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 10, 2022**

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 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 2.02 Results of Operations and Financial Condition.

On November 10, 2022, Relmada Therapeutics, Inc. ("Relmada," the "Company," "we," "us," "our")) issued a press release providing a corporate update and reporting its financial results for the three and nine months ended September 30, 2022 (These results are preliminary and unaudited.) The Company also announced that it would conduct a conference call and audio webcast on November 10, 2022, at 4:30 PM EST, to discuss the update and results. The Company's complete unaudited condensed financial statements and notes thereto as of September 30, 2022, and for the three and nine months then ended, will be contained in its Quarterly Report on Form 10-Q 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 7.01 Regulation FD Disclosure.

On November 10, 2022, Relmada announced that it is further evaluating the data from RELIANCE III, its monotherapy major depressive disorder (MDD) trial of REL-1017. The Company believes that these data were impacted by enrollment of inappropriate subjects, that is, patients not truly suffering from MDD who "responded" dramatically and rapidly to placebo, and that this was the primary driver behind the study not being successful. We believe the measures utilized to guard against the enrollment of inappropriate subjects were not effective enough, and most of the high-enrolling centers in the trial had very big placebo response rates. As an example of this, one high enrolling center had a mean change from baseline of 23 points in the placebo group. Of note, 68 patients, or approximately 30% of the total number of patients enrolled in RELIANCE III, were from high enrolling sites.

With regard to RELIANCE I, the Phase 3 trial of REL-1017 for the adjunctive treatment of MDD that is expected to announce top-line results before the end of 2022, the same

ineffective measures utilized to guard against inappropriate subject enrollment in RELIANCE III were also used in RELIANCE I. High-enrolling centers in RELIANCE III all recruited heavily in RELIANCE I, as well. Specifically, RELIANCE I includes 80 patients, or approximately 40% of the total number enrolled, from high enrolling sites. Those factors suggest that a higher than expected placebo response may be observed in RELIANCE I. Mitigating that to some degree may be the different patient population in RELIANCE I; that is, patients already diagnosed with depression and not responding adequately to at least one, and up to three, true courses of antidepressant therapy. Relmada cannot predict how those factors will balance out.

We intend to apply several protocol and operational changes in the currently enrolling RELIANCE II study (a sister trial to RELIANCE I) and make certain improvements to how the trial is being conducted. We now expect top-line results from this study in 2023.

Moreover, in order to be proactive and increase the likelihood of clinical success for REL-1017 as a potential therapy for MDD, an indication in which two successful studies are required to achieve FDA approval, we may consider initiating new clinical trials in 2023.

In accordance with General Instruction B.2 of Form 8-K, the information in this Item 7.01 of this Current Report on Form 8-K 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 November, 2022, regarding corporate update and third quarter 2022 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: November 10, 2022

RELMADA THERAPEUTICS, INC.

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

Relmada Therapeutics Provides Corporate Update and Reports Third Quarter 2022 Financial Results

CORAL GABLES, Fla., Nov. 10, 2022 /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 three and nine months ended September 30, 2022. The Company will host a conference call today, Thursday, November 10, at 4:30 PM Eastern Time/1:30 PM Pacific Time.

"We are currently further evaluating the recently announced top-line results from RELIANCE III, our monotherapy registrational Phase 3 trial for REL-1017 for individuals living with major depressive disorder (MDD)," said Sergio Traversa, Relmada's Chief Executive Officer. "We continue to expect top-line results before the end of the year from RELIANCE I, the first of two ongoing Phase 3 sister two-arm, placebo-controlled, pivotal studies evaluating REL-1017 as a potential adjunctive treatment. While we await these data, we continue to enroll patients in RELIANCE II, our second adjunctive study, while making certain improvements to how the trial is being conducted. Therefore, we now anticipate the availability of these top-line results in 2023."

"Despite the initial RELIANCE III disappointment,we remain highly confident in the potential of REL-1017 to be a safe and effective new therapy for the adjunctive treatment of MDD," continued Sergio Traversa. "It is also important to note that we have the financial flexibility to continue advancing REL-1017 in the clinic due to our strong balance sheet."

Upcoming Anticipated Milestones for REL-1017

- Results of RELIANCE I adjunctive MDD trial before year-end 2022
- Results of RELIANCE II adjunctive MDD trial in 2023
- Results of RELIANCE – OLS (Long-term, Open-label) study in MDD in 1H 2023

Third Quarter 2022 Financial Results

- Research and development expense for the three months ended September 30, 2022, totaled $30.5 million, compared to $34.0 million for the three months ended September 30, 2021. The decrease was primarily driven by a decrease in stock-based compensation.
- General and administrative expense for the three months ended September 30, 2022, totaled $8.2 million compared to $8.7 million for the three months ended September 30, 2021, a decrease of approximately $0.5 million. The decrease was primarily driven by a decrease in stock-based compensation.

- The net loss for the three months ended September 30, 2022, was $39.4 million, or $1.31 per diluted share, compared with a net loss of $42.6 million, or $2.44 per diluted share, for the three months ended September 30, 2021.

Nine Months Ended September 30, 2022 Financial Results

- Research and development expense for the nine months ended September 30, 2022, totaled $86.5 million, compared to $65.3 million for the nine months ended September 30, 2021. The increase was primarily driven by increased costs associated with preparing and conducting RELIANCE, the Company's Phase 3 program for REL-1017.
- General and administrative expense for the nine months ended September 30, 2022, totaled $36.1 million, compared to $26.2 million for the nine months ended September 30, 2021. The increase was primarily driven by an increase in stock-based compensation.
- Net loss for the nine months ended September 30, 2022 and 2021 was $119.1 million and $91.4 million, respectively. The Company had a net loss of $4.04 and $5.36 per share for the nine months ended September 30, 2022 and 2021, respectively.
- As of September 30, 2022, the Company had cash, cash equivalents, and short-term investments of approximately $184.2 million, compared to cash, cash equivalents, and short-term investments of approximately $211.9 million at December 31, 2021.

Conference Call and Webcast Details

Thursday, November 10th @ 4:30pm ET

Toll Free:	888 660-6597
International:	929 203-1953
Conference ID:	3347957
Webcast:	https://events.q4inc.com/attendee/219987901

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). The ongoing Reliance Clinical Research Program is designed to evaluate the potential for REL-1017 as a rapid-acting, oral, once-daily adjunctive antidepressant treatment. In a Phase 2 trial as an adjunctive treatment, REL-1017 demonstrated rapid, robust, and sustained antidepressant effects with statistically significant improvements compared to placebo. The Phase 2 study also showed a favorable pharmacokinetic, safety, and tolerability profile of REL-1017 consistent with results 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 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. 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. 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 RELIANCE trial results to demonstrate clinically significant evidence of efficacy and/or safety, failure of top-line results to accurately reflect the complete results of the trial, failure to obtain regulatory approval of REL-1017 for the treatment of major depressive disorder, 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.
Condensed Consolidated Balance Sheets

	As of September 30, 2022 (Unaudited)	As of December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 42,524,369	$ 44,443,439
Short-term investments	141,627,805	167,466,167
Lease payments receivable – short term	-	86,377
Prepaid expenses	2,953,739	11,301,535
Total current assets	187,105,913	223,297,518
Other assets	16,095	28,293
Total assets	$ 187,122,008	$ 223,325,811
Commitments and Contingencies (See Note 7)		
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 10,425,841	$ 11,192,502
Accrued expenses	10,351,312	3,868,423
Total current liabilities	20,777,153	15,060,925
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, 28,641,991 and 27,740,147 shares issued and outstanding, respectively	28,642	27,740
Additional paid-in capital	590,482,783	513,304,258
Accumulated deficit	(424,166,570)	(305,067,112)
Total stockholders' equity	166,344,855	208,264,886
Total liabilities and stockholders' equity	$ 187,122,008	$ 223,325,811

Condensed Consolidated Statements of Operations
(Unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	$ 30,529,108	$ 33,993,974	$ 86,454,632	$ 65,347,708
General and administrative	8,208,053	8,659,661	36,092,024	26,173,010
Total operating expenses	38,737,161	42,653,635	122,546,656	91,520,718
Loss from operations	(38,737,161)	(42,653,635)	(122,546,656)	(91,520,718)
Other (expenses) income:				
Gain on settlement of fees	-	-	6,351,606	-
Interest/investment income, net	827,614	297,648	1,544,898	1,040,429
Realized loss on short-term investments	(561,648)	(336,949)	(552,171)	(513,328)
Unrealized (loss) gain on short-term investments	(947,512)	86,745	(3,897,135)	(379,699)
Total other (expense) income – net	(681,546)	47,444	3,447,198	147,402
Net loss	$ (39,418,707)	$ (42,606,191)	$ (119,099,458)	$ (91,373,316)
Loss per common share – basic and diluted	$ (1.31)	$ (2.44)	$ (4.04)	$ (5.36)
Weighted average number of common shares outstanding – basic and diluted	30,063,735	17,478,477	29,470,198	17,038,583

Relmada Therapeutics, Inc.
Condensed Consolidated Statements of Stockholders' Equity
(Unaudited)

	Nine months ended September 30, 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	-	-	11,930,681	-	11,930,681
ATM offering, net	1,609,343	1,610	29,581,932	-	29,583,542
Warrant exercised for cash	33,334	33	299,973	-	300,006
Options exercised for cash	20,000	20	64,780	-	64,800
Net loss	-	-	-	(39,745,783)	(39,745,783)
Balance – March 31, 2022	29,402,824	29,403	555,181,624	(344,812,895)	210,398,132
Stock based compensation	-	-	12,295,016	-	12,295,016
Warrant exercised for cash	91,058	91	595,259	-	595,350
Options exercised for cash	45,812	46	352,698	-	352,744
ATM offering, net of offering costs	484,900	485	13,144,572	-	13,145,057
Net loss	-	-	-	(39,934,968)	(39,934,968)
Balance – June 30, 2022	30,024,594	30,025	581,569,169	(384,747,863)	196,851,331
Stock based compensation	-	-	8,343,139	-	8,343,139
Warrant exercised for cash	51,527	51	332,865	-	332,916
Options exercised for cash	17,886	18	286,158	-	286,176
Share exchange – Pre-funded warrants, net of fees	(1,452,016)	(1,452)	(48,548)	-	(50,000)
Net loss	-	-	-	(39,418,707)	(39,418,707)
Balance – September 30, 2022	28,641,991	$ 28,642	$ 590,482,783	$ (424,166,570)	$ 166,344,855

	Nine months ended September 30, 2021				
	Common Stock		Additional Paid-in	Accumulated	
	Shares	Par Value	Capital	Deficit	Total
Balance – December 31, 2020	16,332,939	$ 16,333	$ 284,881,716	$ (179,315,303)	$ 105,582,746
Stock based compensation	-	-	5,851,284	-	5,851,284
Warrant exercised for cash	273,491	273	1,460,233	-	1,460,506
Options exercised for cash	141,625	142	467,631	-	467,773
Net loss	-	-	-	(22,215,181)	(22,215,181)
Balance – March 31, 2021	16,748,055	16,748	292,660,864	(201,530,484)	91,147,128
Stock based compensation	-	-	8,268,376	-	8,268,376
Warrant exercised for cash	62,059	62	481,387	-	481,449
Options exercised for cash	7,031	7	49,491	-	49,498
ATM offering, net of offering costs	651,674	652	23,457,398		23,458,050
Net loss	-	-	-	(26,551,944)	(26,551,944)
Balance – June 30, 2021	17,468,819	17,469	324,917,516	(228,082,428)	96,852,557

Warrants issued for license agreement	-	-	10,241,599	-	10,241,599
Stock based compensation	-	-	8,013,970	-	8,013,970
Warrant exercised for cash	20,835	21	174,993	-	175,014
Options exercised for cash	11,900	12	52,144	-	52,156
Equity offering costs	-	-	(42,041)	-	(42,014)
Net loss	-	-	-	(42,606,191)	(42,606,191)
Balance – September 30, 2021	17,501,554	$ 17,502	$ 343,358,208	$ (270,688,619)	$ 72,687,091

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

	Nine months ended September 30,	
	2022	2021
Cash flows from operating activities		
Net loss	$ (119,099,458)	$ (91,373,316)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	-	1,258
Warrants issued for license agreement	-	10,241,599
Stock-based compensation	32,568,836	22,133,630
Realized loss on short-term investments	552,171	513,328
Unrealized loss on short-term investments	3,897,135	379,699
Change in operating assets and liabilities:		
Lease payment receivable	86,377	58,967
Prepaid expenses and other assets	8,359,994	(1,812,288)
Accounts payable	(766,661)	4,362,071
Accrued expenses	6,482,889	1,281,821
Net cash used in operating activities	(67,918,717)	(54,213,231)
Cash flows from investing activities		
Purchase of short-term investments	(38,993,173)	(82,476,539)
Sale of short-term investments	60,382,229	119,541,235
Net cash provided by investing activities	21,389,056	37,064,696
Cash flows from financing activities		
Payment of fees for warrants issued for common stock	(50,000)	-
Proceeds from issuance of common stock – net	42,728,599	23,416,036
Proceeds from options exercised for common stock	703,720	569,427
Proceeds from warrants exercised for common stock	1,228,272	2,116,969
Net cash provided by financing activities	44,610,591	26,102,432
Net (decrease) / increase in cash and cash equivalents	(1,919,070)	8,953,897
Cash and cash equivalents at beginning of the period	44,443,439	2,495,397
Cash and cash equivalents at end of the period	$ 42,524,369	11,449,294
Supplemental disclosure of cash flow information:		
Non-cash investing and financing activities:		
Share exchange for Pre-funded warrants	$ 1,452	$ -