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

NEWS PROVIDED BY
Relmada Therapeutics, Inc. →
Aug 11, 2022, 16:15 ET

CORAL GABLES, Fla., Aug. 11, 2022 /PRNewswire/ -- Relmada Therapeutics, Inc. (Nasdaq: RLMD) ("Relmada," the "Company," "we," "us, "our"), 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 three and six months ended June 30, 2022. The Company will host a conference call today, Thursday, August 11, at 4:30 PM Eastern Time/1:30 PM Pacific Time.

Recent Corporate Highlights

- FDA granted Fast Track designation to REL-1017 as a monotherapy for the treatment of major depressive disorder (MDD)
- Appointed John Hixon, a biopharmaceutical marketing and commercial planning veteran, to serve as the newly created position of Head of Commercial
- Published REL-1017 preclinical data on the lack of reinforcement behavior, physical dependence, and withdrawal signs in the peer-reviewed journal, *Scientific Reports*, and preclinical data suggesting that uncompetitive NMDAR blockers with a preference for the GluN1-2D subtype may be of particular therapeutic relevance in the peer-reviewed journal, *Pharmaceuticals*

"We are rapidly approaching multiple key catalysts from Reliance, the ongoing Phase 3 clinical development program for REL-1017 as a paradigm shifting novel treatment for individuals living with MDD," said Sergio Traversa, Relmada's Chief Executive Officer. "We anticipate completing the enrollment of Reliance III, the monotherapy trial, shortly, followed soon thereafter by a top-line readout of the study. We also continue to expect top-line results from Reliance I and Reliance II, the two ongoing sister, two-arm, placebo-controlled, pivotal studies evaluating REL-1017 as a potential adjunctive treatment, in this second half of the year.

"In addition to receiving Fast Track designation for REL-1017 as a monotherapy for the treatment of MDD, we achieved important progress with our commercial preparation activities for REL-1017," continued Sergio Traversa. "To this end, we recently appointed John Hixon, who has over 36 years of sales and marketing experience within the biopharmaceutical industry, including direct marketing expertise in the CNS and depression space, as Head of Commercial."

Upcoming Anticipated Milestones for REL-1017

- Results of RELIANCE III monotherapy MDD trials in the second half of 2022 with last patient enrolled before the end of August, 2022
- Results of RELIANCE I and RELIANCE II adjunctive MDD trials in the second half of 2022
- Results of RELIANCE – OLS (Long-term, Open-label) study in MDD in the first half of 2023

Second Quarter 2022 Financial Results

- Research and development expense for the three months ended June 30, 2022, totaled $24.6 million, compared to $17.3 million for the three months ended June 30, 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 June 30, 2022, totaled $14.6 million compared to $9.1 million for the three months ended June 30, 2021, an increase of approximately $5.5 million. The increase was primarily driven by an increase in stock-based compensation.
- The net loss for the three months ended June 30, 2022, was $39.9 million, or $1.33 per diluted share, compared with a net loss of $26.6 million, or $1.56 per diluted share, for the three months ended June 30, 2021.

Six Months Ended June 30, 2022 Financial Results

- Research and development expense for the six months ended June 30, 2022, totaled $49.6 million, compared to $31.4 million for the six months ended June 30, 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 six months ended June 30, 2022, totaled $27.9 million, compared to $17.5 million for the six months ended June 30, 2021. The increase was primarily driven by an increase in stock-based compensation.
- Net loss for the six months ended June 30, 2022 and 2021 was $79.7 million and $48.8 million, respectively. The Company had a net loss of $2.73 and $2.90 per share for the six months ended June 30, 2022 and 2021, respectively.
- As of June 30, 2022, the Company had cash, cash equivalents, and short-term investments of approximately $212.0 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, August 11th @ 4:30pm ET

Toll Free:	888-220-8474
International:	856-344-9221
Conference ID:	1883312
Webcast:	https://viavid.webcasts.com/starthere.jsp?ei=1559727&tp_key=588ed8d666

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 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. In a Phase 2 trial, REL-1017 demonstrated rapid, robust, 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 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 has entered late-stage development as a novel 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 Relmada's plans to develop REL-1017, and expectations related to trials evaluating REL-1017 and potential regulatory approval of REL-1017. 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.

Investor Contact:
Tim McCarthy
LifeSci Advisors
212-915-2564
tim@lifesciadvisors.com

Media Inquiries:
FischTank PR
relmada@fischtankpr.com

Relmada Therapeutics, Inc.

Condensed Consolidated Balance Sheets

	As of June 30, 2022 (unaudited)	As of December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 37,260,866	$ 44,443,439
Short-term investments	174,694,211	167,466,167
Accounts receivable	256,192	-
Lease payments receivable – short term	42,234	86,377
Prepaid expenses	3,483,744	11,301,535
Total current assets	215,737,247	223,297,518
Other assets	35,238	28,293
Total assets	$ 215,772,485	$ 223,325,811
Commitments and Contingencies (See Note 8)		
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 7,539,686	$ 11,192,502
Accrued expenses	11,381,468	3,868,423
Total current liabilities	18,921,154	15,060,925
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, 30,024,594 and 27,740,147 shares issued and outstanding, respectively	30,025	27,740
Additional paid-in capital	581,169	513,304,258
Accumulated deficit	(384,747,863)	(305,067,112)
Total stockholders' equity	196,851,331	208,264,886
Total liabilities and stockholders' equity	$ 215,772,485	$ 223,325,811

Relmada Therapeutics, Inc.

Condensed Consolidated Statements of Operations

(Unaudited)

	Three months ended June 30,		Six months ended June 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	$ 30,912,671	$ 17,331,507	$ 55,925,524	$ 31,353,734
General and administrative	14,599,401	9,130,373	27,883,971	17,513,349
Total operating expenses	45,512,072	26,461,880	83,809,495	48,867,083
Loss from operations	(45,512,072)	(26,461,880)	(83,809,495)	(48,867,083)
Other (expenses) income:				
Gain on settlement of fees	6,351,606		6,351,606	
Interest/investment income, net	387,333	322,807	717,282	742,781
Realized (loss) gain on short-term investments	24,502	(123,590)	9,480	(176,379)
Unrealized loss on short-term investments	(1,186,337)	(289,281)	(2,949,624)	(466,444)
Total other (expenses) income	5,577,104)	(90,064)	4,128,744)	99,958
Net loss	$ (39,934,968)	$ (26,551,944)	$ (79,680,751)	$ (48,767,125)
Loss per common share – basic and diluted	$ (1.33)	$ (1.56)	$ (2.73)	$ (2.90)
Weighted average number of common shares outstanding – basic and diluted	29,935,895	17,054,646	29,168,511	16,814,991

SOURCE Relmada Therapeutics, Inc.