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

DIVISION OF
CORPORATION FINANCE

December 14, 2021

Harith Rajagopalan, M.D., Ph.D.
Chief Executive Officer
Fractyl Health, Inc.
17 Hartwell Avenue
Lexington, MA 02421

Re: Fractyl Health, Inc.
Draft Registration Statement on Form S-1
Submitted November 9, 2021
CIK 0001572616

Dear Dr. Rajagopalan:

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

A Letter From Our Co-Founder, page iii

1. We refer to the letter from your co-founder. Please revise your presentation so that the letter does not appear in the forepart of the registration statement prior to your Summary.

2. Please revise your founder letter, page 1 of the Summary and page 123 of the Business section to clarify the source for the following three disclosures: (i) there will be 50 million people in the United States with type 2 diabetes in 2035, (ii) more than 50% of these patients will have poorly controlled disease and (iii) that we will be spending $2 trillion per year combating T2D.

Our Solution: Revita, page 2

3. We note your statements here and elsewhere in the prospectus that (i) Revita is intended to target the organ-level root cause of T2D with an endoscopic procedure that does not require ongoing patient adherence and (ii) Revita does not rely on perfect patient adherence or persistence to chronic therapy, unlike diet and lifestyle interventions or pharmacologic management. Please revise your disclosure here and elsewhere in the prospectus to clarify that your studies of the Revita system have involved ongoing OADs and/or a GLP-1ra as well as lifestyle counseling, including a tailored diet. Alternatively, please advise.

4. Please tell us whether you are aware of independent, peer-reviewed studies which characterize the dysfunctional duodenal mucosa as a root cause of T2D. To the extent that these and similar statements throughout the prospectus, including on page 116 and page 130, where you refer to dysfunctional duodenal mucosa as a driver of insulin resistance, are based on management's belief, please so state.

5. We note your statement highlighting that Revita, in combination with ongoing oral antidiabetic agents, or OADs, and/or a glucagon-like peptide-1 receptor agonist, and lifestyle counseling, has been observed to improve glucose control and reduce the need for insulin for 18 to 24 months. With a view to revised disclosure, please tell us your basis for making performance claims beyond 48 weeks. Based on your disclosures on pages 141-152, it is not clear that you have conducted any human trials that assessed patients beyond 48 weeks or that any improvement measured by anyone beyond 48 weeks is statistically significant.

6. Please revise your disclosure to indicate whether the "prototype rendering" of the Revita console is the console that is being used in the Revitalize-1 trial.

7. We note your discussion of the Breakthrough Device designation for Revita. Please revise your disclosure here and throughout the prospectus where the Breakthrough Device designation is mentioned to clarify that the process of medical device development is inherently uncertain and that there is no guarantee that this designation will accelerate the timeline for approval or make it more likely that Revita will be approved. Also, revise the prospectus, where appropriate, to disclose, if known, which of the four criteria discussed on page 161 served as the basis for Revita's designation.

Our Development Pipeline, page 5

8. Please revise your pipeline chart with respect to Rejuva to show Phase 1, Phase 2 and Phase 3 columns.

Our Team, page 5

9. We note that you identify certain entities as investors in your company here and on page 119. However, certain of these entities do not appear to be among your principal stockholders as disclosed on page 203. If material, please expand your disclosure to describe the nature of each such entity's investment in your company and explain to us why including this information is appropriate. Please also explain in the response your plans to update investors about any changes these entities make with respect to their investments in your company. Alternatively, please remove these entities from your disclosure.

What Sets Us Apart, page 6

10. Please balance your summary that describes the advantages of your product candidates with equally prominent disclosure regarding adverse results or disadvantages. For instance, and without limitation, we note your disclosures elsewhere in the prospectus that very few products utilizing gene transfer have been approved in the U.S. or Europe and no gene therapy products that utilize an endoscopic method of administration have been approved.

Summary Risk Factors, page 8

11. Please revise the eighth risk factor on page 8 to explain that there is uncertainty as to whether patients will need additional procedures in the future.

Management's Discussion and Analysis of Financial Condition and Results of Operations
Research and Development expenses, page 107

12. Please separately disclose in tabular form your R&D expenses incurred for each year presented by product candidate or project.

Business, page 116

13. We refer to your risk factor disclosure on page 40 indicating that you have not yet studied the ability of Revita to be used in repeated procedures. Please revise the Business section to discuss your plans for studying this area, including the timing of the referenced study or studies relative to your plans to file a PMA application and commercialize. To the extent that your plans do not call for studies in the near term, please discuss whether the uncertainty cited in the risk factor could impact the scope of your PMA approval, and explain in greater detail how it could have a material adverse impact on clinical utility and commercial adoption.

Type 2 Diabetes Overview, page 124

14. Please revise to provide the source for the figures presented in the graphic at the top of page 124. Please also revise to provide sources for the data that appear in the graphics on pages 134 and 135.

Clinical Data Overview: Revita, page 141

15. Please revise your disclosure regarding the Revita-2 and the Revita First-in-Human studies to clearly state whether (i) each study achieved its endpoints and (ii) the reported reductions in HbA1c, MRI-PDFF, HOMA-IR and weight were statistically significant.

Ongoing Revitalize-1 Pivotal Clinical Study, page 145

16. We note that the primary efficacy endpoint for the Revitalize-1 study occurs at 24 weeks. We note that this timeframe is shorter than for some of the completed studies referenced in this section and for the performance claims highlighted in the Summary. Please discuss the rationale for establishing the pivotal trial endpoint at 24 weeks and your basis for determining, if true, that data at 24 weeks could support a finding of durable effectiveness. To the extent that the scope of PMA approval or commercialization is dictated or impacted by the 24-week timeframe, please revise to discuss.

INSPIRE Pilot Study, page 150

17. Please identify the investigators and indicate whether these results have been published. Depending on your responses to this comment and comment 5 above, we may have further comment.

Intellectual Property, page 155

18. Please revise this section to reflect your disclosure on page 68 indicating that you are aware of (i) third-party patents and patent applications that may be construed to cover your product candidates or technologies, including Revita and (ii) pending patent applications that if they result in issued patents could be alleged to be infringed by some of your product candidates or technologies, including Revita.

Executive and Director Compensation, page 191

19. Please revise this section to describe your employment arrangements with your named executive officers.

General

20. 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 copes of the communications.

You may contact Michael Fay at 202-551-3812 or Daniel Gordon at 202-551-3486 if you have questions regarding comments on the financial statements and related matters. Please contact Alan Campbell at 202-551-4224 or Joe McCann at 202-551-6262 with any other questions.

Sincerely,

Division of Corporation Finance
Office of Life Sciences

cc: Nathan Ajiashvili