

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 15, 2021**

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
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 7.01 Regulation FD Disclosure.

On March 15, 2021, Relmada Therapeutics, Inc., announced the early termination of the ketamine segment of the human abuse potential study program on REL-1017 (esmethadone) due to the failure of control drug oral ketamine 100mg to separate from the placebo therefore invalidating the study design. A copy of this announcement is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated into this Item 7.01 by reference.

The Securities and Exchange Commission encourages registrants to disclose forward-looking information so that investors can better understand the future prospects of a registrant and make informed investment decisions. This Current Report on Form 8-K and exhibits may contain these types of statements, which are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, and which involve risks, uncertainties and reflect the Registrant's judgment as of the date of this Current Report on Form 8-K. Forward-looking statements may relate to, among other things, operating results and are indicated by words or phrases such as "expects," "should," "will," and similar words or phrases. These statements are subject to inherent uncertainties and risks that could cause actual results to differ materially from those anticipated at the date of this Current Report on Form 8-K. Investors are cautioned not to rely unduly on forward-looking statements when evaluating the information presented within.

The information in this Item 7.01 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	Announcement on the early termination of ketamine segment of the human abuse potential study program on REL-1017 (esmethadone)

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 15, 2021

RELMADA THERAPEUTICS, INC.

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

We have recently initiated two separate human abuse potential studies, REL-1017-120 and REL-1017-124, using 100 mg oral ketamine and 40 mg oral oxycodone as positive controls, respectively.

While the oxycodone study is advancing as planned and is expected to generate top line data in the second quarter of 2021, the ketamine study, due to the suspected inadequacy of the active control in the trial, 100 mg of ketamine delivered orally, has been terminated early.

No safety signal and no psychotomimetic symptoms (delusions and/or delirium, hallucinations) were observed in any of the 5 arms of the REL-1017-120 study, including the three tested dose levels of Rel-1017.

As part of data monitoring for the REL-1017-120 study, we analyzed the blinded data of completers from approximately 20% of the planned trial enrollment and observed that a substantial number of subjects discerned no difference between the test doses in the study (100 mg ketamine; 25 mg, 75 mg and 150 mg of Rel-1017 and placebo, all given orally). None of the tested drug arms in these subjects separated from the placebo range (subjects rate test doses on a likability scale ranging from 0 to 100 with 0 implying large dislike, 40 to 60 implying neither like or dislike (placebo range) and 100 implying large likability). Failure of the active control (100 mg oral ketamine) to separate from placebo invalidates this study design.

Within the next 4 weeks, we plan to submit to the FDA a new study design proposing a different active control to enable the trial to meet its objective of assessing the abuse potential of Rel-1017. Alternate routes of administration of ketamine have shown improved bioavailability relative to oral ketamine. As a result, it is our intention to investigate intranasal or intravenous administration in the revised protocol. Our expectation is that we will be able to resume this portion of the Human Abuse Potential Program in the second quarter of this year.
