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

Description

CORAL GABLES, Fla., May 5, 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 first quarter ended March 31, 2022. The Company will host a conference call today, Thursday, May 5, at 4:30 PM Eastern Time/1:30 PM Pacific Time.

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

Recent Corporate Highlights

- Appointed Gino Santini, a global biopharmaceutical industry executive with a successful track-record in both operational and strategic roles, to serve as the Corporate Development Strategic Advisor
- Published REL-1017 preclinical Olney's lesion data in the peer-reviewed journal, *Frontiers in Pharmacology*
- Presented REL-1017 data for both HAP studies in two poster presentations and one oral presentation at the Ketamine & Related Compounds International Hybrid Conference 2022

"The expected catalyst-rich 2022 for our late-stage development program, REL-1017 as an adjunctive and monotherapy treatment for people living with major depressive disorder (MDD), continues to progress as planned," said Sergio Traversa, Relmada's Chief Executive Officer. We intend to generate REL-1017 clinical data readouts for the ongoing Reliance Phase 3 program beginning mid-year," continued Traversa. "We anticipate completing the enrollment of Reliance III, the ongoing monotherapy registrational Phase 3 trial and present the top-line results by mid-year 2022, followed by top-line results from Reliance I and Reliance II, the adjunctive MDD studies, throughout the second half of the year."

Relmada is delighted to announce the addition of Gino Santini, a highly experienced biopharmaceutical industry executive to support the Company. Gino is joining with global expertise in both corporate strategy and operational roles and has demonstrated strong value creation skills. He is a former member of the executive team of Eli Lilly, with responsibilities as President of US Operations and SVP of Corporate Strategy and Business Development. After a 28-year career at Lilly, Gino currently serves on the board of multiple public and private biopharmaceutical companies.

"The potential of REL-1017 to be a transformative therapy for patients suffering with major depressive disorder is an exciting opportunity in the CNS space," said Gino Santini. "I really look forward to leveraging my experience in commercializing innovative drugs and in strategic business development with the Relmada team. Our aim is to expeditiously deliver the most value for those who can potentially

benefit from REL-1017.”

Upcoming Anticipated Milestones for REL-1017

- Mid-’22 – Data for Reliance III monotherapy MDD trial
- 3Q ’22 – Data for Reliance I adjunctive MDD trial
- 4Q ’22 – Data for Reliance II adjunctive MDD trial

First Quarter 2022 Financial Results

- Research and development expense for the three months ended March 31, 2022, totaled $25.0 million, compared to $14.0 million for the three months ended March 31, 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 three months ended March 31, 2022, totaled $13.3 million compared to $8.4 million for the three months ended March 31, 2021, an increase of approximately $4.9 million. The increase was primarily driven by an increase in stock-based compensation.
- The net loss for the three months ended March 31, 2022, was $39.7 million, or $1.40 per diluted share, compared with a net loss of $22.2 million, or $1.34 per diluted share, for the three months ended March 31, 2021.
- As of March 31, 2022, the Company had cash, cash equivalents, and short-term investments of $220.6 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, May 5th @ 4:30pmET	
Toll Free:	1-877-256-3246
International:	1-212-231-2903
Conference ID:	? 22017494
Webcast:	https://viavid.webcasts.com/starthere.jsp?ei=1543079&tp_key=2a9a78ffb7

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 treatment of MDD. The ongoing

Reliance Clinical Research Program is designed to evaluate REL-1017 as a potential rapid-acting, oral, once-daily antidepressant treatment. In a Phase 2 trial, REL-1017 demonstrated robust, rapid, 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 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 and monotherapy 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, including but not limited to statements regarding the expected use of the proceeds from the offering. 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 the 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, 2022 (Unaudited)	As of December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$44,934,376	$44,443,439
Short-term investments	175,715,526	167,466,167
Lease payments receivable – short term	65,454	86,377
Prepaid expenses	5,063,960	11,301,535
Total current assets	225,779,316	223,297,518
Other assets	28,293	28,293
Total assets	$225,807,609	$223,325,811
Commitments and Contingencies (See Note 7)		
Liabilities and Stockholders' Equity		
Current liabilities:		

Accounts payable	$10,670,149	$11,192,502
Accrued expenses	4,739,328	3,868,423
Total current liabilities	15,409,477	15,060,925
Total liabilities	15,409,477	15,060,925
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, 50,000,000 shares authorized, 29,402,824 and 27,740,147 shares issued and outstanding, respectively	29,403	27,740
Additional paid-in capital	555,181,624	513,304,258
Accumulated deficit	(344,812,895)	(305,067,112)
Total stockholders' equity	210,398,132	208,264,886
Total liabilities and stockholders' equity	$225,807,609	$223,325,811

Relmada Therapeutics, Inc.

Condensed Consolidated Statements of Operations

(Unaudited)

	Three months ended

	March 31,	
	2022	**2021**
Operating expenses:		
Research and development	$25,012,853	$14,022,227
General and administrative	13,284,570	8,382,976
Total operating expenses	38,297,423	22,405,203
Loss from operations	(38,297,423)	(22,405,203)
Other (expenses) income:		
Interest/investment income, net	329,949	419,974
Realized loss on short-term investments	(15,022)	(52,789)
Unrealized loss on short-term investments	(1,763,287)	(177,163)
Total other (expense) income	(1,448,360)	190,022
Net loss	$(39,745,783)	$(22,215,181)
Loss per common share – basic and diluted	$(1.40)	$(1.34)
Weighted average number of common shares outstanding – basic and diluted	28,392,601	16,572,672

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SOURCE Relmada Therapeutics, Inc.

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