March 23, 2021

Relmada Therapeutics Provides Corporate Update and Reports Fourth Quarter and Full-Year 2020 Financial Results

Phase 3 Program for REL-1017 as Adjunctive Treatment for Major Depressive Disorder Initiated

Multiple Data Readouts Anticipated Over Next Several Quarters

Company to Host Conference Call and Webcast Today at 4:30 PM ET

NEW YORK, March 23, 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 fourth quarter and full-year ended December 31, 2020.

"We have achieved significant progress in advancing our lead product candidate, REL-1017, which has the potential to be the first U.S. Food and Drug Administration (FDA)-approved anti-depressant for adjunctive treatment of major depressive disorder (MDD)," said Dr. Sergio Traversa, Relmada's Chief Executive Officer. "In our successfully completed Phase 2 study, REL-1017 demonstrated statistically significant, rapid and sustained anti-depressant effects with a favorable safety and tolerability profile. Based on these compelling data and our interactions with the FDA and scientific advisors, late in 2020, we were thrilled to initiate our Phase 3 program for REL-1017. Our first of two Phase 3 trials, RELIANCE I, is enrolling as planned, and we expect to begin the second study, RELIANCE II, imminently."

"Looking ahead, we anticipate multiple key data readouts over the next several quarters, including data from our oxycodone human abuse potential study in the second quarter of this year, followed by data from our IV ketamine human abuse potential study by year-end 2021. Further out, we look to top-line data from both RELIANCE I and RELIANCE II in the first half of 2022," continued Dr. Traversa. "Importantly, we have a strong balance sheet driving our robust development efforts, with a cash runway that is anticipated to support us through multiple potentially value-creating catalysts."

Recent Corporate Highlights

- Initiated Phase 3 program for REL-1017 for the adjunctive treatment of MDD in

December 2020
    - Phase 3 program will consist of two sister, two-arm, placebo-controlled clinical trials to be conducted at 55 clinical sites in the U.S. and include approximately 364 MDD patients in each study
    - Dosed first patient in first pivotal Phase 3 trial, RELIANCE I
- Appointed Paolo Manfredi, M.D., as Acting Chief Scientific Officer
    - Co-founder of Medeor, Inc. (now merged into Relmada), for which he also served as Scientific Director and co-inventor of REL-1017
- Appointed Marco Pappagallo, M.D., as Acting Chief Medical Officer
    - Most recently served as Chief Medical Officer at CerSci Therapeutics, a privately-held biotech company focused on developing pain therapeutics that was acquired by ACADIA Pharmaceuticals in August 2020.

Upcoming Anticipated Milestones for REL-1017

- 1H21 – Start of RELIANCE II, the second pivotal Phase 3 adjunctive MDD trial
- 1H21 – Start of Phase 2 monotherapy MDD trial
- 2Q21 – Results of oxycodone human abuse potential study
- 2H21 – Results of ketamine human abuse potential study
- 4Q21 – Results of Phase 2 monotherapy MDD trial
- 1H22 – Results of RELIANCE I and RELIANCE II adjunctive MDD trials

Fourth Quarter 2020 Financial Results

- Research and development expenses for the fourth quarter ended December 31, 2020, totaled $14.9 million, compared to $1.6 million in the fourth quarter ended December 31, 2019. The increase was primarily driven by increased costs associated with preparations for and conducting the Company's REL-1017 Phase 3 program.
- General and administrative expenses for the fourth quarter ended December 31, 2020, totaled $6.0 million, up from $2.9 million in the fourth quarter ended December 31, 2019. The increase was primarily driven by an increase in salaries and stock-based compensation.
- Net loss for the fourth quarter ended December 31, 2020, was $20.8 million, or a net loss of $1.28 per share, compared with a net loss of $4.5 million, or a net loss of $0.40 per share, in the fourth quarter ended December 31, 2019.

Full-Year 2020 Financial Results

- Research and development expenses for the year ended December 31, 2020, totaled $36.0 million, up from $7.9 million in the year ended December 31, 2019. The increase was primarily due to increased costs associated with preparations for and conducting multiple Phase 2 and Phase 3 studies for REL-1017.
- General and administrative expenses for the year ended December 31, 2020, totaled $24.9 million, up from $7.2 million in the year ended December 31, 2019. The increase was primarily driven by an increase in salaries and stock-based compensation.
- Net loss the year ended December 31, 2020, was $59.5 million, or a net loss of $3.81 per share, compared with a net loss of $15.0 million, or a net loss of $1.62 per share, in the year ended December 31, 2019.
- As of December 31, 2020, the Company had approximately $117.1 in cash, cash equivalents, and short-term investments, compared to $116.4 million at December 31,

2019.

Conference Call and Webcast Details

Date:	Tuesday, March 23
Time:	4:30 PM Eastern Time
Toll Free:	877-407-0792
International:	201-689-8263
Conference ID:	13717689
Webcast:	http://public.viavid.com/index.php?id=143960

An archive of the webcast will be available on the above website until March 23, 2022.

About REL-1017

REL-1017, a novel NMDA receptor (NMDAR) channel blocker that preferentially targets hyperactive channels while maintaining physiological glutamatergic neurotransmission, is entering late-stage studies as an adjunctive treatment for MDD in adults. Our clinical program for REL-1017 will evaluate its potential 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.

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.
Consolidated Statements of Operations
(Preliminary and Unaudited)

	As of December 31, 2020	As of December 31, 2019	As of June 30, 2019
Assets			
Current assets:			
Cash and cash equivalents	$ 2,495,397	$ 36,278,519	$ 9,216,554
Short-term investments	114,595,525	80,164,823	-
Other receivable	-	-	176,980
Lease payments receivable – short term	79,457	73,091	70,102
Prepaid expenses	903,190	423,863	520,745
Total current assets	118,073,569	116,940,296	9,984,381
Fixed assets, net of accumulated depreciation	1,258	5,010	7,210
Other assets	25,000	25,000	25,000
Lease payments receivable – long term	86,377	165,834	203,142
Total assets	$ 118,186,204	$ 117,136,140	$ 10,219,733
Liabilities and Stockholders' Equity (Deficit)			
Current liabilities:			
Accounts payable	$ 8,346,475	$ 522,663	$ 924,359
Accrued expenses	4,256,245	824,936	1,317,855
Notes payable	-	110,247	364,204
Total current liabilities	12,603,458	1,457,846	2,606,418
Total liabilities	12,603,458	1,457,846	2,606,418
Stockholders' Equity (Deficit):			
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, 16,332,939, 14,457,013 and 9,744,643 shares issued and outstanding, respectively	16,333	14,457	9,744
Additional paid-in capital	284,881,716	235,522,746	119,265,938
Accumulated deficit	(179,315,303)	(119,858,909)	(111,662,367)
Total stockholders' equity	105,582,746	115,678,294	7,613,315
Total liabilities and stockholders' equity	$ 118,186,204	$ 117,136,140	$ 10,219,733

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

	Year Ended December 31, 2020	(Unaudited) Year ended December 31, 2019	Six months ended December 31, 2019	Year ended June 30, 2019
Operating expenses:				
Research and development	$ 35,972,731	$ 7,859,453	$ 3,513,606	$ 7,024,747
General and administrative	24,865,942	7,249,858	4,757,999	5,703,173
Total operating expenses	60,838,673	15,109,311	8,271,605	12,727,920
Loss from operations	(60,838,673)	(15,109,311)	(8,271,605)	(12,727,920)
Other income (expenses):				
Change in fair value of derivative liabilities	-	-	-	(54,634)
Interest income (expense), net	1,399,225	104,112	75,063	(761,038)
Realized loss on short-term investments	(156,213)	-	-	-
Unrealized gain on short-term investments	139,267	-	-	-
Loss on extinguishment of debt	-	-	-	(3,774,468)
Total other income (expenses), net	1,382,279	104,112	75,063	(4,590,140)
Net loss	$ (59,456,394)	$ (15,005,199)	$ (8,196,542)	$ (17,318,060)
Net loss per common share – basic and diluted	$ (3.81)	$ (1.62)	$ (0.77)	$ (2.74)
Weighted average number of common shares outstanding – basic and diluted	15,594,228	9,241,219	10,577,866	6,311,769

View original content to download multimedia:http://www.prnewswire.com/news-releases/relmada-therapeutics-provides-corporate-update-and-reports-fourth-quarter-and-full-year-2020-financial-results-301254328.html

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