#### UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

#### FORM 8-K

#### CURRENT REPORT Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 22, 2015

#### **RELMADA THERAPEUTICS, INC.**

(Exact name of registrant as specified in its charter)

Nevada	333-184881	45-5401931
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

10036

(Zip Code)

546 Fifth Avenue, 14<sup>rd</sup> Floor

New York, NY

(Address of principal executive offices)

Registrant's telephone number, including area code (212) 702-7163

N/A

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a -12)

Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d -2(b))

Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

#### Item 7.01. Regulation FD Disclosure.

A copy of the Company's corporate presentation is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated into this Item 7.01 by reference. The presentation is also posted on the Company's website. In accordance with General Instruction B.2 of Form 8-K, the information set forth herein is deemed to be "furnished" and shall not be deemed to be "filed" for purposes of the Securities Exchange Act of 1934, as amended. The information set forth in Item 7.01 of this Current Report on Form 8-K shall not be deemed an admission as to the materiality of any information in this Current Report on Form 8-K that is required to be disclosed solely to satisfy the requirements of Regulation FD.

#### Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit	
No.	Description
99.1	Relmada Therapeutics, Inc., Corporate Presentation.

#### SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: May 22, 2015

#### **RELMADA THERAPEUTICS, INC.**

By: /s/ Sergio Traversa

Name: Sergio Traversa Title: Chief Executive Officer



### Innovations in Pain Medicine™



Ticker Symbol OTCQB:RLMD



#### **Forward Looking Statements**

Certain statements contained in this presentation or in other documents of Relmada Therapeutics (the "Company"), along with certain statements that may be made by management of the Company orally in presenting this material, may contain "forward-looking statements." These statements can be identified by the fact that they do not relate strictly to historic or current facts. They use words such as "estimate," "expect," "intend," "believe," "plan," "anticipate," "projected" and other words and terms of similar meaning in connection with any discussion of future operating or financial performance or condition. These statements are based upon the current beliefs and expectations of the Company's management and are subject to significant risks and uncertainties. Statements regarding future action, future performance and/or future results including, without limitation, those relating to the timing for completion, and results of, scheduled or additional clinical trials and the FDA's or other regulatory review and/or approval and commercial launch and sales results (if any) of the Company's formulations and products and regulatory filings related to the same may differ from those set forth in the forward-looking statements. Peak sales and market size estimates have been determined on the basis of market research and comparable product analysis, but no assurances can be given that such sales levels will be achieved, if at all, or that such market size estimates will prove accurate.

Because actual results are affected by these and other potential risks, contingencies and uncertainties, the Company cautions investors that actual results may differ materially from those expressed or implied in any forward-looking statement. It is not possible to predict or identify all such risks, contingencies and uncertainties. The Company identifies some of these factors in its Securities and Exchange Commission ("SEC") filings on Forms 10-K, 10-Q and 8-K, and investors are advised to consult the Company's filings for a more complete listing of risk factors, contingencies and uncertainties effecting the Company and its business and financial performance.

The Company assumes no obligation to update forward-looking statements as circumstances change. Investors are advised to consult further disclosures that the Company makes or has made on related subjects in the Company's Form 10-K, 10-Q and 8-K reports.



### **Company Highlights**

- Robust portfolio of four drugs in development that address unmet needs in the largest drug prescription market in the world: the treatment of pain
  - Three products combine proven drug candidates with novel delivery methods to create new drugs with new indications, while the fourth is a new entity
  - A low cost, low risk drug development strategy that provides the ability to bring products to market faster for three of our four products
  - A risk balanced, therapeutically focused product portfolio mitigates development risk while promising significant upside
  - Highly experienced drug development leadership and a world class Scientific Advisory Board provide the expertise to efficiently advance product development



# Experienced Senior Management An impressive track record developing and commercializing successful drugs

Sergio Traversa, PharmD Chief Executive Officer	Eli Lilly, Johnson & Johnson, ING Barings, Mehta & Isaly, Merlin BioMed, Rx Capital		
Douglas Beck, CPA Chief Financial Officer	Lev Pharmaceuticals, iBio Inc.		
Michael Becker Senior VP, Finance & Corp Dev	Cytogen Corp, VioQuest Pharma, Kidder Peabody, Kemper Securities, Wayne Hummer Investments		
Richard Mangano, Ph.D. Senior VP, Clinical Dev	Hoffman-La Roche, Lederle Laboratories, Wyeth, Adolor		
Lisa Nolan, Ph.D. Senior VP, Business Dev	Zeneca, Elan, SkyePharma		



#### **Scientific Advisors**

Internationally recognized expertise from world-class scientific advisors

**Imperial College** 

Andrew Rice, MD, FRCA

Professor of Pain Research at Imperial College of London

· Director of the London Pain Consortium

Secretary of the International Association

Steering Committee Member of

for the Study of Pain

EUROPAIN

London

.



Memorial Sloan Kettering Cancer Center.

#### Gavril Pasternak, MD, PhD

- Anne Burnett Tandy Chair in Neurology Laboratory Head, Molecular .
- Pharmacology and Chemistry Program
- Memorial Sloan Kettering Cancer Institute . .
- Professor of Neurology & Neuroscience, Pharmacology and Psychiatry at the Weill Medical School of Cornell University



#### Michael Thase, MD

- Professor of Psychiatry, School of Medicine University of Pennsylvania .
- Chief, Division of Mood and Anxiety Disorders Treatment & Research .
- . Member American College of Psychiatrists and American College of Neuropsychopharmacology



#### Eric C. Strain, MD

- Professor of Psychiatry, Johns Hopkins University School of Medicine .
- · Director, Behavioral Pharmacology Research Unit
- Director, Johns Hopkins Substance Abuse
  Treatment and Research

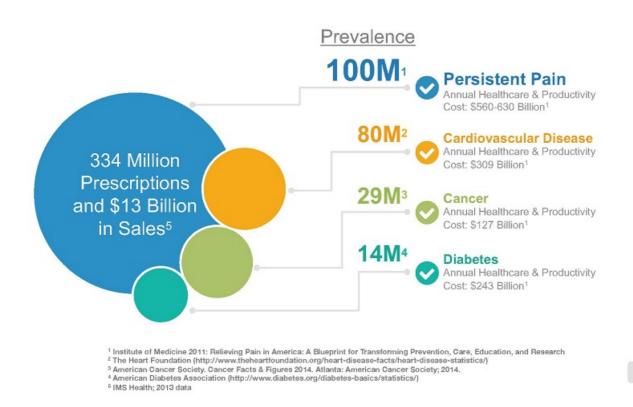


#### Robert H. Dworkin, PhD

- Professor of Anesthesiology, Neurology, Oncology, and Psychiatry
- University of Rochester School of Medicine and Dentistry
- Director, ACTTION, FDA-academic partnership on analgesics



### Pain: Largest U.S. Public Health Crisis





# Portfolio Covers Entire Chronic Pain Spectrum

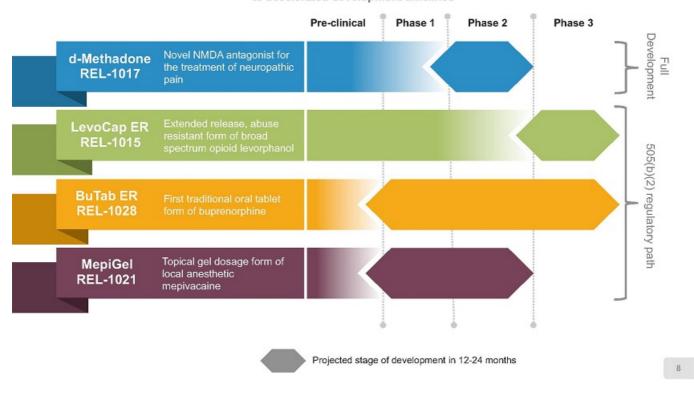
Pain Intensity	Products in Market	2013 Sales (\$M)	Relmada Product Candidate
	Kadian®**	\$264	1
	Avinza®	\$114	LevoCap ER
Severe	Opana®**	\$386	REL-1015
	Nucynta®	\$236	
	OxyContin®	\$2,535	BuTab ER
	Vicodin®*	\$1,051	REL-1028
	Ultram®*	\$173	
Moderate	BuTrans®	\$134	d Mathadawa
	Suboxone®	\$1,404	d-Methadone REL-1017
	Lyrica®	\$4,595	
	Cymbalta®	\$5,084	MeniGel
V	Gabapentin®**	\$2,723	MepiGel REL-1021
Mild	Lidoderm®**	\$948	
	TOTAL	\$19,647	-

\* Includes generics \*\* Peak sales Source: IMS Health, Company Annual Report



### **Robust Product Portfolio**

Significant value creation possible in 12-24 months due to accelerated development timelines



#### d-Methadone

Novel NMDA antagonist for the treatment of neuropathic pain





### d-Methadone – Benefits, Advantages, Features

Neuropathic pain represents a large market opportunity ready for a new effective entry

- d-Methadone is a novel drug
  - Noncompetitive N-methyl-D-aspartate (NMDA) antagonist
  - Potential new treatment for estimated 5 million people suffering from neuropathic pain
  - Created by separating methadone's two isomers
  - Leverages research by Cornell University
  - Virtually exempt from opioid activity and related side effects at studied doses
- Racemic methadone is widely known synthetic opioid
  - Used to treat both drug addiction and pain
  - Poor safety and tolerability due to opioid side effects



### d-Methadone – Proof of Concept

- Upregulation of NMDA plays important role in neuropathic pain
- Inhibition of NMDA produces strong analgesia in neuropathic pain states
  - Example: low dose ketamine<sup>1</sup>
  - Severe side effects limit use of ketamine
    - Psychedelic symptoms (hallucinations, memory defects, panic attacks), nausea/vomiting, somnolence, cardiovascular stimulation
- d-Methadone is well-tolerated NMDA antagonist
  - Administered at doses several fold higher than conventionally used with racemic methadone in opioid naïve patients

<sup>1</sup> Br J Clin Pharmacol. 2014 Feb; 77(2): 357–367. Ketamine for chronic pain: risks and benefits. Marieke Niesters, Christian Martini, and Albert Dahan



# d-Methadone Next Steps

Multiple development milestone potential in next 12-24 months

H1 2015	H2 2015	2016
<ul> <li>Complete Phase I</li></ul>	<ul> <li>Complete Phase I</li></ul>	<ul> <li>Start Phase II in</li></ul>
single dose study in	multi dose study in	+200 patients <li>Report Phase II</li>
~56 patients	~20 patients <li>FDA meeting</li> <li>Human pain model</li>	interim results



Extended release, abuse resistant form of broad spectrum opioid levorphanol





### LevoCap ER – Benefits, Advantages, Features

LevoCap ER will compete in the \$8.5 billion opioid market if approved

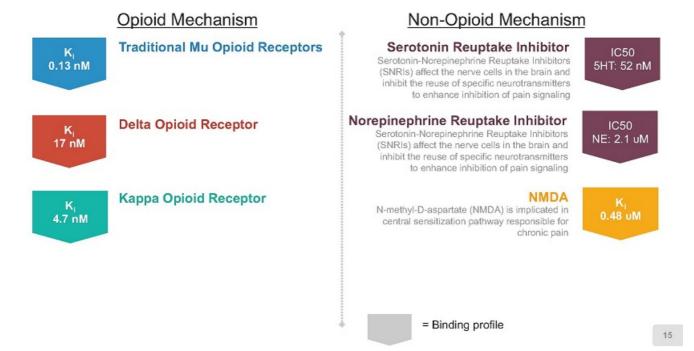
- LevoCap ER is an extended release, abuse deterrent formulation of levorphanol
- Levorphanol is a unique, broad spectrum opioid with additional "non-opioid" mechanisms of action
  - Can treat both pain from damage to body tissue (nociceptive) and nerve damage (neuropathic)
  - Virtually unknown by medical community
  - Limited clinical data and use
- ~90% of patients take multiple medicines to treat severe pain, including opioids, antidepressants, anticonvulsants, etc.<sup>1</sup>

<sup>1</sup> ORC International – Product Profile Evaluation among 150 physicians specializing in pain management



### Levorphanol's Broad Spectrum Activity

Levorphanol's multi-modal mechanism of action provides for a more robust efficacy profile and potentially could be used alone for patients who take multiple drugs





# LevoCap ER Next Steps

Multiple development milestone potential in next 12-24 months

H1 2015	H2 2015	2016
<ul> <li>Obtain regulatory approval from Health Canada to start clinical trial</li> </ul>	<ul> <li>FDA end of Phase II meeting</li> <li>Start Phase III</li> </ul>	Continue Phase 3

\* Pending feedback from FDA meeting

### **BuTab ER**

First oral tablet form of buprenorphine for treating both pain and addiction





### BuTab ER – Benefits, Advantages, Features

The first form of buprenorphine in a tablet for use in pain and treating addiction

- Buprenorphine is a partial opioid agonist with two indications: addiction and pain
  - More than \$1.6 billion in annual revenue
  - Only schedule III opioid under Controlled Substances Act
- · No "traditional oral tablet" available for buprenorphine
  - Historically suffers from poor oral bioavailability due to first-pass metabolism in gut and liver
  - Commercially available only in intravenous (Buprenex), sublingual/buccal (Suboxone®, Bunavail<sup>™</sup>, Zubsolv®), and transdermal patch (Butrans®) formulations
- BuTab ER is an extended release, enteric coated formulation of buprenorphine
  - Coating is designed to bypass upper GI mucosa metabolism of buprenorphine by CYP3A4 enzyme to increase oral bioavailability



### BuTab ER – Proof of Concept

- 1. Positive single dose bioavailability of oral buprenorphine demonstrated in dogs
- 2. Inhibition of CYP3A4 enzyme with steroid budesonide
  - Poor oral drug bioavailability due to cytochrome P450 (CYP)mediated first-pass metabolism
    - Sub-family enzyme CYP3A4 is responsible for metabolism of >50% of marketed drugs
  - Inhibiting enzyme demonstrated dramatically improved bioavailability of the steroid budesonide

Source: Differentiating mucosal and hepatic metabolism of budesonide by local pretreatment with increasing doses of ketoconazole in the proximal jejunum. Seidegård J, Nyberg L, Borgå O. Eur J Pharm Sci. 2012 Aug 15;46(5):530-6.



# BuTab ER Next Steps

Multiple development milestone potential in next 12-24 months

H1 2015	H2 2015	2016
<ul> <li>✓ Obtain regulatory approval from Health Canada to start clinical trial</li> <li>Start Phase 1 in ~30 patients</li> </ul>	<ul> <li>Complete proof-of- concept Phase I</li> </ul>	<ul> <li>NDA filing for opioid dependence</li> <li>Start Phase III for pain</li> </ul>

# MepiGel

Topical gel dosage form of the local anesthetic mepivacaine for the treatment of neuropathic pain





#### MepiGel – Benefits, Advantages, Features

MepiGel will compete with Lidoderm® patch and its \$948 million in peak sales if approved

- MepiGel is the first topical gel dosage form of local anesthetic mepivacaine, which has intrinsic vasoconstrictor attributes
  - Reduces rate at which drug is cleared away from skin
  - Better efficacy may last longer due to greater skin penetration/retention
  - More convenient application for patient
- Two Orphan Drug designations
  - 1. Management of PHN
  - 2. Treatment of painful HIV-associated neuropathy
- Limited number of treatments available for neuropathic pain
  - Topical 5% lidocaine patch (Lidoderm®) provides only modest pain relief in patients with postherpetic neuralgia; reached peak sales of \$948 million
    - 2010 UK Nat'l Instit of Health and Clinical Excellence (NICE) guideline cites "lack of evidence for efficacy for treating neuropathic pain" and 3<sup>rd</sup> line
  - Patches have poor adhesion to hands, feet, and hairy skin



# MepiGel Next Steps

Multiple development milestone potential in next 12-24 months

H1 2015	H2 2015	2016
<ul> <li>File Clinical Trial Application (CTA)</li> </ul>	<ul> <li>Complete Phase I in ~20 patients</li> </ul>	<ul> <li>Human pain model</li> <li>Proof-of-concept Phase II in +200 patients</li> </ul>

# MILESTONES & COMMERCIAL OPPORTUNITY





## **Near-term Value Drivers**

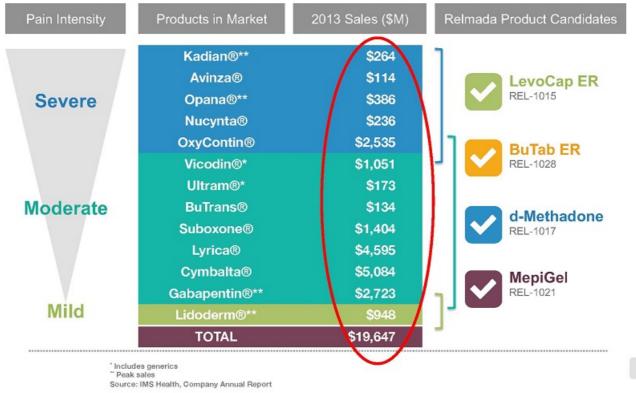
Multiple development milestone potential in next 12-24 months

	H1 2015	H2 2015	2016
d-Methadone REL-1017	Complete Phase I single dose study	<ul> <li>Complete Phase I multi dose study</li> <li>FDA meeting</li> <li>Human pain model results</li> </ul>	<ul> <li>Start Phase II</li> <li>Report Phase II interim results</li> </ul>
LevoCap ER REL-1015	<ul> <li>Obtain regulatory approval to start clinical trial</li> </ul>	<ul> <li>FDA end of Phase II meeting</li> <li>Start Phase III*</li> </ul>	Continue Phase 3
BuTab ER REL-1028	<ul> <li>Obtain regulatory approval to start clinical trial</li> <li>Start Phase 1</li> </ul>	Complete proof-of-concept Phase I	<ul> <li>NDA filing (or start Phase III)</li> </ul>
MepiGel REL-1021	• File CTA	Complete Phase I	<ul> <li>Human pain model results</li> <li>Proof-of-concept Phase II</li> </ul>
Corporate		<ul> <li>Uplisting to National Exchange</li> </ul>	Addition to Russell Index
		* Pending feedback from FDA meet	ling



# **Commercial Opportunity**

Multi-billion established markets for chronic pain therapy





### **Company Highlights**

- Robust portfolio of four drugs in development that address unmet needs in the largest drug prescription market in the world: the treatment of pain
  - Three products combine proven drug candidates with novel delivery methods to create new drugs with new indications, while the fourth is a new entity
  - A low cost, low risk drug development strategy that provides the ability to bring products to market faster for three of our four products
    - A risk balanced, therapeutically focused product portfolio mitigates development risk while promising significant upside
    - Highly experienced drug development leadership and a world class Scientific Advisory Board provide the expertise to efficiently advance product development



#### Innovations in Pain Medicine™

546 Fifth Ave 14th Floor New York, NY 10036 www.relmada.com Tel: (212) 702-7163 Email: info@relmada.com

> Ticker Symbol OTCQB:RLMD