Relmada Therapeutics Provides Corporate Update and Reports First Quarter 2021 Financial Results

Description

NEW YORK, May 12, 2021 /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 financial results for the first quarter ended March 31, 2021.

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

“We continue to advance the development of our lead product candidate, REL-1017, for the treatment of major depressive disorder (MDD),” said Sergio Traversa, Relmada’s Chief Executive Officer. “The RELIANCE Clinical Development Program is underway. The first of two pivotal Phase 3 trials, RELIANCE I, continues to enroll as planned and we recently began enrolling participants in the second study, RELIANCE II. The long-term, open-label safety study, RELIANCE-OLS, is also actively enrolling participants from the pivotal studies as well as new participants. Importantly, we expect multiple key clinical data over the next several quarters. We also continue to build on the clinical evidence in support of REL-1017 through the presentation of data at scientific meetings, particularly through learnings regarding the mechanism of action that underlies the clinical profile of REL-1017.”

Recent Corporate Highlights

- Continued enrollment of participants in the first pivotal Phase 3 clinical trial, RELIANCE I, for REL-1017 as an adjunctive treatment for MDD.
- Initiation of RELIANCE II, the second pivotal Phase 3 clinical trial for REL-1017 as an adjunctive treatment for MDD.
- Presentation of nine posters highlighting preclinical and clinical data for REL-1017 at the American Society for Pharmacology and Experimental Therapeutics Annual Meeting at Experimental Biology 2021, the 2021 Society of Biological Psychiatry Annual Meeting and the American Psychiatric Association Annual Meeting 2021.

Upcoming Anticipated Milestones for REL-1017

- 1H21 – Start of the monotherapy MDD trial
- 2Q21 – Completion of the human abuse potential study with oxycodone
- 2H21 – Completion of the human abuse potential study with ketamine
- 4Q21 – Completion of the monotherapy MDD trial
- 1H22 – Completion of RELIANCE I and RELIANCE II adjunctive MDD trials

First Quarter 2021 Financial Results

- Research and development expenses for the first quarter ended March 31, 2021 totaled $14.0 million, compared to $4.5 million in the first quarter ended March 31, 2020. The increase was primarily driven by increased costs associated with preparations for and conducting the Company's Phase 3 program for REL-1017.
- General and administrative expenses for the first quarter ended March 31, 2021, totaled approximately $8.4 million, up from $5.5 million in the first quarter ended March 31, 2020. The increase was primarily driven by an increase in stock-based compensation.
- Net loss for the first quarter ended March 31, 2021, was $22.2 million, or a net loss of $1.34 per share, compared with a net loss of $10.7 million, or a net loss of $0.72 per share, in the first quarter ended March 31, 2020.
- As of March 31, 2021, the Company had cash, cash equivalents, and short-term investments of approximately $102.7 million, compared to $117.1 million at December 31, 2020.

Conference Call and Webcast Details

Date:	Wednesday, May 12, 2021
Time:	4:30pm Eastern Time
Toll Free:	877-407-0792
International:	201-689-8263
Conference ID:	13719413
Webcast:	http://public.viavid.com/index.php?id=144760

About REL-1017

REL-1017, a novel NMDA receptor (NMDAR) channel blocker that preferentially targets hyperactive channels while maintaining physiological glutamatergic neurotransmission, is currently in late-stage development as an adjunctive treatment for MDD in adults. The ongoing RELIANCE Clinical Research Program is designed to evaluate the potential for REL-1017 as the first rapid-acting, oral, once-daily antidepressant treatment. In a Phase 2 trial, REL-1017 demonstrated rapid onset and sustained antidepressant effects with statistically significant improvements as compared to placebo. The Phase 2 study also confirmed the favorable safety and tolerability profile of REL-1017 observed in previously completed Phase 1 studies. In April 2017, the FDA granted Fast Track designation for REL-1017 for the adjunctive treatment of major depressive disorder.

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). Our 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 novel NMDA receptor (NMDAR) channel blocker that preferentially targets hyperactive channels while maintaining physiological glutamatergic neurotransmission. REL-1017 has entered 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, 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	**As of**

	March 31, 2021	December 2020
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$3,804,042	$2,495,397
Short-term investments	98,899,732	114,595,5
Lease payments receivable – short term	81,133	79,457
Prepaid expenses	990,695	903,190
Total current assets	103,775,602	118,073,5
Fixed assets, net of accumulated depreciation	452	1,258
Other assets	25,000	25,000
Lease payments receivable – long term	65,454	86,377
Total assets	$103,866,508	$118,186,2
Commitments and Contingencies (See Note 8)		
Liabilities and Stockholders' Equity		
Current liabilities:		

Accounts payable	$8,082,796	$8,346,475
Accrued expenses	4,636,584	4,256,983
Total current liabilities	12,719,380	12,603,45
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, 50,000,000 shares authorized, 16,748,055 and 16,332,939 shares issued and outstanding, respectively	16,748	16,333
Additional paid-in capital	292,660,864	284,881,7
Accumulated deficit	(201,530,484)	(179,315,
Total stockholders' equity	91,147,128	105,582,7
Total liabilities and stockholders' equity	$103,866,508	$118,186,2

Relmada Therapeutics, Inc.

Condensed Consolidated Statements of Operations

(Unaudited)

	Three months ended March 31,	
	2021	**2020**
Operating expenses:		
Research and development	$14,022,227	$4,507,784
General and administrative	8,382,976	5,466,654
Total operating expenses	22,405,203	9,974,438
Loss from operations	(22,405,203)	(9,974,438)
Other income (expenses):		
Interest/investment income, net	419,974	407,652
Realized loss on short-term investments	(52,789)	(171,611)
Unrealized loss on short-term investments	(177,163)	(934,919)
Total other income (expenses), net	190,022	(698,878)
Net loss	$(22,215,181)	$(10,673,316)
Net loss per common share – basic and diluted	$(1.34)	$(0.72)
Weighted average number of common shares outstanding – basic and diluted	16,572,672	14,738,230

The accompanying notes are an integral part of these unaudited condensed consolidated financial stater

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