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

Description

NEW YORK, Aug. 10, 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 three and six months ended June 30, 2021.

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

“The multiple clinical studies that comprise RELIANCE, the pivotal Phase 3 program for REL-1017 as a potential adjunctive treatment for the treatment of major depressive disorder (MDD), continue to progress,” said Sergio Traversa, Relmada’s Chief Executive Officer. “The program was further advanced with the clear results of the human abuse potential (HAP) study that reenforced the safety findings of the clinical program to date, establishing a highly statistically significant separation from the active control. Looking ahead, we anticipate multiple key data readouts over the next 12 months, and have added a potential long-term growth driver with the acquisition of development and commercial rights to a novel psilocybin and derivate program. Importantly, our robust R&D initiatives are supported by a strong balance sheet.”

Recent Corporate Highlights

- Announcement of top-line results of the HAP study comparing REL-1017 to oxycodone and placebo, confirming the absence of any meaningful opioid abuse liability of REL-1017.
- Acquisition of development and commercial rights to a novel psilocybin and derivate program from Arbormentis LLC in all ex-Asia territories, including the U.S. and Europe focusing on neurodegenerative disorders.
- Presentation of three posters highlighting preclinical and clinical data for REL-1017 at the College on Problems of Drug Dependence 83rd Annual Meeting, and the 2021 American Society of Clinical Psychopharmacology Annual Meeting.

Second Quarter 2021 Financial Results

- Research and development expenses for the second quarter ended June 30, 2021, totaled $17.3 million, compared to $5.3 million in the second quarter ended June 30, 2020. 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 expenses for the second quarter ended June 30, 2021, totaled $9.1 million, up from $7.4 million in the second quarter ended June 30, 2020. The increase was primarily driven by increases in personnel costs, stock-based compensation and consulting services.

- Net loss for the second quarter ended June 30, 2021, was $26.6 million, or a net loss of $1.56 per share, compared with a net loss of $11.1 million, or a net loss of $0.73 per share, in the second quarter of 2020.

Six Months Ended June 30, 2021 Financial Results

- Research and development expenses for the six months ended June 30, 2021, totaled $31.4 million, compared to $9.8 million for the six months ended June 30, 2020. The increase was primarily driven by increased costs associated with preparations for and conducting RELIANCE, the Company's Phase 3 program for REL-1017.
- General and administrative expense for the six months ended June 30, 2021, totaled $17.5 million, compared to $12.9 million for the six months ended June 30, 2020. The increase was primarily driven by increases in personnel costs, stock-based compensation and consulting services.
- The net loss for the Company for the six months ended June 30, 2021 and 2020 was $48.8 million and $21.8 million, respectively. The Company had a net loss of $2.90 and $1.45 per share for the six months ended June 30, 2021 and 2020, respectively.
- As of June 30, 2021, the Company had cash, cash equivalents, and short term investments of $109.1 million, compared to cash, cash equivalents, and short term investments of approximately $117.1 million at December 31, 2021.

Conference Call and Webcast Details

Date:	Tuesday, August 10, 2021
Time:	4:30pm Eastern Time
Toll Free:	855-327-6837
International:	631-891-4304
Conference ID:	10015943
Webcast:	http://public.viavid.com/index.php?id=146035

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 the potential for REL-1017 as the first 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 confirmed the favorable pharmacokinetic, safety and tolerability profile of REL-1017 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). 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 new chemical entity (NCE) and 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. In addition, the Company is advancing a clinical-stage program in neurodegenerative novel form of psilocybin and derivates. 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 June 30, 2021 (unaudited)	As of December 2020
Assets		
Current assets:		
Cash and cash equivalents	$4,669,345	$2,495,397
Short-term investments	104,399,140	114,595,5
Lease payments receivable – short term	82,845	79,457
Prepaid expenses	1,548,880	903,190
Total current assets	110,700,210	118,073,5
Fixed assets, net of accumulated depreciation	–	1,258
Other assets	25,000	25,000
Lease payments receivable – long term	44,090	86,377
Total assets	$110,769,300	$118,186,2
Commitments and Contingencies (See Note 8)		

Liabilities and Stockholders' Equity

Current liabilities:		
Accounts payable	$10,455,922	$8,346,475
Accrued expenses	3,460,821	4,256,983
Total current liabilities	13,916,743	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, 17,468,819 and 16,332,939 shares issued and outstanding, respectively	17,469	16,333
Additional paid-in capital	324,917,516	284,881,7
Accumulated deficit	(228,082,428)	(179,315,
Total stockholders' equity	96,852,557	105,582,7
Total liabilities and stockholders' equity	$110,769,300	$118,186,2

Relmada Therapeutics, Inc.

Condensed Consolidated Statements of Operations

(Unaudited)

	Three months ended June 30,		Six months ended June 30,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	$17,331,507	$5,323,953	$31,353,734	$9,831,73
General and administrative	9,130,373	7,433,249	17,513,349	12,899,9
Total operating expenses	26,461,880	12,757,202	48,867,083	22,731,6
Loss from operations	(26,461,880)	(12,757,202)	(48,867,083)	(22,731,
Other (expenses) income:				
Interest/investment income, net	322,807	404,004	742,781	811,657
Realized (loss) gain on short-term investments	(123,590)	12,810	(176,379)	(158,801
Unrealized (loss) gain on short-term investments	(289,281)	1,221,947	(466,444)	287,027
Total other (expenses) income	(90,064)	1,638,761	99,958	939,883
Net loss	$(26,551,944)	$(11,118,441)	$(48,767,125)	$(21,791,

Loss per common share – basic and diluted	$(1.56)	$(0.73)	$(2.90)	$(1.45)
Weighted average number of common shares outstanding – basic and diluted	17,054,646	15,323,051	16,814,991	15,030,6

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SOURCE Relmada Therapeutics, Inc.

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