



DIVISION OF
CORPORATION FINANCE

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

August 19, 2020

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

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

Dear Mr. Duncan:

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.

Draft Registration Statement on Form S-1 filed July 24, 2020

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.

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.

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.

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.

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.

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.

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."

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.

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.

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.

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.
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.

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.

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.
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.

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.
 - 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.

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.
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.
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.

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.

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.

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.
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.

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.

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.
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.

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.
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.

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.

Greg Duncan
Virios Therapeutics, LLC
August 19, 2020
Page 7

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.

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.

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.

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.