

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

February 28, 2020

Andrew J. Ritter
Chief Executive Officer
Ritter Pharmaceuticals, Inc.
1880 Century Park East, Suite 1000
Los Angeles, CA 90067

Re: Ritter Pharmaceuticals, Inc. Registration Statement on Form S-4 Filed February 4, 2020 File No. 333-236235

Dear Mr. Ritter:

We have reviewed your 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 amending your registration statement and providing the requested information. 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 any amendment to your registration statement and the information you provide in response to these comments, we may have additional comments.

Registration Statement on Form S-4

Questions and Answers about the Merger

Q: What is the Pre-Closing Qualigen Financing?, page 12

1. Please file the financing commitment letter as an exhibit or tell us why you don't believe it's necessary.

Risks Related to Qualigen

Qualigen relies on its distribution partner Sekisui, page 54

2. Please file the distribution agreement with Sekisui as an exhibit or tell us why you don't believe it's necessary.

Background of the Transaction, page 93

- 3. We note your disclosure that, beginning on October 7, 2019, Ritter management consulted with certain members of the Ritter Board on two occasions and following such consultations, selected a subset of candidates to progress to in-person presentations and to receive an initial draft of a letter of intent, respectively. Please disclose which members of the Ritter Board were consulted on both occasions and what criteria was used to determine the two subsets of candidates.
- 4. We note your disclosure that members of the Transaction Committee received copies of the full proposals submitted by Party B, Party C and Party D and a summary of each of the 13 proposals submitted to AGP, including Qualigen's proposal, on October 26, 2019. Please disclose who determined to provide full copies of only three proposals and how that determination was made.
- 5. We note your disclosure that the Transaction Committee directed Ritter management to continue to explore a potential transaction with each of Qualigen and Parties A, B, C, D, E and F on October 30, 2019, but Qualigen was informed that Ritter would be pursing an alternative transaction and would not be pursuing a transaction with Qualigen on November 1, 2019. Please disclose what transpired between October 30, 2019 and November 1, 2019 to change the Transaction Committee's decision and what factors were considered. Please also revise to disclose the material terms of the bids from Qualigen and Parties A, B, C, D, E and F. To the extent that you have not already done so, please disclose how the material terms of the Qualigen bid were negotiated, including how the deal value, pricing mechanism, exchange ratio and ownership split were negotiated.
- 6. Please disclose what parts of the proposals from Parties B, C and D led the Transaction Committee to determine that Parties B, C and D were the candidates the most likely to have the ability to consummate a merger with Ritter within a compressed timeframe and on terms most likely to maximize shareholder value. Please also discuss whether Ritter considered reaching out to the other parties who submitted proposals to see whether they could make their offers more competitive.
- 7. We note your disclosure that AGP conducted a valuation analysis of each proposal. Please expand your disclosure to describe the analyses performed, including comparables selected for evaluation, the assumptions underlying such analyses and the resulting valuation or valuation range resulting from the analyses.

Ritter Business, page 151

8. We note your disclosure on page 39 that Ritter may continue to seek partnering, collaborative or similar strategic arrangements with third parties to develop and commercialize RP-G28 either as a prescription drug or OTC product or as a dietary supplement if the merger is not completed. Please disclose in this section if the combined company has any plans for RP-G28 if the merger is completed.

9. Please remove statements in this section that RP-G28 could become the first drug approved by the FDA for the treatment of LI if approved and RP-G28 was expected to have the potential to become the first FDA-approved drug for the reduction of symptoms associated with LI. Since you disclose that all further development efforts for RP-G28 have been suspended, it is not appropriate to make these statements. Please also remove the statement that clinical testing demonstrated that Lactagen was an effective and safe product for reducing symptoms for nearly 80% of the clinical participants who were on Lactagen. Determinations of safety and efficacy are solely within the authority of the FDA, and and it appears that Lactagen never received FDA approval.

Galacto-oligosaccharides (GOS), page 153

10. Please revise Figure 1 on page 154 to better differentiate the control, glucose, GOS1 and GOS2 lines.

Products and Solutions, page 169

- 11. We note your disclosure here that your products have been shown preclinically to have the potential to work together, alone or in combination with other therapies, multiplying their effectiveness. Please remove any reference to effectiveness for product candidates which have yet to receive FDA approval, and please do not refer to such product candidates as "products." Similarly, please remove any references to increased potency in preclinical studies for ALAN on page 170. Determinations of efficacy are solely within the authority of the FDA.
- 12. We note references to preclinical studies here and on page 170. To the extent that you reference preclinical data suggestive of the potential of your product candidates, please revise to discuss the studies and present the data supporting your statements.

Qualigen's Business Overview, page 169

13. Please make it clear in this section and in the Products and Solutions section that the only product that is currently commercially available is the FastPack System. Please revise to disclose in this section the current stage of development for each of your product candidates: ALAN, RAS-F3 and STARS.

ALAN (AS1411-GNP), page 170

14. Please revise your disclosure of the ULRF License Agreement and ACT License Agreement to provide the royalty term, the duration of the agreement and the termination provisions. We also note your disclosure that Qualigen has agreed to pay ULRF and ACT payments ranging from \$100,000 to \$5,000,000 upon the achievement of certain milestones. If \$5,000,000 is not the aggregate future milestone payments to be made, please revise your disclosure to include that number. Please also file both license agreements as exhibits or tell us why you don't believe it's necessary.

Regulatory Strategy, page 171

- 15. We note your disclosure that Qualigen has demonstrated success in regulatory affairs, having obtained 17 FDA approvals and 19 CE-Marks for its products to date. Please revise to disclose for which products these approvals and marks have been received and that Qualigen has never received FDA or other regulatory approval for a drug candidate.
- 16. We note your disclosure that your strategy for ALAN will not require Phase 3 trials. Please disclose your basis for this statement and that there is no guarantee that the FDA will not require you to conduct Phase 3 trials for ALAN.

Intellectual Property, page 173

17. Please revise to disclose the specific products, product groups and technologies to which your patents relate, whether they are owned or licensed, the type of patent protection you have, the expiration dates, the applicable jurisdictions and whether there are any contested proceedings or third-party claims.

Qualigen Management's Discussion and Analysis of Financial Condition and Results of Operations, page 193

- 18. Tell us whether you track any of your R&D costs incurred by program area. If so, tell us your consideration given for disclosing a breakdown of this information in your filing to provide additional context to your R&D activities. If not, tell us your consideration for disclosing the fact that you do not track these costs by pipeline program area and for providing other quantitative or qualitative disclosure that provides transparency as to the types of costs incurred and concentrations of effort expended.
- 19. Revise your MD&A to address the following:
 - Discuss the fluctuations in your cost of goods sold, both in terms of dollars as well as percentage of product sales.
 - Discuss the extent to which the amounts were affected by changes in your inventory reserves.
 - Discuss the reasons for the significant reserves against your inventory, as well as the reasons for the changes in the reserves between periods.

<u>Unaudited Pro Forma Condensed Combined Financial Statements</u> <u>Unaudited Pro Forma Condensed Combined Balance Sheet, page 208</u>

- 20. Given that you have determined that Qualigen is the accounting acquirer, revise your proforma presentations to start with the Qualigen historical financial statements as the first column, basing the presentation on the periods presented for Qualigen.
- 21. Please revise to address the following regarding your footnotes:
 - We note your footnotes here on page 208 as well as different footnote descriptions on page 215 which appear to be referring to the same adjustments. Revise to provide a

- comprehensive footnote description that more clearly addresses each adjustment.
- Revise to ensure that your adjustments are self-balancing and that you disclose an amount or amounts for each of your adjustments as part of your description, providing sufficient detail so as to allow the reader to recalculate.
- 22. Please address the following regarding adjustment K:
 - Revise to clearly explain how the \$37,989,079 amount was determined.
 - Revise to disclose the transaction reflected in adjustment K in greater detail.
 - Explain to us the basis for your pro forma adjustments for this amount.
 - Tell us how you determined that there is no ongoing income statement effect from the financing that would warrant adjustment in your pro forma income statements.
- 23. Please explain to us the basis for your pro forma additional paid-in capital methodology and the underlying adjustments. For example, explain why you include both Ritter and Qualigen's additional paid-in capital as part of the pro forma combined. Explain why Ritter's additional paid-in capital is not eliminated.
- 24. Please explain to us the basis for your pro forma accumulated deficit amount and the underlying adjustments. For example, explain why you include Ritter's accumulated deficit as part of the pro forma combined, and adjustments F and L. Explain why Ritter's accumulated deficit is not eliminated.

Unaudited Pro Forma Condensed Combined Statements of Operations, page 209

25. Pro forma weighted average common shares outstanding on a combined basis should retroactively reflect the recapitalization and related transactions (e.g., conversion of preferred stock and convertible notes from the beginning of the periods presented or the date of issuance if later). Accordingly, please provide pro forma shares outstanding to reflect the recapitalization and related transactions, and include a tabular reconciliation of the amount in the notes.

Notes to Unaudited Pro Forma Combined Condensed Financial Statements

1. Description of Transaction, page 212

- 26. Please address the following regarding the 5% commitment fee and the 7.5% advisory fee:
 - Revise to disclose how you will account for these fees, and provide the related amounts.
 - Explain to us the basis for your accounting for these fees, referencing the accounting literature on which you relied.
 - Tell us how you determined whether to give pro forma effect to these fees in your pro forma presentations.

2. Basis of Presentation, page 213

- 27. Please address the following:
 - You disclose throughout your document that you determined to apply reverse

recapitalization accounting for the merger. However, you disclose on page 207 that you will account for the merger as a reverse acquisition, recognizing intangibles. Please revise to reconcile this apparent inconsistency.

- In light of the fact that Ritter Pharmaceuticals, Inc. was an operating company for the periods presented and not a shell company, explain to us how you determined recapitalization accounting for your transaction is appropriate.
- As part of your response, explain how you considered the business combination accounting guidance in ASC 805 and determined that it was not applicable to your situation.
- Specifically address how you considered that the contingent value rights agreement discussed on page 129 seems to imply that the legacy business of Ritter still has some value and continuity.
- 28. Please explain to us why Ritter's estimated transaction costs are part of the purchase price.
- 29. Please disclose how the contingent value rights (CVRs) will be accounted for as part of the recapitalization transaction, and on a go forward basis. Tell us the accounting guidance on which you relied.
- 4. Adjustments to Unaudted Pro Forma Combined Financial Statements, page 215
- 30. Please explain to us why you do not show the pro forma impact from the reverse stock split.

Principal Stockholders of Qualigen, page 228

31. Please revise your disclosure to identify the natural person or persons who have voting and investment control of the shares held by Sekisui Diagnostics, LLC and Alpha Capital Anstalt.

Principal Stockholders of Combined Company, page 232

32. Please revise your disclosure to identify the natural person or persons who have voting and investment control of the shares held by GreenBlock Capital LLC.

Index to Qualigen, Inc. Consolidated Financial Statements, page F-34

We note that you have not provided audited financial statements for Qualigen, Inc. Please revise to provide audited financial statements as required. Refer to Item 17 of Form S-4.

Annual Financial Statements of Qualigen, Inc.

Notes to Financial Statements

General, page F-39

34. Please provide the entity-wide disclosures required by ASC 280-10-50-40 through 50-42.

1. Organization and Summary of Significant Accounting Policies Net Product Sales, page F-41

35. As part of your disclosure, please describe your distributor allowances and how you determine an estimate of the allowance.

Multiple Element Arrangements, page F-42

- 36. Your accounting policy for the allocation of arrangement consideration refers to "relative fair value basis" here and "relative selling price" under Revenue Recognition, above. Please ensure that your wording is consistent and confirms your compliance with ASC 605-25-55-3 and ASC 605-25-15-3A(b).
- 37. Your determination of selling price using VSOE is not clear as you refer to the current sales prices "as if they were sold separately." Please clarify your policy so that it is consistent with ASC 605-25-30-6A.

Research and Licenses, page F-42

- 38. Please explain to us how you determined that amounts received from your various agreements should be characterized as revenue on the statements of operations, and not, for example, a reimbursement of costs presented net.
- 39. Please revise your disclosure to address how you account for research revenue when there is a possibility of contingent payments related to unsuccessful research and development activities, as referred to on page F-46. Provide us additional analysis to support your accounting for research revenue and identify the accounting literature you are relying upon.

New Accounting Pronouncments, page F-45

40. You disclose that ASC 606 is effective for you for annual reporting periods beginning after December 15, 2019, including interim periods therein. Please clarify how you made this determination and how you considered the guidance in ASC 606-10-65-1(b).

5. Equipment held for Lease, net, page F-47

41. Please provide us your analysis of the lease classification criteria under ASC 840-10-25-1, 840-10-25-42 and 25-43 for the leases in your multiple element arrangements.

12. License Agreements, page F-51

- 42. For your various agreements where you might be required to make future sponsored research payments, milestone payments, funding payments, and royalty payments, please separately disclose possible future payments or range of payments, as well as royalty percentages. In addition, describe the milestones related to the milestone payments.
- 43. Please disclose details of the contingent payments related to the partnership with Sekisui,

as referred to on page F-46.

Interim Financial Statements of Qualigen, Inc.

Balance Sheets, page F-62

44. Rather than presenting the balance sheet for the end of prior period dated December 31, 2018, please revise to present the balance sheet as of March 31, 2019, representing the end of the most recent annual period. Refer to Rule 8-03 of Regulation S-X.

12. License Agreements, page F-78

45. You disclose here and on page 193 that as of December 31, 2019 you have a payment obligation due to Sekisui related to your agreement. Please explain to us in further detail the reason for this payment obligation. In addition, you refer to \$7.2 million in future financing. Clarify your disclosure to more clearly identify the party that is providing the funds and the party that is receiving the funds, and the amount that has been provided to date.

Consent of Independent Registered Public Accounting Firm, page II-7

46. Please have your auditor correct the report date contained in the accountants' consent.

We remind you that the company and its management are responsible for the accuracy and adequacy of their disclosures, notwithstanding any review, comments, action or absence of action by the staff.

Refer to Rules 460 and 461 regarding requests for acceleration. Please allow adequate time for us to review any amendment prior to the requested effective date of the registration statement.

You may contact Michael Fay at 202-551-3812 or Kevin Vaughn at 202-551-3494 if you have questions regarding comments on the financial statements and related matters. Please contact Ada D. Sarmento at 202-551-3798 or Celeste Murphy at 202-551-3257 with any other questions.

Sincerely,

Division of Corporation Finance Office of Life Sciences

cc: Wendy Grasso, Esq.