Relmada Therapeutics Provides Corporate Update and Reports Fourth Quarter and Full-Year 2021 Financial Results

Description

CORAL GABLES, Fla., March 23, 2022 /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 preliminary and unaudited financial results for the fourth quarter and full year ended December 31, 2021. The Company will host a conference call today, Wednesday, March 23, at 4:30 PM Eastern Time/1:30 PM Pacific Time.

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

“We are pleased by the significant progress achieved throughout 2021 in advancing our lead program, REL-1017, and we expect 2022 to be a catalyst-rich year for Relmada,” said Sergio Traversa, Relmada’s Chief Executive Officer. “Importantly, we have now successfully completed two human abuse potential (HAP) studies which confirmed no meaningful abuse potential of REL-1017 compared to oxycodone and ketamine, consistent with previously reported data and the DEA statement on esmethadone.”

“Looking ahead, we anticipate multiple key data readouts throughout the remainder of the year, as the Phase 3 ongoing clinical studies that comprise RELIANCE continue to progress. In mid-2022 we expect data from RELIANCE III, our ongoing monotherapy registrational Phase 3 study, followed by data in the third and fourth quarters from RELIANCE I and RELIANCE II, our Phase 3 pivotal studies for adjunctive treatment of MDD, respectively. Importantly, our robust REL-1017 development program continues to be supported by a strong balance sheet, which was further enhanced by the successful over-subscribed follow-on offering that we closed in the fourth quarter of last year.”

Recent Corporate Highlights

- A recent pre-planned interim safety assessment, performed by an independent data monitoring committee (iDMC), confirmed the lack of safety signals and concluded with a recommendation to proceed the RELIANCE studies as planned
- Announced top-line results of the HAP study comparing REL-1017 to ketamine and placebo, confirming the absence of any meaningful abuse liability of REL-1017
- Publication of REL-1017 Phase 2 data in the peer-reviewed *American Journal of Psychiatry*, highlighting the rapid, robust and sustained efficacy, as well as the favorable safety, tolerability, and pharmacokinetic profile of REL-1017
- Presented results of the HAP study comparing REL-1017 to oxycodone and placebo at the 60th Annual Meeting of the American College of Neuropsychopharmacology
- Closed over-subscribed follow-on offering for gross proceeds of $172.5 million

Upcoming Anticipated Milestones for REL-1017

- Mid 22 – Data for RELIANCE III monotherapy MDD trial
- 3Q 22 – Data for RELIANCE I adjunctive MDD trial
- 4Q 22 – Data for RELIANCE II adjunctive MDD trial

Fourth Quarter 2021 Financial Results

- Research and development expenses for the three months ended December 31, 2021, totaled $25.3 million, compared to $14.9 million in the fourth quarter ended December 31, 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 fourth quarter ended December 31, 2021, totaled $8.9 million, compared to $6.0 million in the fourth quarter ended December 31, 2020, an increase of approximately $2.9 million. The increase was primarily driven by increases in personnel costs, stock-based compensation, and consulting services.
- The net loss for the fourth quarter ended December 31, 2021, was $34.4 million, or a net loss of $1.80 per share, compared with a net loss of $20.8 million, or a net loss of $1.30 per share, in the fourth quarter of 2020.

Full-Year 2021 Financial Results

- Research and development expenses for the year ended December 31, 2021, totaled $90.6 million, compared to $36.0 million for the year ended December 31, 2020. The 2021 total includes a one-time expense, consisting of $2.5 million cash and $10.2 million stock-based payment, for the novel psilocybin acquisition from Arbormentis LLC in the third quarter. The remaining increase was primarily driven by increases in costs associated with the execution of a broader clinical program for REL-1017.
- General and administrative expenses for the year ended December 31, 2021, totaled $35.1 million, compared to $24.9 million for the year ended December 31, 2020. The increase was primarily driven by increases in personnel costs, stock-based compensation, and consulting services.
- Net loss for the year ended December 31, 2021 and 2020 was $125.8 million and $59.5 million, respectively. The Company had a net loss per common share of $7.16 and $3.81 for the year ended December 31, 2021 and 2020, respectively.
- As of December 31, 2021, the Company had cash and cash equivalents and short-term investments of $211.9 million, compared to cash, cash equivalents, and short-term investments of approximately $117.1 million at December 31, 2020. This includes $161.2 in net proceeds from the public offering closed in December 2021.

Conference Call and Webcast Details

Date: Wednesday, March 23

Time: 4:30pm Eastern Time

Toll Free:	877-407-0792
International:	201-689-8263
Conference ID:	13727905
Webcast:	https://viavid.webcasts.com/starthere.jsp?ei=1536859&tp_key=0d9f65e796

A replay of the webcast will be available in the Investors section of the Relmada website at https://www.relmada.com/investors/ir-calendar.

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). 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 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, 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.

Investor Contact:
Tim McCarthy
LifeSci Advisors
917-679-9282
tim@lifesciadvisors.com

Media Inquiries:
FischTank PR
relmada@fischtankpr.com

Relmada Therapeutics, Inc.

Consolidated Balance Sheets

(Preliminary and Unaudited)

	As of December 31, 2021	As of December 2020
Assets		
Current assets:		

Cash and cash equivalents	$44,443,439	$2,495,397
Short-term investments	167,466,167	114,595,5
Lease payments receivable – short term	86,377	79,457
Prepaid expenses	11,301,535	903,190
Total current assets	223,297,518	118,073,5
Fixed assets, net of accumulated depreciation	–	1,258
Other assets	28,293	25,000
Lease payments receivable – long term	–	86,377
Total assets	$223,325,811	$118,186,2
Commitments and Contingencies (Note 9)		
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$11,192,502	$8,346,475
Accrued expenses	3,868,423	4,256,983
Total current liabilities	15,060,925	12,603,45
Total liabilities	15,060,925	12,603,45
Stockholders' Equity:		

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, 27,740,147 and 16,332,939 shares issued and outstanding, respectively	27,740	16,333
Additional paid-in capital	513,304,258	284,881,7
Accumulated deficit	(305,067,112)	(179,315,3
Total stockholders' equity	208,264,886	105,582,7
Total liabilities and stockholders' equity	$223,325,811	$118,186,2

Relmada Therapeutics, Inc.

Consolidated Statements of Operations

For the Years Ended December 31, 2021 and 2020

(Preliminary and Unaudited)

	2021	**2020**
Operating expenses:		
Research and development	$ 90,621,570	$ 35,972,731
General and administrative	35,081,922	24,865,942

Total operating expenses	125,703,492	60,838,673
Loss from operations	(125,703,492)	(60,838,673)
Other income (expenses):		
Interest/investment income, net	1,199,077	1,399,225
Realized loss on short-term investments	(636,012)	(156,213)
Unrealized (loss) gain on short-term investments	(611,382)	139,267
Total other (expenses) income, net	(48,317)	1,382,279
Net loss	$ (125,751,809)	$ (59,456,394)
Net loss per common share – basic and diluted	$ (7.16)	$ (3.81)
Weighted average number of common shares outstanding – basic and diluted	17,552,738	15,594,228

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SOURCE Relmada Therapeutics, Inc.

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