Relmada Therapeutics Provides Corporate Update and Reports First Quarter 2023 Financial Results

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Relmada Therapeutics, Inc. →
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CORAL GABLES, Fla., May 11, 2023 /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, 2023. The Company will host a conference call today, Thursday, May 11, at 4:30 PM Eastern Time/1:30 PM Pacific Time.

"We are focused on optimizing the potential for success in the promising late-stage development program of REL-1017 for the adjunctive treatment of major depressive disorder," said Sergio Traversa, Relmada's Chief Executive Officer. "The amended protocol for ongoing Study 302, is now being implemented and enrollment is progressing, with trial completion anticipated in the first half of 2024. For the new planned Study 304, we have finalized site selection and solidified a rigorous patient eligibility process."

"We are optimistic about the protocol and trial design improvements we have made. Based on data generated to date, we believe we have been able to identify those clinical sites that were better able to control placebo response, and those that understand the importance of enrolling appropriate subjects with documented diagnoses and treatment histories. We have increased our own internal oversight of the subject eligibility process with the build-out of an internal

clinical development team led by our Chief Medical Officer, Dr. Cedric O'Gorman, who has previously run positive registrational trials in MDD. Moreover, we are sufficiently funded to execute our plans to reach data readouts from both Phase 3 trials in 2024."

Recent Corporate Highlights

- Implemented the amended protocol for ongoing Reliance II (Study 302), a Phase 3 trial of REL-1017 for the adjunctive treatment of MDD
- Completed protocol and finalized site selection for Study 304, the new planned Phase 3 trial of REL-1017 for the adjunctive treatment of MDD
- Conclusion of Reliance OLS (Study 310), a long-term, open-label study of REL-1017 in MDD
- Two late-breaking posters accepted for presentation at the upcoming 2023 American Society of Clinical Psychopharmacology Meeting

Upcoming Anticipated Milestones for REL-1017

- Complete enrollment in ongoing Reliance II (Study 302), which is planned to enroll approximately 300 patients, in the first half of 2024
- Initiate new Study 304 in mid-2023, with a planned enrollment of approximately 300 patients, with completion anticipated in the second half of 2024
- Announce results from the Reliance OLS (Study 310) in 2023

First Quarter 2023 Financial Results

- Research and development expense for the three months ended March 31, 2023, totaled $15.9 million, compared to $25.0 million for the three months ended March 31, 2022. The decrease was primarily associated with the completion of the Reliance I and Reliance III clinical studies in late 2022.

- General and administrative expense for the three months ended March 31, 2023, totaled $12.3 million, compared to $13.3 million for the three months ended March 31, 2022. The decrease was primarily driven by a decrease in stock-based compensation.

- Net loss for the three months ended March 31, 2023, was $26.3 million, or $0.87 per basic and diluted share, compared with a net loss of $39.7 million, or $1.40 per basic and diluted share, for the three months ended March 31, 2022.

- Net cash used in operating activities for the three months ended March 31, 2023, totaled $16.5 million, compared to $19.4 million for the three months ended March 31, 2022.

- As of March 31, 2023, the Company had cash, cash equivalents, and short-term investments of approximately $132.4 million, compared to cash, cash equivalents, and short-term investments of approximately $148.3 million at December 31, 2022.

Conference Call and Webcast Details

Thursday, May 11 at 4:30 PM ET

Toll Free:	833 470 1428
International:	https://www.netroadshow.com/events/global-numbers?confId=50778
Conference ID:	224217
Webcast:	https://events.q4inc.com/attendee/875321888

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

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 antidepressant treatment.

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 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 March 31, 2023 (Unaudited)	As of December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 28,894,360	$ 5,395,905
Short-term investments	103,547,634	142,926,781
Other receivables	-	512,432
Prepaid expenses	3,089,580	4,035,186
Total current assets	135,531,574	152,870,304
Other assets	34,875	34,875
Total assets	$ 135,566,449	$ 152,905,179
Commitments and Contingencies (See Note 6)		
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 4,421,965	$ 5,261,936
Accrued expenses	5,675,292	7,206,941
Total current liabilities	10,097,257	12,468,877
Total liabilities	10,097,257	12,468,877
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, 30,099,203 shares issued and outstanding	30,099	30,099
Additional paid-in capital	613,871,604	602,517,138
Accumulated deficit	(488,432,511)	(462,110,935)
Total stockholders' equity	125,469,192	140,436,302
Total liabilities and stockholders' equity	$ 135,566,449	$ 152,905,179

Relmada Therapeutics, Inc.

Condensed Consolidated Statements of Operations

(Unaudited)

	Three months ended March 31,	
	2023	**2022**
Operating expenses:		
Research and development	$ 15,861,010	$ 25,012,853
General and administrative	12,292,599	13,284,570
Total operating expenses	28,153,609	38,297,423
Loss from operations	(28,153,609)	(38,297,423)
Other income (expenses):		
Interest/investment income, net	1,207,631	329,949
Realized loss on short-term investments	(666,708)	(15,022)
Unrealized gain (loss) on short-term investments	1,291,110	(1,763,287)
Total other income (expenses)	1,832,033	(1,448,360)
Net loss	$ (26,321,576)	$ (39,745,783)
Loss per common share – basic and diluted	$ (0.87)	$ (1.40)
Weighted average number of common shares outstanding – basic and diluted	30,099,203	28,392,601

Relmada Therapeutics, Inc.

Condensed Consolidated Statements of Changes in Stockholders' Equity

(Unaudited)

	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

	Three months ended March 31, 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

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Condensed Consolidated Statements of Cash Flows

(Unaudited)

	Three months ended March 31,	
	2023	**2022**
Cash flows from operating activities		
Net loss	$ (26,321,576)	$ (39,745,783)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	-	-
Stock-based compensation	11,354,466	11,930,681
Realized loss on short-term investments	666,708	15,022
Unrealized (gain) loss on short-term investments	(1,291,110)	1,763,287
Change in operating assets and liabilities:		
Lease payment receivable	-	20,923
Other receivables	512,432	-
Prepaid expenses	945,606	6,237,575
Accounts payable	(839,971)	(522,353)
Accrued expenses	(1,531,649)	870,905
Net cash used in operating activities	(16,505,094)	(19,429,743)
Cash flows from investing activities		
Purchase of short-term investments	(34,767,287)	(25,915,957)
Sale of short-term investments	74,770,836	15,888,289
Net cash provided by (used in) investing activities	40,003,549	(10,027,668)
Cash flows from financing activities		
Proceeds from issuance of common stock	-	29,583,542
Proceeds from options exercised for common stock	-	64,800
Proceeds from warrants exercised for common stock	-	300,006
Net cash provided by financing activities	-	29,948,348
Net increase in cash and cash equivalents	23,498,455	490,937
Cash and cash equivalents at beginning of the period	5,395,905	44,443,439
Cash and cash equivalents at end of the period	$ 28,894,360	$ 44,934,376

SOURCE Relmada Therapeutics, Inc.