November 7, 2024

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

Pre-planned Phase 3 Reliance II interim analysis, anticipated by YE 2024, could represent an important de-risking event for REL-1017 and the Company

Phase 1 study for REL-P11 for metabolic disease expected to begin by YE 2024

Cash position of $54.1 million provides runway through key near-term milestones, into 2025

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

CORAL GABLES, Fla., Nov. 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 third quarter ended September 30, 2024. The Company will host a conference call today, Thursday, November 7, at 4:30 PM ET.

"We believe that Relmada's clinical programs are poised to achieve meaningful, near-term value inflection points. Our lead product candidate, REL-1017, is in a registrational Phase 3 program as a potential adjunct treatment for major depressive disorder. Two ongoing trials, Reliance II and Relight, have been designed to build on positive Phase 2 results, with enhanced site selection and more stringent patient enrollment criteria," said **Sergio Traversa, Chief Executive Officer** of Relmada. "The Reliance II study also incorporates a pre-planned interim analysis to evaluate futility and sample size. We believe that the outcome, expected by year-end represents an important de-risking event for the REL-1017 program and the Company."

Mr. Traversa continued, "In addition, we expect to initiate a Phase 1 safety study for REL-P11 for metabolic disease shortly. The low-dose, modified-release psilocybin formulation improved multiple metabolic parameters in preclinical models and could provide a valuable therapeutic option in the evolving obesity and metabolic syndrome space. The Phase 1 study is expected to be conducted in Canada and will define the pharmacokinetic, safety and tolerability profile of REL-P11 in obese subjects. A Phase 2a proof-of-concept study is expected to begin in H1 2025."

Upcoming Anticipated Milestones

- **Reliance II Interim Analysis Expected by YE 2024**
- **Initiate Enrollment in the REL-P11 Program by YE 2024**

Third Quarter 2024 Financial Results

- Research and development expense for the three months ended September 30, 2024, totaled $11.1 million, compared to $10.4 million for the three months ended September 30, 2023, an increase of $0.7 million. The increase was primarily driven by an increase in study costs associated with the ramp up of the Reliance II/302 and Relight/304 studies in 2024.
- General and administrative expense for the three months ended September 30, 2024, totaled $11.9 million compared to $12.2 million for the three months ended September 30, 2023, a decrease of approximately $0.4 million. The decrease was primarily driven by a decrease in stock-based compensation expense.
- The net loss for the three months ended June 30, 2024, was $21.7 million, or $0.72 per basic and diluted share, compared with a net loss of $22.0 million, or $0.73 per basic and diluted share, for the three months ended September 30, 2023.

Nine Month Ended September 30, 2024 Financial Results

- Research and development expense for the nine months ended September 30, 2024, totaled $35.2 million, compared to $40.1 million for the nine months ended September 30, 2023, a decrease of $4.9 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) in 2023.
- General and administrative expense for the nine months ended September 30, 2024, totaled $29.6 million compared to $36.8 million for the nine months ended September 30, 2023, a decrease of approximately $7.2 million. The decrease was primarily driven by a decrease in stock-based compensation expense.
- Net cash used in operating activities for the nine months ended September 30, 2024, totaled $43.0 million compared to $41.4 million for the nine months ended September 30, 2023.
- The net loss for the nine months ended September 30, 2024, was $61.3 million, or $2.03 per basic and diluted share, compared with a net loss of $73.6 million, or $2.45 per basic and diluted share, for the nine months ended September 30, 2023.
- As of September 30, 2024, the Company had cash, cash equivalents, and short-term investments of approximately $54.1 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 near-term milestones, into 2025.
- The Company had 30,174,202 common shares outstanding, as of November 4, 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: 60579 or to access the webcast, please Click Here. Participants can also use the "Call me™" feature by clicking the link* https://emportal.ink/3N1UIlu*,* 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.

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 low-dose, modified release formulation of psilocybin, 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.

Investor Contact:
Tim McCarthy
LifeSci Advisors
Tim@LifeSciAdvisors.com

Media Inquiries:
Corporate Communications
media@relmada.com

Relmada Therapeutics, Inc.
Condensed Consolidated Balance Sheets

	As of September 30, 2024 (Unaudited)	As of December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 1,483,789	$ 4,091,568
Short-term investments	52,633,938	92,232,292
Prepaid expenses	1,584,803	1,185,057
Total current assets	55,702,530	97,508,917
Other assets	21,975	43,125
Total assets	$ 55,724,505	$ 97,552,042
Commitments and Contingencies (See Note 8)		
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,345,541	$ 3,506,009
Accrued expenses	5,741,220	8,688,791
	8,086,761	12,194,800
Total current liabilities		
Stock appreciation rights	12,562	-
Total liabilities	8,099,323	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	669,819,907	646,229,824
Accumulated deficit	(622,224,899)	(560,902,681)
Total stockholders' equity	47,625,182	85,357,242

Total liabilities and stockholders' equity	$ 55,724,505	$ 97,552,042

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

	Three months ended September 30,		Nine months ended September 30,	
	2024	2023	2024	2023
Operating expenses:				
Research and development	$ 11,149,136	$ 10,454,072	$ 35,175,531	$ 40,055,287
General and administrative	11,859,702	12,238,566	29,639,951	36,817,686
Total operating expenses	23,008,838	22,692,638	64,815,482	76,872,973
Loss from operations	(23,008,838)	(22,692,638)	(64,815,482)	(76,872,973)
Other (expenses) income:				
Interest/investment income, net	856,478	1,321,441	2,875,379	3,892,478
Realized (loss) gain on short-term investments	147,835	(51,714)	334,082	(718,422)
Unrealized (loss) gain on short-term investments	278,555	(579,147)	283,803	72,329
Total other (expense) income – net	1,282,868	690,580	3,493,264	3,246,385
Net loss	$ (21,725,970)	$ (22,002,058)	$ (61,322,218)	$ (73,626,588)
Loss per common share – basic and diluted	$ (0.72)	$ (0.73)	$ (2.03)	$ (2.45)
Weighted average number of common shares outstanding – basic and diluted	30,174,202	30,099,203	30,160,242	30,099,203

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

	Three and Nine months ended September 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 exercises 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
Stock-based compensation	-	-	7,949,125	-	7,949,125
ATM Fees	-	-	(89,601)	-	(89,601)
Net loss	-	-	-	(21,725,970)	(21,725,970)
Balance – September 30, 2024	30,174,202	$ 30,174	$ 669,819,907	$ (622,224,899)	$ 47,625,182

	Three and Nine months ended September 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
Stock-based compensation	-	-	11,392,938	-	11,392,938
Net loss	-	-	-	(22,002,058)	(22,002,058)
Balance – September 30, 2023	30,099,203	$ 30,099	$ 636,434,059	$ (535,737,523)	$ 100,726,635

Relmada Therapeutics, Inc.
Condensed Consolidated Statements of Cash Flows

	Nine months ended September 30,	
	2024	2023
Cash flows from operating activities		
Net loss	$ (61,322,218)	$ (73,626,588)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	23,458,012	33,916,921
Realized (gain) loss on short-term investments	(334,082)	718,422
Unrealized (gain) loss on short-term investments	(283,803)	(72,329)
Change in operating assets and liabilities:		
Other receivable	-	512,432
Prepaid expenses and other assets	(378,596)	1,188,309
Accounts payable	(1,160,468)	(2,405,184)
Accrued expenses	(2,947,571)	(1,641,475)
Stock appreciation rights compensation	12,562	-
Net cash used in operating activities	(42,956,164)	(41,409,492)
Cash flows from investing activities		
Purchase of short-term investments	(11,424,986)	(57,151,963)
Sale of short-term investments	51,641,225	99,864,149
Net cash provided by investing activities	40,216,239	42,712,186
Cash flows from financing activities		
Proceeds from options exercised for common stock	246,747	-
ATM Fees	(114,601)	-
Net cash provided by financing activities	132,146	-
Net increase /(decrease) in cash and cash equivalents	(2,607,779)	1,302,694
Cash and cash equivalents at beginning of the period	4,091,568	5,395,905
Cash and cash equivalents at end of the period	$ 1,483,789	6,698,599
Supplemental disclosure of cash flow information:		
Cash paid during the period for:		
Interest	$ -	$ -
Income Tax	$ -	$ -

Source: Relmada Therapeutics