

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): **March 23, 2022**

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

**Nevada**  
(State or other jurisdiction  
of incorporation)

**001-39082**  
(Commission File Number)

**45-5401931**  
(IRS Employer  
Identification No.)

**880 Third Avenue, 12th Floor**  
**New York, NY**  
(Address of principal executive offices)

**10022**  
(Zip Code)

Registrant's telephone number, including area code **(212) 547-9591**

(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 |
|--|----------------|--------------------------------------|
| <b>Common stock, \$0.001 par value per share</b> | <b>RLMD</b>    | <b>The NASDAQ Stock Market LLC</b>   |

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 2.02 Results of Operations and Financial Condition.**

On March 23, 2022, Relmada Therapeutics, Inc. (the "Company") issued a press release providing a corporate update and reporting its fourth quarter and full-year 2021 financial results. (These results are preliminary and unaudited.) The Company also announced that it would conduct a conference call and audio webcast on March 23, 2022, at 4:30 PM EDT, to discuss the update and results. The Company's complete audited financial statements and notes thereto as of and for the years ended December 31, 2021 and 2020, will be contained in its Annual Report on Form 10-K to be filed with the Securities and Exchange Commission. A copy of this press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated into this Item 2.02 by reference.

*In accordance with General Instruction B.2 of Form 8-K, the information in this Item 2.02 of this Current Report on Form 8-K, including the information set forth in Exhibit 99.1, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.*

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits

| Exhibit No. | Description  |
|-------------|--|
| 99.1        | <a href="#">Press release dated March 23, 2022, regarding corporate update and fourth quarter and full-year 2021 financial results</a> |
| 104         | Cover Page Interactive Data File (embedded within the Inline XBRL document)  |

**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: March 23, 2022

**RELMADA THERAPEUTICS, INC.**

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



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

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.

“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 multiple 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), found no unfavorable 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 and robust 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 60<sup>th</sup> 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.

The Company's complete audited financial statements and notes thereto as of and for the years ended December 31, 2021 and 2020, will be contained in its Annual Report on Form 10-K to be filed with the Securities and Exchange Commission.

#### 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://viaid.webcasts.com/starthere.jsp?ei=1536859&tp\\_key=0d9f65e796](https://viaid.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](http://www.relmada.com).

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#### 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.

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Relmada Therapeutics, Inc.  
Consolidated Balance Sheets  
(Preliminary and Unaudited)

|   | As of<br>December 31,<br>2021 | As of<br>December 31,<br>2020 |
|---|-------------------------------|-------------------------------|
| <b>Assets</b>                                 |                               |                               |
| Current assets:                               |                               |                               |
| Cash and cash equivalents                     | \$ 44,443,439                 | \$ 2,495,397                  |
| Short-term investments                        | 167,466,167                   | 114,595,525                   |
| Lease payments receivable – short term        | 86,377                        | 79,457                        |
| Prepaid expenses                              | 11,301,535                    | 903,190                       |
| Total current assets                          | <u>223,297,518</u>            | <u>118,073,569</u>            |
| Fixed assets, net of accumulated depreciation | -                             | 1,258                         |
| Other assets                                  | 28,293                        | 25,000                        |
| Lease payments receivable – long term         | -                             | 86,377                        |
| Total assets                                  | <u>\$ 223,325,811</u>         | <u>\$ 118,186,204</u>         |

#### Commitments and Contingencies (Note 9)

| <b>Liabilities and Stockholders' Equity</b>  |                       |                       |
|--|-----------------------|-----------------------|
| Current liabilities:   |                       |                       |
| Accounts payable   | \$ 11,192,502         | \$ 8,346,475          |
| Accrued expenses   | <u>3,868,423</u>      | <u>4,256,983</u>      |
| Total current liabilities  | <u>15,060,925</u>     | <u>12,603,458</u>     |
| Total liabilities  | <u>15,060,925</u>     | <u>12,603,458</u>     |
| 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           | 284,881,716           |
| Accumulated deficit  | <u>(305,067,112)</u>  | <u>(179,315,303)</u>  |
| Total stockholders' equity   | <u>208,264,886</u>    | <u>105,582,746</u>    |
| Total liabilities and stockholders' equity   | <u>\$ 223,325,811</u> | <u>\$ 118,186,204</u> |

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**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   | <u>125,703,492</u>      | <u>60,838,673</u>      |
| Loss from operations   | <u>(125,703,492)</u>    | <u>(60,838,673)</u>    |
| 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                                       | <u>(48,317)</u>         | <u>1,382,279</u>       |
| Net loss   | <u>\$ (125,751,809)</u> | <u>\$ (59,456,394)</u> |
| Net loss per common share – basic and diluted                            | <u>\$ (7.16)</u>        | <u>\$ (3.81)</u>       |
| Weighted average number of common shares outstanding – basic and diluted | <u>17,552,738</u>       | <u>15,594,228</u>      |

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