

Relmada Therapeutics Provides Corporate Update and Reports Third Quarter 2023 Financial Results

Description

CORAL GABLES, Fla., Nov. 8, 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 third quarter ended September 30, 2023. The Company will host a conference call today, Wednesday, November 8, at 4:30 PM Eastern Time/1:30 PM Pacific Time.

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

“We continue to advance our Phase 3 clinical development plan for REL-1017 as an adjunctive treatment for major depressive disorder (MDD),” said Sergio Traversa, Relmada’s Chief Executive Officer. “Enrollment in the ongoing Reliance II (study 302) is progressing as planned and it remains on track to be completed in the first half of 2024. The initial patients have been enrolled into Relight, the new Phase 3 study (study 304), and we continue to anticipate the completion of this trial in the second half of next year. Additionally, we are encouraged by the recently announced efficacy and safety data from the one year, open-label safety study, Reliance-OLS (study 310), which showed rapid and sustained improvement in MADRS score with REL-1017 in both de novo patients and the full analysis set.”

“We also recently presented new compelling preclinical data demonstrating the beneficial effect of non-psychedelic/low dose psilocybin on multiple metabolic parameters in a rodent model of metabolic dysfunction-associated steatotic liver disease (MASLD),” continued Mr. Traversa. “Based on these promising results, we intend to commence a single-ascending dose Phase 1 trial in obese patients with steatotic liver disease in early 2024 to define the pharmacokinetic, safety, and tolerability profile of our modified-release psilocybin formulation in this population, followed by a Phase 2a trial in the same patient population to establish clinical proof-of-concept. Importantly, there are currently no approved drugs for MASLD, and these initial pre-clinical data support the therapeutic potential of non-psychedelic/low dose psilocybin.”

Recent Corporate Highlights

- Enrollment is ongoing in Reliance II (study 302) and Relight (study 304), two sister pivotal Phase 3 trials of REL-1017 for the adjunctive treatment of MDD.
- Announced results from recently completed Reliance-OLS (study 310), a long-term, open-label study of REL-1017 in MDD.
- Rapid and sustained improvements in MADRS score were observed with REL-1017 in both de novo patient and the full analysis sets.
- Announced new preclinical data from novel modified-release psilocybin program to be presented at the American Association for the Study of Liver Diseases (AASLD) The Liver Meeting® 2023.

- Data demonstrated the beneficial effect of non-psychedelic/low dose psilocybin on multiple metabolic parameters in a rodent model of metabolic dysfunction-associated steatotic liver disease (MASLD).
- Data presented from REL-1017 and psilocybin programs at the 36th European College of Neuropsychopharmacology (ECNP) Congress.

Upcoming Anticipated Milestones

- Commence a Phase 1 trial in obese patients with steatotic liver disease in early 2024 to define the pharmacokinetic, safety and tolerability profile of the Company's modified-release psilocybin formulation, followed by a Phase 2a trial to establish clinical proof-of-concept.
- Complete enrollment of Reliance II, which is planned to enroll approximately 300 patients, in the first half of 2024.
- Complete enrollment of Relight (study 304), which is planned to enroll approximately 300 patients, in the second half of 2024.

Third Quarter 2023 Financial Results

- Research and development expense for the three months ended September 30, 2023, totaled \$10.5 million, compared to \$30.5 million for the three months ended September 30, 2022. The decrease was primarily associated with the completion of the Reliance I and Reliance III clinical studies in late 2022.
- General and administrative expense for the three months ended September 30, 2023, totaled \$12.2 million, compared to \$8.2 million for the three months ended September 30, 2022. The increase was primarily driven by an increase in stock-based compensation.
- Net cash used in operating activities for the three months ended September 30, 2023 totaled \$11.6 million, compared to \$26.9 million for the three months ended September 30, 2022.
- Net loss for the three months ended September 30, 2023, was \$22.0 million, or \$0.73 per basic and diluted share, compared with a net loss of \$39.4 million, or \$1.31 per basic and diluted share, for the three months ended September 30, 2022.

Nine Months Ended September 30, 2023 Financial Results

- Research and development expense for the nine months ended September 30, 2023, totaled \$40.1 million, compared to \$86.5 million for the nine months ended September 30, 2022. The decrease was primarily driven by a decrease in study costs associated with the completion of Reliance I and III in late 2022.
- General and administrative expense for the nine months ended September 30, 2023, totaled \$36.8 million, compared to \$36.1 million for the nine months ended September 30, 2022. The increase was primarily driven by an increase in stock-based compensation.
- Net cash used in operating activities for the nine months ended September 30, 2023 totaled \$41.4 million, compared to \$67.9 million for the three months ended September 30, 2022.
- Net loss for the nine months ended September 30, 2023 and 2022 was \$73.6 million and \$119.1 million, respectively. The Company had a net loss of \$2.45 and \$4.04 per share for the nine months ended September 30, 2023 and 2022, respectively.

- As of September 30, 2023, the Company had cash, cash equivalents, and short-term investments of approximately \$106.3 million, compared to cash, cash equivalents, and short-term investments of approximately \$148.3 million at December 31, 2022.

Conference Call and Webcast Details

Wednesday, November 8th at 4:30 PM ET

Toll Free: 888-886-7786

International: 416-764-8658

Conference ID: 54664628

Webcast: https://viaavid.webcasts.com/starthere.jsp?ei=1636783&tp_key=a6209aa189

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 adjunctive treatment of major depressive disorder (MDD). The ongoing clinical research program is designed to evaluate the potential for REL-1017 as a rapid-acting, oral, once-daily antidepressant treatment.

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 is in late-stage development as an adjunctive treatment for MDD in adults. Relmada is also developing a novel non-psychedelic/low dose psilocybin for the treatment of metabolic indications. 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 clinical trial results to demonstrate statistically and/or clinically significant evidence of efficacy and/or safety, failure of top-line results to accurately reflect the complete results of the trial, failure of the 310 open-label study to accurately reflect the results of the ongoing 302 and 304 blinded, randomized and controlled studies, failure to obtain regulatory approval of REL-1017 for the treatment of major depressive disorder, failure of the psilocybin program to advance to later stages of development, 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.

Condensed Consolidated Balance Sheets

As of

September 30, As of

2023	December 31,
(Unaudited)	2022

Assets

Current assets:

Cash and cash equivalents	\$6,698,599	\$5,395,905
Short-term investments	99,568,502	142,926,781
Other receivables	—	512,432
Prepaid expenses	2,834,037	4,035,186
Total current assets	109,101,138	152,870,304
Other assets	47,715	34,875
Total assets	\$109,148,853	\$152,905,179

Commitments and Contingencies (See Note 6)

Liabilities and Stockholders' Equity

Current liabilities:

Accounts payable	\$2,856,752	\$5,261,936
Accrued expenses	5,565,466	7,206,941
Total current liabilities	8,422,218	12,468,877

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, 150,000,000 shares authorized, 30,099,203 shares issued and outstanding	30,099	30,099
Additional paid-in capital	636,434,059	602,517,138
Accumulated deficit	(535,737,523)	(462,110,935)
Total stockholders' equity	100,726,635	140,436,302
Total liabilities and stockholders' equity	\$109,148,853	\$152,905,179

Relmada Therapeutics, Inc.

Condensed Consolidated Statements of Operations

(Unaudited)

	Three months ended		Nine months ended	
	September 30,		September 30,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	\$10,454,072	\$30,529,108	\$40,055,287	\$86,454,632

General and administrative	12,238,566	8,208,053	36,817,686	36,092,024
Total operating expenses	22,692,638	38,737,161	76,872,973	122,546,656
Loss from operations	(22,692,638)	(38,737,161)	(76,872,973)	(122,546,656)
Other (expenses) income:				
Gain on settlement of fees	—	—	—	6,351,606
Interest/investment income, net	1,321,441	827,614	3,892,478	1,544,898
Realized loss on short-term investments	(51,714)	(561,648)	(718,422)	(552,171)
Unrealized (loss) gain on short-term investments	(579,147)	(947,512)	72,329	(3,897,135)
Total other (expense) income – net	690,580	(681,546)	3,246,385	3,447,198
Net loss	\$(22,002,058)	\$(39,418,707)	\$(73,626,588)	\$(119,099,458)
Loss per common share – basic and diluted	\$(0.73)	\$(1.31)	\$(2.45)	\$(4.04)
Weighted average number of common shares outstanding – basic and diluted	30,099,203	30,063,735	30,099,203	29,470,198

Relmada Therapeutics, Inc.

Condensed Consolidated Statements of Stockholders' Equity

(Unaudited)

Nine months ended September 30, 2023

	Common Stock		Additional Paid-in	Accumulated	
	Shares	Par Value	Capital	Deficit	Total
Balance – December 31, 2022	30,099,203	\$30,099	\$602,517,138	\$(462,110,935)	\$140,436,306
Stock-based compensation	—	—	11,354,466	—	11,354,466
Net loss	—	—	—	(26,321,576)	(26,321,576)
Balance – March 31, 2023	30,099,203	30,099	613,871,604	(488,432,511)	125,469,196
Stock-based compensation	—	—	11,169,517	—	11,169,517
Net loss	—	—	—	(25,302,954)	(25,302,954)
Balance – June 30, 2023	30,099,203	\$30,099	\$625,041,121	\$(513,735,465)	\$111,335,756
Stock-based compensation	—	—	11,392,938	—	11,392,938
Net loss	—	—	—	(22,002,058)	(22,002,058)
Balance – September 30, 2023	30,099,203	30,099	636,434,059	(535,737,523)	100,726,635

Nine months ended September 30, 2022

	Common Stock		Additional Paid-in	Accumulated	
	Shares	Par Value	Capital	Deficit	Total
Balance – December 31, 2021	27,740,147	\$27,740	\$513,304,258	\$(305,067,112)	\$208,264,896
Stock-based compensation	–	–	11,930,681	–	11,930,681
ATM offering, net	1,609,343	1,610	29,581,932	–	29,583,542
Warrant exercised for cash	33,334	33	299,973	–	300,006
Options exercised for cash	20,000	20	64,780	–	64,800
Net loss	–	–	–	(39,745,783)	(39,745,783)
Balance – March 31, 2022	29,402,824	29,403	555,181,624	(344,812,895)	210,398,156
Stock-based compensation	–	–	12,295,016	–	12,295,016
Warrant exercised for cash	91,058	91	595,259	–	595,350
Options exercised for cash	45,812	46	352,698	–	352,744
ATM offering, net of offering costs	484,900	485	13,144,572	–	13,145,057
Net loss	–	–	–	(39,934,968)	(39,934,968)
Balance – June 30, 2022	30,024,594	30,025	581,569,169	(384,747,863)	196,851,331
Stock-based compensation	–	–	8,343,139	–	8,343,139

Warrant exercised for cash	51,527	51	332,865	–	332,916
Options exercised for cash	17,886	18	286,158	–	286,176
Share exchange – Pre-funded warrants, net of fees	(1,452,016)	(1,452)	(48,548)	–	(50,000)
Net loss	–	–	–	(39,418,707)	(39,418,707)
Balance – September 30, 2022	28,641,991	\$28,642	\$590,482,783	\$(424,166,570)	\$166,344,806

Relmada Therapeutics, Inc.

Condensed Consolidated Statements of Cash Flows

(Unaudited)

Nine months ended

September 30,

2023

2022

Cash flows from operating activities

Net loss \$ (73,626,588) \$ (119,099,458)

Adjustments to reconcile net loss to net cash used in operating activities:

Stock-based compensation 33,916,921 32,568,836

Realized loss on short-term investments	718,422	552,171
Unrealized (gain) loss on short-term investments	(72,329)	3,897,135
Change in operating assets and liabilities:		
Lease payment receivable	—	86,377
Other receivable	512,432	—
Prepaid expenses and other assets	1,188,309	8,359,994
Accounts payable	(2,405,184)	(766,661)
Accrued expenses	(1,641,475)	6,482,889
Net cash used in operating activities	(41,409,492)	(67,918,717)
Cash flows from investing activities		
Purchase of short-term investments	(57,151,963)	(38,993,173)
Sale of short-term investments	99,864,149	60,382,229
Net cash provided by investing activities	42,712,186	21,389,056
Cash flows from financing activities		
Payment of fees for warrants issued for common stock	—	(50,000)
Proceeds from issuance of common stock – net	—	42,728,599

Proceeds from options exercised for common stock	—	703,720
Proceeds from warrants exercised for common stock	—	1,228,272
Net cash provided by financing activities	—	44,610,591
Net increase /(decrease) in cash and cash equivalents	1,302,694	(1,919,070)
Cash and cash equivalents at beginning of the period	5,395,905	44,443,439
Cash and cash equivalents at end of the period	\$ 6,698,599	42,524,369

Supplemental disclosure of cash flow information:

Non-cash investing and financing activities:

Share exchange for Pre-funded warrants	\$—	\$ 1,452
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SOURCE Relmada Therapeutics, Inc.

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