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Division of Corporation Finance
Securities and Exchange Commission
100 F Street, N.E.
Washington, D.C. 20549

Re Virios Therapeutics, LLC
Draft Registration Statement on Form S-1
Submitted July 24, 2020
CIK No. 0001818844

On behalf of our client, Virios Therapeutics, LLC (the “**Registrant**”), we are responding to the comments of the staff (the “**Staff**”) of the Securities and Exchange Commission (the “**Commission**”) contained in its letter dated August 19, 2020 (the “**Comment Letter**”) relating to the above referenced Draft Registration Statement (the “**Draft Registration Statement**”).

Set forth below are the Registrant’s responses to the Staff’s comments. The numbering of the paragraphs below corresponds to the numbering of the Staff’s comments, which for your convenience we have incorporated into this response letter. Page references in the text of this response letter correspond to the page numbers of the Registration Statement on Form S-1 (the “**Registration Statement**”) filed today. We also describe below the changes the Registrant has made in response to the Staff’s comments in the Registration Statement and the prospectus included therein.

For the Staff’s convenience, we are submitting copies of this letter, clean copies of the Amendment and copies of the Registration Statement marked to show all changes from the Draft Registration Statement via email.

Prospectus Summary, page 1

1. *Please revise to limit discussions of clinical trial results in your prospectus summary to the endpoints of the trial, whether they were met, and serious adverse events. Discussions of p-values and inclusion of graphics with results is more appropriate for your Business section.*
-

The Registrant has revised pages 1- 6 to limit discussion of clinical trial results to endpoints of the trial.

How does IMC-1 work?, page 1

2. *We note your statements throughout your filing that you believe IMC-1 may potentially be a "first-in-class medicine that inhibits both HSV-1 activation and subsequent HSV-1 replication." Given the early stage of development, and your acknowledgement that your results in your earlier studies may not be indicative of results obtained in later trials, these statements are speculative and inappropriate. Please revise these statements. Similarly, we note your references in the Summary and elsewhere in your prospectus that you have a "lead product (IMC-1)." It is premature to describe IMC-1 as a "product." Please remove or revise such statements.*

The Registrant has revised the prospectus to remove speculative statements and to clarify that IMC-1 is not a product at this time but a development candidate at this time.

Our Novel Mechanism of Action ("MOA"), page 1

3. *We note your disclosure here and elsewhere in your prospectus that you observed IMC-1 to have a favorable safety profile in your Phase 2a proof of concept study. Since this disclosure may imply that your product candidate is safe, and safety determinations are solely within the authority of the U.S. Food and Drug Administration and comparable regulatory bodies, please revise your disclosure to remove this implication.*

The Registrant has revised the prospectus to remove implications that the Phase 2a proof of concept study allows the Registrant to determine that IMC-1 is safe.

Our Experience Leads Us Down an Efficient Regulatory and Development Pathway, page 3

4. *We refer to the following statements as examples only:*
- *your statements on page 5 that you are seeking to take IMC-1 to "being Phase 3 ready" after your Phase 2b trial, that you "intend" for your Phase 2b trial to "confirm the findings" in your Phase 2a study, and that the studies will "help to further validate the potential of IMC-1;"*
 - *your statement on page 8 that you aim to "[r]apidly" advance the clinical development of IMC-1 and conduct activities to "ensure rapid progression to Phase 3;" and*
 - *your statement on page 9 that you will explore partnership options after the "successful completion" of the Phase 2b study.*
- You also have similar and additional statements elsewhere in your prospectus, including on page 88, where you state that "Phase 2b probability of success calculates a significantly higher success ratio compared to benchmarks. . . [t]his higher probability of success is due to the high statistically significant endpoints shown in the Phase 2a study and the well characterized safety of the non-NME formulation of IMC-1," and your statement on page 91 that broad clinical utility is to be "further confirmed" in your Phase 2b/3 trials. These types of statements are speculative and not appropriate as they imply successful results from your anticipated trial, or that your trial will be rapidly concluded. Please revise all such statements in your prospectus accordingly.*
-

The Registrant has revised the prospectus to remove statements that are speculative as to the future results Phase 2b or Phase 3 trials and the timing of such trials.

What is FM and why was it selected as the first disease target for IMC-1?, page 5

5. *We note your disclosure that 85% of physicians queried suggest that they are neutral or unsatisfied with their current FM treatment options. Please remove discussions of the surveys in your Summary section. In the Business section, if true, clarify that this survey was conducted in 2014, as your disclosure in the Business section appears to indicate, and state whether the percentages discussed in that section are with respect to 75 physicians or to the 83 physicians and key opinion leaders. With respect to the Q&A chart on page 91, disclose the number of interviewed payors who responded with the answer in the last Q&A, and if true, clarify that the information presented in the chart and in the first full sentence on page 92 was also collected in 2014. Additionally, file consents from Lumleian and Triangle Insights Group pursuant to Securities Act Rule 436 as exhibits to your registration statement.*

The Registrant has revised page 4 to remove references to surveys in the Summary section of the Prospectus. The Registrant has revised page 77 to clarify when the survey was conducted and provide additional details regarding how the survey was conducted.

Further, the Registrant respectfully submits that Lumleian and Triangle Insights Group are not “experts” within the meaning of Rule 436 of the Securities Act and, accordingly, the Registrant does not believe a consent is required to be filed as an exhibit to the Registration Statement.

Rule 436 of the Securities Act requires that a consent be filed if any portion of a report or opinion of an “expert” is quoted or summarized as such in a registration statement. Section 7 of the Securities Act provides that an expert is “any accountant, engineer, or appraiser, or any person whose profession gives authority to a statement made by him.”

Lumleian and Triangle Insights Group are both consulting firms that primarily collect and aggregate survey and statistical data, and the related information contained in the registration statement reflects the aggregate survey and collected data. The Registrant submits that such data does not reflect the opinion or judgment of an “expert,” and that Lumleian and Triangle Insights Group are not amongst the enumerated professions under Section 7 of the Securities Act, nor is it within a “profession [that] gives authority to a statement made by [such providers].” As such, the Registrant believes that Lumleian and Triangle Insights Group are not among the class of persons subject to Section 7 and Rule 436 of the Securities Act as “experts” unless the Registrant expressly identifies it as an expert or the statements are purported to be made on the authority of such provider as an “expert.” The Registrant has neither expressly identified Lumleian or Triangle Insights Group as an “expert” in the registration statement nor purported to make statements in the registration statement on the authority of either Lumleian or Triangle Insights Group as an “expert.” Accordingly, the Registrant believes that Lumleian and Triangle Insights Group should not be considered “experts” within the meaning of U.S. federal securities laws.

In addition, the Registrant notes that the consent requirements of Rule 436 of the Securities Act are generally directed at circumstances in which an issuer has engaged a third-party expert or counsel to prepare a valuation, opinion or other report specifically for use in connection with or incorporated into a registration statement. In this instance, the Registrant respectfully advises the Staff that the data was prepared by Lumleian and Triangle Insights Group for the Registrant for research purposes, not as a report for purposes of the registration statement. The reports were not intended as an industry report to be used in or incorporated into the registration statement, but rather to make an assessment of the Registrant's marketplace. As such, the data provided by each was not prepared specifically in connection with or for the purpose of inclusion in the registration statement or to otherwise satisfy any specific disclosure requirement.

As a result of the foregoing, the Registrant respectfully submits that Lumleian and Triangle Insights Group do not need to provide a consent to be filed as an exhibit to the registration statement.

Building out our Pipeline, page 7

6. *The table of your pipeline chart on page 8 should reflect the actual, and not the anticipated, status of your pipeline candidates as of the latest practicable date. Please shorten the arrow for FM as your disclosure states that you have not yet commenced your Phase 2b trial. Also explain why it is appropriate to show IMC-1 as half-way through Phase 1 clinical trials for IBS and Functional Somatic Syndrome when your disclosure states that you plan to initially target IMC-1 in FM and you indicate on page 7 that you may use one of your other NSAID/antiviral combinations to target other indications. If applicable, please revise to include disclosure regarding your discussions with the FDA regarding the use of the 505(b)(2) pathway for IMC-1 in the treatment of IBS or functional somatic syndrome or revise your pipeline table.*

The Registrant has revised the chart and disclosure on page 6 to more clearly indicate that the Phase 2a study has been completed and that Phase 1 trials are not needed by the Registrant for IBS and Functional Somatic Syndrome. Phase 1 studies are not required for each indication pursued at the molecular level because the completed IMC-1 Phase 1 supports all forward potential therapeutic targets for the development candidate. If the Registrant pursues those paths it may move directly to Phase 2 trials.

FM Phase 2b Clinical Program Timelines Expected to Deliver Results in Q4 2021, page 7

7. *We note your timeline chart indicates that you expect to "deliver results in Q4 2021" and your chart shows topline results beginning in December 2021. However, elsewhere in the prospectus, you state that you "expect to report top line results by Q1 2022," as well as "final results by the first quarter of 2022." Please reconcile your statements and please explain "DBL."*

The Registrant has revised page 5 and page 86 to clarify that the Registrant expects topline results in Q1 2022 and has revised the table to remove the reference to "DBL."

Our Leadership Team, page 8

8. *You refer to Kevin Phelan as your regulatory lead. However, he does not appear to be an officer or director, and is not otherwise discussed in your prospectus. Please delete the reference to Mr. Phelan, or advise.*

The Registrant has revised page 6 to remove the reference to Mr. Phelan.

Implications of Being an Emerging Growth Company, page 10

9. *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.*

The Registrant acknowledges your request and confirms that there are no written communications, as defined in Rule 405 under the Securities Act, that the Registrant, or anyone authorized to do so on the Registrant's behalf, will present to potential investors in reliance on Section 5(d) of the Securities Act other than what will be filed with the Commission as a free writing prospectus pursuant to Rule 433.

Risk Factors, page 15

10. *We note your risk factor disclosure regarding adverse events on page 22 that patients treated with IMC-1 in your Phase 2 study discontinued due to adverse events at a rate lower than patients treated with placebo. We also note your disclosure on page 86 that 2 patients treated with IMC-1 in your Phase 2 study had serious adverse events. Please balance your risk factor disclosure here to discuss the serious adverse events observed.*

The Registrant has revised page 20 to disclose the serious adverse events observed.

11. *On page 11 you state that you have "irrevocably elected to take advantage of this extended transition period" under Section 107(b) of the JOBS Act. However, on page 72 you state you "are electing not to take advantage of the extended transition period" and your risk factor disclosure on page 51 states that you "have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards," but then states that investors may find your common stock less attractive because you may rely on these exemptions. Please correct these apparent inconsistencies. If you elect to opt out of these provisions, please indicate as such on the cover page.*
-

The Registrant has revised pages 9, 49 and 70 to clarify that the Registrant has elected to take advantage of the extended transition period under Section 107(b) of the JOBS Act.

12. *Please add a risk factor discussing the interests of related parties in this transaction. We note, for example, that Mr. Burch will receive restricted stock units upon the closing of this offering equal to 5% of the shares outstanding prior to the closing.*

The Registrant has revised page 47 to include an additional risk factor relating to the interests of the directors and officers of the Registrant and their combined holdings after the closing of the offering.

Use of Proceeds, page 56

13. *Refer to the first and second bullet points. Please clarify whether or not you expect to complete the IMC-1 FM Phase 2b trial and the chronic toxicology study with the proceeds of the offering. To the extent any material amounts of other funds are necessary to accomplish the specified purposes, state the amounts and sources of other funds needed for each specified purpose and the sources. Refer to Instruction 3 to Item 504 of Regulation S-K.*

The Registrant has revised page 54 to clarify that it expects the proceeds of the offering to be sufficient to complete the IMC-1 FM Phase 2b trial and the chronic toxicology study.

Management's Discussion and Analysis of Financial Condition and Results of Operations Results of Operations
Research and Development Expenses, page 68

14. *You disclose on page 66 that you track external research and development expenses for each study. Please expand your disclosures to break out external research and development expenses by each significant product candidate, including at a minimum for IMC-1, for each period presented.*

The Registrant has revised page 64 to included expanded disclosure on research and development expenses.

15. *You disclose that there was an increase in patent costs included in research and development expenses during the six months ended June 30, 2020. Please tell us how patent costs meet the definition of research and development expenses in ASC 730-10 as these costs appear to be the same or similar to activities described in ASC 730-10-55-2i, which are not generally considered research and development.*

The Registrant evaluated all costs presented as research and development costs and determined that the patent costs are related to activities similar to those described in ASC 730-10-55-2i. Accordingly, the Registrant concluded the activities do not meet the definition of research and development activities. The amount of patent costs included in research and development expenses for the six months ended June 30, 2020 and 2019 were \$33,705 and \$15,789, respectively. For the years ended December 31, 2019 and 2018 patent costs included in research and development expense were \$35,555 and \$39,386, respectively. The Registrant evaluated the effect of these errors in classification under ASC 250, Accounting Changes and Error Corrections, Staff Accounting Bulletin (“SAB”) No. 108, Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements and SAB No. 99, Materiality. The errors did not materially misstate any previously issued financial statements and the correction of the errors prospectively is also not expected to be material. The Registrant considered both quantitative and qualitative characteristics of the errors and required corrections and determined it was not necessary to restate the financial statements or unaudited interim period financial statements that were previously issued. The Registrant will reclassify the amounts to general and administrative expenses and disclose the correction to conform the comparative amounts with the proper presentation of costs in future filings. In light of the immateriality of the change and underlying amounts, the Registrant has removed the disclosure of the increase in patent costs to remove the apparent contradiction with accounting under ASC 730-10-55-2i.

Founders' Vision, page 73

16. *Please revise the vision statement as follows:*
- *Revise the first paragraph to explain whether the drug studied in collaboration with the university was IMC-1. If IMC-1 was not used in the study revise your disclosure accordingly. If IMC-1 was the drug candidate, revise your Business section to include a discussion of the study, or advise, and also explain whether you have the rights to use such study results.*

The Registrant has revised page 71 to clarify that Dr. Pridgen conducted the study in his private practice. The University of Alabama assisted with the corroboration of his findings, as further described on page 81.

- *Revise the sixth sentence in the first paragraph and the third paragraph to remove the implication that IMC-1 is effective in treating fibromyalgia, including your statement that IMC-1 "goes much further" than current treatments.*
-

The Registrant has revised page 71 to remove the implication that IMC-1 is effective in treating fibromyalgia.

Business, page 74

17. *We note your references in this section and elsewhere in your prospectus to various external sources, including with respect to your own Phase 2a trial. Referring investors to sources outside your registration statement for material information is not sufficient to meet your disclosure obligation. Please revise your disclosure to include all material information in your prospectus, such that you do not need to refer investors to external sources for additional information, including, for example, a discussion of the secondary endpoints of your Phase 2a trial. To the extent you retain discussions of other studies and/or surveys, ensure that you disclose sufficient information so that an investor may understand their significance, such as how those surveyed were selected, what information was provided to those surveyed, and sufficient explanations of study results. Additionally, all graphics should be accompanied by narrative disclosure that clearly explains the context for the graphic.*

In response to this comment, the Registrant has carefully reviewed each instance in which it cites to an external source. The Registrant respectfully submits that it has not referred investors to outside sources for the purpose of meeting its disclosure obligation. Rather, the Registrant has included citations for certain information as a way of providing the support for the statistics and other information actually included in the registration statement and does not intend that investors should review such external sources to gather additional information.

Notwithstanding the foregoing, based on its review of the citations to external sources, the Registrant has removed nine of the citations, including in the discussion of the secondary endpoints of the Phase 2a trial, and has revised the Registration on pages 76, 77, and 79, accordingly.

Further, the Registrant has revised the Registration Statement to ensure that each chart is labeled and there is a narrative disclosure accompanying each.

18. *We note your disclosure on page F-11 regarding a Know-How License Agreement you entered into with the University of Alabama. Please disclose the material terms of this agreement and file it as an exhibit or explain to us why it is not material to an investment decision.*

The Registrant has revised page 90 to include a description of the material terms of the Know-How License Agreement and the Know-How License agreement is attached as Exhibit 10.7 to the Registration Statement.

19. *We note several statements in this section implying the efficacy of your product candidates, such as your statement on page 81 that the synergistic response is "clear and compelling," and on page 86 that you believe the tolerability of IMC-1 "reflects [its] efficacy." Efficacy is a determination that is solely within the authority of the FDA or similar foreign regulators. You may present clinical trial end points and objective data resulting from trials without concluding efficacy. Please revise these statements accordingly.*

The Registrant has revised pages 79 and 84 to remove statements that imply efficacy of IMC-1.

Our Company, page 74

20. *We note your chart and disclosure on the top of page 76. Please include additional disclosure on the Numerical Rating Scale 24 hour recall pain data and the Revised Fibromyalgia Impact Questionnaire (FIQ-R) with LOCF/BOCF imputation. For example, it is unclear whether or not the measurements are based on a similar pain scale to be included in the same chart.*
-

The Registrant has revised page 82 to include a description of the pain scales used in the studies.

Background of Fibromyalgia (FM), page 77

21. *We refer to your references in the graphics on page 78 and in your numbered list on page 92 that the prevalence of fibromyalgia in the U.S. is approximately 21 million. Please revise your narrative disclose to explain the basis for this conclusion, as we note you state on page 89 that approximately eight million Americans are afflicted with fibromyalgia.*

The Registrant has revised page 86 to clarify that based on estimates up to 21 million people in the U.S. are afflicted with fibromyalgia.

Fibromyalgia: A Serious Condition with Unmet Medical Need, page 79

22. *We refer to your summarization of patient comments regarding limitations of three drugs approved by the FDA for the management of fibromyalgia. Revise to state the number of total patients interviewed or submitted comments at such meeting, and the number of such patients who indicated the disclosed issues. Additionally, please state whether there have been similar PFDD meetings since 2014 where patients submitted comments and explain what is a PFDD meeting.*

The Registrant has revised page 77 to include the additional information you requested regarding the PFDD meetings.

23. *You state on page 80 that current treatments for fibromyalgia are "ineffective," and then cite to an internet survey of 2,596 patients. Please expand your disclosure to explain how the patients were selected for the survey and whether the graphic shows results from the same survey.*

The Registrant has revised page 77 to include additional information regarding the internet survey.

Discovery and Development, page 82

24. *Please clarify your disclosure regarding the GI biopsy study to state whether you were involved with such study. If you were not, please disclose whether you expect to rely on the data in seeking regulatory approval, and if so, whether you have the ability to do so.*
-

The Registrant has revised page 81 relating to the GI biopsy study in accordance with your request.

Adverse Event Report Phase 2a Clinical Study, page 86

25. *We note statements comparing Savella, Cymbalta, Lyrica to IMC-1 at the bottom of page 86. As this comparison is not based on head-to-head studies, please delete this discussion, or advise.*

The Registrant has deleted the head-to-head comparison on page 84.

26. *We refer to your discussion of the questionnaire results on page 87. Please revise to explain whether the results were part of your secondary endpoints or otherwise significant for your approval process, or if the information is being used to inform further studies.*

The Registrant has deleted the discussion referenced above on page 84.

Regulatory and Development Timeline, page 87

27. *We note your planned reliance on the 505(b)(2) approval pathway. Please identify and describe the studies and results you intend to rely on, including the identification of the parties that performed the studies. Additionally, describe the requirements you must satisfy in order to rely on the Section 505(b)(2) pathway.*

The Registrant has revised page 85 to include a description of the studies and results that will be relied on and the requirements for reliance on the Section 505(b)(2) approval pathway.

28. *You state on page 88 that a toxicology study resulted in toxicities that were known and associated with the reference drugs. Please disclose all serious adverse events observed.*

The Registrant has revised page 85 and 86 to include a description of the results that the FDA determined warranted further study, such as testicular and kidney toxicity.

Intellectual Property, page 92

29. *Please expand your disclosure regarding your intellectual property portfolio to clarify whether or not the three Composition of Matter patents relate to your lead product candidate, IMC-1. In addition, please revise your disclosure to include additional information on the foreign patents, including: whether or not they relate to IMC-1, type of patent protection, jurisdiction and patent expiration period.*

The Registrant has revised page 89 to clarify that the patents relate to IMC-1 and the Registrant has provided the additional information requested relating to the Registrant's foreign patents.

Management, page 104

30. *For each director, please ensure that you disclose his principal occupations and employment during the past five years (or more, if material), including the names and principal business of any corporation or other organization at which he was employed. Also briefly discuss the specific experience, qualifications, attributes or skills that led to the conclusion that the person should serve as a director for the company in light of the company's business and structure. Refer to Item 401(e)(1) of Regulation S-K.*

The Registrant has revised pages 102 to 105 to include the principal occupations and employment during the past five years (or more, if material), including the names and principal business of any corporation or other organization at which he was employed and the information required by Item 401(e)(1).

Board Composition and Election of Directors, page 106

31. *You state that your Operating Agreement will not be in effect upon the closing of the offering, and your certificate of incorporation and bylaws will go into effect upon the closing. However, you also state on page 58 that the corporate conversion will take place prior to the effectiveness of the registration statement. Please clarify your disclosure regarding when the conversion will take place, and when the new governing documents will take effect. If the conversion will take place upon closing, please file all governing documents that will continue to be in effect at the time of effectiveness.*

The conversion to a Delaware corporation will occur immediately prior to the effectiveness of the Registration Statement. Consequently, the certificate of incorporation and bylaws will go into effect at that time. The Registrant has revised page 105 to clarify the timing of the corporate conversion and which governing documents will be in effect.

Principal Stockholders, page 118

32. *Please identify the natural persons who hold the investment and voting power of the shares held by the 5% or greater shareholders identified in your table.*

The Registrant has revised page 118 to identify the natural persons who hold the investment power of the shares held by any entity that holds shares of the Registrant in accordance with the Item 403 of Regulation S-K.

Please contact me at (215) 979-1206 with any questions or further comments regarding the Registrant's responses to the Staff's comments.

Sincerely,

Duane Morris LLP

/s/ Darrick M. Mix

Darrick M. Mix

cc: Greg Duncan, Virios Therapeutics, LLC
