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): November 16, 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 Global Select 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 November 16, 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: November 16, 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
November 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

Major Depressive Disorder (MDD): Large potential in underserved markets	• Depression remains the leading cause of ill health and disability worldwide[1] • 50%–66% of patients with depression do not fully recover on an antidepressant medication[2] • Standard anti-depressants can take 4-6 weeks to work, and have significant side-effects • The only FDA-approved adjunctive treatment options are atypical antipsychotics
Highly-compelling de-risked lead product opportunity	• Novel MOA with successful Phase II trial in adjunctive MDD that showed statistically significant, rapid and sustained anti-depressant effects 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
Key catalysts expected over next 12-18 months	• 4Q20 – Start of first pivotal Phase III adjunctive MDD trial • 1H21 – Start of second pivotal Phase III adjunctive MDD trial • 1H21 – Start of Phase II monotherapy MDD trial • 2Q21 – Results of human abuse potential studies • 4Q21 – Results of Phase II monotherapy MDD trial • 1H22 – Results of Phase III adjunctive MDD trials

1. https://www.who.int/news-room/fact-sheets/detail/depression
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.

REL-1017

as a Potential Treatment for Depression

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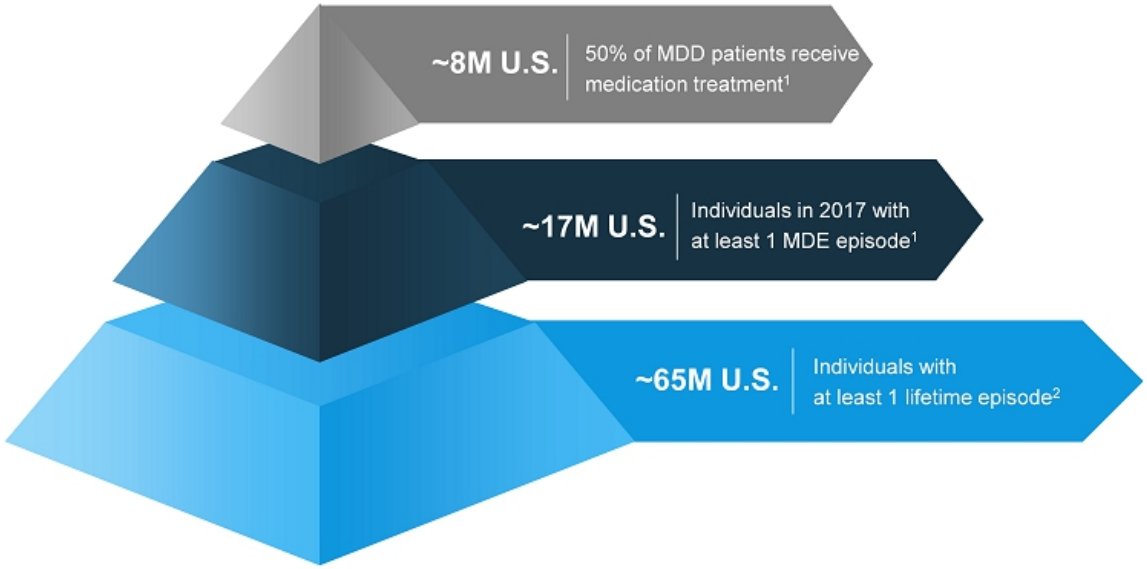
REL-1017: A Novel, Selective NMDAR Blocker being developed for MDD

Potentially significantly differentiated profile

- Potential to be the first rapid-acting, oral, once-daily antidepressant treatment
- Completed Phase 1 and Phase II trial for Adjunctive treatment of MDD
- In a Phase II trial, both doses of REL-1017 demonstrated statistically significant improvement vs. placebo on all efficacy measures, and:
  - 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 difference in opiate withdrawal symptoms in treatment groups vs placebo

Major Depressive Disorder (MDD) Market: Large, Debilitating, Underserved



1. SAMHSA https://www.nimh.nih.gov/health/statistics/major-depression.shtml#:~:text=The%20prevalence%20of%20major%20depressive%20episode%20was%20highest,episode%20was%20highest%20among%20individuals%20aged%2018-25%20%2813.1%25%29
2. 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.

Significant Limitations Characterize Current Standard of Care in MDD

Efficacy

- ~65% MDD patients do not respond to first antidepressant treatment
- ~30% MDD patients do not respond to up to 4 different antidepressant treatments

Onset of Action

- Standard antidepressants take 4-6 weeks to reach efficacy

Safety and Tolerability

- Sleep disturbance, sexual dysfunction, GI distress and weight gain limit adoption
- Atypical anti-psychotics, the only approved adjunctive treatments, have associated AEs including metabolic effects, cognitive impairment, stroke risk, and extrapyramidal symptoms

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

REL-1017: A Novel NMDAR Channel Blocker with Preferential Activity

- Traditional MDD therapeutics have been based on MAO hypothesis
- Increasingly, NMDA receptor recognized for significance in pathophysiology of depression
  - NMDA blockade presents potential mechanism for safe and effective MDD treatment with rapid onset
- **REL-1017 is a novel, NMDAR channel blocker**
  - **Preferentially targets hyperactive channels of particular importance in MDD**
  - **Avoids effects on those channels that are associated with normal physiological functions**

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

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.

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

Safety Endpoints

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

Efficacy 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

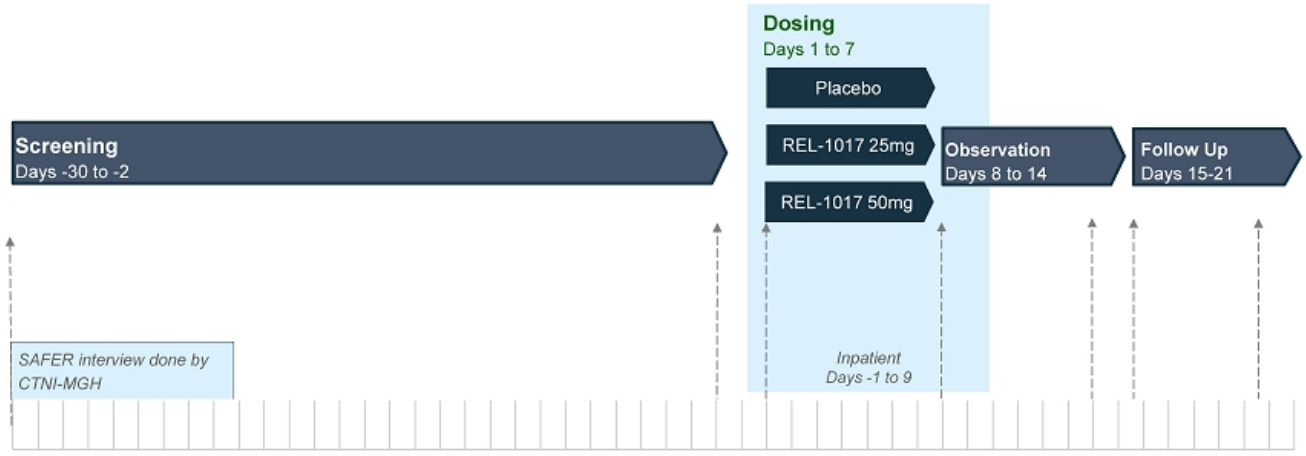
PK parameters for both 25 and 50 mg Q-day

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

REL-1017 Phase II 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

REL-1017 Phase II Trial 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

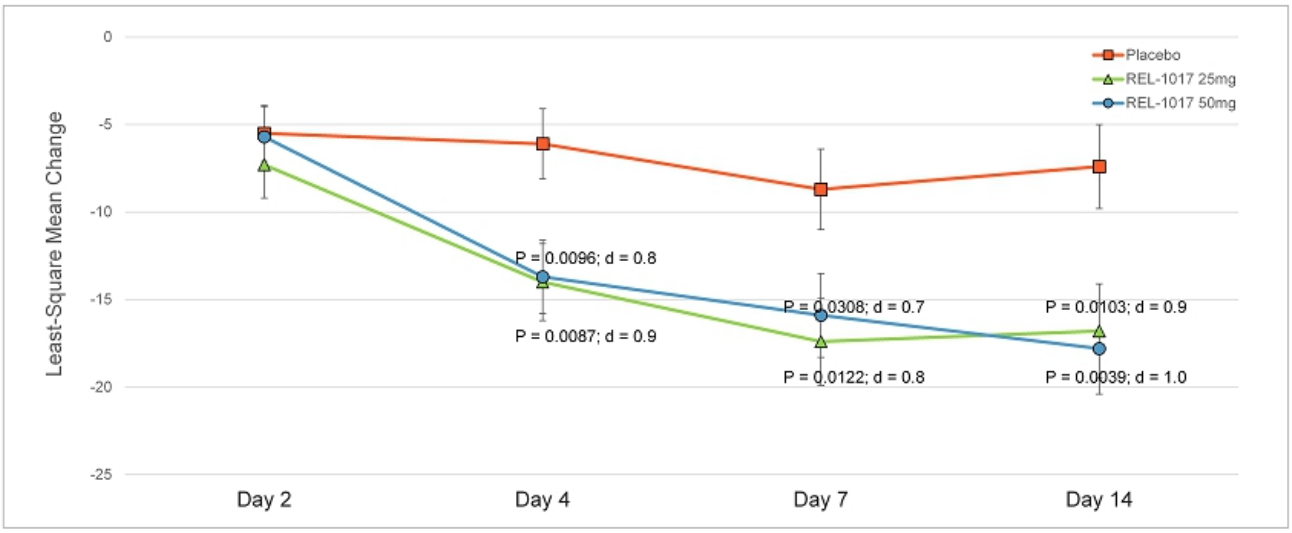
REL-1017 Phase II Study - Baseline Patient Characteristics

	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)

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

REL-1017 Phase II Study Efficacy

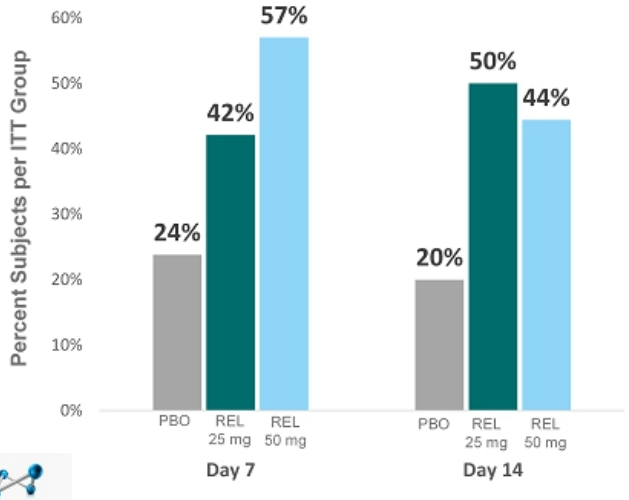
MADRS Scores for Achieved Statistically Significant Difference vs Placebo for Days 4 -14



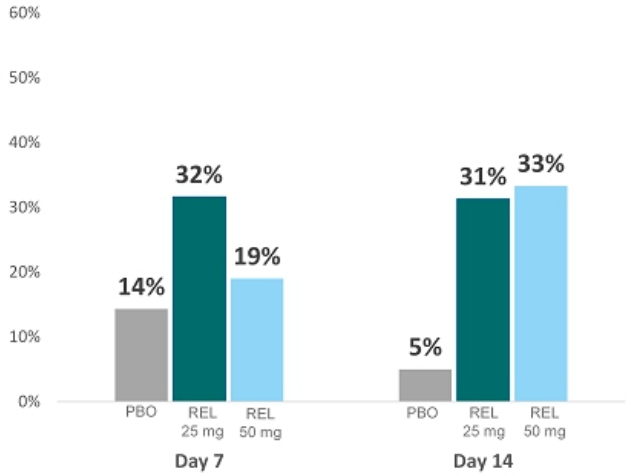
MADRS: Montgomery-Asberg Depression Rating Scale; ITT: Intent-To-Treat; Error Bars: Standard Errors; P and d values as Treatment vs Placebo

REL-1017 Phase II Study Efficacy

Response Rates
(>50% Change vs. Baseline)



Remission Rates
(MADRS <10 Points)



REL-1017 Phase II Study

Indicated Favorable Safety & Tolerability, Consistent with Phase I

- 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 II 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 II

End of Phase II 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 II 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 II 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

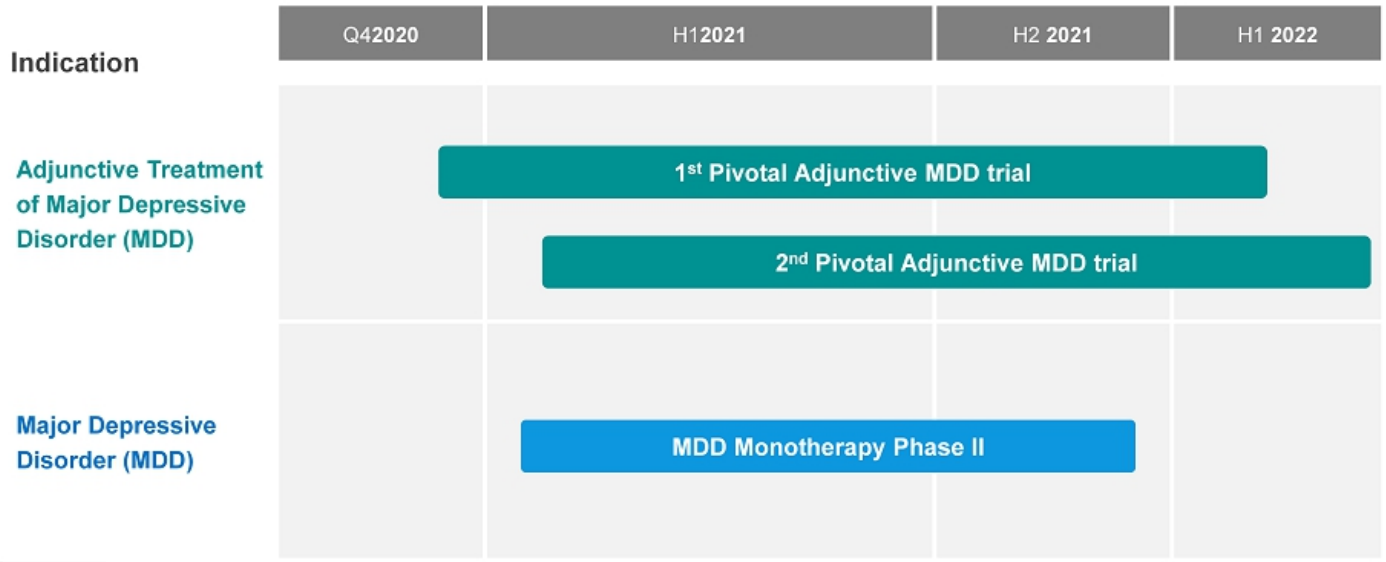
REL-1017 (dextromethadone)

Background & Planned Assessments re: Abuse Potential

> *"Analgesic activity of racemic methadone is entirely due to its l-isomer, 8 to 50 times more potent than d-isomer. The **d-isomer lacks significant respiratory depressant action and addiction liability**, but possesses antitussive activity. "*
>
> - **Methadone Statement, July 2019**

- REL-1017 is dextromethadone, the dextro-isomer of parent, racemic methadone
  - NCE with unique pharmacology
  - Per DEA, distinct from parent and levo-isomer responsible for opioid effects of methadone
  - Phase II assessments during inpatient period and days after treatment discontinuation showed AE, COW profile ~ placebo
- Abuse potential assessments for NDA submission
  - Preclinical program with 3 studies (drug discrimination, self administration, physical dependence)
  - Clinical program with 2 studies (vs. ketamine and vs. oxycodone), data expected H1 2021

REL-1017: Anticipated Development Timeline*



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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 II	Once Daily
Esketamine/Spravato (Janssen/J&J)		Nasal (in-clinic administration)	Approved	Biweekly
AXS-05 DM 45 mg + BUP 105 mg (Axsome)	**Multimodal (NMDA+others)**	Oral	Pre-NDA[1]	Twice daily
Sage-217 (Sage)	**GABA receptor allosteric modulator**	Oral	Phase 3[2]	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 09/30/20)

$123.1 million

Warrants Outstanding
(as of 09/30/20, weighted average exercise price, $7.81)

~2.7 million

Operating Cash Burn 3Q20

$12.5 million

Common Shares Outstanding
(as of 11/9/20)

~16.2 million

Management Team and Key Scientific Advisors

Management

Sergio Traversa	Chief Executive Officer	
Paolo Manfredi, MD	Acting Chief Scientific Officer	
Marco Pappagallo, MD	Acting Chief Medical Officer	
Tom Wessel, MD, Ph.D	Head of Research & Development	
Maged Shenouda	Chief Financial Officer	
Marc de Somer, MD, MBA, ScD, MPH, MSc	SVP, Clinical Development and Safety	
Chuck Ence	Chief Accounting and Compliance Officer	
Molly Harper	Executive Vice President of Operations	

Scientific Advisors

Advisors	
Maurizio Fava, MD, Chair	Massachusetts General Hospital; Harvard Medical School
Stephen M. Stahl, MD	California Department of State Hospitals; Merck
Luca Pani, MD	UHealth University of Miami Health System; University of Miami Miller School of Medicine
Thomas Laughren, MD	FDA; Brown Alpert Medical School
Dan Iosifescu, MD, MSc	New York University
Sanjay Johan Mathew, MD	Baylor College of Medicine
Charles Inturrisi, PhD	Weill Cornell Medical College; Memorial Sloan-Kettering Cancer Center

Key Catalysts Expected Over Next 12-18 Months

- 4Q20 – Start of first pivotal Phase III adjunctive MDD trial
- 1H21 – Start of second pivotal Phase III adjunctive MDD trial
- 1H21 – Start of Phase II monotherapy MDD trial
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1. https://www.who.int/news-room/fact-sheets/detail/depression
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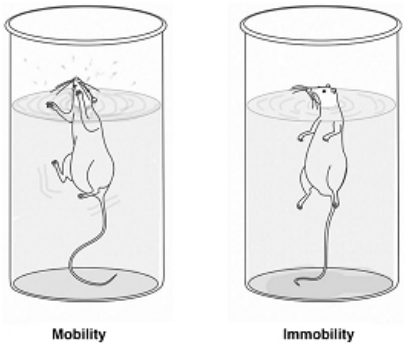
BACK UP

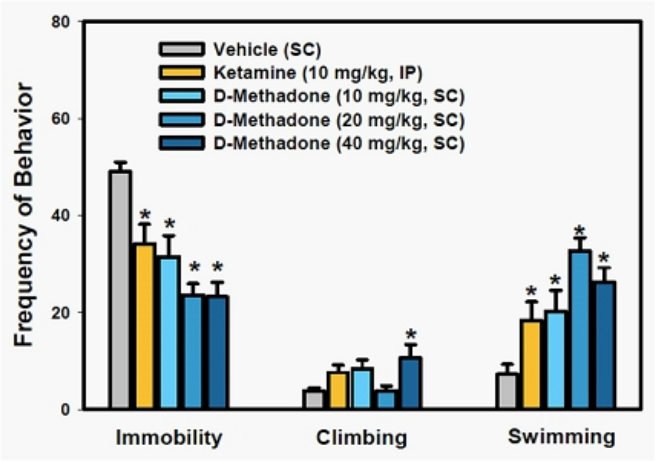
Sept 2020 | Nasdaq: RLMD

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



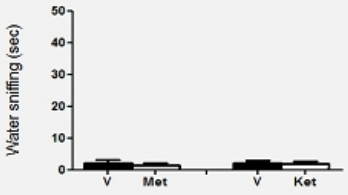


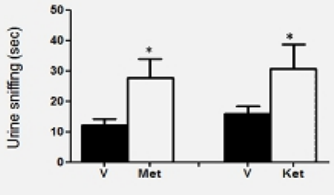
* = p<0.05 compared to placebo group

Strong Anti-Depressant Effects Observed in Three Depression Animal Models

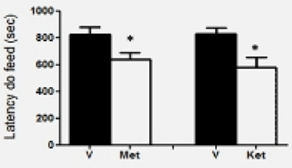
Improved performance on the rat FUST and the NSFT 24 hours after d-methadone treatment

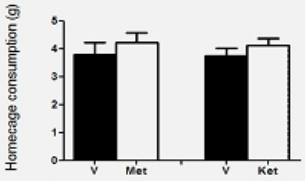
Female Urine Smell Test





Novelty Suppressed Feeding Test





Study REL-1017 Phase II 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