Relmada Therapeutics Provides Corporate Update and Reports Fourth Quarter and Full-Year 2022 Financial Results

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Relmada Therapeutics, Inc. →
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CORAL GABLES, Fla., March 23, 2023 /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, 2022. The Company will host a conference call today, Thursday, March 23, at 4:30 PM Eastern Time/1:30 PM Pacific Time.

"Following the availability of top-line results in the Reliance I (Study 301), one of two Phase 3 sister two-arm, placebo-controlled, pivotal studies evaluating REL-1017 25mg as a potential adjunctive treatment for major depressive disorder (MDD), in December 2022, we have spent the last three months thoroughly analyzing these data and considering the appropriate next steps," said Sergio Traversa, Relmada's Chief Executive Officer. "We are confident that we have identified the key issues that led to the Phase 3 data in Study 301 differing from the positive results we saw in Phase 2. Based on the data generated to date and market potential, we intend to focus on the further development of REL-1017 as an adjunctive treatment. We will implement critical changes to Reliance II (Study 302), the second of our two Phase 3 sister two-

arm trials, which is ongoing, and initiate one new trial, Study 304. The Study 302 protocol amendment has been finalized and is ready to be implemented, and the Study 304 protocol has been drafted, and the study will be ready to initiate by mid-2023."

"We are confident that we have an approvable drug and need to focus on clinical trial execution to accomplish this," continued Mr. Traversa. "From the extensive analyses of Study 301, we now know how to identify the most reliable sites, the most suitable patients, and greatly improve our study protocols. Importantly, all other pre- and clinical, and CMC (Chemistry, Manufacturing, and Controls) pieces are in place for a successful NDA filing for REL-1017. Relmada is sufficiently funded to fully execute the plans for the further development of REL-1017 with Study 302 and Study 304."

Recent Corporate Highlights

- Analyzed full data set and final study report for Study 301 to identify key insights to be leveraged in continued development of REL-1017 for the adjunctive treatment of MDD
    - Based on the primary and pre-specified analyses from Study 301, the Company believes the signal of REL-1017's efficacy is clear and warrants continued development
- Implementing critical changes to ongoing Study 302, for which a protocol amendment has been finalized, and initiating one new trial, Study 304, for which the protocol has been drafted and will be ready to enroll by mid-2023
- Appointed CNS therapeutics expert Cedric O'Gorman, M.D., as Chief Medical Officer to lead medical, clinical, and regulatory functions in support of the Company's late-stage REL-1017 development program
- Appointed Fabiana Fedeli, Chief Investment Officer Equities, Multi Asset and Sustainability, at M&G Investments, one of the United Kingdom's largest and longest established investment houses, as an independent director to the Company's Board of Directors

Upcoming Anticipated Milestones for REL-1017

- Complete enrollment in ongoing Study 302, which is planned to enroll approximately 300 patients, in the first half of 2024
- Initiate Study 304, as adjunctive treatment for MDD, in mid-2023, with a planned enrollment of approximately 300 patients, with completion anticipated in the second-half of 2024
- Complete study 310, the open-label study, with data in mid-2023

Fourth Quarter 2022 Financial Results

- Research and development expense for the three months ended December 31, 2022, totaled $26.9 million, compared to $25.3 million for the three months ended December 31, 2021. The increase was primarily driven by an increase in stock-based compensation costs.
- General and administrative expense for the three months ended December 31, 2022, totaled $11.8 million compared to $8.9 million for the three months ended December 31, 2021, an increase of approximately $2.9 million. The increase was primarily driven by an increase in stock-based compensation costs.
- The net loss for the three months ended December 31, 2022, was $37.9 million, or $1.28 per diluted share, compared with a net loss of $34.4 million, or $1.80 per diluted share, for the three months ended December 31, 2021.

Full-Year 2022 Financial Results

- Research and development expense for the year ended December 31, 2022, totaled $113.3 million, compared to $90.6 million for the year ended December 31, 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 year ended December 31, 2022, totaled $47.9 million, compared to $35.1 million for the year ended December 31, 2021. The increase was primarily driven by an increase in stock-based compensation.
- Net loss for the year ended December 31, 2022 and 2021 was $157.0 million and $125.8 million, respectively. The Company had a net loss of $5.30 and $7.16 per share for the year ended December 31, 2022 and 2021, respectively.
- As of December 31, 2022, the Company had cash, cash equivalents, and short-term investments of approximately $148.3 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, March 23rd @ 4:30pm ET

Toll Free:	877-407-0792
International:	201-689-8263
Conference ID:	13735262
Webcast:	https://viavid.webcasts.com/starthere.jsp?ei=1591728&tp_key=cb7f04a9a4

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 an adjunctive 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 potential failure of Reliance trial results to demonstrate clinically significant evidence of efficacy and/or safety, failure of top-line results to accurately reflect the complete results of the trial, failure to obtain regulatory approval of REL-1017 for the treatment of major depressive disorder, and the other 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 Balance Sheets

(Unaudited)

	As of December 31, 2022	As of December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 5,395,905	$ 44,443,439
Short-term investments	142,926,781	167,466,167
Lease payments receivable – short term	-	86,377
Other receivables	512,432	-
Prepaid expenses	4,035,186	11,301,535
Total current assets	152,870,304	223,297,518
Other assets	34,875	28,293
Total assets	$ 152,905,179	$ 223,325,811
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 5,261,936	$ 11,192,502
Accrued expenses	7,206,941	3,868,423
Total current liabilities	12,468,877	15,060,925
Total liabilities	12,468,877	15,060,925
Commitments and Contingencies (Note 7)		
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, 30,099,203 and 27,740,147 shares issued and outstanding, respectively	30,099	27,740
Additional paid-in capital	602,517,138	513,304,258
Accumulated deficit	(462,110,935)	(305,067,112)
Total stockholders' equity	140,436,302	208,264,886
Total liabilities and stockholders' equity	$ 152,905,179	$ 223,325,811

Relmada Therapeutics, Inc.

Consolidated Statements of Operations

(Unaudited)

	2022	2021	
Operating expenses:			
Research and development	$ 113,322,999	$ 90,621,570	
General and administrative	47,926,077	35,081,922	
Total operating expenses	161,249,076	125,703,492	
Loss from operations	(161,249,076)	(125,703,492)	
Other income (expenses):			
Gain on settlement of fees		6,351,606	-
Interest/investment income, net	2,659,424	1,199,077	
Realized loss on short-term investments	(585,522)	(636,012)	
Unrealized loss on short-term investments	(4,220,255)	(611,382)	
Total other income (expenses), net	4,205,253	(48,317)	
Net loss	$ (157,043,823)	$ (125,751,809)	
Net loss per common share – basic and diluted	$ (5.30)	$ (7.16)	
Weighted average number of common shares outstanding – basic and diluted	29,628,664		17,552,738

Relmada Therapeutics, Inc.

Consolidated Statements of Stockholders' Equity

(Unaudited)

	Common Stock		Additional Paid-in	Accumulated	
	Shares	**Par Value**	**Capital**	**Deficit**	**Total**
Balance – December 31, 2020	16,332,939	$ 16,333	$ 284,881,716	$ (179,315,303)	$ 105,582,746
Stock-based compensation expense	-	-	40,494,476	-	40,494,476
Equity offering, net	10,147,059	10,147	161,216,798	-	161,226,945
Warrants exercised	651,674	652	23,415,384	-	23,416,036
Cashless exercise of warrants	433,856	433	2,627,628	-	2,628,061
Options exercised	174,619	175	668,256	-	668,431
Net loss	-	-	-	(125,751,809)	(125,751,809)
Balance – December 31, 2021	27,740,147	27,740	513,304,258	(305,067,112)	208,264,886
Stock-based compensation expense	-	-	44,194,765	-	44,194,765
ATM offering, net	2,094,243	2,094	42,726,505	-	42,728,599
Share exchange -Prefunded warrants, net of fees	(1,452,016)	(1,452)	(48,548)	-	(50,000)
Net exercise -Prefunded warrants	1,451,795	1,452	(1,452)	-	-
Warrants exercised	181,336	181	1,264,342	-	1,264,523
Options exercised	83,698	84	703,636	-	703,720
Short swing profit, net	-	-	373,632	-	373,632
Net loss	-	-	-	(157,043,823)	(157,043,823)
Balance – December 31, 2022	30,099,203	$ 30,099	$ 602,517,138	$ (462,110,935)	$ 140,436,302

Relmada Therapeutics, Inc.

Consolidated Statements of Cash Flows

(Unaudited)

	2022	2021
Cash flows from operating activities		
Net loss	$ (157,043,823)	$ (125,751,809)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	-	1,258
Stock-based compensation	44,194,765	40,494,476
Gain on settlement	(3,338,518)	-
Realized loss on short-term investments	585,522	636,012
Unrealized loss on short-term investments	4,220,255	611,382
Change in operating assets and liabilities:		
Lease payment receivable	86,377	79,457
Other receivable	(512,432)	-
Prepaid expenses and other assets	7,259,767	(10,401,638)
Accounts payable	(2,717,983)	2,846,027
Accrued expenses	3,338,518	(388,560)
Net cash used in operating activities	(103,801,617)	(91,873,395)
Cash flows from investing activities		
Purchase of short-term investments	(47,293,763)	(222,981,675)
Sale of short-term investments	67,027,372	168,863,639
Net cash provided by (used in) investing activities	19,733,609	(54,118,036)
Cash flows from financing activities		
Payment of fees for warrants issued for common stock	(50,000)	-
Proceeds from issuance of common stock	42,728,599	184,642,981
Proceeds from options exercised for common stock	703,720	668,431
Proceeds from warrants exercised for common stock	1,264,523	2,628,061
Proceeds from short swing profit, net	373,632	-
Net cash provided by financing activities	45,020,474	187,939,473
Net increase (decrease) in cash and cash equivalents	(39,047,534)	41,948,042
Cash and cash equivalents at beginning of the period	44,443,439	2,495,397
Cash and cash equivalents at end of the period	$ 5,395,905	$ 44,443,439

SOURCE Relmada Therapeutics, Inc.