

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

Description

CORAL GABLES, Fla., Nov. 11, 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 nine months ended September 30, 2021.

[Relmada Therapeutics Corporate Logo \(PRNewsFoto/Relmada Therapeutics, Inc.\)](#)

“Our REL-1017 development program for the treatment of major depressive disorder remains on track, and we expect key data catalysts in each quarter of next year,” said Dr. Sergio Traversa, Relmada’s Chief Executive Officer. “We anticipate top-line results from our second human abuse potential study, this one assessing REL-1017 versus intravenous ketamine, in the first quarter, followed by top-line data from RELIANCE III, our ongoing monotherapy registrational Phase 3 study in the second quarter. We expect top-line results from RELIANCE I and RELIANCE II, our Phase 3 pivotal studies for adjunctive treatment, in the third and fourth quarters of 2022, respectively. Importantly, our robust R&D initiatives are supported by a strong balance sheet.”

Recent Corporate Highlights

- RELIANCE III, the ongoing monotherapy study for major depressive disorder, being conducted as a registrational Phase 3 trial.
- The US Food and Drug Administration (FDA) confirmed that Relmada will not be required to conduct a two-year carcinogenicity study or a TQT cardiac study in humans to support regulatory approval submissions for REL-1017, as the data provided to date and the additional data to be generated by the Phase 3 program will be adequate to evaluate the cardiac safety profile of REL-1017.
- Presented eight posters on REL-1017 at the Neuroscience Education Institute (NEI) Congress, including three posters with new data from post-hoc analyses related to the REL-1017 Phase 2 program.

Third Quarter 2021 Financial Results

- Research and development expenses for the three months ended September 30, 2021, totaled \$34.0 million, compared to \$11.2 million in the third quarter ended September 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 third quarter ended September 30, 2021, totaled \$8.7 million, up from \$5.9 million in the third quarter ended September 30, 2020, an increase of

approximately \$2.8 million. The increase was primarily driven by increases in personnel costs, stock-based compensation, and consulting services.

- The net loss for the third quarter ended September 30, 2021, was \$42.6 million, or a net loss of \$2.44 per share, compared with a net loss of \$16.9 million, or a net loss of \$1.05 per share, in the third quarter of 2020.

Nine Months Ended September 30, 2021 Financial Results

- Research and development expenses for the nine months ended September 30, 2021, totaled \$65.3 million, compared to \$21.1 million for the nine months ended September 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 expenses for the nine months ended September 30, 2021, totaled \$26.2 million, compared to \$18.8 million for the nine months ended September 30, 2020. The increase was primarily driven by increases in personnel costs, stock-based compensation, and consulting services.
- Net loss for the nine months ended September 30, 2021 and 2020 was \$91.4 million and \$38.7 million, respectively. The Company had a net loss per common share of \$5.36 and \$2.52 for the nine months ended September 30, 2021 and 2020, respectively.
- As of September 30, 2021, the Company had cash and short-term investments of \$88.1 million, compared to cash, cash equivalents, and short-term investments of approximately \$117.1 million at December 31, 2020.

Conference Call and Webcast Details

Date: Thursday, November 11

Time: 4:30pm Eastern Time

Toll Free: 855-407-0792

International: 201-689-8263

Conference ID: 13724499

Webcast: <https://78449.themediaframe.com/dataconf/productusers/vvdb/mediaframe/47253/index.html>

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 a 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). 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 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. 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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	As of	
	September 30,	As of
	2021	December 31,
	(Unaudited)	2020
Assets		
Current assets:		
Cash and cash equivalents	\$ 11,449,294	\$ 2,495,397
Short-term investments	76,637,802	114,595,525
Lease payments receivable – short term	84,592	79,457
Prepaid expenses	2,715,478	903,190
Total current assets	90,887,166	118,073,569
Fixed assets, net of accumulated depreciation	–	1,258
Other assets	25,000	25,000

Lease payments receivable – long term	22,275	86,377
Total assets	\$ 90,934,441	\$ 118,186,204

Liabilities and Stockholders' Equity

Current liabilities:

Accounts payable	\$ 12,708,546	\$ 8,346,475
Accrued expenses	5,538,804	4,256,983
Total current liabilities	18,247,350	12,603,458

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, 17,501,554 and 16,332,939 shares issued and outstanding, respectively	17,502	16,333
Additional paid-in capital	343,358,208	284,881,716
Accumulated deficit	(270,688,619)	(179,315,303)
Total stockholders' equity	72,687,091	105,582,746
Total liabilities and stockholders' equity	\$ 90,934,441	\$ 118,186,204

Relmada Therapeutics, Inc.
Condensed Consolidated Statements of Operations
(Unaudited)

	Three months ended		Nine months ended	
	September 30,		September 30,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	\$33,993,974	\$11,237,186	\$65,347,708	\$21,068,923
General and administrative	8,659,661	5,946,396	26,173,010	18,846,299
Total operating expenses	42,653,635	17,183,582	91,520,718	39,915,222
Loss from operations	(42,653,635)	(17,183,582)	(91,520,718)	(39,915,222)
Other (expenses) income:				
Interest/investment income, net	297,648	363,300	1,040,429	1,174,957
Realized loss on short-term investments	(336,949)	(86,171)	(513,328)	(244,972)
Unrealized gain (loss) on short-term investments	86,745	3,946	(379,699)	290,973
Total other income – net	47,444	281,075	147,402	1,220,958

Net loss	\$(42,606,191)	\$(16,902,507)	\$(91,373,316)	\$(38,694,264)
Loss per common share – basic and diluted	\$(2.44)	\$(1.05)	\$(5.36)	\$(2.52)
Weighted average number of common shares outstanding – basic and diluted	17,478,477	16,044,670	17,038,583	15,371,118

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SOURCE Relmada Therapeutics, Inc.

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