Relmada Therapeutics Provides Corporate Update and Reports First Quarter 2024 Financial Results

Description

CORAL GABLES, Fla., May 8, 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 first quarter ended March 31, 2024. The Company will host a conference call today, Wednesday, May 8, at 4:30 PM Eastern Time/1:30 PM Pacific Time.

Relmada Therapeutics Corporate Logo (PRNewsFoto/Relmada Therapeutics, Inc.)

“Enrollment continues to advance in 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. “As such, we continue to expect that the Reliance II study (study 302) will be fully enrolled with top-line data anticipated in the second half of 2024. In addition, we continue to enroll in our second ongoing Phase 3 trial of REL-1017, Relight (study 304).”

“We also continue to plan for the initiation of a single-ascending dose Phase 1 trial for our promising preclinical novel modified-release psilocybin in obese patients, which is anticipated to commence in the first half of this year. The goal of this study will be to define the pharmacokinetic, safety and tolerability profile of our modified-release psilocybin formulation in this population, and it will be followed by a Phase 2a trial to establish clinical proof-of-concept,” continued Mr. Traversa.

Upcoming Anticipated Milestones

- Complete enrollment in the ongoing Reliance II study, which is planned to enroll approximately 300 patients, with top-line data in the second half of 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.

First Quarter 2024 Financial Results

- Research and development expense for the three months ended March 31, 2024, totaled $13.3 million, compared to $15.9 million for the three months ended March 31, 2023. 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 March 31, 2024, totaled $9.7 million compared to $12.3 million for the three months ended March 31, 2023, a decrease of

approximately $2.6 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 March 31, 2024, totaled $13.0 million compared to $16.5 million for the three months ended March 31, 2023.
- The net loss for the three months ended March 31, 2024, was $21.8 million, or $0.72 per basic and diluted share, compared with a net loss of $26.4 million, or $0.87 per basic and diluted share, for the three months ended March 31, 2023.
- As of March 31, 2024, the Company had cash, cash equivalents, and short-term investments of approximately $83.6 million, compared to cash, cash equivalents, and short-term investments of approximately $96.3 million at December 31, 2023.

Conference Call and Webcast Details

Wednesday, May 8th @ 4:30pm ET

Toll Free:	888-886-7786
International:	416-764-8658
Conference ID:	38754189
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 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.

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

Media Inquiries:
Corporate Communications
media@relmada.com

Relmada Therapeutics, Inc.

Consolidated Balance Sheets

(Unaudited)

	As of March 31, 2024 (Unaudited)	As of Dece 2023
Assets		
Current assets:		
Cash and cash equivalents	$1,335,018	$4,09
Short-term investments	82,277,687	92,2
Prepaid expenses	752,334	1,18
Total current assets	84,365,039	97,5
Other assets	43,125	43,1
Total assets	$84,408,164	$97,5
Commitments and Contingencies (See Note 6)		
Liabilities and Stockholders' Equity		

Current liabilities:		
Accounts payable	$5,189,101	$3,50
Accrued expenses	7,172,732	8,68
Total current liabilities	12,361,833	12,1
Total liabilities	12,361,833	12,1
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, 30,174,202 and 30,099,203 shares issued and outstanding, respectively	30,174	30,0
Additional paid-in capital	654,746,964	646,
Accumulated deficit	(582,730,807)	(560
Total stockholders' equity	72,046,331	85,3
Total liabilities and stockholders' equity	$84,408,164	$97,5

Relmada Therapeutics, Inc.

Consolidated Statements of Operations

(Unaudited)

	Three months ended March 31,	
	2024	**2023**
Operating expenses:		
Research and development	$13,305,306	$15,861,010
General and administrative	9,682,554	12,292,599
Total operating expenses	22,987,860	28,153,609
Loss from operations	(22,987,860)	(28,153,609)
Other income (expenses):		
Interest/investment income, net	1,055,888	1,207,631
Realized gain (loss) on short-term investments	53,133	(666,708)
Unrealized gain on short-term investments	50,713	1,291,110
Total other income (expenses)	1,159,734	1,832,033

Net loss	$(21,828,126)	$(26,321,576)
Loss per common share – basic and diluted	$(0.72)	$(0.87)
Weighted average number of common shares outstanding – basic and diluted	30,132,170	30,099,203

Relmada Therapeutics, Inc.

Condensed Consolidated Statements of Changes in Stockholders' Equity

(Unaudited)

	Three months ended March 31, 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

	Three months ended March 31, 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

Relmada Therapeutics, Inc.

Condensed Consolidated Statements of Cash Flows

(Unaudited)

	Three months ended March 31,	
	2024	2023
Cash flows from operating activities		
Net loss	$ (21,828,126)	$ (26,321,576)

Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	8,295,468	11,354,466
Realized (gain) loss on short-term investments	(53,133)	666,708
Unrealized gain on short-term investments	(50,713)	(1,291,110)
Change in operating assets and liabilities:		
Other receivables	–	512,432
Prepaid expenses	432,723	945,606
Accounts payable	1,683,092	(839,971)
Accrued expenses	(1,516,059)	(1,531,649)
Net cash used in operating activities	(13,036,748)	(16,505,094)
Cash flows from investing activities		
Purchase of short-term investments	(7,013,933)	(34,767,287)
Sale of short-term investments	17,072,384	74,770,836
Net cash provided by investing activities	10,058,451	40,003,549
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 increase in cash and cash equivalents	(2,756,550)	23,498,455
Cash and cash equivalents at beginning of the period	4,091,568	5,395,905
Cash and cash equivalents at end of the period	$ 1,335,018	$ 28,894,360

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SOURCE Relmada Therapeutics, Inc.

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