As filed with the Securities and Exchange Commission on October 2, 2015

Registration No. 333-

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM S-8

REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

RELMADA THERAPEUTICS, INC.

(Exact Name of Registrant as Specified in Its Charter)

Nevada	**45-5401931**
(State or other Jurisdiction of Incorporation or Organization)	(I.R.S Employer Identification Number)
757 Third Avenue, Suite 2018, New York, New York	**10017**
(Address of Principal Executive Offices)	(Zip Code)

RELMADA THERAPEUTICS, INC.
2014 STOCK OPTION AND EQUITY INCENTIVE STOCK PLAN, AS AMENDED
(Full Title of the Plan)

Sergio Traversa
Chief Executive Officer
757 Third Avenue, Suite 2018
New York, New York 10017
Phone: (212) 376-5776
Fax: (888) 228-5672
(Name, Address and Telephone Number of Agent for Service)

Copy to:
Thomas Slusarczyk, Esq.
Barclay Damon, LLP
300 South State Street
Syracuse, New York 13202
(315) 235-2299

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer	☐	Accelerated filer	☒
Non-accelerated filer (Do not check if a smaller reporting company)	☐	Smaller reporting company	☐

CALCULATION OF REGISTRATION FEE

Title of securities to be registered	Amount to be registered (1)	Proposed maximum offering price per share (2)	Proposed maximum aggregate offering price (2)	Amount of registration fee
Common Stock $0.001 par value (3)	1,611,769	$ 4.98	$ 8,026,615	$ 808.28
Total	1,611,769	$ 4.98	$ 8,026,615	$ 808.28

(1) This Registration Statement also covers additional shares of Relmada Therapeutics, Inc. common stock that may be issuable by reason of stock splits, stock dividends, or other adjustment provisions of the Relmada Therapeutics, 2014 Stock Option and Equity Incentive Plan, as amended, in accordance with Rule 416 under the Securities Act of 1933, as amended.

(2) Estimated solely for the purpose of calculating the registration fee computed pursuant to Rule 457(c) and (h), upon the basis of the average of the high and low prices of the common stock as quoted on OTCQB on September 29, 2015.

(3) Represents the number of shares of Common Stock issuable upon the exercise of (a) currently outstanding stock options granted pursuant to the Relmada Therapeutics 2014 Stock Option and Equity Incentive Plan, as amended, and (b) stock options and other awards that are expected to be granted pursuant to the Relmada Therapeutics, Inc. 2014 Stock Option and Equity Incentive Plan, as amended.

EXPLANATORY NOTE

This Form S-8 relates to (i) the offer and resale of up to an aggregate of 847,147 shares of common stock, par value $0.001 per share (the "Common Stock"), of Relmada Therapeutics, Inc., a Nevada corporation (the "Company"), consisting of restricted shares of the Company's Common Stock previously issued under the Relmada Therapeutics, Inc. 2014 Stock Option and Equity Incentive Plan, as amended (the "Plan) as well as shares of the Company's Common Stock underlying outstanding options previously granted under the Plan, (ii) options that may be granted under the Plan to purchase up to an aggregate of 764,622 shares of the Company's Common Stock, and (iii) up to an aggregate of 764,622 shares of Common Stock of the Company, which may underlie options to be granted under the Plan, or which may be stock or other awards which are subject to future grants under the Plan. This Registration Statement contains two parts. First, the materials that follow Part I up to Part II of this Registration Statement constitute the reoffer prospectus, prepared in accordance with Part I of Form S-3, in accordance with General Instruction C of Form S-8, covering resales of "restricted securities" or "control securities" (as defined in General Instruction C of Form S-8). Such resale prospectus relates to shares of the Common Stock of the Company, and together with its subsidiaries, ("we", "our" and "us") previously issued to certain of our employees pursuant to the Plan. The amount of shares to be reoffered or resold by means of the reoffer prospectus contained herein by each selling stockholder, and any other person with whom such selling stockholder is acting in concert for the purpose of selling securities of the Company, may not exceed, during any three-month period, the amount specified in Rule 144(e) of the Securities Act of 1933, as amended (the "Securities Act"). The second part contains information required to be set forth in the registration statement pursuant to Part II of Form S-8.

PART I

INFORMATION REQUIRED IN THE SECTION 10(a) PROSPECTUS*

Item 1. Plan Information.*

Item 2. Registrant Information and Employee Plan Annual Information.**

* The documents containing the information specified in Part I of Form S-8 will be sent or given to plan participant as specified in Rule 428(b)(1) of the Securities Act. Such documents need not be filed with the Securities and Exchange Commission (the "Commission") either as part of this Registration Statement or as prospectuses or prospectus supplements pursuant to Rule 424 of the Securities Act. These documents and the documents incorporated by reference in this Registration Statement pursuant to Item 3 of Part II of this Registration Statement, taken together, constitute a prospectus that meets the requirements of Section 10(a) of the Securities Act.

** Upon written or oral request, any document incorporated by reference in Item 3 of Part II of this Registration Statement (which documents are incorporated by reference in this Section 10(a) prospectus), and any document required to be delivered to a participant in the Plans pursuant to Rule 428(b) or additional information about the Relmada Therapeutics, Inc. 2014 Stock Option and Equity Incentive Plan is available, without charge, by contacting the Company at:

Relmada Therapeutics, Inc.
757 Third Avenue, Suite 2018
New York, New York 10017

Attention: Sergio Traversa, Tel: (212) 376-5741

Reoffer Prospectus

RELMADA THERAPEUTICS, INC.

847,147 Shares of Common Stock

This reoffer prospectus relates to the offer and resale of up to an aggregate of 847,147 shares of common stock, par value $0.001 per share, of Relmada Therapeutics, Inc. a Nevada corporation, underlying outstanding options previously granted under the Relmada Therapeutics, Inc. 2014 Stock Option and Equity Incentive Plan, as amended. The shares of common stock subject to this prospectus may be offered and sold from time to time by the selling stockholders listed in this prospectus after the filing of the related registration statement on Form S-8. This prospectus has been prepared for the purpose of registering future sales of the shares of common stock by the selling stockholders, on a continuous or delayed basis, to the public without restriction. Upon the effectiveness of the related registration statement, the selling stockholders may offer these shares for resale for his/her own account from time to time.

The selling stockholders may sell the shares of common stock covered by this prospectus through various means, including directly or indirectly to purchasers, in one or more transactions on any stock market on which such shares are traded at the time of sale, in privately negotiated transactions, or through a combination of these methods. The selling stockholders selling any shares pursuant to this prospectus may be deemed to be an "underwriter" within the meaning of the Securities Act of 1933, as amended. Any commissions received by a broker or dealer in connection with resales of shares may be deemed to be underwriting commissions or discounts under the Securities Act. For additional information on the selling stockholders' possible methods of sale, you should refer to the section in this prospectus entitled "Plan of Distribution."

We will not receive any proceeds from the sale of the shares of common stock being offered by the selling stockholders. We will pay all of the expenses associated with this prospectus. Brokerage commissions and similar selling expenses, if any, attributable to the offer or sale of the shares of common stock covered by this prospectus will be borne by the respective selling stockholders.

Our common stock is quoted on OTCQB under the symbol "RLMD." On September 29, 2015, the closing price of our common stock on such market was $4.35 per share.

An investment in our securities is highly speculative, involves a high degree of risk and should be considered only by persons who can afford the loss of their entire investment. Please see "Risk Factors" beginning on page 12 of this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined whether this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this Prospectus is October 2, 2015.

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ABOUT THIS PROSPECTUS

You should rely only on the information contained in or incorporated by reference into this prospectus. We have not authorized any other person to provide you with additional information or information different from that contained in or incorporated by reference into this prospectus. The selling stockholders may, from time to time, offer to sell shares of our common stock only in jurisdictions where the offer or sale is permitted. You should not assume that the information contained in this prospectus is accurate as of any date other than the date on the front cover of this prospectus or that the information contained in any document incorporated by reference into this prospectus is accurate as of any date other than the date of the document incorporated by reference.

FORWARD-LOOKING STATEMENTS

This prospectus and other documents we file with the Commission contain forward-looking statements, such as statements concerning our expected results of operations, financial resources or our projected plans for the expansion of our business, as well as other estimates relating to future operations. Words or phrases of expectation or uncertainty like “expect,” “believe,” “continue,” “anticipate,” “estimate,” “may,” “will,” “could,” “opportunity,” “future,” “project,” “can,” “intend,” “plan,” “potential,” “predict”, the negative of these terms or variations of such words and similar expressions are intended to identify “forward-looking statements,” although not all forward-looking statements contain these identifying words. 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 prospectus, 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 assumes no obligation to update any such forward-looking statements.

PROSPECTUS SUMMARY

The following summary contains basic information about Relmada Therapeutics, Inc. and this prospectus. It may not contain all of the information that is important to you. For a more complete understanding, we encourage you to read the entire prospectus and the documents incorporated by reference into this prospectus. In this prospectus, the words "Company," "we," "our" and "us" refer to Relmada Therapeutics, Inc. and our subsidiary.

The Securities and Exchange Commission allows us to "incorporate by reference" certain information that we file with it, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is considered to be part of this prospectus, and information that we file later with the Commission will update automatically, supplement and/or supersede this information. Any statement contained in this prospectus or in a document incorporated or deemed to be incorporated by reference in this prospectus shall be deemed to be modified or superseded for purposes of this prospectus to the extent that a statement contained in this prospectus or in any other document which also is or is deemed to be incorporated by reference in this prospectus modifies or supersedes such statement. Any such statement so modified or superseded shall not be deemed, except as so modified or superseded, to constitute a part of this prospectus. You should read the following summary together with the more detailed information regarding our company, our common stock and our financial statements and the notes to those statements appearing elsewhere in this prospectus or incorporated herein by reference.

Company 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, 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.

Acorda 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. Acorda 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.

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 $312,600 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.

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.

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'-Pipecoloxylidide 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, Inspirion 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, New York, NY 10017 and our telephone number is (212) 376-5776. Our website address is *www.relmada.com.* Information accessed through our website is not incorporated into this prospectus and is not a part of this prospectus.

The Offering	
Common stock offered by selling stockholders	847,147 shares of our common stock (i) underlying outstanding options and restricted stock previously granted under the Relmada Therapeutics, Inc 2014 Stock Option and Equity Incentive Plan, as amended (the "Plan") to the selling stockholders.
Use of proceeds	We will not receive any proceeds from the sales of these shares. We will receive proceeds to the extent that options to purchase common stock may be issued and thereafter exercised. We will use the exercise proceeds, if any, for working capital and general corporate purposes.
Trading Symbol	RLMD
Risk Factors	The common stock offered hereby involves a high degree of risk and should not be purchased by investors who cannot afford the loss of their entire investment. You should carefully consider the risk factors described in this prospectus in the "Risk Factors" section before making a decision to invest.

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 prospectus.

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 $76,100,200, 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 y 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 addition. If our drug development efforts in pain management fail, or if the competitive landscape or investment climate for analgesic dug 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 a 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.

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'

-Pipecoloxylidide 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 prospectus 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 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.

USE OF PROCEEDS

The shares which may be sold pursuant to this prospectus will be sold for the respective accounts of each of the selling stockholders. Accordingly, the Company will not realize any proceeds from the sale of the shares, except that it will derive proceeds if options currently outstanding or hereafter granted are exercised. If exercised, such funds will be available to the Company for working capital and general corporate purposes. No assurance can be given, however, as to when or if any or all of the options will be exercised. All expenses of the registration of the shares have been paid for by the Company. See "Selling Stockholders" and "Plan of Distribution."

SELLING STOCKHOLDERS

The 847,147 shares of our common stock to which this reoffer prospectus relates is comprised entirely of shares issuable upon the exercise of options granted under the Plan to the selling stockholders named below, and are being registered for reoffers and resales by such selling stockholders, who acquired the shares pursuant to one of our "employee benefit plans" as that term is defined in Rule 405 of Regulation C under the Securities Act. The shares of common stock that may be resold pursuant to this prospectus may be subject the satisfaction of certain applicable vesting conditions pursuant to the terms of the respective grants. Such selling stockholders may resell all, a portion, or none of the shares of common stock from time to time while this prospectus is effective. Any changed information will be set forth in an amendment to the registration statement or supplement to this reoffer prospectus, to the extent required by law.

The following table sets forth the name and relationship to the Company of the selling stockholders and information regarding beneficial ownership of our common stock by the selling stockholders as of October 1, 2015. Unless otherwise indicated, beneficial ownership is determined in accordance with the rules of the Commission, and is based upon information provided by each respective selling stockholder identified below and other public documents filed with the Commission.

Unless otherwise specified, the address of each of the selling stockholders listed below is c/o Relmada Therapeutics, Inc., 757 Third Avenue, Suite 2018, New York, NY 10017.

Selling Stockholder	Position	Total Shares Beneficially Owned Prior to Offering (1)	Maximum Shares Offered Pursuant to this Prospectus	Shares Beneficially Owned Following Resale (2)	Percentage of Outstanding Shares of Common Stock after the Offering (3)
Charles Casamento	Director	25,765	25,765(4)		
Christopher James	Employee	30,000	30,000(5)	-	*
Christine Silverstein	Employee	50,400	50,400(6)	-	*
Danny Kao	Employee	46,380	42,500(7)	3,880	*
Donna Cummings	Employee	1,700	1,700(8)	-	*
Douglas Beck	Chief Financial Officer	71,840	71,840(9)	-	*
Elizabeth Nolan	Employee	80,000	80,000(10)		
Fai Jim	Employee	24,000	24,000(11)	-	*
Kulendiran Purushothaman	Employee	40,000	40,000(12)	-	*
Michael Becker	Employee	82,000	82,000(13)	-	*
Nabil Yazgi	Director	49,733	9,733(14)	40,000	*
Richard Mangano	Employee	56,000	56,000(15)	-	*
Sandesh Seth	Director	9,733	9,733(16)	-	*
Sergio Traversa	Chief Executive Officer	413,284	313,743(17)	99,541	*
Sheeram Agharkar	Director	9,733	9,733(18)	-	*

(1) The securities "beneficially owned" by a person are determined in accordance with the definition of "beneficial ownership" set forth in the rules and regulations promulgated under the Exchange Act, and accordingly, may include securities owned by and for, among others, the spouse and/or minor children of an individual and any other relative who has the same home as such individual, as well as other securities as to which the individual has or shares voting or investment power or which such person has the right to acquire within 60 days of October 1, 2015 pursuant to the exercise of options, or otherwise. Beneficial ownership may be disclaimed as to certain of the securities.

(2) Assumes that all shares of common stock offered by this prospectus are sold in this offering and that no other transactions with respect to shares of our common stock occur.

(3) Based on 11,014,155 shares of common stock and 71,672 shares of Class A preferred stock issued and outstanding as of October 1, 2015.

(4) Includes 25,765 shares of common stock underlying outstanding options granted to the selling stockholder .

(5) Includes (i) 16,000 shares of common stock underlying outstanding options granted to the selling stockholder and (ii) 14,000 shares of restricted common stock granted to the selling stockholder.

(6) Includes (i) 40,400 shares of common stock underlying outstanding options granted to the selling stockholder and (ii) 10,000 shares of restricted common stock granted to the selling stockholder.

(7) Includes all shares of common stock underlying outstanding options granted to the selling stockholder.

(8) Includes all shares of common stock underlying outstanding options granted to the selling stockholder.

(9) Includes all shares of common stock underlying outstanding options granted to the selling stockholder.

(10) Includes (i) 50,000 shares of common stock underlying outstanding options granted to the selling stockholder and (ii) 30,000 shares of restricted common stock granted to the selling stockholder.

(11) Includes all shares of common stock underlying outstanding options granted to the selling stockholder.

(12) Includes (i) 20,000 shares of common stock underlying outstanding options granted to the selling stockholder and (ii) 20,000 shares of restricted common stock granted to the selling stockholder.

(13) Includes (i) 62,000 shares of common stock underlying outstanding options granted to the selling stockholder and (ii) 20,000 shares of restricted common stock granted to the selling stockholder.

(14) Includes all shares of common stock underlying outstanding options granted to the selling stockholder.

(15) Includes all shares of common stock underlying outstanding options granted to the selling stockholder.

(16) Includes all shares of common stock underlying outstanding options granted to the selling stockholder

(17) Includes all shares of common stock underlying outstanding options granted to the selling stockholder.

(18) Includes all shares of common stock underlying outstanding options granted to the selling stockholder.

* Less than 1% of our common stock.

PLAN OF DISTRIBUTION

The common shares being offered for resale by the selling stockholders consist of 847,147 shares of common stock underlying outstanding options and restricted common stock granted to the selling stockholders under the Plans. We will pay any fees and expenses incurred by us incident to the registration of the securities.

Each selling stockholder of the securities and any of their pledgees, assignees and successors-in-interest permitted under the Plan may, from time to time, sell any or all of their securities covered hereby on OTCQB or any other stock exchange, market or trading facility on which the securities are traded or in private transactions. These sales may be at fixed or negotiated prices. A selling stockholder may use any one or more of the following methods when selling securities:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the securities as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- settlement of short sales entered into after the effective date of the registration statement of which this prospectus is a part;
- in transactions through broker-dealers that agree with the selling stockholders to sell a specified number of such securities at a stipulated price per security;
- through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;
- a combination of any such methods of sale; or
- any other method permitted pursuant to applicable law.

The selling stockholders may also sell securities under Rule 144 under the Securities Act, if available, rather than under this prospectus.

The amount of our common stock to be reoffered or resold by means of this prospectus by each selling stockholder, and any other person with whom such selling stockholder is acting in concert for the purpose of selling securities of our company, may not exceed, during any three month period, the amount specified in Rule 144(e) of the Securities Act.

Broker-dealers engaged by the selling stockholders may arrange for other brokers-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the selling stockholders (or, if any broker-dealer acts as agent for the purchaser of securities, from the purchaser) in amounts to be negotiated, but, except as set forth in a supplement to this prospectus, in the case of an agency transaction not in excess of a customary brokerage commission in compliance with FINRA Rule 2440; and in the case of a principal transaction a markup or markdown in compliance with FINRA IM-2440.

In connection with the sale of the securities or interests therein, the selling stockholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the securities in the course of hedging the positions they assume. The selling stockholders may also sell securities short and deliver these securities to close out their short positions, or loan or pledge the securities to broker-dealers that in turn may sell these securities. The selling stockholders may also enter into option or other transactions with broker-dealers or other financial institutions or create one or more derivative securities which require the delivery to such broker-dealer or other financial institution of securities offered by this prospectus, which securities such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

The selling stockholders and any broker-dealers or agents that are involved in selling the securities may be deemed to be “underwriters” within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the securities purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. Each selling stockholder has informed us that it does not have any written or oral agreement or understanding, directly or indirectly, with any person to distribute the securities.

The resale securities will be sold only through registered or licensed brokers or dealers if required under applicable state securities laws. In addition, in certain states, the resale securities covered hereby may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

Under applicable rules and regulations under the Exchange Act, any person engaged in the distribution of the resale securities may not simultaneously engage in market making activities with respect to the common stock for the applicable restricted period, as defined in Regulation M, prior to the commencement of the distribution. In addition, the selling stockholders will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including Regulation M, which may limit the timing of purchases and sales of securities of the common stock by the selling stockholders or any other person. We will make copies of this prospectus available to the selling stockholders and have informed them of the need to deliver a copy of this prospectus to each purchaser at or prior to the time of the sale (including by compliance with Rule 172 under the Securities Act).

LEGAL MATTERS

The validity of the shares of common stock being offered pursuant to this prospectus will be passed upon by Fennemore Craig, P.C., Reno, NV.

EXPERTS

The audited financial statements incorporated by reference in this prospectus and elsewhere in the registration statement have been so incorporated by reference in reliance upon the report of GBH CPAs, PC an independent registered public accounting firm, upon the authority of said firm as experts in accounting and auditing in giving said report.

WHERE YOU CAN FIND MORE INFORMATION

We filed with the Commission a registration statement under the Securities Act for the common stock in this offering. This prospectus does not contain all of the information in the registration statement and the exhibits and schedule that were filed with the registration statement. For further information with respect to us and our common stock, we refer you to the registration statement and the exhibits that were filed with the registration statement. Statements contained in this prospectus about the contents of any contract or any other document that is filed as an exhibit to the registration statement are not necessarily complete, and we refer you to the full text of the contract or other document filed as an exhibit to the registration statement.

We file annual, quarterly, and current reports and other information with the Commission. Our filings with the the Commission are available to the public on the commission's website at www.sec.gov. Those filings are also available to the public on our corporate website at www.relmada.com. The information we file with the Commission or contained on, or linked to through, our corporate website or any other website that we may maintain is not part of this prospectus or the registration statement of which this prospectus is a part. You may also read and copy, at the Commission's prescribed rates, any document we file with the Commission, including the registration statement (and its exhibits) of which this prospectus is a part, at the Commission's Public Reference Room located at 100 F Street, N.E., Washington, D.C. 20549. You can call the Commission at 1-800-SEC-0330 to obtain information on the operation of the Public Reference Room.

INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE

We are incorporating by reference certain information that we have filed with the Commission under the informational requirements of the Exchange Act, which means that we are disclosing it to you by referring to another document filed separately with the Commission. The information contained in the documents we are incorporating by reference is considered to be a part of this prospectus, and the information that we later file with the Commission will automatically update and supersede the information contained or incorporated by reference in this prospectus. Accordingly, we incorporate by reference:

- Our Form 10-K for the year ended June 30, 2015, filed with the Securities and Exchange Commission on September 11, 2015; and
- The description of our common stock, which is contained in our Form 8-K, filed with the Securities and Exchange Commission on May 27, 2014.

All documents subsequently filed by us pursuant to Sections 13(a), 13(c), 14 and 15(d) of the Exchange Act after the date of this prospectus and prior to the filing of a post-effective amendment indicating that all securities offered have been sold or which deregisters all securities then remaining unsold, are incorporated by reference in this prospectus and are a part of this prospectus from the respective dates of filings of such documents. Any statement contained herein or in a document incorporated or deemed to be incorporated by reference herein shall be deemed to be modified or superseded for purposes of this prospectus to the extent that a statement contained herein or in any other filed document which also is or is deemed to be incorporated by reference herein modifies or supersedes such statement. Any such statement so modified or superseded shall not be deemed, except as so modified or superseded, to constitute a part of this prospectus.

You may request a copy of any filings or information incorporated herein by reference, at no cost, by writing or telephoning us at the following address and telephone number: Relmada Therapeutics, Inc., 757 3rd Avenue, Suite 2018, New York, NY 10017, Attention: Sergio Traversa, telephone number (212) 376-5776.

DISCLOSURE OF COMMISSION POSITION ON INDEMNIFICATION FOR SECURITIES ACT LIABILITIES

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, by-laws, 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, by-laws, 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 or her against such liability and expenses.

The By-laws implement the indemnification and insurance provisions permitted by Chapter 78 of the NRS.

The indemnification rights set forth above shall not be exclusive of any other right which an indemnified person may have or hereafter acquire under any bylaw, agreement, vote of stockholders or disinterested directors or otherwise, both as to action in such person's official capacity and as to action in another capacity while holding such office, and shall continue as to a person who has ceased to be a director, officer, employee, or agent and shall inure to the benefit of the heirs, executors, and administrators of such person.

We maintain a general liability insurance policy that covers liabilities of directors and officers of our corporation arising out of claims based on acts or omissions in their capacities as directors or officers.

No one has been authorized to give any information or to make any representations other than those contained or incorporated by reference in this prospectus and, if given or made, such information or representations must not be relied upon as having been authorized by us. This prospectus does not constitute an offer or a solicitation by anyone in any jurisdiction in which such offer or solicitation is not authorized or in which the person making such offer is not qualified to do so or to anyone to whom it is unlawful to make such offer or solicitation. Neither the delivery of this prospectus nor any sale hereunder shall, under any circumstances, create any implication that there has not been any change in our affairs since the date hereof.

PART II

INFORMATION REQUIRED IN THE REGISTRATION STATEMENT

Item 3. Incorporation of Documents by Reference.

We are subject to the informational requirements of the Securities Exchange Act of 1934, as amended (the "Exchange Act") and, in accordance therewith, file reports and other information with the Commission. The following documents, or portions thereof, filed by us with the Commission pursuant to the Exchange Act, are incorporated by reference in this Registration Statement:

- Our Form 10-K as of June 30, 2015 and 2014 and for the year ended June 30, 2015, for the six months ended June 30, 2014, and for the year ended December 31, 2013, filed with the Securities and Exchange Commission on September 11, 2015; and

- The description of our common stock, which is contained in our Form 8-K, filed with the Securities and Exchange Commission on May 27, 2014.

All documents subsequently filed by us pursuant to Sections 13(a), 13(c), 14 and 15(d) of the Exchange Act after the date of this Registration Statement and prior to the filing of a post-effective amendment to this Registration Statement indicating that all securities offered have been sold or which deregisters all securities then remaining unsold, are incorporated by reference in this Registration Statement and are a part of this Registration Statement from the respective dates of filings of such documents. Any statement contained herein or in a document incorporated or deemed to be incorporated by reference herein shall be deemed to be modified or superseded for purposes of this Registration Statement to the extent that a statement contained herein or in any other filed document which also is or is deemed to be incorporated by reference herein modifies or supersedes such statement. Any such statement so modified or superseded shall not be deemed, except as so modified or superseded, to constitute a part of this Registration Statement.

Item 4. Description of Securities.

Not applicable.

Item 5. Interests of Named Experts and Counsel.

Not applicable.

Item 6. 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.

The indemnification rights set forth above shall not be exclusive of any other right which an indemnified person may have or hereafter acquire under any bylaw, agreement, vote of stockholders or disinterested directors or otherwise, both as to action in such person's official capacity and as to action in another capacity while holding such office, and shall continue as to a person who has ceased to be a director, officer, employee, or agent and shall inure to the benefit of the heirs, executors, and administrators of such person.

We maintain a general liability insurance policy that covers liabilities of directors and officers of our corporation arising out of claims based on acts or omissions in their capacities as directors or officers.

Item 7. Exemption From Registration Claimed.

Not applicable.

Item 8. Exhibits.

Exhibit No.	Description
4.1	Specimen Common Stock Certificate*
4.2	Articles of Incorporation (incorporated by reference to Exhibit 3.1 to Registration Statement on Form S-1 filed with the SEC on November 13, 2012).
4.3	Certificate of Designation dated May 13, 2014 (incorporated by reference to Exhibit 4.1 to Report on Form 8-K filed with the SEC on May 19, 2014).
4.4	Nevada Certificate of Amendment to Articles of Incorporation, effective May 30, 2014 (incorporated by reference to Exhibit 3.1 to Form 8-K filed with the SEC on May 27, 2014).
4.5	Nevada Certificate of Amendment to Articles of Incorporation, effective July 8, 2014 (incorporated by reference to Exhibit 3.1 to Form 8-K filed with the SEC on July 14, 2014).
4.6	Nevada Certificate of Amendment to Articles of Incorporation, effective February 12, 2015 (incorporated by reference to Exhibit 3.1 to Form 10-Q filed with the SEC on February 13, 2015).
4.7	Nevada Certificate of Change Pursuant to NRS 78,209, effective August 11, 2015 (incorporated by reference to Exhibit 3.1 to Form 8-K filed with the SEC on August 10, 2015).
4.8	Bylaws of Relmada Therapeutics, Inc. (incorporated by reference to Exhibit 3.3 of the Company's Form 8-K filed with the SEC on May 27, 2014).
5.1	Opinion of Fennemore Craig, P.C. *
10.1	Relmada Therapeutics, Inc. 2014 Stock Option and Equity Incentive Plan (incorporated by reference to Exhibit 10.14 to Form S-1/A filed with the SEC on December 9, 2015).
10.2	First Amendment to Relmada Therapeutics, Inc. 2014 Stock Option and Equity Incentive Plan (incorporated by reference to Exhibit 10.1 to Form 8-K filed with the SEC on August 7, 2015).
23.1	Consent of GBH CPAs, PC *
23.2	Consent of Fennemore Craig, P.C. (included in Exhibit 5.1) *
24.1	Power of Attorney (included on signature page) *

* Filed herewith

Item 9. Undertakings.

The undersigned Company hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this Registration Statement:

(i) To include any prospectus required by Section 10(a)(3) of the Securities Act;

(ii) To reflect in the prospectus any facts or events arising after the effective date of the Registration Statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the Registration Statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20 percent change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective Registration Statement;

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the Registration Statement or any material change to such information in the Registration Statement;

Provided, *however*, that paragraphs (1)(i) and (1)(ii) above do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Commission by the Company pursuant to Section 13 or Section 15(d) of the Securities Exchange Act that are incorporated by reference in the Registration Statement.

(2) That, for the purpose of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

The undersigned Company hereby undertakes that, for purposes of determining any liability under the Securities Act, each filing of the Company's annual report pursuant to Section 13(a) or Section 15(d) of the Exchange Act (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Exchange Act) that is incorporated by reference in the Registration Statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

The undersigned Company hereby undertakes to deliver or cause to be delivered with the prospectus, to each person to whom the prospectus is sent or given, the latest annual report, to security holders that is incorporated by reference in the prospectus and furnished pursuant to and meeting the requirements of Rule 14a–3 or Rule 14c–3 under the Exchange Act; and, where interim financial information required to be presented by Article 3 of Regulation S-X is not set forth in the prospectus, to deliver, or cause to be delivered to each person to whom the prospectus is sent or given, the latest quarterly report that is specifically incorporated by reference in the prospectus to provide such interim financial information.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the Company pursuant to the foregoing provisions, or otherwise, the Company has been advised that in the opinion of the Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Company of expenses incurred or paid by a director, officer or controlling person of the Company in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Company will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the Company certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-8 and has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of New York, State of New York, on this 2nd day of October, 2015.

Relmada Therapeutics, Inc.

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

By: /s/ Douglas Beck
Name: Douglas Beck
Title: Chief Financial Officer
(Duly Authorized Officer and Principal Financial and Accounting Officer)

POWER OF ATTORNEY

Each person whose signature appears below hereby appoints each of Sandesh Seth and Sergio Traversa, severally, acting alone and without the other, his or her true and lawful attorney-in-fact, with full power of substitution, and with the authority to execute in the name of each such person, any and all amendments (including without limitation, post-effective amendments) to this registration statement, to sign any and all additional registration statements relating to the same offering of securities as this registration statement that are filed pursuant to Rule 462(b) of the Securities Act of 1933, and to file such registration statements with the Securities and Exchange Commission, together with any exhibits thereto and other documents therewith, necessary or advisable to enable the registrant to comply with the Securities Act of 1933, and any rules, regulations and requirements of the Securities and Exchange Commission in respect thereof, which amendments may make such other changes in the registration statement as the aforesaid attorney-in-fact executing the same deems appropriate.

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Sergio Traversa Sergio Traversa	Chief Executive Officer and Director (principal executive officer)	October 2, 2015
/s/ Douglas Beck Douglas Beck	Chief Financial Officer (Principal Financial and Accounting Officer)	October 2, 2015
/s/ Sandesh Seth Sandesh Seth	Chairman of the Board	October 2, 2015
/s/ Shreeram Agharkar Shreeran Agharkar	Director	October 2, 2015
/s/ Nabil Yazgi Nabil Yazgi	Director	October 2, 2015
/s/ Charles Casamento Charles Casamento	Director	October 2, 2015

INDEX TO EXHIBITS

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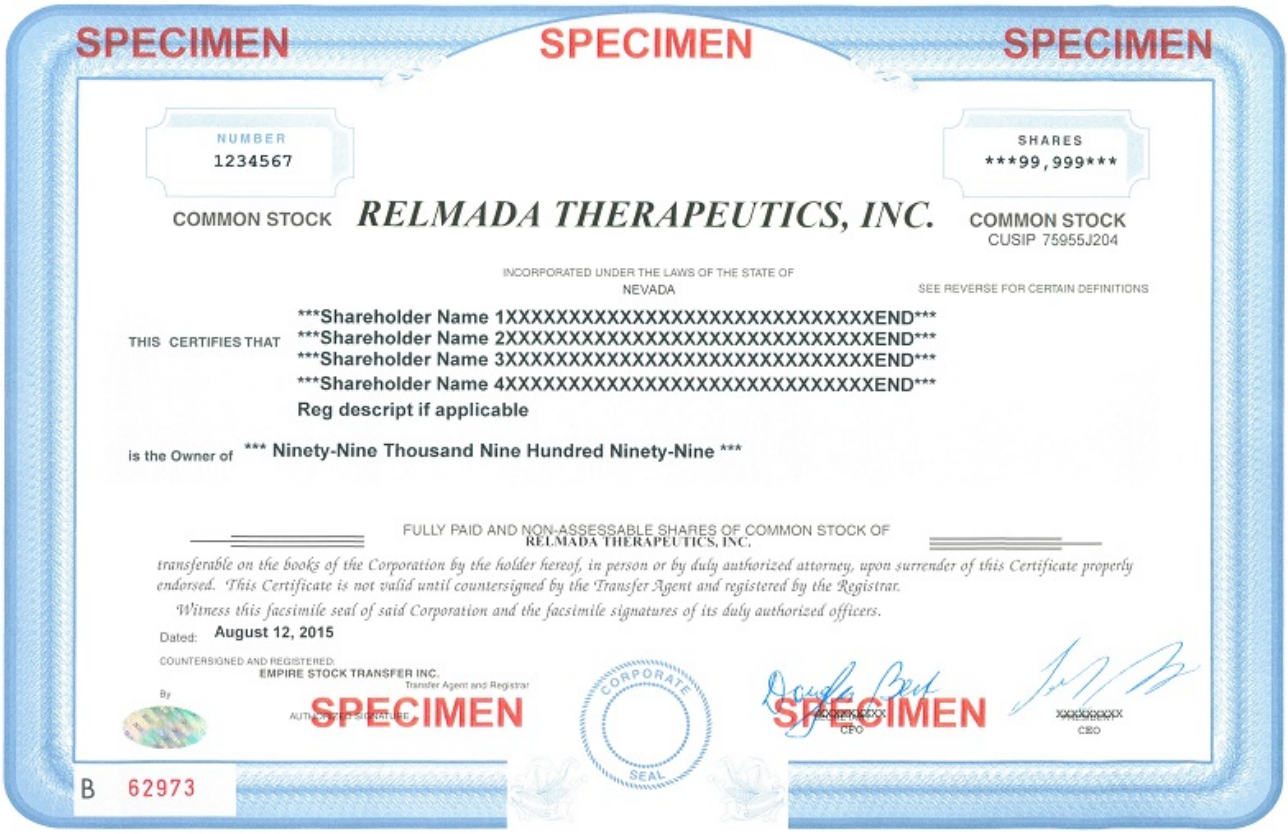
23.1	Consent of GBH CPAs, PC *
23.2	Consent of Fennemore Craig, P.C. (included in Exhibit 5.1) *
24.1	Power of Attorney (included on signature page) *

* Filed herewith

Exhibit 4.1


SPECIMEN
SPECIMEN
SPECIMEN
NUMBER
1234567
SHARES
99,999
COMMON STOCK
RELMADA THERAPEUTICS, INC.
COMMON STOCK
CUSIP 75955J204
INCORPORATED UNDER THE LAWS OF THE STATE OF
NEVADA
SEE REVERSE FOR CERTAIN DEFINITIONS
THIS CERTIFIES THAT
Shareholder Name 1XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXEND
Shareholder Name 2XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXEND
Shareholder Name 3XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXEND
Shareholder Name 4XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXEND
Reg descript if applicable
is the Owner of *** Ninety-Nine Thousand Nine Hundred Ninety-Nine ***
FULLY PAID AND NON-ASSESSABLE SHARES OF COMMON STOCK OF
RELMADA THERAPEUTICS, INC.
transferable on the books of the Corporation by the holder hereof, in person or by duly authorized attorney, upon surrender of this Certificate properly endorsed. This Certificate is not valid until countersigned by the Transfer Agent and registered by the Registrar.
Witness this facsimile seal of said Corporation and the facsimile signatures of its duly authorized officers.
Dated: August 12, 2015
COUNTERSIGNED AND REGISTERED:
EMPIRE STOCK TRANSFER INC.
Transfer Agent and Registrar
By
AUTHORIZED SIGNATURE
SPECIMEN
CORPORATE
SEAL
SPECIMEN
CEO
CEO
B 62973

The following abbreviations, when used in the inscription of the face of this certificate, shall be construed as though they were written out in full according to applicable laws or regulations:

TEN COM — as tenants in common

TEN ENT — as tenants by the entireties

JT TEN — as joint tenants with right of survivorship and not as tenants in common

UNIF GIFT MIN ACT — _____Custodian_____
(Cust) (Minor)
under Uniform Gifts to Minors Act

_____
(State)

Additional abbreviations may also be used though not in the above list.

For Value Received, _____ *hereby sells, assigns and transfers unto*

PLEASE INSERT SOCIAL SECURITY OR OTHER IDENTIFYING NUMBER

_____

_____

(PLEASE PRINT OR TYPE NAME AND ADDRESS INCLUDING POSTAL ZIP CODE OF ASSIGNEE)

_____

_____ *Shares of the Capital Stock represented by this Certificate and hereby irrevocably constitutes and appoints*

_____ *Attorney to transfer the said stock on the books of the within-named Corporation with full power of substitution in the premises.*

Dated _____

NOTICE THE SIGNATURE(S) TO THIS ASSIGNMENT MUST CORRESPOND WITH THE NAME(S) AS WRITTEN UPON THE FACE OF THIS CERTIFICATE IN EVERY PARTICULAR WITHOUT ALTERATION OR ENLARGEMENT OR ANY CHANGE WHATSOEVER.

SIGNATURE(S) GUARANTEED

NOTICE THE SIGNATURE(S) SHOULD BE GUARANTEED BY AN ELIGIBLE GUARANTOR INSTITUTION, (BANKS, STOCKBROKERS, SAVINGS AND LOAN ASSOCIATION AND CREDIT UNIONS) WITH MEMBERSHIP IN AN APPROVED SIGNATURE GUARANTEE MEDALLION PROGRAM PURSUANT TO S.E.C. RULE 17AD-15.

Exhibit 5.1

FENNEMORE CRAIG, P.C.

300 E. Second Street
Suite 1510
Reno, Nevada 89501
(775) 788-2200

Law Offices
Denver (303) 291-3200
Las Vegas (702) 692-8000
Nogales (520) 281-3480
Phoenix (602) 916-5000
Reno (775) 788-2200
Tucson (520) 879-6800

October 2, 2015

Relmada Therapeutics, Inc.
757 3rd Avenue, Suite 2018
New York, New York 10017

Ladies and Gentlemen:

You have requested our opinion with respect to certain matters in connection with the registration under the Securities Act of 1933, as amended (the "Act"), by Relmada Therapeutics, Inc., a Nevada corporation (the "Company"), by means of a registration statement on Form S-8 (as it may be amended and supplemented, the "Registration Statement") filed with the Securities and Exchange Commission (the "Commission") relating to (i) the registration and resale of 996,818 shares (the "Current Shares") of common stock, par value $0.001 per share (the "Common Stock"), consisting of restricted shares of the Company's Common Stock previously issued pursuant to the Relmada Therapeutics, Inc. 2014 Stock Option and Equity Incentive Plan, as amended (the "Plan") as well as shares of the Company's Common Stock underlying outstanding options previously granted under the Plan, (ii) options ("Options") that may be granted under the Plan to purchase up to an aggregate of 614,952 shares of the Company's Common Stock, and (iii) up to an aggregate of 614,952 shares of Common Stock of the Company which may underlie options to be granted under the Plan, or which may be stock or other awards which are subject to future grants under the Plan (the "Future Shares").

In connection with this opinion, we have examined and relied upon the Registration Statement, the Company's Articles of Incorporation and Bylaws, each as amended and currently in effect, and the originals or copies certified to our satisfaction of such other documents, records, certificates, memoranda and other instruments as in our judgment are necessary or appropriate to enable us to render the opinion expressed below. We have examined originals or copies of such other corporate records, certificates of corporate officers and public officials and other agreements and documents as we have deemed necessary or advisable for purposes of this opinion letter. We have relied upon the certificates of all public officials and corporate officers with respect to the accuracy of all factual matters contained therein.

On the basis of the foregoing, and in reliance thereon, we are of the opinion that:

1. That portion of the Current Shares that have been previously issued as restricted stock have been validly issued and are fully paid and nonassessable.

2. That portion of the Current Shares that are issued pursuant to stock options issued under the Plan, when issued in accordance with such stock options will be validly issued, fully paid and nonassessable.

3. When Options are issued pursuant to the Plan, such Options will be validly issued, fully paid, and nonassessable.

4. When Future Shares are issued pursuant to the Plan or pursuant to stock options or other instruments that have been issued pursuant to the Plan, such Future Shares will be validly issued, fully paid and nonassessable.

With respect to any Current Shares or Future Shares that are issued after the date of this opinion letter, we have assumed that at the time of issuance, the Corporation has sufficient authorized, but unissued shares available to allow for such issuance.

The opinions expressed above are limited to the laws of the State of Nevada, including reported judicial decisions. This Opinion Letter is intended solely for use in connection with the registration and offering of the Common Stock as described in the Registration Statement and resales of the Common Stock, and it may not be reproduced or filed publicly, without the written consent of this firm; provided, however, we hereby consent to the filing of this Opinion Letter as an exhibit to the Registration Statement and to the use of our name under the heading "Legal Matters" contained in the Prospectus included in the Registration Statement. In giving this consent, we do not hereby admit that we are in a category of persons whose consent is required pursuant to Section 7 of the Securities Act of 1933 or the rules and regulations of the Securities and Exchange Commission promulgated thereunder.

Very truly yours,

Fennemore Craig, P.C.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in this Registration Statement of Relmada Therapeutics, Inc. on Form S-8 of our report dated September 11, 2015 relating to the consolidated financial statements of Relmada Therapeutics, Inc. as of June 30, 2015 and 2014 and for the year ended June 30, 2015, for the six months ended June 30, 2014, and for the year ended December 31, 2013. We also consent to the reference to our firm under the headings "Experts" appearing therein.

/s/ GBH CPAs, PC
GBH CPAs, PC
www.gbhcpas.com
Houston, Texas
October 2, 2015