpas.com](http://www.gbhcpas.com)  
Houston, Texas  
September 11, 2015

**REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM  
ON CONSOLIDATED FINANCIAL STATEMENTS**

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

We have audited the accompanying consolidated balance sheets of Relmada Therapeutics, Inc. (the “Company”) as of June 30, 2015 and 2014 and the related consolidated statements of operations, stockholders’ equity (deficit), and cash flows for the year ended June 30, 2015, for the six months ended June 30, 2014 and for the year ended December 31, 2013. Relmada Therapeutics, Inc.’s management is responsible for these financial statements. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Relmada Therapeutics, Inc. as of June 30, 2015 and 2014 and the results of its operations and its cash flows for the year ended June 30, 2015, for the six months ended June 30, 2014 and for the year ended December 31, 2013 in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Relmada Therapeutics Inc.’s internal control over financial reporting as of June 30, 2015, based on criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated September 11, 2015 expressed an unqualified opinion.

/s/ GBH CPAs, PC

GBH CPAs, PC  
[www.gbhcpas.com](http://www.gbhcpas.com)  
Houston, Texas  
September 11, 2015

**Relmada Therapeutics, Inc.**  
**Consolidated Balance Sheets**

	<u>As of June 30, 2015</u>	<u>As of June 30, 2014</u>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 22,469,960	\$ 25,564,351
Prepaid expenses	1,497,911	178,158
Total current assets	<u>23,967,871</u>	<u>25,742,509</u>
Fixed assets, net of accumulated depreciation	23,911	9,841
Other assets	400,825	12,100
Total assets	<u>\$ 24,392,607</u>	<u>\$ 25,764,450</u>
<b>Liabilities and Stockholders' Equity (Deficit)</b>		
Current liabilities:		
Accounts payable	\$ 835,285	\$ 746,098
Accrued expenses	482,267	382,023
Note payable	263,752	58,357
Derivative liabilities	14,001,369	25,586,933
Total current liabilities	<u>15,582,673</u>	<u>26,773,411</u>
Long-term liability - accrued expense	-	100,000
Total liabilities	<u>15,582,673</u>	<u>26,873,411</u>
Commitments and contingencies		
Stockholders' equity (deficit):		
Preferred stock, \$0.001 par value, 200,000,000 shares authorized and no shares issued	-	-
Class A convertible preferred stock, \$0.001 par value, 3,500,000 shares authorized, 71,672 and 667,462 shares issued and outstanding, respectively	72	667
Common stock, \$0.001 par value, 100,000,000 shares authorized, 10,778,474 and 8,058,843 shares issued and outstanding, respectively	10,778	8,059
Additional paid-in capital	84,921,327	54,200,960
Accumulated deficit	(76,122,243)	(55,318,647)
Total stockholders' equity (deficit)	<u>8,809,934</u>	<u>(1,108,961)</u>
Total liabilities and stockholders' equity (deficit)	<u>\$ 24,392,607</u>	<u>\$ 25,764,450</u>

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

**Relmada Therapeutics, Inc.**  
**Consolidated Statements of Operations**

	<b>For the Year Ended June 30, 2015</b>	<b>For the Six Months Ended June 30, 2014</b>	<b>For the Year Ended December 31, 2013</b>
Operating expenses:			
Research and development	\$ (7,872,397)	\$ (839,959)	\$ (5,248,669)
General and administrative	(9,226,883)	(12,106,859)	(1,525,257)
Total operating expenses	<u>(17,099,280)</u>	<u>(12,946,818)</u>	<u>(6,773,926)</u>
Loss from operations	<u>(17,099,280)</u>	<u>(12,946,818)</u>	<u>(6,773,926)</u>
Other (expenses) income:			
Loss on change in fair value of derivative liabilities	(3,710,277)	(7,954,970)	(12,877,675)
Interest income	10,883	1,411	-
Interest expense	(4,922)	(435,611)	(220,307)
Total other expenses	<u>(3,704,316)</u>	<u>(8,389,170)</u>	<u>(13,097,982)</u>
Net loss	<u>\$ (20,803,596)</u>	<u>\$ (21,335,988)</u>	<u>\$ (19,871,908)</u>
Net loss per common share - basic and diluted	<u>\$ (2.09)</u>	<u>\$ (8.65)</u>	<u>\$ (40.90)</u>
Weighted average number of common shares outstanding - basic and diluted	<u>9,941,156</u>	<u>2,466,466</u>	<u>485,853</u>

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



**Relmada Therapeutics, Inc.**  
**Consolidated Statements of Stockholders' Equity (Deficit)**  
**For the Period from December 31, 2012 to June 30, 2015**

	Series A Preferred Stock		Class A Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total
	Shares	Par Value	Shares	Par Value	Shares	Par Value			
Balance - December 31, 2012	1,700,701	\$ 1,701	-	-	480,477	\$ 481	\$ 10,397,250	\$ (14,110,751)	\$ (3,711,319)
Issuance of Series A preferred stock and warrants for cash net of offering costs	1,020,125	1,020	-	-	-	-	1,483,690	-	1,484,710
Issuance of common stock to acquire Medeor, Inc. at fair value	-	-	-	-	500,000	500	3,749,500	-	3,750,000
Issuance of common stock for fair value of services	-	-	-	-	11,279	11	16,907	-	16,918
Stock-based compensation expense	-	-	-	-	-	-	382,343	-	382,343
Net loss	-	-	-	-	-	-	-	(19,871,908)	(19,871,908)
Balance - December 31, 2013	<u>2,720,826</u>	<u>\$ 2,721</u>	<u>-</u>	<u>\$ -</u>	<u>991,756</u>	<u>\$ 992</u>	<u>\$ 16,029,690</u>	<u>\$ (33,982,659)</u>	<u>\$ (17,949,256)</u>

**Relmada Therapeutics, Inc.**  
**Consolidated Statements of Stockholders' Equity (Deficit)**  
**For the Period from December 31, 2012 to June 30, 2015**

	Series A Preferred Stock		Class A Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total
	Shares	Par Value	Shares	Par Value	Shares	Par Value			
Issuance of common stock, Series A warrants and Series B warrants for cash, net of offering costs	-	-	-	-	3,432,760	\$ 3,433	\$ 22,225,888	-	\$ 22,229,321
Issuance of common stock for services	-	-	-	-	5,810	6	8,708	-	8,714
Stock-based compensation expense	-	-	-	-	-	-	10,319,137	-	10,319,137
Fair value of warrant derivative liabilities issued in units offering	-	-	-	-	-	-	(4,333,163)	-	(4,333,163)
Reclassification of derivative liabilities to additional paid-in capital upon Share Exchange	-	-	-	-	-	-	6,804,625	-	6,804,625
Conversion of Series A preferred stock, notes payable and accrued interest to common stock	(2,720,826)	\$ (2,721)	-	-	2,961,055	2,961	960,682	-	960,922
Issuance of common stock and Class A preferred stock in connection with share exchange	-	-	667,462	\$ 667	667,462	667	1,998,666	-	2,000,000
Beneficial conversion feature	-	-	-	-	-	-	186,727	-	186,727
Net loss	-	-	-	-	-	-	-	(21,335,988)	(21,335,988)
Balance - June 30, 2014	-	\$ -	667,462	\$ 667	8,058,843	\$ 8,059	\$ 54,200,960	\$ (55,318,647)	\$ (1,108,961)

**Relmada Therapeutics, Inc.**  
**Consolidated Statement of Stockholders' Equity (Deficit)**  
**For the Period from December 31, 2012 to June 30, 2015**

	Series A Preferred Stock		Class A Convertible Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total
	Shares	Par Value	Shares	Par Value	Shares	Par Value			
Issuance of common stock for services	-	-	-	-	83,333	\$ 84	\$ 1,180,326	-	\$ 1,180,410
Issuance of common stock in connection with A warrant exercises	-	-	-	-	2,033,915	2,034	13,421,804	-	13,423,838
Stock-based compensation expense	-	-	-	-	-	-	796,952	-	796,952
Reclassification of derivative liabilities to additional paid-in capital for warrant exercises	-	-	-	-	-	-	15,295,841	-	15,295,841
Issuance of common stock resulting from warrant exercises from consultants and Series A preferred stock warrant holder	-	-	-	-	6,362	6	25,444	-	25,450
Conversion of Class A preferred stock to common stock	-	-	(595,790)	(595)	595,790	595	-	-	-
Fractional shares issued	-	-	-	-	231	-	-	-	-
Net loss	-	-	-	-	-	-	-	(20,803,596)	(20,803,596)
Balance - June 30, 2015	-	\$ -	71,672	\$ 72	10,778,474	\$ 10,778	\$ 84,921,327	\$ (76,122,243)	\$ 8,809,934

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

**Relmada Therapeutics, Inc.**  
**Consolidated Statements of Cash Flows**

	<b>For the Year Ended June 30, 2015</b>	<b>For the Six Months, June 30 Ended 2014</b>	<b>For the Year Ended December 31, 2013</b>
<b>Cash flows from operating activities</b>			
<b>Net loss</b>	\$ (20,803,596)	\$ (21,335,988)	\$ (19,871,908)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation expense	9,256	2,330	373
Common stock issued for services	1,180,410	8,714	3,766,918
Stock-based compensation	796,952	10,319,137	382,343
Amortization of debt discount	-	327,776	118,639
Amortization of deferred financing costs	-	78,724	69,546
Loss on change in fair value of derivative liabilities	3,710,277	7,954,970	12,877,675
Changes in operating assets and liabilities:			
Prepaid expenses and other assets	(1,209,458)	(89,983)	160,283
Accounts payable	89,187	565,779	(57,102)
Accrued expenses	244	4,287	315,704
<b>Net cash used in operating activities</b>	<u>(16,226,728)</u>	<u>(2,164,254)</u>	<u>(2,237,529)</u>
<b>Cash flows from investing activities</b>			
Purchase of fixed assets	(23,326)	(3,673)	(8,871)
<b>Net cash used in investing activities</b>	<u>(23,326)</u>	<u>(3,673)</u>	<u>(8,871)</u>
<b>Cash flows from financing activities</b>			
Proceeds from sale of Series A preferred stock and warrants	-	-	3,494,428
Proceeds from sale of common stock and warrants, net of fees	-	22,229,321	-
Proceeds from sale of common and Class A Series A preferred stock, pursuant to Share Exchange	-	2,000,000	-
Proceeds from exercise of A warrants, net of fees	13,423,838	-	-
Proceeds from warrant exercises from consultants and Series A preferred stock warrant holder	25,450	-	-
Payment of notes payable	(293,625)	(19,493)	-
Proceeds from subordinated promissory notes payable, net of financing costs	-	-	501,600
<b>Net cash provided by financing activities</b>	<u>13,155,663</u>	<u>24,209,828</u>	<u>3,996,028</u>
<b>Net (decrease) increase in cash</b>	(3,094,391)	22,041,901	1,749,628
<b>Cash at beginning of the period</b>	<u>25,564,351</u>	<u>3,522,450</u>	<u>1,772,822</u>
<b>Cash at end of the period</b>	<u>\$ 22,469,960</u>	<u>\$ 25,564,351</u>	<u>\$ 3,522,450</u>

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

**Relmada Therapeutics, Inc.**  
**Consolidated Statements of Cash Flows**

	<b>For the Year Ended June 30, 2015</b>	<b>For the Six Months Ended June 30, 2014</b>	<b>For the Year Ended December 31, 2013</b>
Supplemental disclosure of cash flow information:			
Cash paid during the period for:			
Income taxes	\$ -	\$ -	\$ -
Interest	\$ 4,922	\$ 1,103	\$ -
Non-cash investing and financing transactions:			
Conversion of Series A preferred stock and subordinated notes to common stock	\$ -	900,000	-
Conversion of accrued interest to common stock	\$ -	60,922	-
Note payable issued in connection with director and officer insurance policies	\$ 557,377	77,850	-
Cancellation of note payable in connection with director and officer insurance policy	\$ 55,220	-	-
Reclassification of derivative liabilities to additional paid-in capital for warrant exercises	\$ 15,295,841	-	-
Fair value of derivative reclassified to additional paid-in-capital in connection with Share Exchange	\$ -	6,804,625	-
Conversion of Class A preferred stock to common stock	\$ 595	-	-
Fair value of derivative warrants issued with units offering	\$ -	4,333,163	-
Beneficial conversion feature	\$ -	186,727	-
Fair value of derivatives issued in connection with issuance of preferred stock	\$ -	\$ -	\$ 1,761,063
Fair value of derivative warrants issued to lenders in connection with issuance of subordinated promissory notes	\$ -	\$ -	\$ 83,363
Fair value of warrants issued in connection with deferred financing costs	\$ -	\$ -	\$ 41,681
Fair value of derivative warrants issued for offering costs in connection with the issuance of Series A preferred stock	\$ -	\$ -	\$ 248,655

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

**Relmada Therapeutics, Inc.**  
**Notes to Consolidated Financial Statements**

**NOTE 1 - BUSINESS**

Relmada Therapeutics, Inc. (“Relmada” or the “Company”) (a Nevada corporation), is a clinical-stage, publicly traded biopharmaceutical company developing novel versions of proven drug products together with new molecules that potentially address areas of high unmet medical need in the treatment of pain. The Company has a diversified portfolio of four lead products at various stages of development including LevoCap ER, its abuse resistant, sustained release dosage form of the opioid analgesic levorphanol; d-Methadone, its N-methyl-D-aspartate (“NMDA”) receptor antagonist for neuropathic pain; BuTab, its oral dosage form of the opioid analgesic buprenorphine; and MepiGel, its orphan drug designated topical formulation of the local anesthetic mepivacaine.

Relmada Therapeutics, Inc. (“RTI”) which was previously a private company commenced operations in May 2004. In May 2014, RTI completed a Share Exchange with Camp Nine, Inc., a publicly traded Nevada corporation that was formed in May 2012. In July 2014, we changed the name of Camp Nine, Inc. to Relmada Therapeutics, Inc. At the Share Exchange, RTI shareholders exchanged 10 shares of RTI common stock for one share of our common stock. As a result of the Share Exchange, RTI’s shareholders acquired the majority of the Company’s issued and outstanding capital stock and RTI became the Company’s subsidiary.

The Share Exchange was accounted for as a “reverse merger” rather than a business combination, wherein Relmada is considered the acquirer for accounting and financial reporting purposes. The statement of operations reflects the activities of RTI from the commencement of its operations since inception. Unless the context suggests otherwise, when we refer in this Report to business and financial information for periods prior to the consummation of the Share Exchange, we are referring to the business and financial information of RTI.

During the six months ended June 30, 2014, we changed our year end to June 30 and increased its authorized common stock to 500,000,000 shares and its authorized preferred stock to 200,000,000 shares of which 3,500,000 was designated for Class A preferred stock. On August 12, 2015, the Company completed a one-for-five reverse stock reducing the authorized common share to 100,000,000 common shares. The consolidated financial statements reflects a retroactive adjustment for the reverse stock split.

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 FDA and other governmental regulations and approval requirements.

**NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

**Principles of Consolidation**

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.

**Use of Estimates**

The preparation of financial statements in conformity with accounting principles generally accepted in the United States (“U.S. GAAP”) requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses for the reporting period. Actual results could differ from those estimates. The significant estimates are the valuation of derivative liabilities, stock-based compensation expenses and income taxes and its associated valuation allowance.

**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 at these institutions exceed federally insured limits.

**Patents**

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

**Relmada Therapeutics, Inc.**  
**Notes to Consolidated Financial Statements**

**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 related assets, which is three years.

**Derivatives**

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

**Fair Value of Financial Instruments**

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

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

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

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

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

**Fair Value on a Recurring Basis**

As required by Accounting Standard Codification ("ASC") Topic No. 820 - 10 *Fair Value Measurement*, financial assets and liabilities are classified based on the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the fair value measurement requires judgment, and may affect the valuation of the fair value of assets and liabilities and their placement within the fair value hierarchy levels. The estimated fair value of the derivative instruments included in the B warrants that have a down-round protection provision was calculated with the Black-Scholes Option pricing model.

The following table sets forth, by level within the fair value hierarchy, the Company's financial liabilities that were accounted for at fair value on a recurring basis as of June 30, 2015:

Description	Quoted Prices In Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total Carrying Value as of June 30, 2015
Derivative liabilities - warrant instruments	\$ -	\$ -	\$ 14,001,369	\$ 14,001,369

**Relmada Therapeutics, Inc.**  
**Notes to Consolidated Financial Statements**

The following table sets forth, by level within the fair value hierarchy, the Company's financial liabilities that were accounted for at fair value on a recurring basis as of June 30, 2014:

Description	Quoted Prices In Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total Carrying Value as of June 30, 2014
Derivative liabilities - warrant instruments	\$ -	\$ -	\$ 25,586,933	\$ 25,586,933

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:

	Significant Unobservable Inputs (Level 3)		
	Year Ended June 30, 2015	Six Months Ended June 30, 2014	Year Ended December 31, 2013
Beginning balance	\$ 25,586,933	\$ 20,103,425	\$ 5,090,988
Change in fair value of derivative liabilities included in net loss for the year ended June 30, 2015, for the six months ended June 30, 2014, and for the year ended December 31, 2013, respectively	3,710,277	7,954,970	12,877,675
Additions - warrant instruments	-	4,333,163	373,699
Transfer of warrant instruments to additional paid-in-capital	(15,295,841)	(6,804,625)	-
Additions - conversion feature of Series A preferred stock	-	-	1,761,063
Ending balance	<u>\$ 14,001,369</u>	<u>\$ 25,586,933</u>	<u>\$ 20,103,425</u>

**Income Taxes**

The Company accounts for income taxes using the asset and liability method. Accordingly, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between financial statement carrying amounts of existing assets and liabilities and their respective tax bases. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in the tax rate is recognized in income or expense in the period that the change is effective. Tax benefits are recognized when it is probable that the deduction will be sustained. A valuation allowance is established when it is more likely than not that all or a portion of a deferred tax asset will either expire before the Company is able to realize the benefit, or that future deductibility is uncertain. At June 30, 2015 and 2014, the Company had recorded a valuation allowance to the full extent of the Company's net deferred tax assets since the likelihood of realization of the benefit does not meet the more likely than not threshold.

The Company files a U.S. Federal income tax return and various state returns. Uncertain tax positions taken on our tax returns will be accounted for as liabilities for unrecognized tax benefits. The Company will recognize interest and penalties, if any, related to unrecognized tax benefits in general and administrative expenses in the statements of operations. There were no liabilities recorded for uncertain tax positions at June 30, 2015 and 2014. The open tax years, subject to potential examination by the applicable taxing authority, for the Company are from 2012 through 2014.

**Research and Development**

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



**Relmada Therapeutics, Inc.**  
**Notes to Consolidated Financial Statements**

**Stock-Based Compensation**

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

**Net Loss per Common Share**

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

Potentially dilutive securities are not included in the calculation of diluted net loss per share attributable to common stockholders because to do so would be anti-dilutive as follows (in common stock equivalent shares):

	Year Ended June 30, 2015	Six Months Ended June 30, 2014	Year Ended December 31, 2013
Class A convertible preferred stock	71,672	667,462	-
Series A preferred stock	-	-	2,720,826
Common stock warrants	5,362,183	8,628,911	1,785,303
Restricted stock awards	94,000	-	-
Common stock options	777,630	673,034	373,082
Total	<u>6,305,485</u>	<u>9,969,407</u>	<u>4,879,211</u>

**Recent Accounting Pronouncements**

In June 2014, the Financial Accounting Standards Board issued Accounting Standards Update ("ASU") 2014-12, Compensation—Stock Compensation. The amendments in this update apply to reporting entities that grant their employees stock-based payments in which the terms of the award provide that a performance target can be achieved after the requisite service period. The amendments in this Update are effective for annual periods and interim periods within those annual periods beginning after December 15, 2015, and early adoption is permitted. The Company is currently evaluating the effects of ASU 2014-12 on the consolidated financial statements.

In August 2014, the Financial Accounting Standards Board issued Accounting Standards Update 2014-15, Presentation of Financial Statements- Going Concern. The Update provides U.S. GAAP guidance on management's responsibility in evaluating whether there is substantial doubt about a company's ability to continue as a going concern and about related footnote disclosures. For each reporting period, management will be required to evaluate whether there are conditions or events that raise substantial doubt about a company's ability to continue as a going concern within one year from the date the financial statements are issued. The amendments in this update are effective for the annual period ending after December 15, 2016, and for annual periods and interim periods thereafter. The Company is currently evaluating the effects of ASU 2014-15 on the consolidated financial statements.

The Company does not expect that any recently issued accounting pronouncements will have a significant impact on the results of consolidated operations, consolidated financial position, or consolidated cash flows of the Company.

**Subsequent Events**

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

**Relmada Therapeutics, Inc.**  
**Notes to Consolidated Financial Statements**

**NOTE 3 – PREPAID EXPENSES**

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

	June 30, 2015	June 30, 2014
Rent	\$ 450,700	\$ 11,400
Research and development	565,100	-
Insurance	337,100	77,600
Taxes	82,000	-
Other	63,000	89,200
Total	<u>\$ 1,497,900</u>	<u>\$ 178,200</u>

**NOTE 4 - NOTES PAYABLE**

In May 2014, the Company entered into a note for approximately \$77,850 to finance its director and officer insurance policy. At June 30, 2014, the Company owed approximately \$58,400 in connection with this note payable and the interest rate was 3.4% per annum. This policy was cancelled and replaced in July 2014, whereby the Company financed another director and officer insurance policy and entered into a note for approximately \$293,200. This note was fully paid during the year and it had an interest rate of 3.0% per annum. In June 2015, the Company entered into a note for approximately \$263,800 and renewed its director and officer insurance policy. The interest rate is 2.8% per annum. At June 30, 2015, the note payable balance outstanding was approximately \$263,800.

**NOTE 5 - 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. As the conversion features within the Series A preferred stock, and certain detachable warrants issued in connection with the subordinated promissory notes payable and equity offerings from 2012 to 2014, do not have fixed settlement provisions because their conversion and exercise prices may be lowered if the Company issues securities at lower prices in the future, the Company concluded that the instruments are not indexed to the Company's stock and are to be treated as derivative liabilities. Upon the reverse merger in May 2014, the Series A preferred stock, subordinated promissory notes including accrued interest were converted to common stock. The fair market value of the warrants at the time of the reverse merger was transferred to additional paid-in capital and the derivative liabilities were reduced to zero. At June 30, 2015 and 2014, the Company had warrants resulting from equity offerings in May 2014 and June 2014 that do not have fixed settlement provisions because their conversion and exercise prices may be lowered if the Company issues securities at lower prices in the future, the Company concluded that the instruments are not indexed to the Company's stock and are to be treated as derivative liabilities. In determining the fair value of the derivative liabilities, the Company used the Black-Scholes option pricing model at June 30, 2015 and 2014.

The following is a summary of the assumptions used in the valuation model at June 30, 2015 and 2014:

	June 30, 2015	June 30, 2014
Common stock issuable upon exercise of warrants	2,574,570	6,007,330
Market value of common stock on measurement date (1)	\$ 10.15	\$ 10.00
Exercise price	\$ 7.50 and 11.25	\$ 7.50 and 11.25
Risk free interest rate (2)	1.6%	1.6%
Expected life in years	3.9	0.3 and 4.9
Expected volatility (3)	70%	71% and 73%
Expected dividend yields (4)	None	None

- (1) Quoted market value of the common stock, reflects a one-for-five reverse stock split.
- (2) The risk-free interest rate was determined by management using the applicable Treasury Bill interest rate as of the measurement date, when applicable.
- (3) The historical trading volatility was determined by calculating the volatility of the Company's peer group.
- (4) The Company does not expect to pay a dividend in the foreseeable future.

**Relmada Therapeutics, Inc.**  
**Notes to Consolidated Financial Statements**

During the year ended June 30, 2015, 2,033,915 A warrants were exercised and 1,398,845 A warrants expired, see Note 2, Fair Value on a Recurring Basis. The following were the summary of the assumptions at the transactions dates for the warrant exercises during the year ended June 30, 2015.

Common stock issuable upon exercise of warrants	2,033,915
Market value of common stock on measurement date	\$ 15.00
Exercise price	\$ 7.50
Risk free interest rate	0.02%
Expected life in years	0.0
Expected volatility	71.2%
Expected dividend yields	None

The following table sets forth, by level within the fair value hierarchy, the Company's derivative liabilities that were accounted for at fair value on a recurring basis as of June 30, 2015:

	Balance at June 30, 2014	Initial valuation of derivative liabilities upon issuance of new warrants during the period	Increase (decrease) in fair value of derivative liabilities	Fair value of derivatives upon reclass to additional paid-in- capital	Balance at June 30, 2015
Series A warrants issued in May and June 2014 offering	\$ 10,040,822	\$ -	\$ 5,255,019	\$ (15,295,841)	\$ -
Series B warrants issued in connection with May and June 2014 offering	9,894,930	-	(1,124,230)	-	8,770,700
Placement Agent warrants issued in connection with May and June 2014 offering	5,651,181	-	(420,512)	-	5,230,669
<b>Total</b>	<b>\$ 25,586,933</b>	<b>\$ -</b>	<b>\$ (3,710,277)</b>	<b>\$ (15,295,841)</b>	<b>\$ 14,001,369</b>

The following table sets forth, by level within the fair value hierarchy, the Company's derivative liabilities that were accounted for at fair value on a recurring basis as June 30, 2014:

	Balance at December 31, 2013	Initial valuation of derivative liabilities upon issuance of new warrants during the period	Increase (decrease) in fair value of derivative liabilities	Fair value of derivatives upon reclass to additional paid-in- capital	Balance at June 30, 2014
Convertible preferred derivative liability issued in connection with Series A preferred stock offering	\$ 11,762,115	\$ -	\$ (7,214,804)	\$ (4,547,311)	\$ -
Convertible preferred derivative liability issued to Wonpung for services	2,030,589	-	(1,370,262)	(660,327)	-
Convertible preferred derivative liability issued to lenders in connection with exchange of debt for Series A preferred stock	2,219,854	-	(1,262,858)	(956,996)	-
Warrants issued in connection with Series A preferred stock offering	2,424,167	-	(1,945,669)	(478,498)	-
Warrants issued as offering costs to placement agent	1,217,083	-	(1,109,421)	(107,662)	-
Warrants issued to lenders in connection with subordinated promissory notes offering	313,258	-	(259,427)	(53,831)	-
Warrants issued to placement agent in connection with subordinated promissory notes offering	136,359	-	(136,359)	-	-
A warrants issued in May and June 2014 offering	-	842,370	9,198,452	-	10,040,822
B warrants issued in connection with May and June 2014 offering	-	2,494,655	7,400,275	-	9,894,930
Placement Agent warrants issued in connection with May and June 2014 offering	-	996,138	4,655,043	-	5,651,181
<b>Total</b>	<b>\$ 20,103,425</b>	<b>\$ 4,333,163</b>	<b>\$ 7,954,970</b>	<b>\$ (6,804,625)</b>	<b>\$ 25,586,933</b>



**Relmada Therapeutics, Inc.**  
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The following table sets forth, by level within the fair value hierarchy, the Company's derivative liabilities that were accounted for at fair value on a recurring basis as of December 31, 2013:

	Balance at December 31, 2012	Initial valuation of derivative liabilities upon issuance of new warrants during the period	Increase in fair value of derivative liabilities	Balance at December 31, 2013
Convertible preferred derivative liability issued in connection with Series A preferred stock offering	\$ 2,492,166	\$ 1,647,910	\$ 7,622,039	\$ 11,762,115
Convertible preferred derivative liability issued to Wopung for services	880,214	-	1,150,375	2,030,589
Convertible preferred derivative liability issued to lenders in connection with exchange of debt for Series A preferred stock	958,861	-	1,260,993	2,219,854
Warrants issued in connection with Series A preferred stock offering	475,000	113,153	1,836,014	2,424,167
Warrants issued as offering costs to placement agent	242,500	248,655	725,928	1,217,083
Warrants issued to lenders in connection with subordinated promissory notes offering	29,158	83,363	200,737	313,258
Warrants issued to placement agent in connection with subordinated promissory notes offering	13,089	41,681	81,589	136,359
<b>Total</b>	<u>\$ 5,090,988</u>	<u>\$ 2,134,762</u>	<u>\$ 12,877,675</u>	<u>\$ 20,103,425</u>

**NOTE 6 - STOCKHOLDERS' EQUITY**

**Series A Preferred Stock**

During 2013, in a series of closings, the Company issued investors 1,020,125 shares of Series A preferred stock and 255,031 warrants to purchase shares of common stock at an exercise price of \$4.00 per share with an expiration date of seven years, for gross proceeds of approximately \$4,080,500 (\$3,494,428 net of offering costs). In addition, the Company issued the placement agent 127,516 warrants to purchase common stock with an exercise price of \$4.00 per share. Both the warrants and the Series A preferred stock contained anti-dilution features deemed to be derivatives, see Note 5.

The table below reflects the gross proceeds received in connection with the 2013 offerings allocated to components of stockholders' equity (deficit) and to derivative liabilities based upon fair value:

Par value of Series A preferred stock issued	\$ 1,020
Additional paid-in-capital	1,483,690
Derivative warrant liabilities	113,153
Derivative preferred stock conversion feature	1,647,910
Derivative warrants issued to placement agent as offering costs	248,655
Offering costs paid-in cash	586,072
<b>Total</b>	<u>\$ 4,080,500</u>

Each share of Series A preferred stock automatically converted into common stock on a one-for-one basis upon the Share Exchange. There were 2,720,826 shares that were converted to common stock in May 2014. In addition, the conversion price was subject to adjustment upon a future down round if any future stock offerings are issued below \$4.00 per share. This anti-dilution feature for the Series A preferred stock and for the warrants, made these instruments a derivative liability. The anti-dilution feature was terminated upon the Share Exchange and the corresponding derivative liabilities were transferred to additional paid-in capital.

**Class A Convertible Preferred Stock ("Class A Stock")**

On May 20, 2014, the Company's subsidiary completed a Share Exchange with the Company, whereby the Company acquired 94.6% of the issued and outstanding capital stock of the subsidiary's stockholders in exchange ("Share Exchange") for the issuance of 5,658,215 shares of common stock to the Company's stockholders, which represented 80.9% of Relmada's issued and outstanding common stock after the consummation of the Share Exchange. In addition, the outstanding options and warrants were exchanged for options and warrants to purchase shares of common stock of the Company at a ratio of 10 to 1. Prior to the Share Exchange, the Company had no other assets or liabilities. The principal shareholders of the Company contributed \$2 million in cash for 667,462 shares of the Company's common stock and 667,462 shares of Class A Stock.

**Relmada Therapeutics, Inc.**  
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The Class A Stock has dividend rights to two times the amount of any dividend granted by the Board of Directors of the Company to the holders of common stock. In the event of any dissolution, liquidation or winding up of the Company, whether voluntary or involuntary, the holders of Class A Stock shall be entitled to participate in any distribution out of the assets of the Corporation on an equal basis per share with the holders of the Company's common stock. The holders of Class A Stock shall have no right to vote on any matter submitted to a vote of the holders of the Company's common stock, including the election of directors.

The Class A Stock is automatically converted on a monthly basis into common stock on a one-for-one basis by action of the Corporation, in the event the total of all shares of common stock and Class A Stock held by the shareholder do not exceed 9.9% of the issued and outstanding shares of common stock of the Company. In no event can Class A Stock be converted into common stock of the Corporation if such conversion would cause the holder to own, beneficially or otherwise, more than 9.9% of the Company's stock. During the year ended June 30, 2015, 595,790 Class A Stock were converted to common stock.

**Common Stock**

Common stock issued in merger

During 2012, an executive was granted 30,760 shares of common stock. The grant date fair value of the common stock was \$1.50 per share (based on a third party valuation), or approximately \$46,100 in total. The vesting schedule provided that approximately 13,670 shares vested on July 10, 2012, 11,278 shares vested on July 10, 2013 and 5,812 shares vested on January 10, 2014. As a result, the Company recorded stock-based compensation expense of approximately \$8,700 and \$16,900 for the six months ended June 30, 2014 and for the year ended December 31, 2013, respectively, in connection with this agreement.

Common stock issued for cash

On May 12, May 15 and June 10, 2014, the Company completed a private placement for the sale of units for gross proceeds of approximately \$25,745,700. The units consisted of 3,432,760 shares of the Company's common stock, A warrants to purchase 3,432,760 shares of common stock at an exercise price of \$7.50 per share and B warrants to purchase 1,716,379 shares of common stock, at a exercise price of \$11.25 per share. The A warrants were exercisable through October 10, 2014 and the B warrants are exercisable immediately up to a period of five years from the date of issuance. The Company may call the B warrants for redemption upon written notice to all investors of the May and June 2014 units ("investors") at any time if the closing price of the common stock exceeds \$18.75 per share for twenty consecutive trading days provided that there is an effective registration statement. Sixty business days following the date the redemption notice ("Exercise Period") is sent to the investors, each may choose to exercise their B warrants or a portion of their B warrants, by paying the exercise price of \$11.25 per share. Any warrants not exercised on the last day of the Exercise Period, will be redeemed by the Company at \$0.001 per share. The Placement Agent shall receive a warrant solicitation fee equal to five % of the aggregate exercise price paid by the B warrant holders upon such exercise, following a call for redemption by the Company. The Company shall direct the B warrant holder to make such solicitation fee payment directly to the Placement Agent and the B warrant holder shall comply with such direction. The Company issued warrants to purchase 858,190 shares of common stock at \$7.50 to its Placement Agent ("Agent Warrants"). The Agent Warrants are immediately exercisable and expire five years from the date of issuance. The Company paid approximately \$3,516,000 including expenses to the Placement Agent and the net proceeds were approximately \$22,229,300. All the warrants in this transaction have an anti-dilution provision and shall terminate upon an up-listing of the Company to a national securities exchange such as NYSE or NASDAQ. A registration rights agreement was entered into in connection with the private placement that required the Company to file a registration statement for the resale of shares of common stock and common stock issuable upon the exercise of the A warrants and B warrants. The Company was required to use commercially reasonable efforts to have the registration statement declared effective within 45 days from the filing date. If the SEC reviewed the registration statement, the Company had 180 days to have the registration statement declared effective. If the registration statement was not filed on time or declared effective within the pre-requisite time frame, the penalty was one percent of the purchase price with a maximum penalty of six percent (6%). The Securities and Exchange Commission declared the registration effective on December 30, 2014.

**Relmada Therapeutics, Inc.**  
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The table below reflects the gross proceeds received in connection with the May and June 2014 offerings allocated to components of stockholders' equity (deficit) and to derivative liabilities based upon fair value:

Par value of common stock issued	\$ 3,433
Additional paid-in-capital	17,892,725
Derivative warrant liabilities	3,337,025
Derivative warrants issued to placement agent as offering costs	996,138
Net proceeds	22,229,321
Offering costs paid-in cash	3,516,378
Gross proceeds	<u>\$ 25,745,699</u>

Common stock issued for services

For the year ended June 30, 2015, the Company issued 83,333 shares of common stock for consulting services that had a fair market of approximately \$1,180,400 which was based upon the stock price at each issuance date. The Company recorded the stock-based compensation expense value to general and administrative expense.

The Company is obligated to issue 16,667 shares of common stock divided equally over two quarterly installments commencing in September 2015 for consulting services. The Company will record these share issuances at the applicable fair value of the common stock on the date of issuance.

Common stock issued in connection with exercise of warrants

During the year ended June 30, 2015, shareholders from the May and June 2014 equity offerings exercised Series A warrants to purchase 2,033,915 shares of common stock at an exercise price of \$7.50 per share that resulted in net proceeds of approximately \$13,423,800 to the Company, net of approximately \$1,830,500 of offering costs.

During the year ended June 30, 2015, three consultants exercised their warrants and also a Series A preferred warrant holder exercised warrants aggregating 6,512 shares of common stock. The Company received approximately \$25,500.

**Options and warrants**

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 allows for the granting of 1,611,769 options or stock awards. In August 2015, the board approved an amendment to the Plan. Among other things, the Plan Amendment updates the definition of "change of control" and provides for accelerated vesting of all awards granted under the plan in the event of a change of control of the Company. At June 30, 2015, no stock appreciation rights have been issued. Stock options are exercisable generally for a period of 10 years from the date of grant and generally vest over four years. As of June 30, 2015, 740,138 shares were available for future grants under the Plan.

The Company utilizes the Black-Scholes option pricing model to estimate the fair value of stock options and warrants. The price of common stock prior to the Company being public was determined from a third party valuation. The risk-free interest rate assumptions were based upon the observed interest rates appropriate for the expected term of the equity instruments. The expected dividend yield was assumed to be zero as the Company has not paid any dividends since its inception and does not anticipate paying dividends in the foreseeable future. The expected volatility was based upon its peer group. The Company routinely reviews its calculation of volatility changes in future volatility, the Company's life cycle, its peer group, and other factors.

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. The Company uses the contractual term for non-employee options to estimate the expected term, for share-based compensation in its option-pricing model.

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**Stock-based compensation - options**

The Company granted an officer options to purchase 133,150 shares of its common stock in September 2013. The option has a ten-year term and an exercise price of \$4.00 per share. 25% of each of the options vest immediately and the remaining 75% of the options vest in equal quarterly increments over a four-year period. The fair value of the option at the grant date was \$2.70 per share using the Black-Scholes Option pricing model.

During December 2013 and February 2014, the Company granted two officers options to purchase 66,840 and 200,755 (150,566, were forfeited as of June 30, 2015) shares of common stock, respectively. The options have a 10 year term and an exercise price of \$4.00 and \$7.50 per share, respectively. 25% of the options vest on the one year anniversary of the grant date and the remaining options vest quarterly over the following 3 years. The fair value of the options at the grant date during December 2013 and January 2014 was \$2.71 per share and \$4.65 per share, respectively. During November 2013, the Company an employee options to purchase 37,500 shares of common stock. The options have a 10 year term and an exercise price of \$4.00. 25% of the options vest on the one year anniversary of the grant date and the remaining options vest in equal quarterly increments over the following 3 years. The fair value of the options on the grant date was \$3.13 per share using the Black-Scholes Option pricing model.

During February 2014, the Company granted to three directors, an aggregate of options to purchase 29,197 shares of common stock. Each option has a ten year term and an exercise price of \$7.50 per share, respectively. 25% of the options vest on the one year anniversary of the grant date and the remaining options vest quarterly over the following 3 years. The fair value of the options at the grant date was approximately \$4.55 per share using the Black-Scholes Option pricing model.

During May 2014, the Company granted various employees options to purchase 70,000 shares of common stock, respectively. Each option has a 10 year term and an exercise price of \$7.50 per share, respectively. 25% of the options vest on the one year anniversary of the grant date and the remaining options vest quarterly over the following 3 years. The fair value of the options on the grant date ranges were \$3.58 per share using the Black-Scholes Option pricing model.

During the year ended June 30, 2015, the Company granted to its current officers options to purchase 55,000 shares of common stock. Each option has a ten year term and an exercise price of \$13.50 per share. 6.25% of the options vest each quarter over the following four years. The fair value of the options at the grant date was \$9.08 per share using the Black-Scholes Option pricing model.

During the year ended June 30, 2015, the Company granted various employees options to purchase 256,100 shares of common stock. Each option has a ten year term and has an exercise price ranging from \$8.60 to \$13.50 per share. A total of 135,400 options vest as follows: 25% on the one year anniversary of the grant date and the remaining options vest quarterly over the following 3 years. The remaining 120,700 options vest at a rate of 6.25% each quarter over 4 years. The fair value of the options on the grant date ranges from \$3.59 to \$9.96 per share using the Black-Scholes Option pricing model.

A summary of the changes in options outstanding for the period from December 31, 2012 to June 30, 2015 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 December 31, 2012	135,592	\$ 4.00	9.5	\$ -
Granted	237,490	\$ 4.00		
Outstanding and expected to vest at December 31, 2013	373,082	\$ 4.00	8.8	\$ 1,305,000
Granted	299,952	\$ 7.50		
Outstanding and expected to vest at June 30, 2014	673,034	\$ 5.56	9.2	\$ 2,988,000
Granted	311,100	\$ 12.63		
Forfeited	(206,504)	\$ 9.12		
Outstanding and expected to vest at June 30, 2015	777,630	\$ 7.44	8.6	\$ 2,787,000
Options exercisable at June 30, 2015	301,499	\$ 5.03	8.0	\$ 1,557,000



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At June 30, 2015, the Company has unrecognized stock-based compensation expense of approximately \$2,496,400 related to unvested stock options over the weighted average remaining service period of 3.4 years. The weighted average fair value of options granted during the year ended June 30, 2015, for the six months ended June 30, 2014 and for the years ended December 31, 2013 was approximately \$8.35, \$3.60 and \$2.90 per share respectively, on the date of grant using the Black-Scholes option pricing model with the following assumptions:

	Year Ended June 30, 2015	Six Months Ended June 30, 2014	Year Ended December 31, 2013
Risk free interest rate	1.5% to 1.8%	1.5 to 1.6%	0.6%
Dividend yield	0%	0%	0%
Volatility	71% to 76%	76% to 77%	73% to 80%
Expected term (in years)	6.25	6.25	5.75 to 10

The following summarizes the components of stock-based compensation expense which includes stock options, warrants and restricted stock in the consolidated statements of operations for the year ended June 30, 2015, for the six months ended June 30, 2014, and for the year ended December 31, 2013, respectively:

	Year Ended June 30, 2015	Six Months Ended June 30, 2014	Year Ended December 31, 2014
Research and development	\$ 321,900	\$ 115,500	\$ 11,800
General and administrative	475,100	10,203,600	370,500
<b>Total</b>	<b>\$ 797,000</b>	<b>\$ 10,319,100</b>	<b>\$ 382,300</b>

During the year ended June 30, 2015, the Company granted 104,000 shares of restricted stock to employees which will be issued upon vesting. At June 30, 2015, there were 94,000 restricted stock awards outstanding of which, 10,000 were forfeited which had a fair value of \$14.65 per share. The restricted stock grants vest over four years. The Company has an unrecognized expense of approximately \$1,179,300, related to unvested restricted stock grants which will be recognized over the remaining weighted average service period of 3.7 years. The fair value per share of the restricted stock granted during the year ended June 30, 2015 was \$13.80.

**Stock-based compensation - warrants**

During the year ended December 31, 2013, the Company issued 382,547 warrants in connection with Series A preferred stock offering, see Note 6 - Series A Preferred Stock.

In connection with the subordinated promissory notes offerings during the year ended December 31, 2013, the Company issued the debt holders warrants to purchase 42,750 shares of common stock of the Company, exercisable at \$4.00 per share. The Placement Agent was issued warrants to purchase 21,375 shares of common stock exercisable at \$4.00 per share and expire in seven years. These warrants contained an anti-dilution features with down-round protection, thus the Company accounted for these warrants as derivative liabilities. The anti-dilution feature was eliminated upon the Share Exchange and the corresponding derivative liabilities were reclassified to additional paid-in capital.

During 2012, the Company issued its founder 173,643 warrants to purchase common stock in connection with a transaction that exchanged debt for stock. These warrants were cancelled by the Company in January 2014 and in November 2014, the Company reissued the warrants back to the founder. The warrants have an exercise price of \$4.00 per share and expire in five years.

**Relmada Therapeutics, Inc.**  
**Notes to Consolidated Financial Statements**

In December 2013, the Company purchased Medeor Inc. and in connection with the purchase, the Company issued the Placement Agent warrants to purchase 40,000 shares of common stock at an exercise price of \$5.50 per share and expire in seven years. The Company recorded the fair value of stock-based compensation of \$237,400 in connection with the issuance of these warrants based upon the Black-Scholes option pricing model.

In conjunction with a strategic advisor agreement, to a related party, the Company issued warrants to purchase 1,731,157 shares of common stock (402,451 warrants for the year ended December 31, 2012, 321,285 warrants for the year ended December 31, 2013 and 1,007,421 warrants for the six months ended June 30, 2014) shares of common stock at a \$0.001 exercise price and expire in May 2021. The warrants had a performance based requirement for vesting and became fully vested upon completion of a public transaction. During the six months ended June 30, 2014, the performance achievement was met. The Company recorded the fair value of stock-based compensation expense of approximately \$10,119,000 based upon the Black-Scholes option pricing model.

During the six months ended June 30, 2014, the Company issued 6,007,329 warrants in a connection with a common stock offering, see Note 6 - Common stock issued for cash.

During the six months ended June 30, 2014 and for the year ended and December 31, 2013, the Company issued to consultants warrants to purchase 2,500 and 4,300 shares of common stock, respectively. The exercise price of the warrants issued during the six months ended June 30, 2014 and for the year ended December 31, 2013 were all at \$4.00 per share. The grant date fair value of the warrants issued for the six months ended June 30, 2014 and for the year ended December, 31, 2013 was approximately \$14,300 and \$10,800, respectively, and the fair value was amortized over the term of the agreements.

A summary of the changes in outstanding warrants during the year ended June 30, 2015, for the six months ended June 30, 2014 is as follows:

	Number of Shares	Weighted Average Exercise Price Per Share
Outstanding at December 31, 2012	973,046	\$ 2.41
Granted	812,257	2.49
Outstanding at December 31, 2013	1,785,303	\$ 2.41
Granted	7,017,251	\$ 7.35
Forfeited	(173,643)	\$ 4.00
Outstanding and vested at June 30, 2014	8,628,911	\$ 6.40
Granted	173,643	\$ 4.00
Exercised	(2,040,277)	\$ 7.50
Forfeited	(1,400,094)	\$ 7.50
Outstanding and vested at June 30, 2015	<u>5,362,183</u>	<u>\$ 5.60</u>

At June 30, 2015, the Company has does not have any unrecognized stock based compensation expense related to outstanding warrants. At June 30, 2015, the aggregate intrinsic value of warrants vested and outstanding is approximately \$26,270,000.

**Relmada Therapeutics, Inc.**  
**Notes to Consolidated Financial Statements**

There were no common stock warrants granted by the Company during the year ended June 30, 2015 other than the reissuance of the warrants to the founder. The weighted average fair value of warrants granted for the year ended June 30, 2015, for the six months ended June 30, 2014 and for the year ended December 31, 2013 was N/A, \$7.00 per share and \$4.00 per share, respectively, on the date of grant, using the Black-Scholes option pricing model using the following assumptions:

	Year Ended June 30, 2015	Six Months Ended June 30, 2014	Year Ended June 30, 2013
Risk-free interest rate	N/A	0.7% to 2.0%	0.9% to 1.8%
Dividend yield	N/A	0%	0%
Expected volatility	N/A	75% to 76%	73% to 83%
Expected term (in years)	N/A	4 and 7	4-7

**NOTE 7 - RELATED PARTY TRANSACTIONS**

**Placement Agent**

On December 6, 2011, the Company entered into an engagement agreement with its placement agent ("Placement Agent") for the Series A Preferred Stock and Notes Offering (collectively the "Financings"), of which Mr. Seth, a director of the Company, was also the former Head of Healthcare Investment Banking. The agreement was amended on April 12, 2012 and again on February 25, 2013. Pursuant to the agreement, the placement agent was engaged on an exclusive basis for the Series A Preferred Stock and Notes Offering and as a financial advisor for assisting the Company with the restructuring of its capitalization and negotiating the conversion of its outstanding debt obligations to enable a successful financing (the "Notes Conversion"). In consideration for its services, the placement agent received: (a) re-activation fee of \$15,000, (b) a cash fee equal to 7% of the Notes Conversion and 10% of the gross proceeds raised in the Financings, and (c) non-accountable expense reimbursement equal to 2% of the gross proceeds raised. The placement agent or its designees also received warrants to purchase shares of the Company's common stock in an amount equal to 10% of the shares of common stock and warrants issued or issuable as part of the units sold in the Series A Preferred Stock Offering and Notes Offerings. The agreement also contains certain provisions including termination as provider for in the agreement, see Note 5 on the warrants issued with respect to the Series A Preferred Stock and subordinated promissory notes.

Due to the Share Exchange, the anti-dilution feature for the warrants that were issued for the Series A Preferred Stock and Notes Offering were terminated, see Note 5. There were Series A warrants, Series B warrants and Placement Agent warrants. See Note 5, Common Stock. These warrants contain an anti-dilution feature and shall terminate upon an up-listing to a national stock exchange, see Note 5.

On October 24, 2013, the Company entered into an engagement agreement which was amended December 19, 2013 with its Placement Agent to advise on the acquisition of Medeor Inc. In consideration for its services, the Placement Agent was eligible to receive: (a) a cash success fee equal to 8% of the value of the transaction plus a 2% non-reimbursable expense fee which was subsequently modified to a maximum of \$150,000 plus, (b) \$50,000 for a Fairness Opinion fee deductible against the success fee, and (c) a \$50,000 activation fee. The agreement also provided that: (i) if the Company consummates any merger, acquisition, business combination or other transaction (other than the Share Exchange) with any party introduced to it by the Placement Agent, the placement agent would receive a fee equal to 8% of the aggregate consideration in such transactions, and (ii) if, within a period of 12 months after termination of the advisory services described above, the Company requires a financing or similar advisory transaction the Placement Agent will have the right to act as the Company's financial advisor and investment banker in such financing or transaction pursuant to a set fee schedule set forth in the engagement agreement.

On February 18, 2014 and May 19, 2014, the Company entered into two engagement agreements with the Placement Agent for the May 2014 offering. The Company agreed to pay Placement Agent: (a) a cash commission in the amount of ten percent (10%) of the gross proceeds of the Offering received from investors at a Closing as well as a non-accountable expense reimbursement equal to two percent; and (b) (2%) of the gross proceeds of the Offering received from investors at a Closing and an activation fee of \$25,000. The Placement Agent or its designees also received five-year warrants to purchase 858,190 shares of Relmada's common stock at a price of \$7.50 per share. The Placement Agent shall also be entitled to the compensation set forth above as well for any cash exercise of Warrants within six (6) months of the final closing of the Offering as well as a five percent (5%) solicitation fee for any Warrants exercised as a result of any redemption of any Warrants. If the Company elects to call the warrants, the Placement Agent shall receive a warrant solicitation fee equal to 5% of the funds solicited by the Placement Agent upon exercise of the warrants. The Company shall pay the Placement Agent a non-refundable financial advisory fee to be paid monthly, at the rate of \$25,000 per month for a period of six months commencing after the May offerings. The Company extended the monthly \$25,000 financial advisory fee to May 2015 and the Company did not renew the agreement.

**Relmada Therapeutics, Inc.**  
**Notes to Consolidated Financial Statements**

The Placement Agent also received cash proceeds from the Company of approximately \$1,830,500, \$3,089,500, \$554,700, for the year ended June 30, 2015, for the six months ended June 30, 2014 and for the year ended December 31, 2013, respectively, from the warrant exercises from the warrant holders from the May and June 2014 equity offerings; and from the Series A preferred stock offerings. The Placement Agent received cash proceeds from the Company of \$68,400 from the issuance of subordinated promissory notes issued during 2013.

The Placement Agent received the following warrants during the year ended December 31, 2013:

	Number of warrants	Exercise price per share	Expiration
Series A preferred offering	127,516	\$ 4.00	2020
Subordinated promissory note offering	21,375	\$ 4.00	2020
Acquisition of Medeor	40,000	\$ 5.50	2020
	<u>188,891</u>		

The Placement Agent received the following warrants during the six months ended June 30, 2014:

	Number of warrants	Exercise price per share	Expiration
May and June 2014 offering	<u>858,190</u>	<u>\$ 7.50</u>	<u>2019</u>

**Advisory Firm**

On December 6, 2011, the Company entered into an advisory agreement with Jamess Capital Group, LLC (formerly known as Amerasia Capital Group, LLC), a consulting firm affiliated with Mr. Seth, a Director of the Company (“Advisory Firm”) to provide non-investment banking related advisory services. The Advisory Firm is due a monthly fee of \$12,500 and the agreement is terminable by either party with three months written notice and is to be issued fully vested warrants to purchase common stock equal to 12% of the outstanding capital stock of the Company as of the Share Exchange (exercisable at an exercise price of \$0.001 per share), see Note 5. The Advisory Firm is also eligible to be reimbursed upon the submission of proper documentation for ordinary and necessary out-of-pocket expenses not to exceed \$5,000 per month. This agreement was terminated effective June 30, 2015.

On August 4, 2015, the Company entered into an Advisory and Consulting Agreement (the “Consulting Agreement”) with Sandesh Seth, the Company’s Chairman of the Board. The effective date of the Consulting Agreement is June 30, 2015. Mr. Seth has substantial experience in, among other matters, business development, corporate planning, corporate finance, strategic planning, investor relations and public relations, and an expansive network of connections spanning the biopharmaceutical industry, accounting, legal and corporate communications professions. Mr. Seth will provide advisory and consulting services to assist the Company with strategic advisory services, assist in prioritizing product development programs per strategic objectives, assist in recruiting of key personnel and directors, corporate planning, business development activities, corporate finance advice, and assist in investor and public relations services. In consideration for the services to be provided, the Company agrees to pay Mr. Seth \$12,500 per month.

**Relmada Therapeutics, Inc.**  
**Notes to Consolidated Financial Statements**

**Acquisition of Medeor**

In April 2012, the Company (sub licensee) entered into a license agreement with Medeor (licensee) and issued 683 shares of common stock for the license agreement. The Chief Executive Officer was a shareholder of Medeor. At December 31, 2013, the Company issued 100,000 shares of common stock in exchange for all the outstanding stock of Medeor whose only asset was a research and development project. The parties also amended the license agreement on December 31, 2013. The transaction was valued at its fair value of \$3,750,000 and was expensed to research and development expense. The fair value of the shares was determined via a third party valuation. The Company will make royalty and a milestone payments as defined in the amended license agreement. The Company (A) will make royalty payments up to 2% on net sales of licensed products that are not sold by sub licensee and (B) on each and every sublicense earned royalty payment received by licensee from its sub licensee on sales of license product by sub-licensee, the higher of (i) 20% of the royalties received by licensee; or (ii) up to 2% of net sales of sub-licensee. The Company will also make milestone payments of up to \$4 million and up to \$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.

**NOTE 8 - INCOME TAXES**

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

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

	June 30, 2015	June 30, 2014
Deferred tax assets:		
Net operating loss	\$ 8,257,000	\$ 3,556,600
Stock-based compensation	4,268,200	4,248,700
Research and development tax credits	767,000	197,700
Accruals	46,400	22,900
Other	2,900	2,900
Valuation allowance	(13,341,500)	(8,028,800)
<b>Total</b>	<b>\$ -</b>	<b>\$ -</b>

The Company has maintained a full valuation allowance against its deferred tax at June 30, 2015 and 2014. 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 for the years ended June 30, 2015 and for the six months ended June 30, 2014, by approximately \$5,312,700 and \$4,736,200, respectively.

At June 30, 2015, the Company had federal net operating loss carryforwards of approximately \$24,285,000, which begin expiring in 2027. The Company also had federal research and development tax credit carryforwards of approximately \$767,000 which will begin to expire in 2027. The United States Tax Reform Act of 1986 contains provisions that may limit the Company's net operating loss carryforwards available to be used in any given year in the event of significant changes in the ownership interests of significant stockholders, as defined. The effect of an ownership change would be the imposition of an annual limitation on the use of NOL carryforwards attributable to periods before the change. The amount of the annual limitation depends upon the value of the Company immediately before the change, changes to the Company's capital during a specified period prior to the change, and the federal published interest rate.

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

	Year Ended June 30, 2015	Six Months Ended June 30, 2014	Year Ended December 31, 2013
Statutory federal income tax rate	34%	34%	34%
State (net of federal benefit)	6.6%	6.6%	6.6%
Non-deductible expenses	(9.7)%	(13.1)%	(29.7)%
Other	0.6%	(2.3)%	-
Change in valuation allowance	(31.5)%	(25.2)%	(10.9)%
<b>Effective income tax rate</b>	<b>0%</b>	<b>0%</b>	<b>0%</b>

**Relmada Therapeutics, Inc.**  
**Notes to Consolidated Financial Statements**

The Company does not have any uncertain tax positions at June 30, 2015 and 2014 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 9 - COMMITMENTS AND CONTINGENCIES**

**License Agreements**

Wonpung

On August 20, 2007, the Company entered into a License Development and Commercialization Agreement with Wonpung, 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. The Company’s current focus is on developing and marketing its products in the United States and not Asia. It will be several years before the Company markets its products in Asia.

Third Party Licensor

Based upon the Medeor transaction, the Company assumed an obligation to pay a third party (A) royalty payments up to 2% on net sales of licensed products that are not sold by sublicensee and (B) on each and every sublicense earned royalty payment received by licensee from its sublicensee on sales of license product by sublicensee, the higher of (i) 20% of the royalties received by licensee; or (ii) up to 2% of net sales of sublicensee. The Company will also make milestone payments of up to \$4 million and up to \$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, see Note 7.

**Research and Development Contracts**

At June 30, 2015, the Company has approximately \$3,985,000 in commitments, primarily related to its research and development contracts for its clinical research organizations through March 31, 2016.

**Leases**

The Company currently leases corporate office spaces for its New York City offices on a month-to-month basis. The Company is planning on moving its New York City corporate office location in October 2015 to another space in New York City. The lease expires in December 2023. In addition, the Company has a lease expiring in 2017 for its Pennsylvania office location. Future minimum lease payments are as follows:

For the year ended June 30:

Year	Amount
2016	\$ 266,800
2017	357,800
2018	336,700
2019	335,100
2020	347,300
Thereafter	909,800
Total	<u>\$ 2,553,500</u>

The Company incurred rent expense of approximately \$239,800, \$13,300 and \$ 67,800 and for year ended June 30, 2015, for the six months ended June 30, 2014, and for the year ended December 31, 2013, respectively.

**Letter Of Credit**

The Company has an outstanding letter of credit of approximately \$390,800 in connection with the Company’s New York City corporate office lease. The letter of credit is secured by a restricted certificate of deposit in the same amount which is included in other assets at June 30, 2015. On the second anniversary of the commencement date which is expected to be in October 2017, the letter of credit will be reduced to approximately \$234,400. In October 2022, the letter of credit will be reduced to approximately \$156,000.



**Relmada Therapeutics, Inc.**  
**Notes to Consolidated Financial Statements**

**Legal**

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

**Lawsuit Brought by Former Officer:** In 2014, Relmada was dismissed with prejudice of its lawsuit against Najib Babul, which had sought to compel Mr. Babul, Relmada's former President and sole stockholder, to account for questionable expenditures of Relmada funds made while Babul controlled the Company. Relmada's decision to surrender 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 the subsidiary, Relmada Delaware, for shares in the Company.

Subsequently, Babul has brought a second lawsuit against Relmada, making claims for breach of contract, defamation, intentional infliction of emotional distress, and wrongful use of civil process. The Company has moved to dismiss Babul's claims, brought in the United States District Court for the Eastern District of Pennsylvania. Management also believes that, if the litigation is permitted to proceed, it will have good defenses to all of Babul's claims. However, litigation is an inherently uncertain process, and there can be no assurance that the Company will succeed in its defense. Management believes that the outcome of the Babul litigation, even if unfavorable, would not materially affect the Company's operations or financial position.

**NOTE 10 - TRANSITION PERIOD COMPARABLE INFORMATION (UNAUDITED)**

The Company changed from a calendar year end to a fiscal year end for the period from January 1, 2014 to June 30, 2014. The Statements of Operations reflect a six month reporting period. For comparison purposes, we have disclosed twelve months of operations for the transition period and such information is used for the Management and Discussion Analysis.

The following table presents certain unaudited financial information for the twelve months ended June 30, 2015 and 2014 and for the six months ended June 30, 2014 and 2013.

	For the Twelve Months Ended June 30,		For the Six Months Ended June 30,	
	2015	2014	2014	2013
	(Unaudited)		(Unaudited)	
<b>Statement of Operations Data:</b>				
<b>Operating expenses:</b>				
Research and development	\$ (7,872,397)	\$ (5,380,077)	\$ (839,959)	\$ (708,551)
General and administrative	(9,226,883)	(13,103,764)	(12,106,859)	(528,352)
Total operating expenses	<u>(17,099,280)</u>	<u>(18,483,841)</u>	<u>(12,946,818)</u>	<u>(1,236,903)</u>
Loss from operations				
Other (expenses) income:				
Loss on change in fair value of derivative liabilities	(3,710,277)	(8,971,343)	(7,954,970)	(11,861,302)
Interest income	10,883	1,411	1,411	-
Interest expense	(4,922)	(614,251)	(435,611)	(41,667)
Total other expenses	<u>(3,704,316)</u>	<u>(9,584,183)</u>	<u>(8,389,170)</u>	<u>(11,902,969)</u>
Net loss	<u>\$ (20,803,596)</u>	<u>\$ (28,068,024)</u>	<u>\$ (21,335,988)</u>	<u>\$ (13,139,872)</u>
Net loss per common share				
- basic and diluted	<u>\$ (2.09)</u>	<u>\$ (18.89)</u>	<u>\$ (8.65)</u>	<u>\$ (27.35)</u>
Weighted average common shares outstanding				
- basic and diluted	<u>9,941,156</u>	<u>1,486,126</u>	<u>2,466,466</u>	<u>480,477</u>
<b>Statements of Cash Flows Data:</b>				
Net cash used in operations	\$ (16,226,728)	\$ (7,213,709)	\$ (2,164,254)	\$ (992,190)
Net cash used in investing activities	(23,326)	(11,740)	(3,673)	-
Net cash provided by financing activities	13,155,663	31,230,072	24,209,828	779,096
Increase (decrease) in cash and cash equivalents	<u>\$ (3,094,391)</u>	<u>\$ 24,004,623</u>	<u>\$ 22,041,901</u>	<u>\$ (213,094)</u>



**Relmada Therapeutics, Inc.**  
**Notes to Consolidated Financial Statements**

**NOTE 11 - SUBSEQUENT EVENTS**

On August 4, 2015, the Company entered into a consulting agreement with a related party, see Note 7.

Subsequent to June 30, 2015, the Company issued 36,439 shares of common stock from the exercise of warrants (28,939 warrants) and for the issuance of services (7,500 shares).

In August 2015, the board approved an amendment to the Plan. Among other things, the Plan Amendment updates the definition of “change of control” and provides for accelerated vesting of all awards granted under the plan in the event of a change of control of the Company, see Note 6.

## 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 May 27, 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).
3.3	By-laws of Camp Nine, Inc. (incorporated by reference to Exhibit 3.3 of Relmada's Form 8-K filed with the SEC on May 27, 2014).
3.4	By-laws of Relmada Therapeutics, Inc. (incorporated by reference to Exhibit 3.4 of Relmada's Form 8-K filed with the SEC on May 27, 2014).
3.5	Amended and Restated Bylaws of Relmada Therapeutics, Inc. (incorporated by reference to Exhibit 3.1 of Relmada's Form 8-K filed with the SEC on August 7, 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 A Warrant dated May __, 2014 issued to investors by Relmada Therapeutics, Inc. (incorporated by reference to Exhibit 4.3 of Relmada's Form 8-K filed with the SEC on May 27, 2014).
4.4	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).



- 4.5 (i) Option dated July 10, 2012 to Sergio Traversa to purchase common stock of Relmada Therapeutics, Inc. (incorporated by reference to Exhibit 4.5(i) of Relmada's Form 8-K filed with the SEC on May 27, 2014).
- (ii) Option dated September 30, 2013 to Sergio Traversa to purchase common stock of Relmada Therapeutics, Inc. (incorporated by reference to Exhibit 4.5(ii) of Relmada's Form 8-K filed with the SEC on May 27, 2014).
- 4.6 Option dated December 2, 2013 to Douglas J. Beck to purchase common stock of Relmada Therapeutics, Inc. (incorporated by reference to Exhibit 4.6 of Relmada's Form 8-K filed with the SEC on May 27, 2014).
- 4.7 Option dated February 24, 2014 to Dr. Eliseo O. Salinas to purchase common stock of Relmada Therapeutics, Inc. (incorporated by reference to Exhibit 4.7 of Relmada's Form 8-K filed with the SEC on May 27, 2014).
- 4.8 Option dated November 25, 2013 to Dr. H. Danny Kao to purchase common stock of Relmada Therapeutics, Inc. (incorporated by reference to Exhibit 4.8 of Relmada's Form 8-K filed with the SEC on May 27, 2014).
- 4.9 Form of D&O Lock Up Letter Agreement (May 2014 financing) (incorporated by reference to Exhibit 4.9 of Relmada's Form 8-K filed with the SEC on May 27, 2014).
- 4.10 Form of CEO Lock Up Letter Agreement (May 2014 financing) (incorporated by reference to Exhibit 4.10 of Relmada's Form 8-K filed with the SEC on May 27, 2014).
- 4.11 Form of Lock Up Letter Agreement (Class A Preferred Convertible Stock) (incorporated by reference to Exhibit 4.11 of Relmada's Form 8-K filed with the SEC on May 27, 2014).
- 4.12 Form of A Warrant dated June 10, 2014 issued to investors by Camp Nine, Inc. (incorporated by reference to Exhibit 4.1 of Relmada's Form 8-K filed with the SEC on June 16, 2014).
- 4.13 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).
- 10.1 Agreement and Plan of Merger dated as of December 31, 2013 between Relmada Therapeutics, Inc. and Medeor, Inc. (incorporated by reference to Exhibit 10.1 of Relmada's Form 8-K filed with the SEC on May 27, 2014).
- 10.2 Non-Disclosure, Assignment of Inventions, Non-Solicitation and Non-Compete Agreement dated as of April 18, 2012 between Sergio Traversa and Relmada Therapeutics, Inc. (incorporated by reference to Exhibit 10.2 of Relmada's Form 8-K filed with the SEC on May 27, 2014).
- 10.3 Employment Agreement dated April 15, 2013 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 May 27, 2014).
- 10.4 Offer letter dated November 25, 2013 between Douglas J. Beck and Relmada Therapeutics, Inc. (incorporated by reference to Exhibit 10.4 of Relmada's Form 8-K filed with the SEC on May 27, 2014).
- 10.5 Employment Agreement dated January 31, 2014 between Dr. Eliseo Salinas and Relmada Therapeutics, Inc. (incorporated by reference to Exhibit 10.5 of Relmada's Form 8-K filed with the SEC on May 27, 2014).
- 10.6 Confidential Information and Invention Assignment Agreement dated January 31, 2014 between and Dr. Eliseo Salinas and Relmada Therapeutics, Inc. (incorporated by reference to Exhibit 10.6 of Relmada's Form 8-K filed with the SEC on May 27, 2014).
- 10.7 Form of Unit Purchase Agreement dated May \_\_, 2014 by and among Relmada Therapeutics, Inc. and the Purchasers party thereto (incorporated by reference to Exhibit 10.7 of Relmada's Form 8-K filed with the SEC on May 27, 2014).
- 10.8 Form of 2014 Unit Investor Rights Agreement dated \_\_\_\_\_, 2014 by and among Relmada Therapeutics, Inc. and the Investors party thereto (incorporated by reference to Exhibit 10.8 of Relmada's Form 8-K filed with the SEC on May 27, 2014).
- 10.9 Form of Subscription Agreement dated as of May 12, 2014 and May 15, 2014 by and among Relmada Therapeutics, Inc. and the Purchasers party thereto (incorporated by reference to Exhibit 10.9 of Camp Nine's Form 8-K filed with the SEC on May 27, 2014).
- 10.10 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).
- 10.11 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).
- 10.12 Unit Purchase Agreement, dated June 10, 2014, by and among Camp Nine, Inc. and signatories thereto (incorporated by reference to Exhibit 10.1 of Relmada's Form 8-K filed with the SEC on June 16, 2014).



10.13	Subscription Agreement, dated June 10, 2014, by and among Camp Nine, Inc. and signatories thereto (incorporated by reference to Exhibit 10.2 of Relmada's Form 8-K filed with the SEC on June 16, 2014).
10.14	Form of Investor Rights Agreement, dated June 10, 2014, by and among Camp Nine, Inc. and signatories thereto (incorporated by reference to Exhibit 10.3 of Relmada's Form 8-K filed with the SEC on June 16, 2014).
10.15	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)
10.16	Agreement of Lease, dated June 9, 2015, by and between Relmada Therapeutics, Inc. and GP 275 Owner, LLC (incorporated by reference to Exhibit 99.1 of Relmada's Form 8-K filed with the SEC on June 15, 2015)
10.17	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)
10.18	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)
10.19	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).
10.20	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).
10.21	Termination Agreement, dated August 3, 2015, by and between Relmada Therapeutics, Inc. and James Capital Group LLC (incorporated by reference to Exhibit 10.3 of Relmada's Form 8-K filed with the SEC on August 7, 2015).
10.22	Amended and Restated Employment Agreement, dated August 5, 2015, by and between Relmada Therapeutics, Inc. and Sergio Traversa (incorporated by reference to Exhibit 10.4 of Relmada's Form 8-K filed with the SEC on August 7, 2015).
10.23	Amended and Restated Employment Agreement, dated August 5, 2015, by and between Relmada Therapeutics, Inc. and Douglas Beck (incorporated by reference to Exhibit 10.5 of Relmada's Form 8-K filed with the SEC on August 7, 2015).
10.24	Advisory and Consulting Agreement, dated August 4, 2015, by and between Relmada Therapeutics, Inc. and Sandesh Seth (incorporated by reference to Exhibit 10.6 of Relmada's Form 8-K filed with the SEC on August 7, 2015).
21.1	List of Subsidiaries (incorporated by reference to Exhibit 21.1 of Relmada's Form 10-K filed with the SEC on September 9, 2014).
31.1	Certification of Principal Executive Officer, pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Principal Financial and Accounting Officer, pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Principal Executive Officer, pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Principal Financial and Accounting Officer, pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS **	XBRL Instance Document
101.SCH **	XBRL Taxonomy Schema
101.CAL **	XBRL Taxonomy Calculation Linkbase
101.DEF **	XBRL Taxonomy Definition Linkbase
101.LAB **	XBRL Taxonomy Label Linkbase
101.PRE **	XBRL Taxonomy Presentation Linkbase

## SIGNATURES

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

Dated: September 11, 2015

**RELMADA THERAPEUTICS, INC.**

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

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

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Sergio Traversa</u> Sergio Traversa	Chief Executive Officer and Director	September 11, 2015
<u>/s/ Douglas Beck</u> Douglas Beck	Chief Financial Officer (Principal Financial and Accounting Officer)	September 11, 2015
<u>/s/ Shreeram Agharkar</u> Shreeram Agharkar	Director	September 11, 2015
<u>/s/ Sandesh Seth</u> Sandesh Seth	Chairman and Director	September 11, 2015
<u>/s/ Nabil Yazgi</u> Nabil Yazgi	Director	September 11, 2015
<u>/s/ Charles J. Casamento</u> Charles Casamento	Director	September 11, 2015

Subsidiaries

Relmada Therapeutics, Inc. (a Delaware corporation)



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

I, Sergio Traversa, certify that:

1. I have reviewed this report on Form 10-K of Relmada Therapeutics, Inc. for the year ended June 30, 2015.
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiary, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Sergio Traversa

Sergio Traversa  
Chief Executive Officer  
(Principal Executive Officer)

Date: September 11, 2015

**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, Douglas Beck, certify that:

1. I have reviewed this report on Form 10-K of Relmada Therapeutics, Inc. for the year ended June 30, 2015.
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/ Douglas Beck

Douglas Beck, CPA

Chief Financial Officer

(Principal Financial and Accounting Officer)

Date: September 11, 2015

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

In connection with the Annual Report of Relmada Therapeutics, Inc. a Nevada corporation (the "Company"), on Form 10-K for the year ended June 30, 2015 as filed with the Securities and Exchange Commission (the "Report"), I, Sergio Traversa, Chief Executive Officer of the Company, certify, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, 18 U.S.C. Section 1350, that to my knowledge:

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

/s/ Sergio Traversa

Sergio Traversa  
Chief Executive Officer  
(Principal Executive Officer)

Date: September 11, 2015

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

In connection with the Annual Report of Relmada Therapeutics, Inc. a Nevada corporation (the "Company"), on Form 10-K for the year ended June 30, 2015 as filed with the Securities and Exchange Commission (the "Report"), I, Douglas Beck, 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/ Douglas Beck

Douglas Beck, CPA

Chief Financial Officer

(Principal Financial and Accounting Officer)

Date: September 11, 2015