UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **October 4, 2021**

RELMADA THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Nevada	**001-39082**	**45-5401931**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

2222 Ponce de Leon Blvd., Floor 3 Coral Gables, FL	**33134**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code **(786) 629-1376**

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of exchange on which registered
Common stock, $0.001 par value per share	**RLMD**	**The NASDAQ Stock Market LLC**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01 Other Events.

On October 4, 2021, Relmada Therapeutics, Inc. (the "Company"), issued a press release which provided regulatory and development updates regarding its ongoing late-stage clinical program for REL-1017 in major depressive disorder (MDD). A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The Company has updated its corporate presentation, a copy of which is attached hereto as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	**Description**
99.1	Press Release issued on October 4, 2021
99.2	Corporate Presentation
104	Cover Page Interactive Data File (formatted as Inline XBRL)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: October 7, 2021

RELMADA THERAPEUTICS, INC.

By: */s/ Sergio Traversa*
Name: Sergio Traversa
Title: Chief Executive Officer

Exhibit 99.1

Relmada Therapeutics Provides Regulatory and Development Updates on Ongoing Late-Stage Clinical Program for REL-1017 for Treatment of Major Depressive Disorder

Relmada is actively enrolling patients in RELIANCE III, a Monotherapy Registrational Phase 3 Study

FDA Confirms Relmada Not Required to Conduct Two-Year Carcinogenicity Study and TQT Cardiac Study in Humans to Support Potential Regulatory Approval Submissions for REL-1017

CORAL GABLES, Fla., Oct. 4, 2021 /PRNewswire/ -- Relmada Therapeutics, Inc. (NASDAQ: RLMD), a late-stage biotechnology company addressing diseases of the central nervous system (CNS), today provided regulatory and development updates regarding its ongoing late-stage clinical program for REL-1017 in major depressive disorder (MDD).

RELIANCE III, the new ongoing monotherapy trial, aims to randomize 364 patients and it is expected to be completed in the second quarter of 2022.

In addition, in order to support potential regulatory submissions seeking approval for REL-1017 as monotherapy and adjunctive treatment, the FDA confirmed that, based on what is known at this time, Relmada will not be required to conduct a two-year carcinogenicity study of esmethadone (REL-1017), as sufficient pre-clinical safety data have been generated to date. The FDA also confirmed that Relmada does not need to conduct a TQT cardiac study in humans to support cardiac safety in potential regulatory submissions for REL-1017, as the data provided so far and the data generated by the Phase 3 program will be adequate to evaluate the cardiac safety profile of REL-1017.

“We are pleased that the RELIANCE III monotherapy registrational Phase 3 trial is up and running,” said Dr. Paolo Manfredi, CSO of Relmada Therapeutics. “We believe that this advancement is indicative of the significant potential of REL-1017 to treat MDD. Importantly, conducting RELIANCE III as a Phase 3 study may meaningfully reduce the time to potential approval for REL-1017 as MDD monotherapy. We are continuing to actively enroll patients into RELIANCE I and RELIANCE II, our MDD adjunctive treatment pivotal trials, as well as into the new RELIANCE III monotherapy study. Meanwhile, RELIANCE OLE, the open label extension safety study, which is enrolling patients from RELIANCE I, II AND III, as well as de novo patients, is progressing steadily.”

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 the first 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 in all tested measures of depression. The Phase 2 study also confirmed the favorable safety, tolerability and pharmacokinetics profile of REL-1017 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 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 Relmada or on its 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 Relmada’s plans to develop REL-1017; and expectations related to trials evaluating REL-1017 and potential regulatory approval of REL-1017, including those related to feedback from the FDA. 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 Relmada’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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Disclosures

Certain statements contained in this presentation or in other documents of Relmada Therapeutics, Inc. (the "Company"), along with certain statements that may be made by management of the Company orally in presenting this material, may contain "forward-looking statements." These statements can be identified by the fact that they do not relate strictly to historic or current facts. They use words such as "estimate," "expect," "intend," "believe," "plan," "anticipate," "projected" and other words and terms of similar meaning in connection with any discussion of future operating or financial performance or condition. These statements are based upon the current beliefs and expectations of the Company's management and are subject to significant risks and uncertainties. Statements regarding future action, future performance and/or future results, those relating to the timing for completion, and results of, scheduled or additional clinical trials and the FDA's or other regulatory review and/or approval and commercial launch and sales results (if any) of the Company's formulations and products and regulatory filings related to the same may differ from those set forth in the forward-looking statements. Peak sales and market size estimates have been determined on the basis of market research and comparable product analysis, but no assurances can be given that such sales levels will be achieved,
if at all, or that such market size estimates will prove accurate.

Because actual results are affected by these and other potential risks, contingencies and uncertainties, the Company cautions investors that actual results may differ materially from those expressed or implied in any forward-looking statement. It is not possible
to predict or identify all such risks, contingencies and uncertainties. The Company identifies some of these factors in its Securities
and Exchange Commission ("SEC") filings on Forms 10-K, 10-Q and 8-K, and investors are advised to consult the Company's filings for a more complete listing of risk factors, contingencies and uncertainties affecting the Company and its business and financial performance.

The Company assumes no obligation to update forward-looking statements as circumstances change. Investors are advised to consult further disclosures that the Company makes or has made on related subjects in the Company's Form 10-K, 10-Q and 8-K reports.

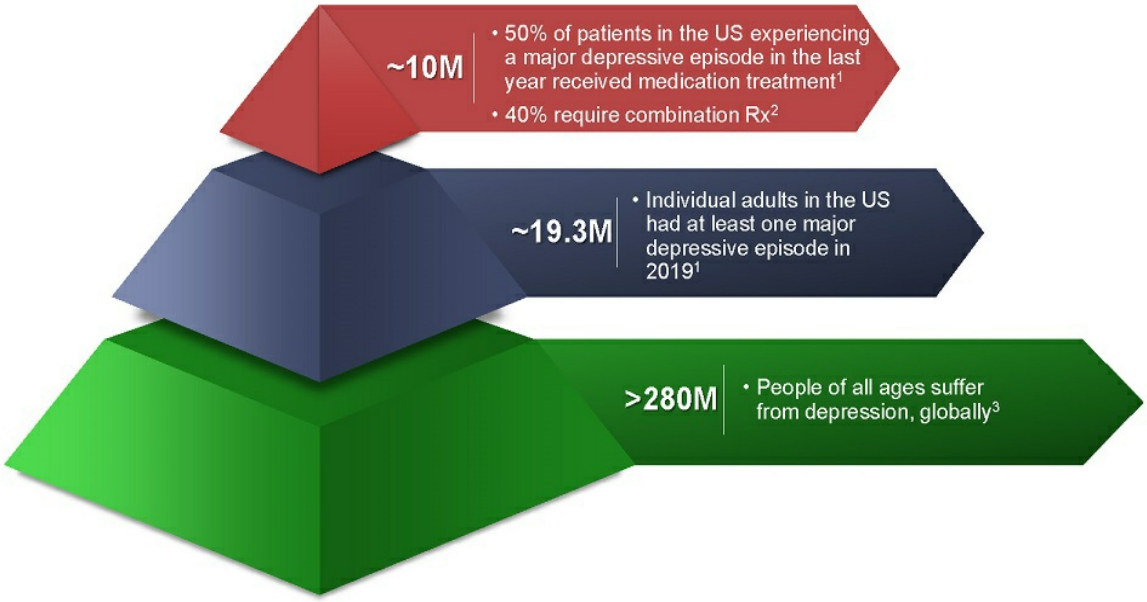
Investment Highlights

- CNS Focus with Lead Program in Major Depressive Disorder (MDD)
- Highly Compelling Opportunity in REL-1017
- Multiple Catalysts Expected Over Next 18 Months

CNS= Central Nervous System
**Our fiscal year end is December 31. The periods referred to in this slide are calendar years and quarters.

Major Depressive Disorder & REL-1017

Prevalence of Depression



Rx = prescription
1. Substance Abuse and Mental Health Services Administration (SAMHSA), U.S. Department of Health and Human Services (HHS) 2019 National Survey on Drug Use and Health; 2. Decision Resources Group Unipolar Depression 2020; 3. WHO Depression Fact Sheet

Limitations of Current Treatments for MDD

Limited Efficacy

~65% MDD patients do not respond to first antidepressant treatment[1]

Slow Onset of Action

Standard antidepressants take 2-4 weeks to reach efficacy[1]

Safety & Tolerability Challenges

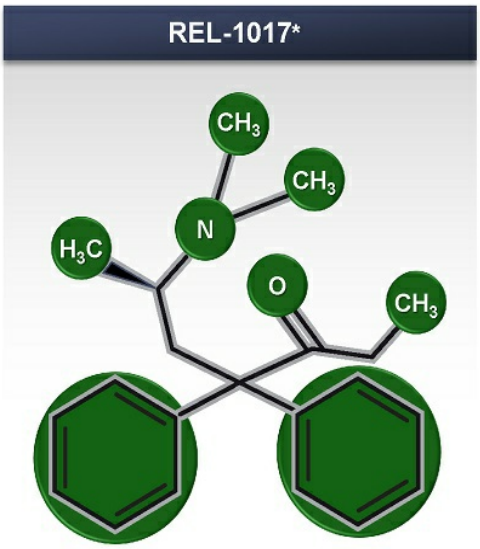
Risks for atypical antipsychotics approved as adjunctive treatments for MDD include tardive dyskinesia, metabolic syndrome, cognitive impairment and stroke[2]

MDD = major depressive disorder
1. Trivedi MH, et al. *Am J Psychiatry*. 2006;163:28-40; 2. Ashton AK, et al. *Curr Ther Res*. 2005;66(2):97-106; 2. US Prescribing Information, brexpiprazole, quetiapine, aripiprazole

Differentiated Profile of REL-1017

Potential as first oral, once-daily antidepressant for adjunctive treatment of MDD, if approved

- Novel Mechanism of Action: preferentially targets NMDAR channels associated with MDD
- Available clinical data demonstrated:
  - Robust, rapid and sustained statistically significant antidepressant effects on all tested scales[2]
  - Rapid onset: significant efficacy effects by Day 4[2]
  - Favorable safety and tolerability profile consistent across Phases 1 & 2 studies: no opioid and no psychotomimetic adverse events[1]
- Orally administered, once-daily tablet



MDD = major depressive disorder; NMDAR = N-methyl-D-aspartate receptor
*Diagram reflects chemical structure of REL-1017 (esmethadone); molecules are CH_3 = Methyl Group, O = Oxygen, N = Nitrogen
1. Bernstein, et al. *2019 Journal of Clinical Psychopharmacology*; 2. Relmada data on file

REL-1017 Ph 1 & 2 Efficacy & Safety Data

Phase 1 SAD & MAD Studies for REL-1017, Data Published 2019

Single Ascending Dose (SAD) Study Design
Parallel group, double-blind, placebo controlled

Objectives

Establish PK, PD and safety of single dose administration

Treatment Administration

- 6 Cohorts: 5, 20, 60, 100, 150, 200 mg
- N = 42

Study Conclusions

- Maximum Tolerated Dose (MTD) = 150 mg
- PK demonstrated linear proportionality of C_{max}, $AUC_{0\text{-}inf}$ vs. dose
- No clinically significant opioid or NMDA AESI signal

Multiple Ascending Dose (MAD) Study Design
Parallel group, double-blind, placebo controlled

Objectives

Establish PK, PD and safety of once daily, 10-day administration

Treatment Administration

- 3 Cohorts: 25, 50, 75 mg
- N = 24

Study Conclusions

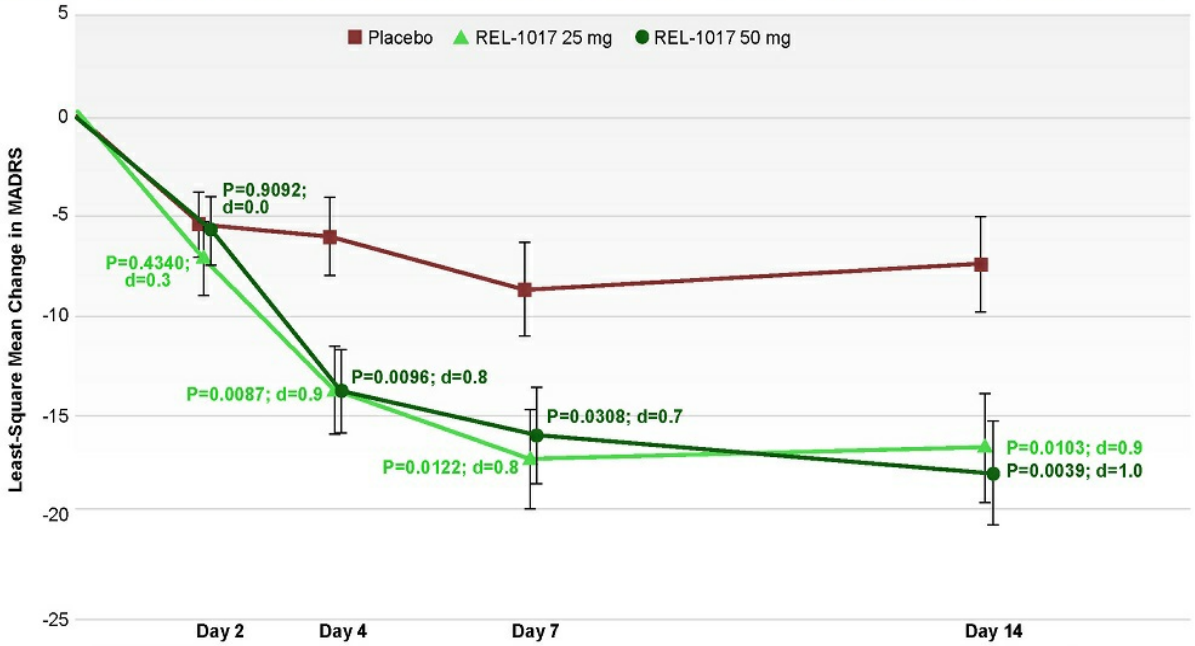
- Doses up to max does studied 75 mg per day well tolerated
- Favorable safety and tolerability profile
- No clinically significant opioid or NMDA AESI signal

PK = pharmacokinetics; PD = pharmacodynamics; MTD: =maximum tolerated dose; C_{max} = maximum plasma concentration; $AUC_{0\text{-}inf}$ = area under the curve 0 to infinite time; AUC_t = area under the curve to the end of dosing period; N = number of patients; NMDA = N-methyl-D-aspartate receptor antagonist; AESI = adverse event of special interest

Source: Bernstein, G. et al., J. Clin. Psychopharmacology 2019 May/Jun; 39(3):226-237.

Phase 2 Study REL-1017: Primary Efficacy Endpoint

REL-1017 showed rapid and sustained differences in MADRS change vs. placebo



		Day 2	Day 4	Day 7	Day 14
Δ MADRS vs Placebo	25 mg		7.9	8.7	9.4
	50 mg		7.6	7.2	10.4

Safety & Tolerability Findings from Phase 2

Safety & Tolerability Comparable to Placebo

- Only Mild and Moderate AEs – no SAEs
- No increased prevalence of specifically relevant organ group AEs in treatment groups vs placebo
- No evidence of opiate effects or withdrawal symptoms in treatment groups vs placebo
- No evidence of treatment-induced dissociative or psychotomimetic symptoms in the treatment groups vs placebo

AE = adverse event; SAE = serious adverse event
Source: Relmada data on file

Primary Endpoint - Drug Liking [Emax]
REL-1017 vs. Oxycodone

Statistic Parameter	Placebo	REL-1017 25 mg	REL-1017 75 mg	REL-1017 150 mg	Oxycodone 40 mg
n	44	44	44	44	44
Mean	**51.7**	**53**	**58.2**	**64.9**	**85**
Median	50	50	50	**58**	**89**
SD	4.28	8.67	14.98	16.74	15.4
SE	0.64	1.31	2.26	2.52	2.32

Statistical Analysis

Treatment 1	Treatment 2	P-value
Oxycodone 40 mg	Placebo	**<0.0001**
Oxycodone 40 mg	REL-1017 25 mg	**<0.0001**
Oxycodone 40 mg	REL-1017 75 mg	**<0.0001**
Oxycodone 40 mg	REL-1017 150 mg	**<0.0001**

- **All REL-1017 doses are highly statistically different from oxycodone for the primary endpoint ("Drug Liking at this Moment"). Comparable results were seen for the two key secondary endpoints ("Overall Drug Liking" and "Take Drug Again")**

RELIANCE: The Phase 3 Program for REL-1017

REL-1017 Phase 3 Program for the Adjunctive Treatment of MDD

Initiated December 2020

Reliance I

Reliance II

Two sister two-arm, placebo-controlled pivotal studies:

- In MDD patients with inadequate response to 1-3 ADT (n= ~364 per study)
- Primary Endpoint: Change in MADRS at Day 28
- Key Secondary Endpoints:
  - Change in CGI-S score at Day 28
  - Change in MADRS score at Day 7

Reliance OLS

Long-term, open-label safety study:

- Patients continuing from RELIANCE I & II
- Patients new to REL-1017

MDD = major depressive disorder; ADT = antidepressant treatment ; OLS = open label study; MADRS = Montgomery-Asberg Depression Rating Scale; CGIs = Clinical Global Impression scales

Pivotal Phase 3 Trial Design

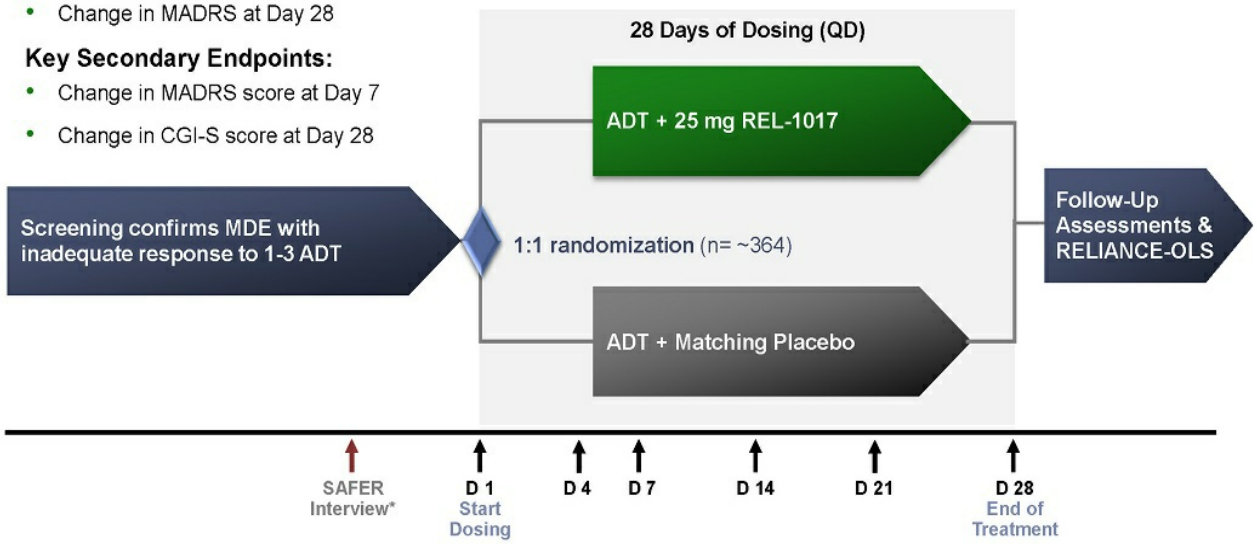
Reliance I
Reliance II

Primary Endpoint:

- Change in MADRS at Day 28

Key Secondary Endpoints:

- Change in MADRS score at Day 7
- Change in CGI-S score at Day 28



MADRS = Montgomery-Asberg Depression Rating Scale; CGIs = Clinical Global Impression scales; MDE = major depressive episode; ADT = antidepressant treatment; QD = once daily; OLS = open label study
*SAFER interview confirms that the illness is a specific state and excludes patients with any symptoms that are nonspecific or not readily assessable. Desseilles M, et al 2013. Massachusetts General Hospital SAFER criteria for clinical trials and research. Harv Rev Psychiatry. Sep-Oct;21(5):269-74.

Relmada Development Programs & Timeline*

Program	H1 21	H2 21	H1 22	H2 22	1H 2023	2H 23
REL-1017	RELIANCE I: 1st Pivotal Adjunctive MDD trial					
	RELIANCE II: 2nd Pivotal Adjunctive MDD trial					
	RELIANCE-OLS: Long-Term, Open-Label Study in MDD					
	RELIANCE-III: MDD Monotherapy					
	Human Abuse Potential vs. Oxycodone					
		Human Abuse Potential vs. Ketamine				
Psilocybin and Derivates		★ Acquisition Announced (Licensing Agreement)				

MDD = Major Depressive Disorder; OLS = Open Label Study
*Subject to FDA feedback **Our fiscal year end is December 31. The periods referred to in this slide are calendar years and quarters

Novel Psilocybin and Derivates

Novel Psilocybin and Derivates

Rights to Co-Develop and Commercialize

- **July 2021 announcement of licensing agreement:** development and commercial rights to a novel psilocybin and derivate program
- **Complementary focus:** potential therapies for neurodegenerative conditions
- **Synergy in neuroplasticity:** Expands R&D portfolio while building on expertise in neural plasticity, specifically the neuroplastogen mechanism of action
  - Like REL-1017, will build upon Relmada's expertise on neuroplasticity
  - Development and commercial rights in all ex-Asia territories, including the U.S. and Europe

CSO = Chief Scientific Officer, CMO = Chief Medical Officer

Corporate Information

Financial Overview

Cash, Cash Equivalents & Short-Term Investments (as of 6/30/2021)	Warrants Outstanding (as of 6/30/21, weighted average exercise price, $13.22)	Operating Cash Burn 2Q21	Common Shares Outstanding* (as of 6/30/2021)
$109.1 million	~2.8 million	$17.2 million	~17.5 million

*As converted share count of 25.4 MM share as of 6/30/2021

Investment Highlights

Focus on CNS diseases and Lead Program in Major Depressive Disorder (MDD)

- REL-1017, lead candidate, is in Phase 3 for depression, a leading cause of disability worldwide[1]
- CNS focus, with expertise in developing novel therapeutics that show potential for neuroplasticity
- 50%–66% of patients with depression do not fully recover on an antidepressant medication[2]
- Standard anti-depressants can take 2-4 weeks to work, and have significant side-effects

Highly Compelling Lead Product Opportunity in REL-1017

- Novel MOA with successful Phase 2 trial in adjunctive MDD that showed statistically significant, robust, rapid and sustained anti-depressant effects with favorable safety and tolerability profile
- **Phase 3 program underway** following successful End of Phase 2 Meeting with the FDA
- Fast track designation from FDA
- Strong intellectual property position around REL-1017 with expirations through the mid/late-2030s

Key Catalysts Expected Over Next 3-18 Months

- 3Q21 – Start of the monotherapy MDD trial
- 1Q22 – Completion of the human abuse potential study with ketamine
- 2Q22 – Completion of the monotherapy MDD trial
- 2H22 – Completion of RELIANCE I and RELIANCE II adjunctive MDD trials
- 2H22 – Completion of RELIANCE – OLS (Long-term, Open-label study in MDD)

CNS= Central Nervous System;; MDD = major depressive disorder; MOA = mechanism of action
**Our fiscal year end is December 31. The periods referred to in this slide are calendar years and quarters.
1. WHO Depression Fact Sheet, 2. Al-Harbi K.S. 2012 *Patient Preference and Adherence*

Q&A