August 7, 2024

Relmada Therapeutics Reports Second Quarter 2024 Financial Results and Provides Business Update

Outcome of pre-planned Reliance II interim analysis anticipated by YE 2024

Enrollment in Phase 3 Reliance II study expected to be completed by YE 2024

Preparations on track to initiate Phase 1 study for REL-P11 for metabolic disorders by YE 2024

Cash position of $70.4 million provides runway through key milestones, into 2025

Management hosting conference call and webcast today at 4:30 PM ET

CORAL GABLES, Fla., Aug. 07, 2024 (GLOBE NEWSWIRE) -- Relmada Therapeutics, Inc. (Nasdaq: RLMD, “Relmada”, “the Company”), 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 second quarter ended June 30, 2024. The Company will host a conference call today, Wednesday, August 7, at 4:30 PM ET.

“Relmada’s clinical programs have made meaningful progress this year. We believe that the portfolio, led by the Phase 3 program for REL-1017 as a potential adjunctive treatment for major depressive disorder (MDD), is poised to reach important milestones that could represent inflection points for Relmada,” said Sergio Traversa, Chief Executive Officer of Relmada. “We believe that our two ongoing Phase 3 trials, Reliance II and Relight, have been carefully designed to enhance the probability of success by appropriate patient adjudication in each study. We expect to complete enrollment in Reliance II by year-end 2024, to be followed by Relight
6-months after that.”

Dr. Traversa continued, “The Reliance II study design incorporates a pre-planned interim analysis to evaluate futility and a sample size re-estimation, if necessary, aimed at de-risking the program. We expect to conduct this analysis and report the outcome before year-end 2024. In addition, we are advancing preparations to begin the clinical program for REL-P11, our low-dose, modified-release psilocybin formulation for potential treatment of metabolic disorders, and intend to initiate a Phase 1 study in Canada before year-end 2024. Importantly, we believe that our financial resources are adequate to support our planned operations through key milestones, into 2025.”

Upcoming Anticipated Milestones

- **Output of Reliance II Interim Analysis Expected before YE 2024** Relmada intends to announce the output of a pre-planned interim analysis for the Phase 3 Reliance II

study as soon as available. The interim analysis will assess futility and, if recommended, provide a sample size re-estimation for the study.

- **Completion of Enrollment in Phase 3 Reliance II Study Anticipated by YE 2024** Relmada expects to complete enrollment in the randomized, controlled Phase 3 Reliance II study by YE 2024, to be followed by Relight approximately 6-months after. The two pivotal studies are designed to evaluate REL 1017's potential to improve treatment outcomes, measured by a change in the Montgomery-Asberg Depression Rating Scale (MADRS10) at Day 28.
- **Initiate Enrollment in the REL-P11 Program by YE 2024**: Relmada plans to initiate a Phase 1 safety study in Canada for REL-P11 by YE 2024. The Phase 1 study will define the pharmacokinetic, safety and tolerability profile of REL-P11 in obese subjects. Topline Phase 1 results and the initiation of a Phase 2a proof-of-concept study are expected in H1 2025.

Second Quarter 2024 Financial Results

- Research and development expense for the three months ended June 30, 2024, totaled $10.7 million, compared to $13.7 million for the three months ended June 30, 2023, a decrease of $3.0 million. 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 June 30, 2024, totaled $8.1 million compared to $12.3 million for the three months ended June 30, 2023, a decrease of approximately $4.2 million. The decrease was primarily driven by a decrease in stock-based compensation expense.
- Net cash used in operating activities for the three months ended June 30, 2024, totaled $13.3 million compared to $13.3 million for the three months ended June 30, 2023.
- The net loss for the three months ended June 30, 2024, was $17.8 million, or $0.59 per basic and diluted share, compared with a net loss of $25.3 million, or $0.84 per basic and diluted share, for the three months ended June 30, 2023.

Six Month Ended June 30, 2024 Financial Results

- Research and development expense for the six months ended June 30, 2024, totaled $24.0 million, compared to $29.6 million for the six months ended June 30, 2023, a decrease of $5.6 million. 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 six months ended June 30, 2024, totaled $17.8 million compared to $24.6 million for the six months ended June 30, 2023, a decrease of approximately $6.8 million. The decrease was primarily driven by a decrease in stock-based compensation expense.
- Net cash used in operating activities for the six months ended June 30, 2024, totaled $26.3 million compared to $29.8 million for the six months ended June 30, 2023.
- The net loss for the six months ended June 30, 2024, was $39.6 million, or $1.31 per basic and diluted share, compared with a net loss of $51.6 million, or $1.72 per basic

and diluted share, for the six months ended June 30, 2023.

- As of June 30, 2024, the Company had cash, cash equivalents, and short-term investments of approximately $70.4 million, compared to cash, cash equivalents, and short-term investments of approximately $96.3 million at December 31, 2023. The company believes its cash balance is adequate to support planned operations through key milestones, into 2025.
- The Company had 30,174,202 common shares outstanding, as of August 2, 2024.

Conference Call and Webcast Information:
Relmada will host a conference call and webcast today at 4:30 PM ET to discuss recent business progress and financial results. *To access the call, please dial: 1-800-717-1738 (United States) or 1-646-307-1865 (International) and reference conference ID: 39584 or to access the webcast, please Click Here. Participants can also use the "Call me™" feature by clicking the link https://emportal.ink/3zo6zXz,* which will be made active 15 minutes prior to scheduled start time.

A replay of the webcast will be available in the "Investors" section of the Relmada website at https://www.relmada.com/investors/ir-calendar.

About REL-1017 and the Phase 3 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. Relmada is developing REL-1017 as a rapid-acting, oral, once-daily adjunctive treatment for major depressive disorder (MDD). The clinical program includes two Phase 3 randomized, double-blind, placebo-controlled studies, Reliance II (Study 302, NCT04855747) and Relight (Study 304, NCT06011577). The studies are designed to evaluate the safety and efficacy of REL-1017. The primary endpoint of each study is the change in the Montgomery-Asberg Depression Rating Scale (MADRS10) at Day 28.

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. Relmada identified the potential to use low dose psilocybin as a treatment for metabolic diseases and published the data at the American Society for the Study of Liver Disease (AASLD 2023). Relmada intends to initiate a Phase 1 study of its proprietary low-dose, modified-release formulation of psilocybin, REL-P11, by YE 2024.

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 Reliance-OLS (study 310) to accurately reflect the results of the ongoing Reliance II (study 302) and Relight (study 304) blinded, randomized and controlled studies of REL-1017, failure of the planned Phase 1 and Phase 2a trials for REL-P11, the Company's modified release psilocybin formulation, to be successfully carried out, 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 June 30, 2024 (Unaudited)	As of December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 2,086,260	$ 4,091,568
Short-term investments	68,351,069	92,232,292
Prepaid expenses	537,522	1,185,057
Total current assets	70,974,851	97,508,917
Other assets	53,625	43,125
Total assets	$ 71,028,476	$ 97,552,042
Liabilities and Stockholders' Equity		

Commitments and Contingencies (See Note 6)		
Current liabilities:		
Accounts payable	$ 4,174,568	$ 3,506,009
Accrued expenses	5,362,280	8,688,791
Total current liabilities	9,536,848	12,194,800
Stockholders' Equity:		
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, 30,174,202 and 30,099,203 shares issued and outstanding, respectively	30,174	30,099
Additional paid-in capital	661,960,383	646,229,824
Accumulated deficit	(600,498,929)	(560,902,681)
Total stockholders' equity	61,491,628	85,357,242
Total liabilities and stockholders' equity	$ 71,028,476	$ 97,552,042

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

	Three months ended June 30,		Six months ended June 30,	
	2024	2023	2024	2023
Operating expenses:				
Research and development	$ 10,721,089	$ 13,740,205	$ 24,026,395	$ 29,601,215
General and administrative	8,097,695	12,286,521	17,780,249	24,579,120
Total operating expenses	18,818,784	26,026,726	41,806,644	54,180,335
Loss from operations	(18,818,784)	(26,026,726)	(41,806,644)	(54,180,335)
Other (expenses) income:				
Interest/investment income, net	963,013	1,363,406	2,018,901	2,571,037
Realized (loss) gain on short-term investments	133,114	-	186,247	(666,708)
Unrealized (loss) gain on short-term investments	(45,465)	(639,634)	5,248	651,476
Total other income	1,050,662	723,772	2,210,396	2,555,805
Net loss	$ (17,768,122)	$ (25,302,954)	$ (39,596,248)	$ (51,624,530)
Loss per common share – basic and diluted	$ (0.59)	$ (0.84)	$ (1.31)	$ (1.72)
Weighted average number of common shares outstanding – basic and diluted	30,174,202	30,099,203	30,153,186	30,099,203

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

	Three and Six months ended June 30, 2024				
	Common Stock		Additional Paid-in	Accumulated	
	Shares	Par Value	Capital	Deficit	Total
Balance – December 31, 2023	30,099,203	$ 30,099	$646,229,824	$(560,902,681)	$85,357,242
Stock based compensation	-	-	8,295,468	-	8,295,468
Options exercised for common stock	74,999	75	246,672	-	246,747
ATM Fees	-	-	(25,000)	-	(25,000)
Net loss	-	-	-	(21,828,126)	(21,828,126)
Balance – March 31, 2024	30,174,202	30,174	654,746,964	(582,730,807)	72,046,331
Stock based compensation	-	-	7,213,419	-	7,213,419

Net loss	-	-	-	(17,768,122)	(17,768,122)
Balance – June 30, 2024	30,174,202	$ 30,174	$661,960,383	$(600,498,929)	$61,491,628

	Three and Six months ended June 30, 2023				
	Common Stock		Additional Paid-in	Accumulated	
	Shares	Par Value	Capital	Deficit	Total
Balance - December 31, 2022	30,099,203	$30,099	$602,517,138	$(462,110,935)	$140,436,302
Stock based compensation	-	-	11,354,466	-	11,354,466
Net loss	-	-	-	(26,321,576)	(26,321,576)
Balance – March 31, 2023	30,099,203	30,099	613,871,604	(488,432,511)	125,469,192
Stock based compensation	-	-	11,169,517	-	11,169,517
Net loss	-	-	-	(25,302,954)	(25,302,954)
Balance – June 30, 2023	30,099,203	$30,099	$625,041,121	$(513,735,465)	$111,335,755

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

	Six months ended June 30,	
	2024	2023
Cash flows from operating activities		
Net loss	$(39,596,248)	$(51,624,530)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	15,508,887	22,523,983
Realized loss (gain) on short-term investments	(186,247)	666,708
Unrealized (gain) loss on short-term investments	(5,248)	(651,476)
Change in operating assets and liabilities:		
Other receivables	-	512,432
Prepaid expenses and other assets	637,035	560,931
Accounts payable	668,559	(408,320)
Accrued expenses	(3,326,511)	(1,358,091)
Net cash (used in) operating activities	(26,299,773)	(29,778,363)
Cash flows from investing activities		
Purchase of short-term investments	(8,313,312)	(45,577,832)
Sale of short-term investments	32,386,030	84,429,644
Net cash provided by investing activities	24,072,718	38,851,812
Cash flows from financing activities		
Proceeds from options exercised for common stock	246,747	-
ATM Fees	(25,000)	-
Net cash provided by financing activities	221,747	-
Net (decrease)/increase in cash and cash equivalents	(2,005,308)	9,073,449
Cash and cash equivalents at beginning of the period	4,091,568	5,395,905
Cash and cash equivalents at end of the period	$ 2,086,260	$ 14,469,354
Supplemental disclosure of cash flow information:		
Cash paid during the period for:		
Interest	$ -	$ -
Income Tax	$ -	$ -

Source: Relmada Therapeutics