

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

September 11, 2020

Greg Duncan Chief Executive Officer Virios Therapeutics, LLC 44 Milton Avenue Alpharetta, GA 30009

> Re: Virios Therapeutics, LLC Registration Statement on Form S-1 Filed August 28, 2020 File No. 333-248447

Dear Mr. Duncan:

We have reviewed your amended 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. Unless we note otherwise, our references to prior comments are to comments in our August 19, 2020 letter.

#### Registration Statement on Form S-1 filed August 28, 2020

# Prospectus Summary, page 1

- 1. We refer to prior comment 1. Please further revise your disclosures on page 1 to disclose that in the treatment group, there were two serious adverse events, one of which is a non-ST segment elevation myocardial infarction, which may be treatment-related. Explain to us why it is appropriate to include a discussion in the Prospectus Summary of discontinuation rates. Also we note that the graphic above the timeline on page 5 appears to be a remainder reference to your surveys, and your graphic at the top of page 6 refers to detailed study results including p-values. Revise to delete the graphics.
- 2. Please add a bullet in your summary of risks section or balancing disclosure elsewhere in the Prospectus Summary to note that the fast track designation may not lead to a faster

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development or regulatory review process. Additionally, revise the summary of risks section so that they are of the same prominence as the discussion of your strategies.

# Building out our Pipeline, page 5

3. We note your response to prior comment 6 and your revised pipeline table. We note, in your response, that you will be relying on completed Phase 1 study data for IMC-1. However, you do not disclose elsewhere in the prospectus the results or completion of Phase 1 trials for IMC-1. If you have completed Phase 1 trials for IMC-1 please describe them in your Business section. If you are not relying on Phase 1 trials for IMC-1, please clarify the table to make clear that you believe you will be able to rely on the 505(b)(2) regulatory pathway for IBS and Functional Somatic Syndrome, and disclose whether you have had discussions with the FDA regarding your ability to rely on the pathway for IMC-1 for these two indications.

#### Risk Factors, page 13

4. We note your revised disclosures on page 47 in response to prior comment 12. Please expand your disclosures, including in the title of the risk factor, either here or elsewhere, to also explain that Mr. Burch will be receiving equity awards in connection with the IPO.

# Management's Discussion and Analysis of Financial Condition and Results of Operations Research and Development Expenses, page 66

5. We note your response to prior comment 14. Please further revise the disclosure to break out the dollar amount of external research and development expenses incurred for each period presented. Alternatively, disaggregate research and development expenses by nature or type of expense for each period presented.

#### Business, page 72

6. We acknowledge your revised disclosures in response to prior comment 17. However, we note your disclosure still includes many footnote references to various external sources. We continue to note that it is not appropriate to refer investors to external sources for additional information. To the extent you intend to retain your discussion of the information from these sources, revise to disclose sufficient information so that an investor may understand their significance without needing to refer to these sources, and if you are referring to results from studies, clearly state whether you are able to rely on such data in seeking FDA approval for your product candidates, and if you are not, explain why such information is relevant. As examples only, you present a graphic of patient prescription usage from 2008 to 2010 without sufficient narrative information explaining how the results were derived, and you have multiple statements on page 79 discussing conclusions without sufficient information regarding those studies. Additionally, as such detailed information is not appropriate for the Prospectus Summary, please revise to

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remove all references to external sources in such section.

7. Please move the graphic on page 74 discussing secondary endpoints to accompany your narrative discussion of the Phase IMC-1 trial so that the results are shown in the appropriate context and ensure that there is narrative disclosure for all information shown in the table.

#### Our Company, page 72

8. We note your response to prior comment 4 and your revised disclosure in various places of your prospectus. Please remove your statements on page 75 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."

### Our Novel Mechanism of Action ("MOA"), page 79

9. We note your response to prior comment 3 and your revised disclosure in the Prospectus Summary. Please remove your references here and elsewhere to any statement that IMC-1 has a "favorable" safety profile given this determination is solely within the authority of the U.S. Food and Drug Administration.

#### Market and Competition, page 86

- 10. We acknowledge your response to prior comment 5. However, we continue to believe that consents are required from Lumleian and Triangle Insights Group pursuant to Securities Act Rule 436 because your registration statement attributes certain disclosures and conclusions to these entities. For guidance please refer to Question 141.02 of Compliance and Disclosure Interpretations for Securities Act Sections. In the alternative, substantially revise your disclosures relating to these surveys so that disclosures and conclusions are not attributed to them.
- 11. We note your revised disclosures in response to prior comment 21 that there are up to 21 million Americans afflicted with fibromyalgia. As previously requested, please revise your narrative disclosure to explain the basis for this conclusion. We note that the National Fibromyalgia & Chronic Pain Association states on its website that approximately 10 million Americans have fibromyalgia.

# Board Composition and Election of Directors, page 105

12. We note your response to prior comment 31 and your revised disclosure on page 105. However, we still note inconsistencies throughout the prospectus on when the certificate of incorporation will go into effect. For example on page 49 and page 105 you state that the certificate of incorporation will go into effect "effective upon the closing of the offering." Please reconcile your disclosures.

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**Executive and Director Compensation** 

Employment Agreements, page 110

13. We note that the employment agreement for Richard Burch contains provisions relating to potential payments upon termination or change in control. Please revise to discuss such provisions, as required by Item 402(q) of Regulation S-K.

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 Vanessa Robertson at 202-551-3649 or Kevin Vaughn at 202-551-3494 if you have questions regarding comments on the financial statements and related matters. Please contact Jason Drory at 202-551-8342 or Dorrie Yale at 202-551-8776 with any other questions.

Sincerely,

Division of Corporation Finance Office of Life Sciences

cc: Darrick M. Mix, Esq.