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): June 2, 2020

RELMADA THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Nevada	**000-55347**	**45-5401931**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

880 Third Avenue, 12th Floor New York, NY	**10022**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code **(646) 876-3459**

(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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol**	**Name of exchange on which registered**
Common stock, $0.001 par value per share	RLMD	The Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

EXPLANATORY NOTE

Item 8.01. Other Events

The Company updated its corporate presentation, a copy of which is attached as Exhibit 99.1 hereto and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Corporate Presentation, dated June 2, 2020

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: June 3, 2020

RELMADA THERAPEUTICS, INC.

By: /s/ Sergio Traversa
Name: Sergio Traversa
Title: Chief Executive Officer

Exhibit 99.1


RELMADA
THERAPEUTICS
Targeting Major
Advances in
Treatment of
CNS Disorders
June 2020 | Nasdaq: RLMD

Disclosures

Certain statements contained in this presentation or in other documents of Relmada Therapeutics, Inc. (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, the proposed offering, 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 affecting 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.

Investment Highlights

Highly-compelling de-risked lead product opportunity	• Phase 2 Adjunctive MDD trial completed with statistically significant rapid and sustained anti-depressant effects observed with favorable safety and tolerability profile • Successful EoP2 meeting with the FDA with clear pathway to NDA • Fast track designation from FDA • Strong IP position around REL-1017 with protection to the mid/late-2030s
Large potential in multiple underserved markets[1]	• Over 17M Americans suffered from MDD in 2017[1] • 50%–66% of patients with depression do not fully recover on an antidepressant medication[2] • Traditional antidepressants have a 4 to 6 weeks time lapse to reach full efficacy
Key catalysts expected over next 12-18 months	• Publication of REL-1017 Phase 2 study full data H2 2020 • Start of pivotal program in Adjunctive treatment of MDD in Q4 2020 • Start of Phase 2 study in MDD Q4 2020

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1. https://www.nimh.nih.gov/health/statistics/major-depression.shtml
2. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3363299/

* MDD = Major Depressive Disorder
** Our fiscal year end is December 31. The periods referred to in this slide are calendar years and quarters.

Dextromethadone (REL-1017)

as a Potential Treatment for Depression

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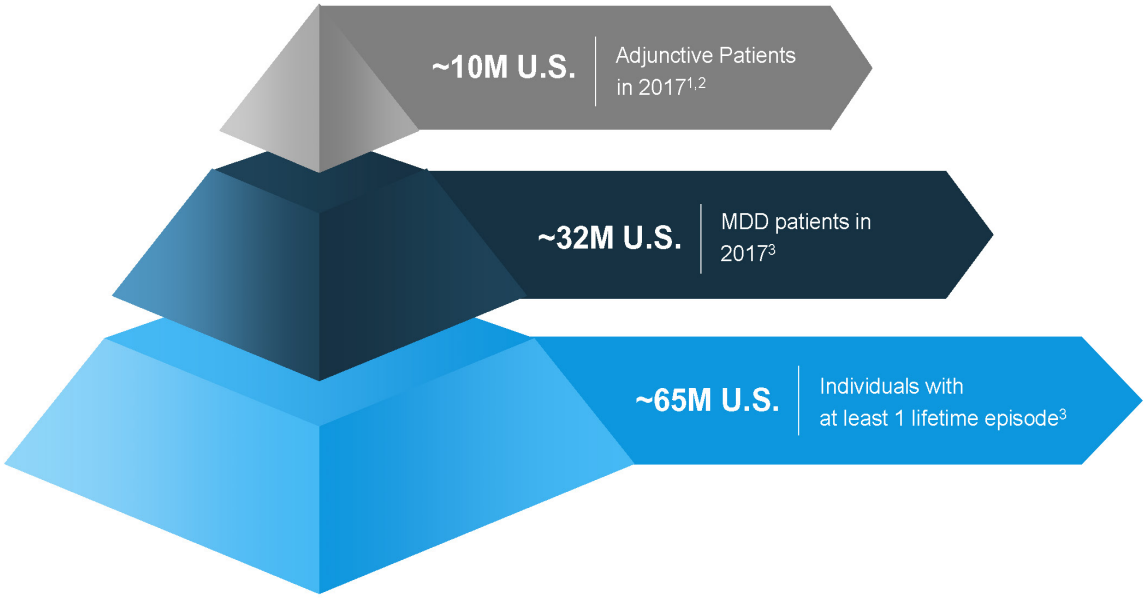
Dextromethadone (REL-1017) as a single agent rapid-acting and sustained effect oral treatment for depression

- REL-1017 has the potential to be the first single agent oral NMDAR antagonist for the adjunctive treatment of depression and potentially for front line monotherapy treatment
- Completed Phase 1 and Phase 2 trial for Adjunctive treatment of Major Depressive Disorder
- In a Phase 2 trial, both doses of REL-1017 25 mg and 50 mg demonstrated statistically significant differences compared to placebo on all efficacy measures
  - Study demonstrated rapid onset and sustained antidepressant effects
  - Only mild and moderate AEs - no serious AEs
  - No evidence of treatment induced dissociative and psychotomimetic AEs
  - No evidence of opiate withdrawal symptoms in treatment groups vs placebo

A New Effective Treatment for Major Depressive Disorder Remains a High Unmet Need



1. Am J Psychiatry. 2006 Nov;163(11):1905-17. Acute and longer-term outcomes in depressed outpatients requiring one or several treatment steps: a STAR*D report. Rush AJ, et al
2. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3363299/
3. Hasin DS, et al. Epidemiology of Adult *DSM-5* Major Depressive Disorder and Its Specifiers in the United States. *JAMA Psychiatry.* Published online February 14, 2018.

Dextromethadone Has Significant Potential Advantages in the Treatment of Depression

Novel mechanism of action

d-Methadone and other NMDA antagonists represent a new approach to treating depression with MOA markedly different from currently approved drugs (SSRIs, SNRIs, TCAs, MAOIs, etc.)

Low rate of response for traditional antidepressant in patients with MDD[1]

~65% MDD patients do not respond to first antidepressant treatment

~30% MDD patients do not respond to up to 4 different antidepressant treatments

Slow time to efficacy

Traditional currently approved drug can take up to 4 to 6 weeks to show antidepressant activity

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1 Source: Am J Psychiatry. 2006 Nov;163(11):1905-17, https://www.samhsa.gov/data/sites/default/files/cbhsq-reports/NSDUHDetailedTabs2017/NSDUHDetailedTabs2017.htm#tab8-10A

Phase 1 SAD and MAD Study Showed Favorable Safety and Tolerability Profile

Single Ascending Dose (SAD) Study Design

Parallel group, double-blind, placebo controlled

Objectives

Establish PK, PD and safety of single dose administration

Treatment Administration

Cohorts 5, 20, 60, 100, 150, 200 mg

N = 42

Study Conclusions

- MTD = 150 mg (single dose)
- PK demonstrated linear proportionality of C_{max} and $AUC_{0\text{-}inf}$ vs. dose
- No clinically significant opioid effects of dextromethadone up to 150 mg

Multiple Ascending Dose (MAD) Study Design

Parallel group, double-blind, placebo controlled

Objectives

Establish PK, PD and safety of once daily, 10 day administration

Treatment Administration

Cohorts 25, 50, 75 mg

N = 24

Study Conclusions

- Doses up to 75mg per day well tolerated
- Dose proportionality was demonstrated for the single-dose parameters Cmax and AUCt on Day 1 and for the steady state parameters Cmax, AUCt, and Css on Day 10

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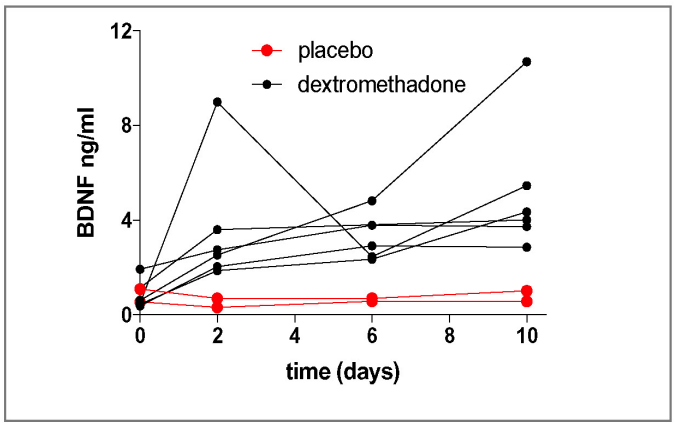
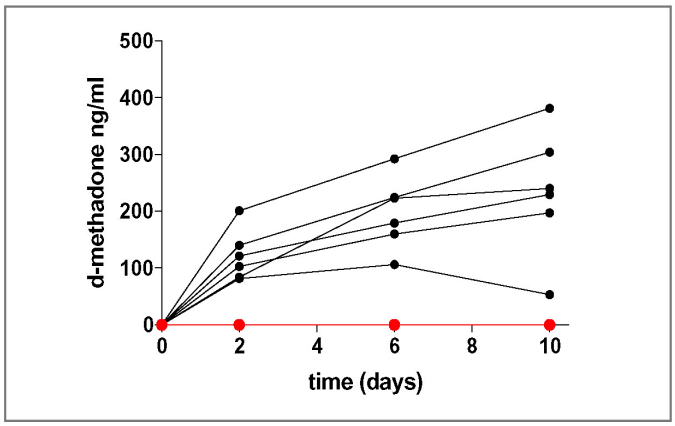
PK: pharmacokinetics; PD: pharmacodynamics; MTD: maximum tolerated dose; Cmax: maximum plasma concentration; AUC: area under the curve 0 to infinite time; AUCt : area under the curve to the end of dosing period
Data published: Bernstein, G. et al., J. Clin. Psychopharmacology 2019 May/Jun;39(3):226-237.

Dextromethadone Significantly Increased BDNF Plasma Levels Compared to Placebo in Phase 1 MAD Study in Healthy Volunteers





Treatment Arm	Average Plasma BDNF ng/ml (±SD)	
	Pre-treatment	Post treatment
Dextromethadone	0.84 (0.60)	5.84 (2.83)
Placebo	0.81 (0.38)	0.79 (0.30)

BDNF: Brain Derived Neutrophic Factor; SD: standard deviation

Dextromethadone Phase II Study in Adjunctive Treatment of MDD – Overview

Primary Objectives

Safety and tolerability of 25 mg and 50 mg of REL-1017 vs placebo as adjunctive treatment

Secondary Objectives

Evaluate efficacy of 25 mg and 50 mg of REL-1017 as adjunctive treatment in patients with MDD

To characterize pharmacokinetic (PK) profile of REL-1017 25 mg and 50 mg x 7 days

Endpoints

- PE, Laboratory studies, ECG, AEs
- CADSS (dissociative symptoms)
- 4-item PSRS (psychotomimetic symptoms)
- COWS (opiate withdrawal symptoms)
- C-SSRS (suicidality)

Endpoints

Change from BSL at Day 2, 4, 7 and 14 on:

- MADRS
- SDQ
- CGI-S

Difference in CGI-I score placebo vs treatment groups Day 2 to 14

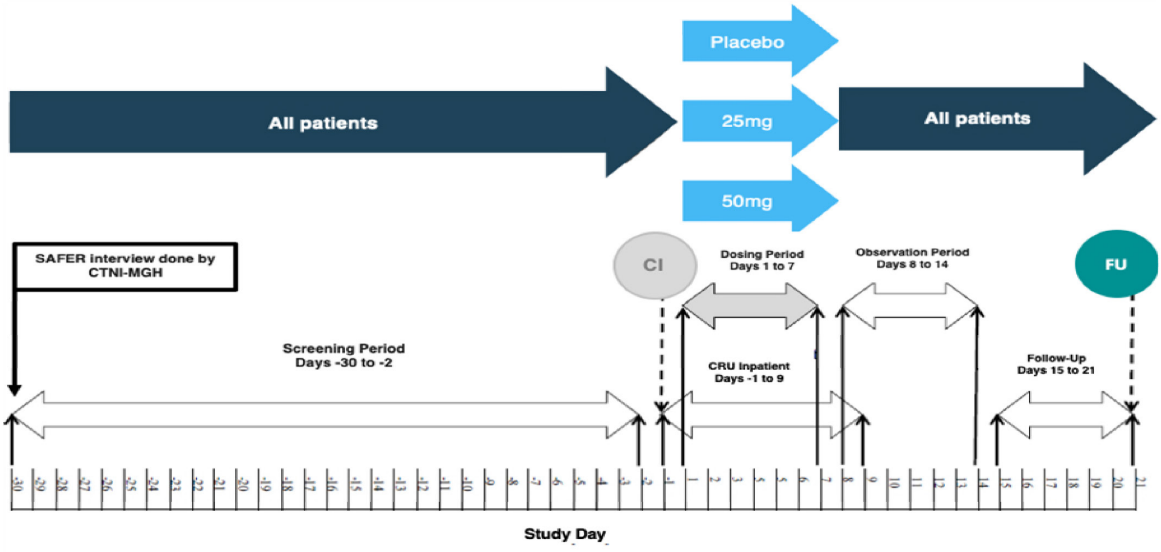
PK parameters for both 25 and 50 mg Q-day

MDD: Major Depressive Disorder; PE: Physical exam; ECG: Electrocardiogram; AEs: Adverse Events; CADSS: Clinician Administered Dissociative States Scale; PSRS: Positive Symptom Rating Scale; COWS: Clinical Opiate Withdrawal Scale; C-SSRS: Columbia-Suicide Severity Rating Scale; MADRS: Montgomery Asberg Depression Rating Scale; SDQ: Symptoms of Depression Questionnaire; CGI-S and CGI-I: Clinical Global Impression- Severity and Improvement

Dextromethadone Phase 2 Study Design

- 60 patients three arm placebo-controlled trial
- Two doses tested 25mg and 50mg once a day versus placebo
- 7 days daily treatment in clinic + 7 days observation as outpatient
- Follow up at day 14 for efficacy and safety
- Follow up at day 21 for safety only

Dextromethadone Phase II Study in Adjunctive Treatment of MDD – Design



MDD = Major Depressive Disorder; RDPC = randomized double-blind placebo controlled; MADRS = Montgomery-Asberg Depression Rating Scale; SDQ = Symptoms of Depression Questionnaire; CGIs = Clinical Global Impression scales

Dextromethadone Phase II Study - Baseline Patient Characteristics

	Placebo	REL-1017 25 mg	REL-1017 50 mg	All Subjects
Randomized Subjects	22	19	21	62
Completed all visits (Day 21)	20	18	19	57
Received all doses	21	19	21	61
Age: mean years (SD)	49.7 (11.1)	49.4 (12.4)	48.6 (10.9)	49.2 (11.3)
Females	11 (50%)	8 (42.1%)	9 (42.9%)	28 (45.2%)
Subjects ITT	22	19	21	62
Subjects PPP	21	19	21	61
Screening HAMD - Mean (SD)	25.6 (3.5)	25.1 (3.5)	25.0 (3.8)	25.3 (3.6)
Baseline MADRS - Mean (SD)	33.8 (4.0)	32.9 (6.0)	35.2 (3.9)	34.0 (4.7)

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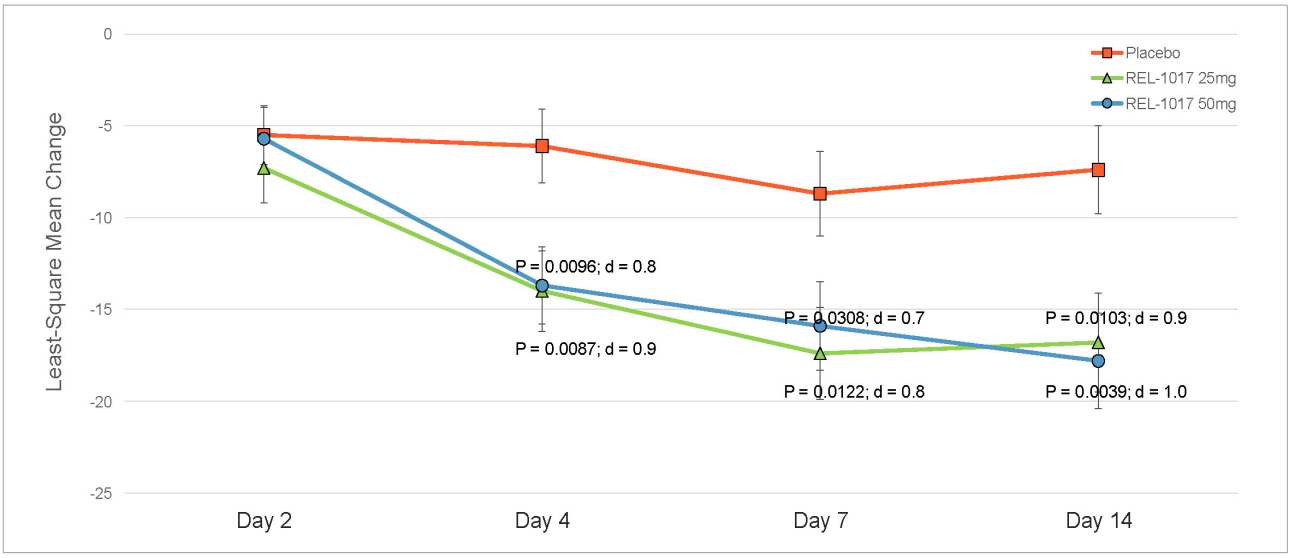
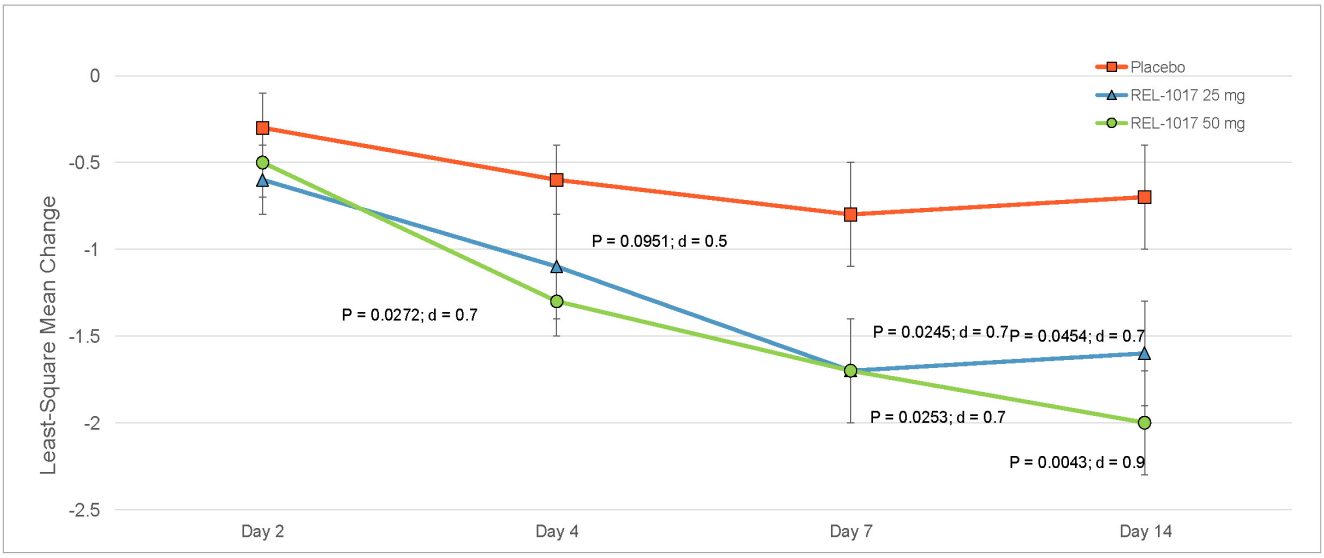
ITT: Intent-To-Treat; PPP: Per-Protocol-Population; HAMD: Hamilton Depression Rating Scale; MADRS: Montgomery-Asberg Depression Rating Scale

MADRS Scores in the Treatment Groups Achieved Statistically Significant Difference vs Placebo from Day 4 through Day 14



MADRS: Montgomery-Asberg Depression Rating Scale; ITT: Intent-To-Treat; Error Bars: Standard Errors; P and d values as Treatment vs Placebo

CGI-S Scores Achieved Statistically Significant Difference vs Placebo from Day 4 for REL-1017 50 mg and for both Doses on Day 7 and Day 14



CGI-S: Clinical Global Impression of Severity; ITT: Intent-To-Treat; Error Bars = Standard Errors; P and d values as Treatment vs Placebo

REL-1017-202 results confirm the favorable tolerability and safety profile observed in the Phase 1 SAD and MAD studies

Only Mild and Moderate AEs - no SAEs

No increased prevalence of specifically relevant organ group AEs in treatment groups vs placebo

No evidence of treatment induced dissociative symptoms in the treatment groups vs placebo

No evidence of treatment induced psychotomimetic symptoms in treatment groups vs placebo

No evidence of opiate withdrawal symptoms in treatment groups vs placebo

End of Phase 2 Meeting Outcome

REL-1017 can advance into Phase 3 registration studies w/o additional clinical studies. FDA and Relmada are aligned on all key aspects of Phase 3 program to be initiated in Q4 '20

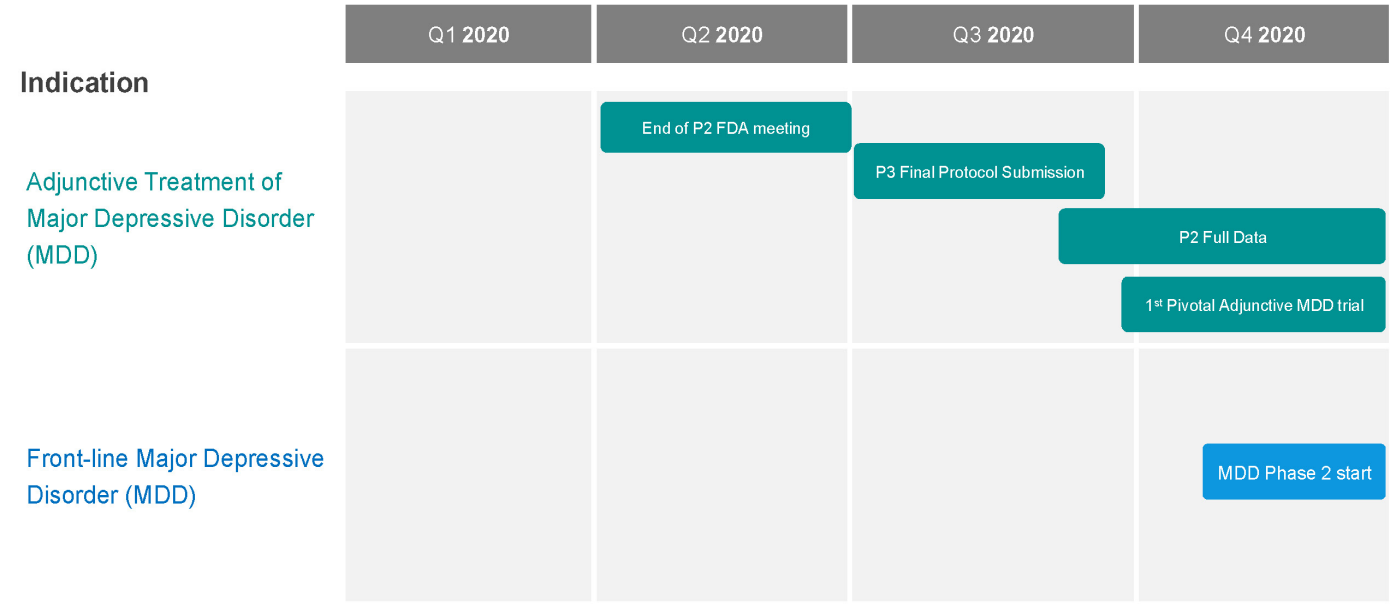
Indication:	Studies will assess REL-1017 as adjunctive treatment in MDD patients who have failed at least one prior treatment in current depression episode
Two Pivotal Studies:	Two sister two-arm placebo-controlled clinical studies
Primary Endpoint:	Change from baseline on MADRS at day-28 for REL-1017 vs. placebo and collection of sufficient safety data to support use as chronic treatment
Key Secondary Endpoints:	Change from baseline on 7-day MADRS to evaluate time to onset of treatment effect; achieved by day 4 in Phase 2

End of Phase 2 Meeting Outcome

REL-1017 can advance into Phase 3 registration studies w/o additional clinical studies. FDA and Relmada are aligned on all key aspects of Phase 3 program to be initiated in Q4 '20

Dosing:	25 mg dose of REL-1017 to be evaluated. PD relationship in Phase 2 supports equivalence of 25 mg and 50 mg doses
Tablet formulation Equivalence Established:	No PK bridging studies required to support transition from powder-in-solution formulation of REL-1017 utilized in Phase 2 to tablet formulation to be used in Phase 3
Abuse Liability Testing:	Studies to determine scheduling not required prior to starting Phase 3 and will be conducted pre-NDA

Anticipated Development Timeline REL-1017*



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*subject to FDA feedback

Potential Competitive Advantages of Dextromethadone

Compound (Company)	Mechanism of Action	Delivery	Current Clinical Stage	Dosing Regimen
Dextromethadone (Relmada)	**Non-competitive NMDA channel blocker**	Oral	Completed Phase 2	Once Daily
Esketamine/Spravato (Janssen/J&J)		Nasal (in clinic administration)	Approved and launched	Biweekly
AXS-05 DM 45 mg + BUP 105 mg (Axsome)	**Multimodal (NMDA+others)**	Oral	Phase 3/Pre-NDA[1]	Twice daily
Sage-217 (Sage)	**GABA receptor allosteric modulator**	Oral	Phase 3[2]	Once Daily
Pimavanserin/Nuplazid (Acadia)	**Selective serotonin inverse agonist (SSIA) preferentially targeting 5-HT2A receptors**	Oral	Phase 3/lunched	Once Daily

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1 First P3 study met primary endpoint
2 First P3 study did not meet primary endpoint

Corporate Information

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Financial Overview

Cash, Cash Equivalents & ST Investments
(as of 03/31/19)

Warrants Outstanding
(as of 03/31/19, weighted average exercise price, $6.79)

Operating Cash Burn 1Q20

Common Shares Outstanding
(as of 5/13/20)

Management Team and Key Scientific Advisors

Management		
Sergio Traversa	Chief Executive Officer	Johnson & Johnson, Lilly
Tom Wessel, MD, Ph.D	Head of Research & Development	ACORDA THERAPEUTICS, SEPRACOR, janssen
Maged Shenouda	Chief Financial Officer	J.P.Morgan, UBS, pwc, Abbott
Marc de Somer, MD, MBA, ScD, MPH, MSc	SVP, Clinical Development and Safety	Alkermes, PPD Biotech, NOVARTIS
Chuck Ence	Chief Accounting and Compliance Officer	PEPSICO, NEWAGE
Molly Harper	Executive Vice President of Operations	AKCEA THERAPEUTICS, SANOFI GENZYME, MERCK

Advisors		
Maurizio Fava, MD	Scientific Advisor	HARVARD UNIVERSITY, MASSACHUSETTS GENERAL HOSPITAL
Charles Inturrisi, Ph.D	Scientific Advisor	Cornell University
Paolo Manfredi, MD	Scientific Advisor	Memorial Sloan Kettering Cancer Center, MD Anderson Cancer Network, MASSACHUSETTS GENERAL HOSPITAL, Mount Sinai
Luca Pani, MD	Scientific Advisor	EUROPEAN MEDICINES AGENCY, UNIVERSITY OF MIAMI

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Investment Highlights

Highly-compelling de-risked lead product opportunity	• Phase 2 Adjunctive MDD trial completed with statistically significant rapid and sustained anti-depressant effects observed with favorable safety and tolerability profile • Successful EoP2 meeting with the FDA with clear pathway to NDA • Fast track designation from FDA • Strong IP position around REL-1017 with protection to the mid/late-2030s
Large potential in multiple underserved markets[1]	• Over 17M Americans suffered from MDD in 2017[1] • 50%–66% of patients with depression do not fully recover on an antidepressant medication[2] • Traditional antidepressants have a 4 to 6 weeks time lapse to reach full efficacy
Key catalysts expected over next 12-18 months	• Publication of REL-1017 Phase 2 study full data H2 2020 • Start of pivotal program in Adjunctive treatment of MDD in Q4 2020 • Start of Phase 2 study in MDD Q4 2020

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* MDD = Major Depressive Disorder

** Our fiscal year end is December 31. The periods referred to in this slide are calendar years and quarters.


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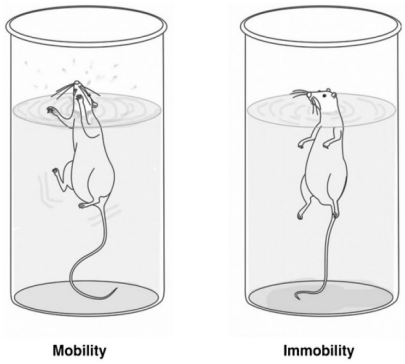
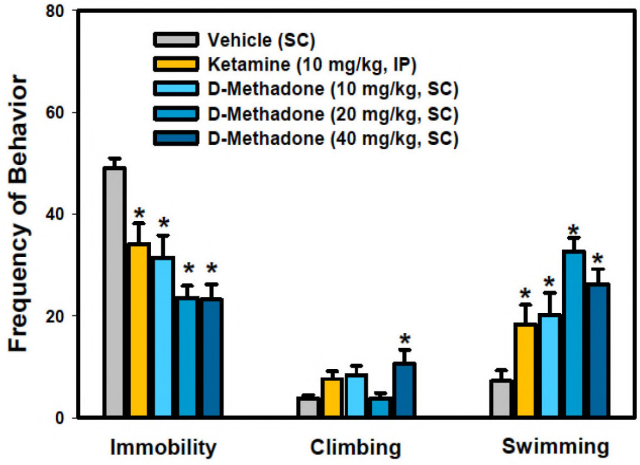
Targeting Major Advances in Treatment of CNS Disorders
June 2020
Nasdaq: RLMD

Strong Anti-Depressant Effects Observed in Three Animal Models of Depression

Improved performance on the rat forced swim test 24 hours after d-methadone treatment

Forced Swim Test



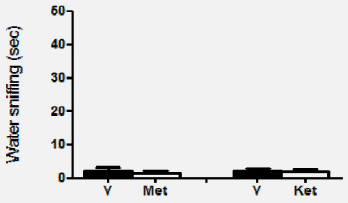


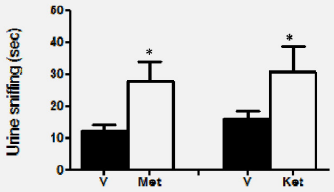
* = p<0.05 compared to placebo group

Strong Anti-Depressant Effects Observed in Three Depression Animal Models

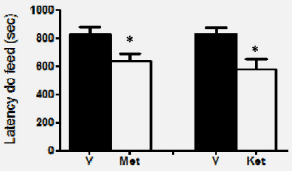
Improved performance on the rat FUST and the NSFT 24 hours after d-methadone treatment

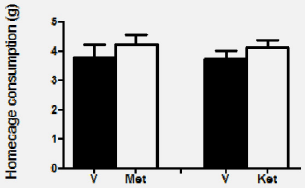
Female Urine Smell Test





Novelty Suppressed Feeding Test





Study REL-1017 Phase 2 Key Efficacy Findings

REL-1017 25 mg and 50 mg show rapid onset and sustained antidepressant effects with statistically significant differences compared to placebo on all efficacy measures

- Solid effects observed on MADRS with P values < 0.03 and large effect sizes (0.7- 1.0) from Day 4 to Day 14
- CGI-S and CGI-I solid findings consistent with MADRS results with P-values and effect sizes of similar magnitude
- SDQ scores with moderate effect size differences (d = 0.4 and 0.5) from Day 4 to Day 7 and with both statistically significant differences and large effect size for both 25 mg (P = 0.0066; d = 0.9) and 50 mg (P= 0.0014; d = 1.1) arms at Day 14
- Study demonstrates rapid onset and long-lasting antidepressant effects
- Findings support continuing clinical development and larger pivotal study