

# UNITED STATES SECURITIES AND EXCHANGE COMMISSION WASHINGTON, D.C. 20549

September 30, 2014

Via E-mail
Sergio Traversa
Chief Executive Officer
Relmada Therapeutics, Inc.
546 Fifth Avenue
14th Floor
New York, NY 10036

Re: Relmada Therapeutics, Inc.

Amendment No. 1 to Registration Statement on Form S-1

Filed September 16, 2014

File No. 333-197109

Dear Mr. Traversa:

We have reviewed your responses to the comments in our letter dated July 24, 2014 and have the following additional comments.

#### General

- 1. We note your response to our prior comment 1. Please provide us with a more detailed analysis in support of your conclusion that the press release dated July 1, 2014 "substantially complies" with Rule 134. In your response, please address which of the items of information enumerated in Rule 134(a) covers the statements you make in the second paragraph, the second sentence of the third paragraph, and the second, third, and fourth sentences of the paragraph immediately following the caption "About Relmada Therapeutics . . . ." In your response please also tell us why it appears you have omitted the legend pursuant to Rule 134(b)(1).
- 2. We note your response to our prior comment 2. The press release on your website dated September 18, 2014 references the PSLRA. Please explain to us why this reference was made, in light of your confirmation dated September 15, 2014, that you would refrain from such references for so long as you are an issuer of penny stock.
- 3. We note your response to our prior comment 3. We note that you have provided audited financial statements for the six month transition period ended June 30, 2014. Please tell us and revise to disclose whether you have changed your year-end date.

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# Prospectus Summary, page 1

- 4. We note your response to our prior comment 6. Please disclose here your accumulated deficit.
- 5. We note your response to our prior comment 7. Please clarify which production activities you intend to engage in compared to those developed or to be undertaken by third parties. If you have not yet determined this given your stage of development, please discuss the factors you will consider in determining whether to outsource production and distribution.
- 6. We note your response to our prior comment 9. We are unable to locate your revised discussion of your competitive position and the effect of your particular strategy on this position on page 1. In this regard, please balance the comparison of your product to established commercial products of your competitors in light of your size and the stage of development of your product candidates.
- 7. We note your response to our prior comment 11. It does not appear your prospectus has been revised to include a discussion of your product pipeline in the business section, or any other section. Please revise accordingly. Additionally, please clarify why you have not discussed a Phase II trial for LevoCap. Please also clarify that d-Methadone is preclinical, and discuss why it appears you will skip Phase I studies. Similarly, please clarify that that MepiGel is pre-clinical.

#### Selling Stockholders, page 25

8. We note your response to our prior comment 22. Please identify in footnote 287 the person or persons who have voting or investment control over KMR Agency Inc.'s securities.

## Description of Business, page 53

9. We note your response to our prior comment 23. Please describe in greater detail your current and anticipated manufacturing plans, along with your plans for distribution. If you have not yet determined this given your stage of development, please discuss the factors you will consider in determining whether to outsource production and distribution. In this regard, we note your disclosure on page F-26 that you have a license agreement to distribute products in Asia. Please also discuss the steps you intend to take, if any, to locate adequate sources of supply of levorphanol for production and distribution.

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# Product Development, page 56

10. We note your response to our prior comment 27. Please disclose that Memorial Sloan Kettering Hospital has filed an IND for d-methadone, and reconcile this with your disclosure under the "Operations" subheading that you are "preparing to open the U.S. IND for d-methadone . . . ." Please also briefly describe the significance of and discuss the material risks associated with parties other than you sponsoring or filing applications.

## Intellectual Property Portfolio and Market Exclusivity, page 56

11. We note your response to our prior comment 28. Please provide a basis for your statement that your technology and products are "protected by an extensive intellectual property estate of several patents" when it appears that you currently own no patents. Similarly, revise the statement on page 57 that you have "secured an intellectual property portfolio comprised of several patents and patent applications." Please also provide us your analysis that the license agreement from Cornell University for d-methadone is not material to your business, or file this agreement as an exhibit.

#### Competition Overview, page 57

12. We note your response to our prior comment 30 and reissue. Please discuss here your competitive business conditions and competitive position in the industry. Refer to Item 101(h)(4)(iv) of Regulation S-K.

#### Government Regulation, page 57

- 13. Please discuss the requirement under the Controlled Substances Act that products containing Schedule II controlled substances are manufactured in the United States and discuss the steps you have taken and intend to take to comply with this requirement. We note in this regard your disclosure in the last risk factor on page 9 and the second risk factor on page 10.
- 14. We note your response to our prior comment 31. Please disclose the terms by which you have obtained "the right to two orphan drug designations for MepiGel from Cinergen, LLC" and explain your relationship, if any, with Cinergen.

# Management's Discussion and Analysis, page 61

- 15. We note your response to our prior comment 33. Please characterize the description of your portfolio as "diversified" as your belief and briefly disclose the basis of this belief.
- 16. We note your disclosure on page 62 that in December 2013 you acquired Medeor and "assumed the obligation to pay a third party for a license agreement." Please identify this

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third party and revise to include a summary of the material terms of this license agreement and file it as an exhibit to the extent material.

# Description of Securities, page 79

17. We note your response to our prior comment 46. Please quantify how many advisory firm warrants are currently issued and outstanding.

## Audited Financial Statements, page F-1

## Report of Independent Registered Public Accounting Firm, page F-3

18. The audit report dated March 25, 2014 contained a going concern paragraph. The new audit report dated September 3, 2014 does not. Please tell us in further detail why the new audit report does not have a going concern paragraph.

You may contact Aamira Chaudhry (202) 551-3389 or Amy Geddes at (202) 551-3304 if you have questions regarding comments on the financial statements and related matters. Please contact Ryan Adams at (202) 551-3191 or me at (202) 551-3217 with any other questions.

Sincerely,

/s/ J. Nolan McWilliams

J. Nolan McWilliams Attorney-Advisor

cc: <u>Via-Email</u>
Thomas R. Slusarczyk
The Matt Law Firm, PLLC