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): **January 4, 2024**

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: **(786) 629-1376**

(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. ☐

Item 7.01 Regulation FD Disclosure.

On January 4, 2024, Relmada Therapeutics, Inc. (the "Company"), issued a press release that provided a corporate update, highlighting the Company's key 2023 accomplishments and outlining its anticipated 2024 clinical development milestones. Pursuant to Regulation FD, the press release is furnished with this Current Report as Exhibit 99.1.

The information set forth in Item 7.01 of this Current Report on Form 8-K and in the attached Exhibit 99.1 is deemed to be "furnished" and shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section. The information set forth in Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed incorporated by reference into any filing under the Exchange Act or the Securities Act of 1933, as amended (the "Securities Act"), regardless of any general incorporation language in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	**Description**
99.1*	Press release issued on January 4, 2024
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* *This Exhibit attached to this Form 8-K shall not be deemed "filed" for purposes of Section 18 of the Exchange Act or otherwise subject to liability under that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act or the Exchange Act, except as expressly set forth by specific reference in such filing.*

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: January 4, 2024

RELMADA THERAPEUTICS, INC.

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

Exhibit 99.1

Relmada Therapeutics Provides Corporate Update

Company Well-Positioned for a Pivotal 2024 with Multiple Key Clinical Development Milestones Anticipated

Relmada's Strong Balance Sheet to Support the Company Through All of 2024's Expected Critical Catalysts

CORAL GABLES, Fla., January 4, 2024 /PRNewswire/ -- Relmada Therapeutics, Inc. (Nasdaq: RLMD), a late-stage biotechnology company addressing diseases of the central nervous system (CNS), today provided a corporate update, highlighted the Company's key 2023 accomplishments and outlined its anticipated 2024 clinical development milestones.

"We made significant operational progress throughout our business in 2023 and believe we are well-positioned for making 2024 the pivotal and most important year for Relmada to date," said Sergio Traversa, Relmada's Chief Executive Officer. "In our ongoing Phase 3 program for REL-1017 as an adjunctive treatment for major depressive disorder (MDD), we completed a thorough analysis of the study 301 and study 303 results, and subsequently made important revisions to our clinical development plan, including optimizing the study protocols, improving the patient adjudication process, enhancing the site engagement strategy, and reorganizing our clinical team to better align with the ongoing study 302 and study 304 clinical study operations requirements. Importantly, study 302 is now approximately 50% enrolled. We have also completed all of the necessary pre-clinical, manufacturing and Phase 1 studies required for a potential REL-1017 NDA filing, and are currently conducting various pre-commercial readiness activities."

"In addition, we advanced our valuable non-psychedelic/low dose metabolic psilocybin program, which showed significant therapeutic potential on multiple parameters in pre-clinical rodent studies," continued Mr. Traversa. "Looking ahead, we have multiple clinical development milestones expected in 2024, for both REL-1017 and our non-psychedelic/modified-release psilocybin program, and we expect our cash runway to extend beyond all of these anticipated catalysts."

We would like to thank our outgoing Chief Medical Officer, Dr. Cedric O'Gorman, for his contribution in the optimization of the clinical development strategy for the REL 1017 studies 302 and 304. We also welcome Dr. Andrew Cutler as Senior Clinical Development Advisor, who will help Relmada through the completion of the REL-1017 Phase 3 program and the NDA/approval process.

Upcoming Anticipated Milestones

- Complete enrollment in REL-1017 study 302 (Reliance II), which is planned to enroll approximately 300 patients, in the first half of 2024.
- Complete enrollment in REL 1017 study 304 (Relight), which is planned to enroll approximately 300 patients, by year-end 2024.
- Commence a Phase 1 trial in obese patients with steatotic liver disease in the first half of 2024 to define the pharmacokinetic, safety and tolerability profile of the Company's modified-release psilocybin formulation (REL-P11), followed by a Phase 2a trial to establish clinical proof-of-concept with data expected in the first half of 2025.

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 adjunctive treatment of major depressive disorder (MDD). Relmada's ongoing clinical research program is designed to evaluate the potential for REL-1017 as a rapid-acting, oral, once-daily antidepressant treatment. The development program for REL-1017 as an adjunctive treatment for MDD includes two Phase 3 randomized, double-blind, placebo-controlled studies, Reliance II (Study 302) and Relight (Study 304). Reliance II and Relight have the same key study design parameters.

About REL-P11

Relmada acquired the development and commercial rights to a novel psilocybin and derivative program in July of 2021. Psilocybin has neuroplastogen™ effects that have the potential to ameliorate neurodegenerative conditions. The pleiotropic metabolic effects of low-dose psilocybin were discovered while studying its neuroplastogen™ potential in a rodent model deficient in neurogenesis – obese rats maintained on a high fructose, high fat diet (HFHFD), and were then replicated in mice.

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 is in late-stage development as an adjunctive treatment for MDD in adults. 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. 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 potential failure of clinical trial results to demonstrate statistically and/or clinically significant evidence of efficacy and/or safety, failure of top-line results to accurately reflect the complete results of the trial, failure of the 310 open-label study to accurately reflect the results of the ongoing 302 and 304 blinded, randomized and controlled studies, failure to obtain regulatory approval of REL-1017 for the treatment of major depressive disorder, failure of the planned psilocybin Phase 1 and Phase 2a trials to be successfully initiated and carried out, and the other 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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