

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

DIVISION OF CORPORATION FINANCE

February 25, 2015

<u>Via E-mail</u> Michael D. Step Chief Executive Officer Ritter Pharmaceuticals, Inc. 1801 Century Park East #1820 Los Angeles, CA 90067

> Re: Ritter Pharmaceuticals, Inc. Draft Registration Statement on Form S-1 Submitted January 29, 2015 CIK No. 0001460702

Dear Mr. Step:

We have reviewed your draft registration statement and have the following comments. In some of our comments, we may ask you to provide us with information so we may better understand your disclosure.

Please respond to this letter by providing the requested information and either submitting an amended draft registration statement or publicly filing your registration statement on EDGAR. If you do not believe our comments apply to your facts and circumstances or do not believe an amendment is appropriate, please tell us why in your response.

After reviewing the information you provide in response to these comments and your amended draft registration statement or filed registration statement, we may have additional comments.

Table of Contents, page i

1. We note your statement, "While we believe that these industry publications and thirdparty research, surveys and studies are reliable, we have not independently verified such data." As it is not appropriate to disclaim liability for information contained in your prospectus, please revise your disclosure to delete these statements.

Prospectus Summary

Our Leading Product Candidate - RP-G28, page 1

- 2. Please define the term "prebiotic" at your first reference in the prospectus summary.
- 3. Please provide a brief explanation of the term "oligosaccharide" at your first reference in the prospectus summary.

- 4. Please expand your disclosure in this section to briefly describe the "patient-reported symptom assessment instrument" referenced in the second paragraph of this section.
- 5. Please expand your disclosure in this section to explain the term "principal component analyses."
- 6. Please explain the meaning and significance of the term "statistically significant" at its first use in the fourth paragraph of this section. To the extent that your explanation of "statistical significance" involves the minimum "p-value" associated with statistical significance, please explain the relationship between the terms and the significance of p-values to the FDA's evidentiary standards of efficacy. Please also revise your disclosure in the section entitled "Phase 2a Study" on page 76 as required.
- 7. We note your disclosure that you have received FDA guidance on RP-G28's clinical and regulatory pathway. Please expand your disclosure to provide a brief description of the FDA's guidance on RP-G28.

Substantial Patent Portfolio and Product Exclusivity, page 3

8. Please revise your disclosure in this section to identify the prominent oligosaccharide manufacturer in Europe with whom you have secured an exclusive supply agreement which provides for under certain circumstances the transfer of the manufacturer's patent applications for the process to produce ultra high purity oligosaccharide active pharmaceutical ingredients, including RP-G28.

# **Risk Factors**

<u>Risks Related to Our Financial Position and Need for Additional Capital</u> We will require substantial additional funding, which may not be available..., page 11

9. Please expand your risk factor disclosure to quantify the amount of your cash and cash equivalents.

<u>Risks Relating to Regulatory Review and Approval of Our Product Candidates</u> We cannot be certain that RP-G28 will receive regulatory approval, and..., page 13

10. Please expand your disclosure in the third paragraph of this risk factor to describe the purpose of the "ICH-compliant GLP embryo-fetal developmental toxicology studies" and the "ICH standard battery of genotoxicity tests (GLP) using RP-G28.

<u>Risks Related to Our Business</u> and <u>Strategy</u> We may not be able to manage our business effectively if we are unable to..., page 25

11. Please identify your other key employees and consultants to whom you refer in the second paragraph of this risk factor.

We face potential product liability exposure, and if successful claims are..., page 27

12. Please explain what you mean when you state that you expect to obtain "limited" product liability insurance coverage by quantifying the amount of coverage you plan on obtaining and whether the amount of your coverage is typical for a company in your industry. Please also provide this information when you discuss any other types of insurance you carry.

### Use of Proceeds, page 42

13. Please revise your first bullet point in this section to indicate whether the allocated proceeds will allow you to fund your Phase 2b and Phase 3 trials to completion. If not, please indicate how far in the development process the allocated proceeds will allow you to reach.

Management's Discussion and Analysis of Financial Condition and Results of Operations Critical Accounting Policies and Estimates Stock-Based Compensation, page 53

14. We may have additional comments on your accounting for equity issuances including stock compensation and beneficial conversion features. Once you have an estimated offering price, please provide us an analysis explaining the reasons for the differences between recent valuations of your common stock leading up to the IPO and the estimated offering price.

#### Business, page 67

- 15. We note your discussion on page 61 regarding your R&D agreement with KPT and KPM. Please include disclosure under the appropriate subheading of your Business section describing the material terms of the R&D agreement, including the nature and scope of the agreement, the parties' rights and obligations, duration of the agreement, termination provisions, aggregate payments to be received by you under the agreement and royalties you are obligated to pay under the agreement.
- 16. We note your disclosure on page 75 under the heading "Substantial Patent Portfolio and Product Exclusivity" where you state that you secured an exclusive supply agreement for GMP produced product from a prominent oligosaccharide manufacturer in Europe, which provides for, under certain conditions, the transfer of the manufacturer's patent

> applications for the process to product ultra high purity oligosaccharide active pharmaceutical ingredients, including RP-G28. Please expand your disclosure under the appropriate subheading of your Business section to identify the manufacturer and to describe the material terms of the supply agreement, including the parties' rights and obligations, the duration of the agreement, termination provisions and any payment provisions. Also, please describe under what conditions the manufacturer will transfer its patent applications to you.

## <u>Our Lead Product Candidate – RP-G28</u> Galacto-oligosaccharides (GOS), page 70

17. We note your statements that RP-G28 is manufactured to ultra-high purity specifications and that in comparison, commercially available GOS are typically 50-60% GOS. Please expand your disclosure to provide the specifications of RP-G28.

Clinical and Regulatory Phase 2a Study, page 76

18. We note your statement, "Principal component analyses showed statistically significant shifts in the microbiome of subjects treated with RP-G28" in the fourth paragraph of this section. Please expand your disclosure to provide the results, including p-values, of the component analysis showing statistically significant shifts in the microbiome of subjects treated with RP-G28.

# Competition, page 78

19. We note that you believe that RP-G28 is one of the few drug candidates in advanced clinical trials for treating lactose intolerance. Please expand your disclosure to identify the other drug candidates that are under development with which you may compete and the companies that are developing these product candidates. In this regard, we note that you currently provide such information in the risk factor entitled, "We face competition from other biotechnology and pharmaceutical companies and our operating results will suffer if we fail to compete effectively."

Intellectual Property Patents and Proprietary Rights Covering Our Drug Candidates, page 79

20. We note that your intellectual property portfolio related to RP-G28 contains four issued patents and at least 15 other related pending patent applications in the United States and worldwide of both in-licensed and Ritter Pharmaceutical-owned inventions. Please revise your disclosure in this section to provide the following information:

- a description of your fourth issued patent, including the type of patent protection such as use or process, the expiration date of the patent and the jurisdiction where it is issued;
- with regard to your patent applications, please describe the type of patent protection you are seeking such as composition of matter, use or process, the expected expiration date of the issued patent if the patent application is granted, and the jurisdictions where the patent application is pending; and
- with regard to your patents and patent applications, which ones are owned and which ones are licensed from third parties and the name of the third party if the patent or patent application is licensed from a third party.

Statements of Operations, F-4

21. Please revise to include "Compensation and benefits" either in or as a separate line within another operating cost and expense line item(s).

# Notes to Financial Statements

Note 7 Stockholders' Deficit and Preferred Stock Subject to Redemption, F-15

22. Please revise to explain why conversion of all preferred stock as shown in your pro forma presentation on pages 9 and 44 is factually supportable.

# Other Comments

- 23. We note that there are a number of additional exhibits that still need to be filed. Please provide these exhibits as promptly as possible. Please note that we may have comments on these materials once they are provided.
- 24. Please confirm that the graphics included in your registration statement are the only graphics you will use in your prospectus. If those are not the only graphics, please provide any additional graphics prior to their use for our review.
- 25. Please supplementally provide us with copies of all written communications, as defined in Rule 405 under the Securities Act, that you, or anyone authorized to do so on your behalf, present to potential investors in reliance on Section 5(d) of the Securities Act, whether or not they retain copies of the communications.

You may contact Rolf Sundwall at (202) 551-3105 or Joel Parker at (202) 551-3679 if you have questions regarding comments on the financial statements and related matters. Please contact Johnny Gharib at (202) 551-3170, Bryan Pitko at (202) 551-3203 or me at (202) 551-3715 with any other questions.

Sincerely,

/s/ Bryan J. Pitko for

Jeffrey P. Riedler Assistant Director

cc: <u>Via E-mail</u> Yvan-Claude Pierre, Esq. Reed Smith LLP