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

Description

CORAL GABLES, Fla., Aug. 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 second quarter ended June 30, 2023. The Company will host a conference call today, Tuesday, August 8, at 4:30 PM Eastern Time/1:30 PM Pacific Time.

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

“We continue to execute on the 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 expected, and we remain on track to complete this trial in the first half of 2024. We were also pleased to initiate Relight, our new Phase 3 Study (study 304), with screening ongoing. We currently anticipate the completion of Relight in the second half of next year. Moreover, the one year, open-label safety study, Reliance-OLS (study 310), with REL-1017 was recently completed, and we are preparing for the availability of data from that study during the current quarter.”

“Importantly, we are sufficiently funded to execute on all of our plans to reach data readouts from both Phase 3 trials, Reliance (study 302) and Relight (study 304), in 2024,” concluded Mr. Traversa.

Recent Corporate Highlights

- Enrollment is ongoing in Reliance II (study 302), a Phase 3 trial of REL-1017 for the adjunctive treatment of MDD.
- Screening has begun in Relight (study 304), a Phase 3 trial of REL-1017 for the adjunctive treatment of MDD.
- Data from the human abuse potential studies of REL-1017 were recently published in the peer-reviewed journal, *Translational Psychiatry.*

- Investigator meetings have been successfully hosted focusing on our amended and new protocols, quality expectations, increased oversight and engagement, and optimizing clinical execution for both ongoing Phase 3 studies.

Upcoming Anticipated Milestones for REL-1017

- Complete enrollment in ongoing Reliance II (study 302), which is planned to enroll approximately 300 patients, in the first half of 2024.
- Complete enrollment in new Relight study (study 304), which is planned to enroll approximately 300 patients, in the second half of 2024.
- Announce results from recently completed Reliance-OLS (study 310), a long-term, open-label study of REL-1017 in MDD, later in the current quarter.

Second Quarter 2023 Financial Results

- Research and development expense for the three months ended June 30, 2023, totaled $13.7 million, compared to $30.9 million for the three months ended June 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 June 30, 2023, totaled $12.3 million, compared to $14.6 million for the three months ended June 30, 2022. The decrease was primarily driven by a decrease in stock-based compensation.
- Net loss for the three months ended June 30, 2023, was $25.3 million, or $0.84 per basic and diluted share, compared with a net loss of $39.9 million, or $1.33 per basic and diluted share, for the three months ended June 30, 2022.

Six Months Ended June 30, 2023 Financial Results

- Research and development expense for the six months ended June 30, 2023, totaled $29.6 million, compared to $55.9 million for the six months ended June 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 six months ended June 30, 2023, totaled $24.6 million, compared to $27.9 million for the six months ended June 30, 2022. The decrease was primarily driven by a decrease in stock-based compensation.
- Net loss for the six months ended June 30, 2023 and 2022 was $51.6 million and $79.7 million, respectively. The Company had a net loss of $1.72 and $2.73 per share for the six months ended June 30, 2023 and 2022, respectively.
- As of June 30, 2023, the Company had cash, cash equivalents, and short-term investments of approximately $118.5 million, compared to cash, cash equivalents, and short-term investments of approximately $148.3 million at December 31, 2022.

Conference Call and Webcast Details

Tuesday, August 8 at 4:30 PM ET

Toll Free: 877-407-0792

International: 201-689-8263

Conference ID: 13740070

Webcast: https://viavid.webcasts.com/starthere.jsp?ei=1624681&tp_key=1f9f03a8ac

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. 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 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.
Condensed Consolidated Balance Sheets

	As of June 30, 2023 (unaudited)	As of Decemb 2022
Assets		
Current assets:		
Cash and cash equivalents	$14,469,354	$5,395,
Short-term investments	104,059,737	142,92
Other receivables	–	512,43
Prepaid expenses	3,474,540	4,035,
Total current assets	122,003,631	152,87
Other assets	34,590	34,875
Total assets	$122,038,221	$152,90

Commitments and Contingencies (See Note 6)		
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$4,853,616	$5,261,
Accrued expenses	5,848,850	7,206,
Total current liabilities	10,702,466	12,468
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	625,041,121	602,51
Accumulated deficit	(513,735,465)	(462,1
Total stockholders' equity	111,335,755	140,43
Total liabilities and stockholders' equity	$122,038,221	$152,90

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

	Three months ended June 30,		Six months ended June 30,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	$13,740,205	$30,912,671	$29,601,215	$55,9
General and administrative	12,286,521	14,599,401	24,579,120	27,8
Total operating expenses	26,026,726	45,512,072	54,180,335	83,8
Loss from operations	(26,026,726)	(45,512,072)	(54,180,335)	(83,
Other (expenses) income:				
Gain on Settlement	–	6,351,606		6,35
Interest/investment income, net	1,363,406	387,333	2,571,037	717
Realized (loss) gain on short-term investments	–	24,502	(666,708)	9,48
Unrealized (loss) gain on short-term investments	(639,634)	(1,186,337)	651,476	(2,9
Total other (expenses) income	723,772	5,577,104	(2,555,805)	4,12

Net loss	$(25,302,954)	$(39,934,968)	$(51,624,530)	$(79,
Loss per common share – basic and diluted	$(.84)	$(1.33)	$(1.72)	$(2.7
Weighted average number of common shares outstanding – basic and diluted	30,099,203	29,935,895	30,099,203	29,1

Relmada Therapeutics, Inc.
Condensed Consolidated Statements of Stockholders' Equity
(Unaudited)

Three and Six months ended June 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)	$ 140,436,302
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)	125,469,192
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)	$ 111,335,755

Three and Six months ended June 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)	$ 208,264,886
Stock based compensation	–	–	11,930,681	–	11,930,681
TM 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)	210,398,132
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

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

	Six months ended June 30,	
	2023	2022
Cash flows from operating activities		
Net loss	$ (51,624,530)	$ (79,680,751)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	22,523,983	24,225,697
Gain on settlement of fees	–	(6,351,606)
Realized loss (gain) on short-term investments	666,708	(9,480)
Unrealized (gain) loss on short-term investments	(651,476)	2,949,624
Change in operating assets and liabilities:		
Lease payment receivable	–	44,143

Other receivables	512,432	(256,192)
Prepaid expenses and other assets	560,931	7,810,846
Accounts payable	(408,320)	2,698,790
Accrued expenses	(1,358,091)	7,513,045
Net cash (used in) operating activities	(29,778,363)	(41,055,884)
Cash flows from investing activities		
Purchase of short-term investments	(45,577,832)	(33,412,425)
Sale of short-term investments	84,429,644	23,244,237
Net cash provided by (used in) investing activities	38,851,812	(10,168,188)
Cash flows from financing activities		
Proceeds from issuance of common stock, net	–	42,728,599
Proceeds from options exercised for common stock	–	417,544
Proceeds from warrants exercised for common stock	–	895,356
Net cash provided by financing activities	–	44,041,499
Net increase/(decrease) in cash and cash equivalents	9,073,449	(7,182,573)
Cash and cash equivalents at beginning of the period	5,395,905	44,443,439

Cash and cash equivalents at end of the period	$14,469,354	$37,260,866
Supplemental disclosure of cash flow information:		
Cash paid during the period for:		
Interest	$–	$–
Income Tax	$–	$–

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