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): **October 15, 2019**

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

Nevada	**001-39082**	**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 **(212) 547-9591**

(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 Stock Market LLC**

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. ☐

Item 7.01 Regulation FD Disclosure.

On October 15, 2019, Relmada Therapeutics, Inc. (the "Company") hosted a conference call to discuss top-line data from its double-blind, placebo-controlled Phase 2 clinical study evaluating the safety, tolerability and efficacy of REL-1017 (dextromethadone) as an adjunctive treatment in patients with treatment resistant depression (the "REL-1017 Phase 2 Results"). A live webcast of the conference call was, and a replay is, available online from the News and Events—Company Events page of the Company's corporate website at www.relmada.com. In connection with the conference call, the Company utilized a slide presentation (the "REL-1017 Phase 2 Presentation"). A copy of the REL-1017 Phase 2 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 information in this Item 7.01 of this Current Report on Form 8-K, including the information set forth in Exhibit 99.1, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 8.01. Other Events

On October 15, 2019, the Company issued a press release in which it reported the REL-1017 Phase 2 Results. A copy of the press release is attached as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated into this Item 8.01 by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Relmada Therapeutics, Inc., REL-1017 Phase 2 Presentation, dated October 15, 2019
99.2	Press release of Relmada Therapeutics, Inc., dated October 15, 2019

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: October 21, 2019

RELMADA THERAPEUTICS, INC.

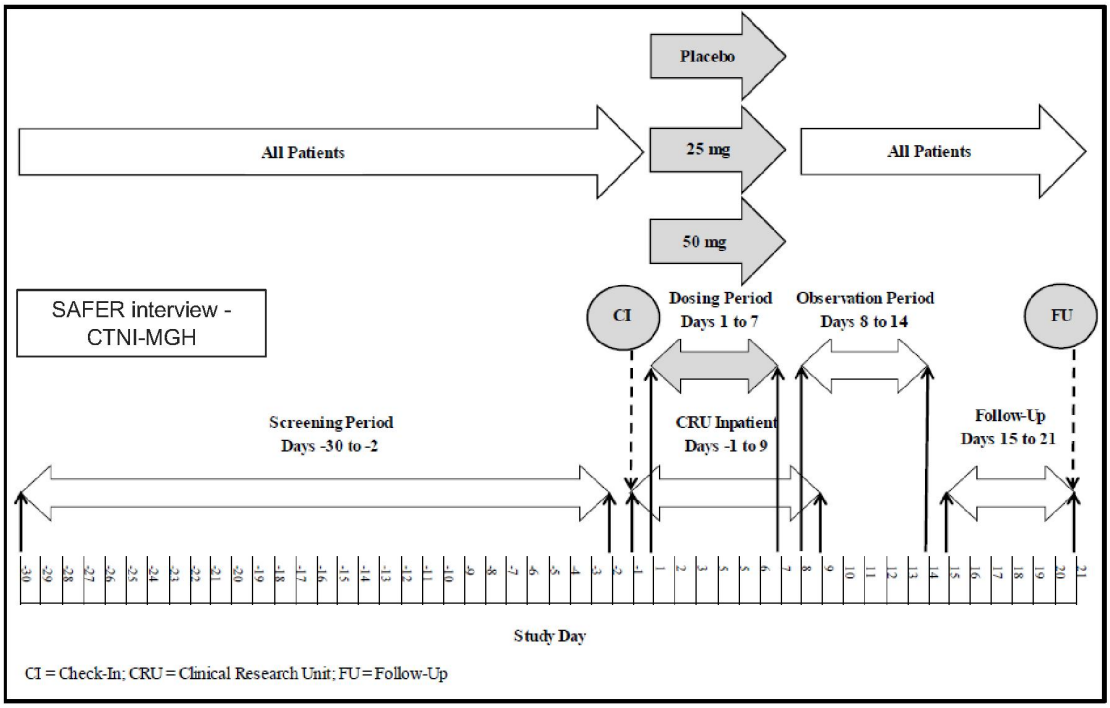
By: */s/ Sergio Traversa*
Name: Sergio Traversa
Title: Chief Executive Officer

REL-1017-202 Phase 2 Study Top Line Results

Ottavio V. Vitolo, M.D., M.M.Sc.
SVP, Head of R&D and Chief Medical Officer

Conference Call 15 October 2019

REL-1017-202: a Phase 2 Study of REL-1017 at Two Doses in Subjects with Treatment Resistant Depression



Study REL-1017-202 Was Designed to Provide Data on Safety, PK and Efficacy of REL-1017 in Treatment Resistant Depression

Primary Objectives	Primary Endpoints
Safety and tolerability of 25 mg and 50 mg of REL-1017 vs Placebo as adjunctive treatment	PE, Laboratory studies, ECG, AEs CADSS (dissociative symptoms) 4-item PSRS (psychotomimetic symptoms) COWS (opiate withdrawal symptoms) C-SSRS (suicidality)
Secondary Objectives	**Secondary Endpoints**
To characterize pharmacokinetic (PK) profile of REL-1017 25 mg and 50 mg x 7 days To explore the efficacy of 25 mg and 50 mg of REL-1017 as adjunctive treatment in patients with TRD	PK parameters for both 25 and 50 mg qday 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

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

Subjects' Disposition, Demographic Characteristics and Depression Severity Were Homogeneously Distributed Across Arms

	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

Study REL-1017-202 Key Safety Findings

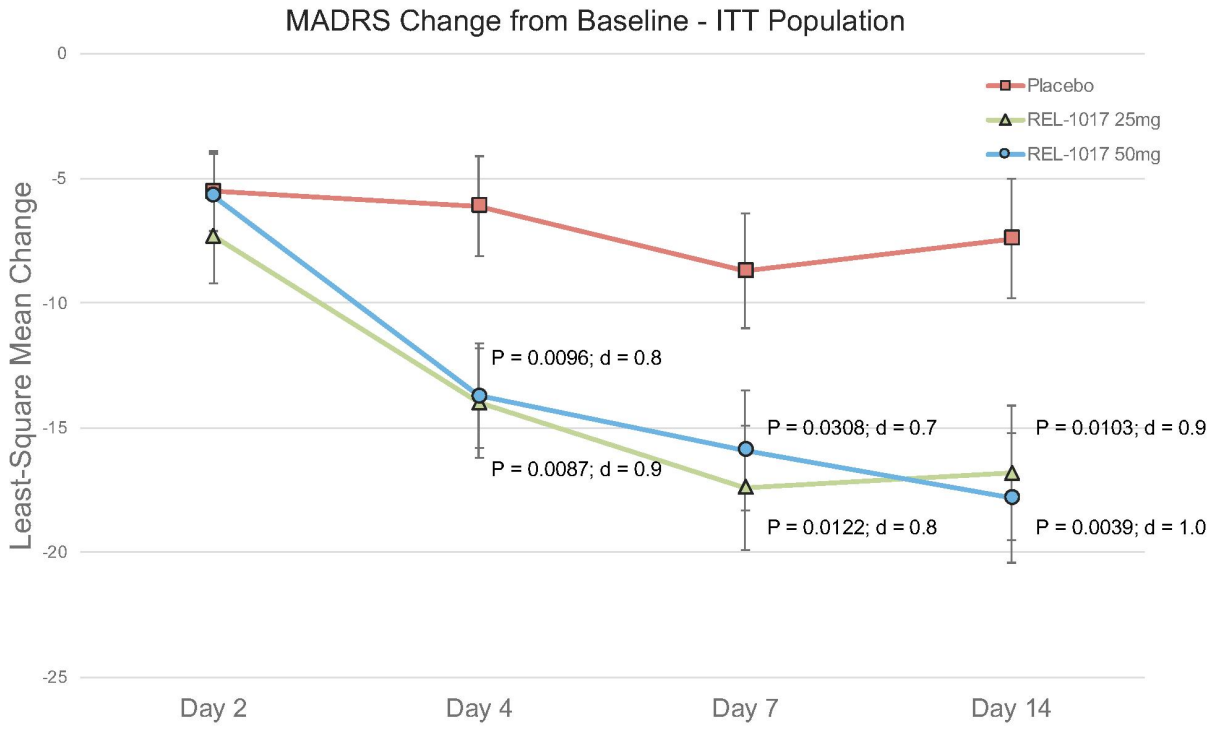
REL-1017-202 results confirm the favorable tolerability and safety profile observed in the Phase 1 SAD and MAD studies
Only Mild and Moderate AEs - no SAEs
No increased prevalence of specifically relevant organ group AEs in treatment groups vs placebo
No evidence of treatment induced dissociative symptoms 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

RELMADA THERAPEUTICS

Study REL-1017-202 Key Efficacy Findings

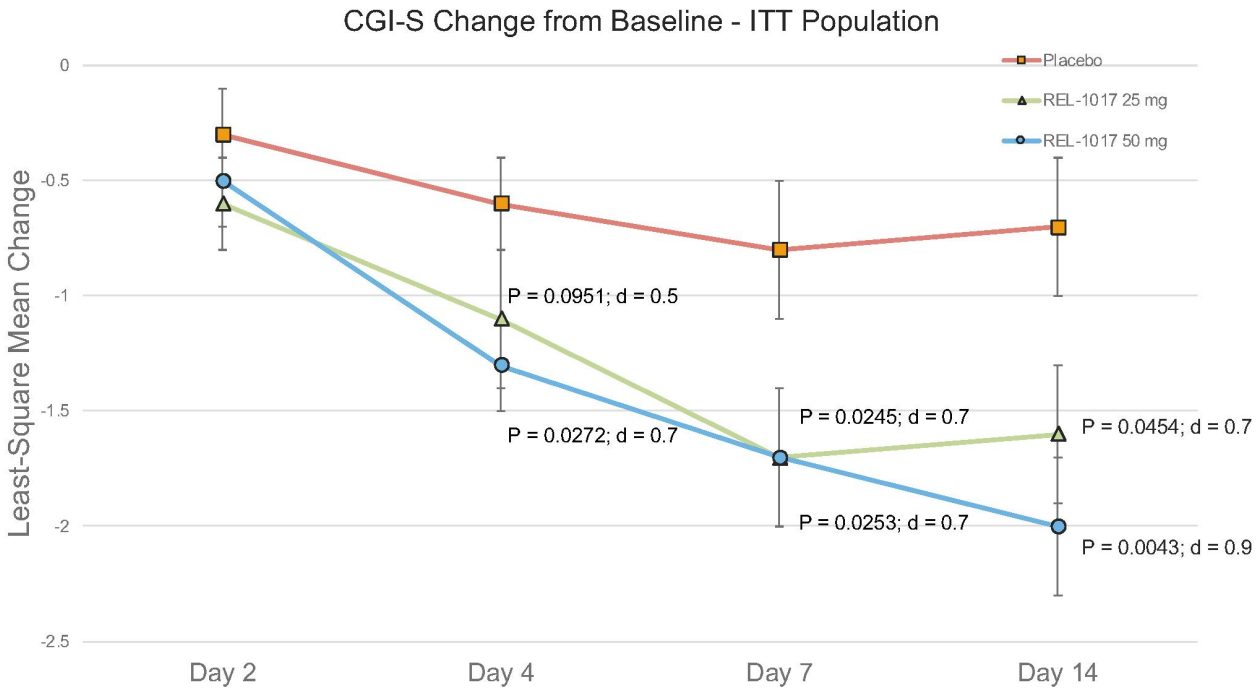
REL-1017 25 mg and 50 mg show rapid onset and sustained antidepressant efficacy with statistically significant differences compared to placebo on all efficacy measures
Solid efficacy results on MADRS with P values < 0.03 and large effect sizes (0.7- 1.0) from Day 4 to Day 14
CGI-S and CGI-I solid findings 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 = 9.9) and 50 mg (P= 0.0014; d = 1.1) arms at Day 14
Study demonstrates rapid onset and long lasting antidepressant efficacy
Findings support continuing clinical development and larger pivotal study

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

Exhibit 99.2

Relmada Therapeutics Announces Top-Line Results from REL-1017 Phase 2 Study in Individuals with Treatment Resistant Depression

Findings show that REL-1017 has rapid onset and sustained antidepressant efficacy with statistically significant differences compared to placebo on all efficacy measures

NEW YORK, Oct. 15, 2019 /PRNewswire/ -- Relmada Therapeutics, Inc. (NASDAQ: RLMD), a clinical-stage company developing novel therapies for the treatment of central nervous system (CNS) diseases, today reported top-line data from REL-1017-202, a double-blind, placebo-controlled Phase 2 clinical study evaluating the safety, tolerability and efficacy of two doses of REL-1017 (dextromethadone), 25 mg once a day and 50 mg once a day, as an adjunctive treatment in patients with treatment resistant depression.

Subjects were adults with major depressive disorder (MDD) who did not respond to one to three courses of antidepressant treatment in their current episode. 62 subjects, average age 49.2 years, with an average Hamilton Depression Rating Scale score of 25.3 and an average Montgomery-Asberg Depression Rating Scale (MADRS) score of 34.0 (severe depression), were randomized. Other demographic characteristics were balanced across all arms. After an initial screening period, subjects were randomized to one of three arms: placebo, REL-1017 25 mg or REL-1017 50 mg, in addition to stable background antidepressant therapy. Subjects in the REL-1017 treatment arms received one loading dose of either 75 mg (25 mg arm) or 100 mg (50 mg arm) of REL-1017. Subjects were treated inpatient for 7 days and discharged home at Day 9. They returned for follow-up visits at Day 14 and Day 21. Efficacy was measured on Days 2, 4 and 7 in the dosing period and on Day 14, one week after treatment discontinuation. 61 subjects received all treatment doses and were included in the per-protocol population (PPP) treatment analysis; 57 subjects completed all visits. All 62 randomized subjects were part of the intention-to-treat population (ITT) analysis. No differences were observed between the ITT and PPP analyses and results.

Key findings:

- Subjects in both the REL-1017 25 mg and 50 mg treatment groups experienced statistically significant improvement of their depression compared to subjects in the placebo group on all efficacy measures, including: the Montgomery-Asberg Depression Rating Scale (MADRS); the Clinical Global Impression – Severity (CGI-S) scale; the Clinical Global Impression – Improvement (CGI-I) scale; and the Symptoms of Depression Questionnaire (SDQ).

- The improvement on the MADRS appeared on Day 4 in both REL-1017 dose groups and continued through Day 7 and Day 14, seven days after treatment discontinuation, with P values < 0.03 and large effect sizes (a measure of quantifying the difference between two groups), ranging from 0.7 to 1.0. Similar findings emerged from the CGI-S and CGI-I scales.

MADRS: Analysis of Change from Baseline to Day 7 and to Day 14 ITT Population

	Day 2			Day 4			Day 7			Day 14		
	LS Means Difference	P-value	d	LS Means Difference	P-value	d	LS Means Difference	P-value	d	LS Means Difference	P-value	d
REL-1017 25mg vs Placebo	-1.9	0.4340	0.3	-7.9	0.0087	0.9	-8.7	0.0122	0.8	-9.4	0.0103	0.9
REL-1017 50mg vs Placebo	-0.3	0.9092	0.0	-7.6	0.0096	0.8	-7.2	0.0308	0.7	-10.4	0.0039	1.0

LS = Least Squares; d = Cohen's effect size

- The study also confirmed the favorable safety and tolerability profile of REL-1017, which was also observed in the Phase 1 studies. Subjects experienced mild and moderate adverse events (AEs), and no serious adverse events, without significant differences between placebo and treatment groups. There was no evidence of either treatment induced psychotomimetic and dissociative AEs or withdrawal signs and symptoms upon treatment discontinuation.

"We are very pleased to announce these highly compelling results," said Dr. Ottavio Vitolo, Relmada Head of R&D and CMO. "This is the first clinical evidence that REL-1017 exerts a rapid and robust antidepressant effect, which continues even after treatment discontinuation. These findings replicate what was previously observed in animal studies and support a potentially neurotrophic effect of REL-1017. We would like to thank the participating investigators, our collaborators at Syneos Health and our colleagues at the Massachusetts General Hospital (MGH) Clinical Trials Network and Institute, whose contribution was critical to controlling the placebo response. We look forward to continuing the development of REL-1017 with the goal of bringing a new effective treatment to the millions of patients suffering from depression."

"The results of this Phase 2 study demonstrate a solid and rapid antidepressant effect and overall favorable tolerability and safety profile of REL-1017," said Maurizio Fava, M.D., Chief of the Department of Psychiatry, Massachusetts General Hospital. "Ultimately, the goal is to improve the lives of individuals with serious depression who have not responded to standard therapies. These data suggest that REL-1017 could offer a treatment option to such patients, and I am hopeful that the results of ongoing studies will continue to show great promise."

"We are delighted to report these data that we believe represent a critical step forward in the effort to bring a new and potentially treatment paradigm changing option to patients who suffer from major depression," said Sergio Traversa, CEO of Relmada. "These results confirm for the first time in severely depressed patients that REL-1017 is showing rapid, statistically and clinically meaningful antidepressant activity, in conjunction with a favorable tolerability and safety profile, and a simple oral administration regime. We look forward to discussing with the U.S. Food and Drug Administration the next steps to enable us to rapidly advance the clinical development of this important clinical program."

About dextromethadone (REL 1017)

Relmada is currently developing dextromethadone as a rapidly acting oral agent for the treatment of depression. Working as an NMDA receptor antagonist and on the same binding site as ketamine but having shown no ketamine psychotomimetics side effects, dextromethadone is fundamentally differentiated from all currently FDA-approved antidepressants, as well as all atypical antipsychotics used adjunctively. In April 2017, the FDA granted Fast Track designation for dextromethadone for the adjunctive treatment of major depressive disorder.

About Relmada Therapeutics, Inc.

Relmada Therapeutics is a clinical-stage, publicly traded biotechnology company developing novel medicines that potentially address areas of high unmet medical need in the treatment of central nervous system (CNS) diseases. The Company has a diversified portfolio of products at various stages of development. Relmada's lead program, dextromethadone (REL-1017), is an N-methyl-D-aspartate (NMDA) receptor antagonist. NMDA receptor antagonists may have potential in the treatment of a range of psychiatric and neurological disorders associated with a variety of cognitive, neurological and behavioral symptoms. For more information, please visit Relmada's website at www.relmada.com.

Forward-Looking Statements

The Private Securities Litigation Reform Act of 1995 provides a safe harbor for forward-looking statements made by us or on our behalf. We may from time to time make written or oral statements in this letter, the proxy statements filed with the SEC communications to stockholders and press releases which constitute "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These forward-looking statements are based upon management's current expectations, estimates, assumptions and beliefs concerning future events and conditions and may discuss, among other things, anticipated future performance, expected product development, product potential, future business plans and costs. Any statement that is not historical in nature is a forward-looking statement and may be identified by the use of words and phrases such as "expects," "anticipates," "believes," "will," "will likely result," "will continue," "plans to" and similar expressions. No forward-looking statement can be guaranteed and actual results may differ materially from those projected. Relmada undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events, or otherwise. Readers are cautioned that it is not possible to predict or identify all of the risks, uncertainties and other factors that may affect future results and that the risks described herein should not be considered to be a complete list.

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