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): **March 19, 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 2.02 Results of Operations and Financial Condition.

On March 19, 2024, Relmada Therapeutics, Inc. (the "Company") issued a press release providing a corporate update and reporting its financial results for the fourth quarter and full year ended December 31, 2023. (These results are preliminary and unaudited.) The Company also announced that it would conduct a conference call and audio webcast on March 19, 2024, at 4:30 PM EDT/1:30 PM PDT, to discuss the update and results. The Company's complete audited financial statements and notes thereto as of, and for the fiscal years ended, December 31, 2023 and 2022, will be contained in its Annual Report on Form 10-K to be filed with the Securities and Exchange Commission. A copy of this press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated into this Item 2.02 by reference.

In accordance with General Instruction B.2 of Form 8-K, the information in this Item 2.02 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 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	**Description**
99.1	Press release dated March 19, 2024, regarding corporate update and fourth quarter and full year 2023 financial results
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: March 19, 2024

RELMADA THERAPEUTICS, INC.

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

Relmada Therapeutics Provides Corporate Update and Reports Fourth Quarter and Full-Year 2023 Financial Results

CORAL GABLES, Fla., Mar 19, 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 and announced preliminary and unaudited financial results for the fourth quarter and full year ended December 31, 2023. The Company will host a conference call today, Tuesday, March 19, at 4:30 PM Eastern Time/1:30 PM Pacific Time.

"We continue to make solid progress in advancing our ongoing Phase 3 program for REL-1017 as an adjunctive treatment for major depressive disorder (MDD)," said Sergio Traversa, Relmada's Chief Executive Officer. "Enrollment in the ongoing Reliance II (study 302) is steadily proceeding, and we expect top line data in the second half of 2024. In our second Phase 3 trial for REL-1017, Relight (study 304), we began dosing patients during the third quarter of last year, and we plan to complete enrollment in this study by year-end 2024."

"In our promising low dose metabolic psilocybin program (REL-P11) , which showed significant therapeutic potential on multiple parameters in pre-clinical rodent studies, we intend to initiate a single-ascending dose Phase 1 trial in obese patients in the first half of this year to define the pharmacokinetic, safety, and tolerability profile of our modified-release psilocybin formulation in this population," continued Mr. Traversa. "This will be followed by a Phase 2a trial to establish clinical proof-of-concept."

Recent Corporate Highlights

- Presented new preclinical data on its novel psilocybin at the American Association for the Study of Liver Diseases (AASLD) The Liver Meeting 2023® 2023 in November 2023
- Appointed Dr. Andrew Cutler as Senior Clinical Development Advisor. Dr. Cutler has been conducting clinical research since 1993 and has been a Principal Investigator on over 400 clinical trials in a variety of CNS and medical indications, focusing on MDD, Bipolar Disorder, ADHD and Schizophrenia in children, adolescents and adults.

Upcoming Anticipated Milestones

- Complete enrollment in ongoing RELIANCE II, which is planned to enroll approximately 300 patients, with top-line data in the second half of 2024.
- Complete enrollment in the Relight study (study 304), which is planned to enroll approximately 300 patients, by year-end 2024.
- Commence a Phase 1 trial in obese patients 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.

Fourth Quarter 2023 Financial Results

- Research and development expense for the three months ended December 31, 2023, totaled $14.8 million, compared to $26.9 million for the three months ended December 31, 2022. The decrease was primarily driven by a decrease in study costs associated with the completion of two Phase 3 trials and the long-term, open-label, safety trial (Study 310).
- General and administrative expense for the three months ended December 31, 2023, totaled $12.1 million compared to $11.8 million for the three months ended December 31, 2022, an increase of approximately $0.3 million. The increase was primarily driven by an increase in compensation expensedue to higher employee-related costs.
- Net cash used in operating activities for the three months ended December 31, 2023, totaled $10.3 million compared to $35.9 million for the three months ended December 31, 2022.
- The net loss for the three months ended December 31, 2023, was $25.2 million, or $0.84 per basic and diluted share, compared with a net loss of $37.9 million, or $1.28 per basic and diluted share, for the three months ended December 31, 2022.

Full-Year 2023 Financial Results

- Research and development expense for the year ended December 31, 2023, totaled $54.8 million, compared to $113.3 million for the year ended December 31, 2022. The decrease was primarily driven by a decrease in study costs associated with the completion of two Phase 3 trials and the long-term, open-label, safety trial (Study 310).
- General and administrative expense for the year ended December 31, 2023, totaled $48.9 million, compared to $47.9 million for the year ended December 31, 2022The increase was primarily driven by an increase in compensation.
- Net cash used in operating activities for the year ended December 31, 2023, totaled $51.7 million, compared to $103.8 million for the year ended December 31, 2022.
- Net loss for the year ended December 31, 2023 and 2022 was $98.8 million and $157.0 million, respectively. The Company had a net loss of $3.28 and $5.30 per basic and diluted share for the year ended December 31, 2023 and 2022, respectively.
- As of December 31, 2023, the Company had cash, cash equivalents, and short-term investments of approximately $96.3 million, compared to cash, cash equivalents, and short-term investments of approximately $148.3 million at December 31, 2022.

Conference Call and Webcast Details

Tuesday, March 19th @ 4:30pm ET

Toll Free:	888-886-7786
International:	416-764-8658
Conference ID:	35626110
Webcast:	Click Here

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 derivatives 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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Relmada Therapeutics, Inc.
Consolidated Balance Sheets
(Unaudited)

	As of December 31, 2023	As of December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 4,091,568	$ 5,395,905
Short-term investments	92,232,292	142,926,781
Other receivables	-	512,432
Prepaid expenses	1,185,057	4,035,186
Total current assets	97,508,917	152,870,304
Other assets	43,125	34,875
Total assets	$ 97,552,042	$ 152,905,179
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,506,009	$ 5,261,936
Accrued expenses	8,688,791	7,206,941

Total current liabilities	12,194,800	12,468,877
Total liabilities	12,194,800	12,468,877
Commitments and Contingencies (Note 7)		
Stockholders' Equity:		
Preferred stock, $0.001 par value, 200,000,000 shares authorized, none issued and outstanding	-	-
Class A convertible preferred stock, $0.001 par value, 3,500,000 shares authorized, none issued and outstanding	-	-
Common stock, $0.001 par value, 150,000,000 shares authorized, 30,099,203 and 30,099,203 shares issued and outstanding, respectively	30,099	30,099
Additional paid-in capital	646,229,824	602,517,138
Accumulated deficit	(560,902,681)	(462,110,935)
Total stockholders' equity	85,357,242	140,436,302
Total liabilities and stockholders' equity	$ 97,552,042	$ 152,905,179

Relmada Therapeutics, Inc.
Consolidated Statements of Operations
(Unaudited)

	2023	2022
Operating expenses:		
Research and development	$ 54,807,348	$ 113,322,999
General and administrative	48,894,945	47,926,077
Total operating expenses	103,702,293	161,249,076
Loss from operations	(103,702,293)	(161,249,076)
Other income (expenses):		
Gain on settlement of fees	-	6,351,606
Interest/investment income, net	5,151,704	2,659,424
Realized loss on short-term investments	(4,064,391)	(585,522)
Unrealized gain (loss) on short-term investments	3,823,234	(4,220,255)
Total other income (expenses), net	4,910,547	4,205,253
Net loss	$ (98,791,746)	$ (157,043,823)
Net loss per common share – basic and diluted	$ (3.28)	$ (5.30)
Weighted average number of common shares outstanding – basic and diluted	30,099,203	29,628,664

Relmada Therapeutics, Inc.
Consolidated Statements of Changes in Stockholders' Equity
For the Years Ended December 31, 2023 and 2022

	Common Stock		Additional Paid-in	Accumulated	
	Shares	Par Value	Capital	Deficit	Total
Balance – December 31, 2021	27,740,147	$ 27,740	$ 513,304,258	$ (305,067,112)	$ 208,264,886
Stock-based compensation expense	-	-	44,194,765	-	44,194,765
ATM offering, net	2,094,243	2,094	42,726,505	-	42,728,599
Share exchange – Prefunded warrants, net of fees	(1,452,016)	(1,452)	(48,548)	-	(50,000)
Net exercise – Prefunded warrants	1,451,795	1,452	(1,452)	-	-
Warrants exercised	181,336	181	1,264,342	-	1,264,523
Options exercised	83,698	84	703,636	-	703,720
Short swing profit, net	-	-	373,632	-	373,632
Net loss	-	-	-	(157,043,823)	(157,043,823)
Balance – December 31, 2022	30,099,203	30,099	602,517,138	(462,110,935)	140,436,302
Stock-based compensation expense	-	-	43,811,149	-	43,811,149
ATM fees	-	-	(98,463)	-	(98,463)
Net loss	-	-	-	(98,791,746)	(98,791,746)
Balance – December 31, 2023	30,099,203	$ 30,099	$ 646,229,824	$ (560,902,681)	$ 85,357,242

Relmada Therapeutics, Inc.
Consolidated Statements of Cash Flows
(Unaudited)

	2023	2022
Cash flows from operating activities		
Net loss	$ (98,791,746)	$ (157,043,823)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	43,811,149	44,194,765
Gain on settlement	-	(6,351,606)
Realized loss on short-term investments	4,064,391	585,522
Unrealized (gain) loss on short-term investments	(3,823,234)	4,220,255
Change in operating assets and liabilities:		
Lease payment receivable	-	86,377
Other receivable	512,432	(512,432)
Prepaid expenses and other assets	2,841,879	7,259,767
Accounts payable	(1,755,927)	421,040
Accrued expenses	1,481,850	3,338,518
Net cash used in operating activities	(51,659,206)	(103,801,617)
Cash flows from investing activities		
Purchase of short-term investments	(90,463,532)	(47,293,763)
Sale of short-term investments	140,916,864	67,027,372
Net cash provided by investing activities	50,453,332	19,733,609
Cash flows from financing activities		
Payment of ATM fees	(98,463)	-
Payment of fees for warrants issued for common stock	-	(50,000)
Proceeds from issuance of common stock	-	42,728,599
Proceeds from options exercised for common stock	-	703,720
Proceeds from warrants exercised for common stock	-	1,264,523
Proceeds from short swing profit, net	-	373,632
Net cash (used in) provided by financing activities	(98,463)	45,020,474
Net decrease in cash and cash equivalents	(1,304,337)	(39,047,534)
Cash and cash equivalents at beginning of the period	5,395,905	44,443,439
Cash and cash equivalents at end of the period	$ 4,091,568	$ 5,395,905