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): **December 22, 2021**

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.)

2222 Ponce de Leon Blvd., Floor 3 Coral Gables, FL	**33134**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code **+1-786-629-1376**

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))

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 December 22, 2021, Relmada Therapeutics, Inc., issued a press release regarding the publication of Phase 2 data from the clinical study of REL-1017 as adjunctive treatment for patients with major depressive disorder (MDD) in the peer-reviewed *American Journal of Psychiatry*. A copy of the press release is furnished herewith as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	**Description**
99.1	Press Release dated December 22, 2021
104	Cover Page Interactive Data File (formatted as Inline XBRL)

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: December 22, 2021

RELMADA THERAPEUTICS, INC.

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

Relmada Therapeutics Announces Publication of REL-1017 Phase 2 Study Results in The American Journal of Psychiatry

- **Manuscript further details findings from study assessing REL-1017 as adjunctive treatment for MDD**

- **Primary endpoint results included rapid, significant, and sustained efficacy vs. placebo**

- **Safety analysis showed adverse event profile comparable to placebo, with no signs or symptoms of withdrawal or psychotomimetic effects associated with NMDAR blocking**

CORAL GABLES, Fla., Dec. 22, 2021 /PRNewswire/ -- Relmada Therapeutics, Inc. (NASDAQ: RLMD), a late-stage biotechnology company addressing diseases of the central nervous system (CNS), today announced the publication of Phase 2 data from the clinical study of REL-1017 as adjunctive treatment for patients with major depressive disorder (MDD) in the peer-reviewed *American Journal of Psychiatry*, the most widely read psychiatric journal in the world. The article is titled, "*REL-1017 (Esmethadone) as Adjunctive Treatment in Patients with Major Depressive Disorder: a Phase 2a Double-Blind Randomized Trial,*" and is available online at: https://ajp.psychiatryonline.org/doi/full/10.1176/appi.ajp.2021.21020197.

"These compelling data confirm the favorable safety and tolerability profile of REL-1017 without opioid, dissociative, or psychotomimetic effects" said Paolo L. Manfredi, M.D., Chief Scientific Officer of Relmada.

The objectives of the Phase 2, randomized, double-blind, placebo-controlled clinical study were to evaluate the safety, tolerability, and efficacy of two doses of REL-1017 tablets, 25 mg once a day and 50 mg once a day, when given as an adjunctive treatment for MDD in patients with inadequate response to standard antidepressants. A total of 62 patients were randomized to one of three arms: placebo, REL-1017 25 mg, or REL-1017 50 mg. The primary efficacy endpoint was the Montgomery–Asberg Depression Scale (MADRS) score. The trial was conducted at ten centers in the United States from May 2018 to August 2019.

"We look forward to seeing esmethadone potentially helping millions of depressed patients with inadequate response to antidepressants if these efficacy and safety results are replicated in the ongoing Phase 3 trials" said Maurizio Fava, M.D., Principal Investigator and Chair of the Department of Psychiatry at Massachusetts General Hospital (MGH).

Key Findings:

- These results confirmed the favorable safety, tolerability, and pharmacokinetic profile of REL-1017 and demonstrated that both doses of REL-1017 produced rapid, robust, and sustained antidepressant effects when compared to placebo in patients with MDD.

- The improvement on MADRS shown on Day 4 in both REL-1017 25mg and 50mg groups was sustained through Day 7 (last dose) and Day 14 (7 days after the last dose) with $p \leq 0.0308$ and effect sizes (a measure of quantifying the difference between two groups), from 0.7 to 1.0.

- There were no serious adverse events and no patients experienced treatment-emergent adverse events (TEAEs) that resulted in treatment discontinuation. Patients experienced only transient mild or moderate transient adverse events comparable to placebo. Additionally, there were no opioid, dissociative or psychotomimetic symptoms or withdrawal effects upon treatment discontinuation.

"We are pleased to share these important Phase 2 data with the psychiatry community," said Sergio Traversa, Relmada's Chief Executive Officer. "Importantly, these Phase 2 findings enabled us to advance REL-1017 into the multiple clinical studies RELIANCE Phase 3 program for REL-1017 in MDD."

About REL-1017

REL-1017, a new chemical entity (NCE) and novel NMDA receptor (NMDAR) channel blocker that preferentially targets hyperactive channels while maintaining physiological glutamatergic neurotransmission, is currently in late-stage development for the treatment of MDD in adjunctive and monotherapy Phase 3 studies. The ongoing RELIANCE Phase 3 Clinical Research Program is designed to evaluate the potential for REL-1017 as a rapid-acting, oral, once-daily antidepressant treatment. In a Phase 2 trial, REL-1017 demonstrated rapid, robust, and sustained antidepressant effects with statistically significant improvements compared to placebo in tested measures of depression. The Phase 2 study also showed a favorable safety, tolerability, and pharmacokinetics profile of REL-1017, consistent with observed in previously completed Phase 1 studies.

About Relmada Therapeutics, Inc.

Relmada Therapeutics is a late-stage biotechnology company addressing diseases of the central nervous system (CNS), with a focus on major depressive disorder (MDD). Relmada's experienced and dedicated team is committed to making a difference in the lives of patients and their families. Relmada's lead program, REL-1017, is a new chemical entity (NCE) and novel NMDA receptor (NMDAR) channel blocker that preferentially targets hyperactive channels while maintaining physiological glutamatergic neurotransmission. REL-1017 has entered late-stage development as an adjunctive treatment and monotherapy treatment for MDD in adults. In addition, Relmada is advancing a clinical-stage program in neurodegenerative diseases based on psilocybin and select derivative molecules. Learn more 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. This press release contains statements 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, including but not limited to statements regarding the expected use of the proceeds from the offering. 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," "potential," "promising," and similar expressions. These statements are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and assumptions that could cause actual results to differ materially from those described in the forward-looking statements, including the risk factors described under the heading "Risk Factors" set forth in the Company's reports filed with the SEC from time to time. 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 the risks, uncertainties and other factors that may affect future results and that the risks described herein should not be a complete list.

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