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

DIVISION OF
CORPORATION FINANCE

January 4, 2022

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

Re: Fractyl Health, Inc.
Amendment No. 1 to Draft Registration Statement on Form S-1
Submitted December 20, 2021
CIK 0001572616

Dear Dr. Rajagopalan:

We have reviewed your amended 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.

Amendment No. 1 to Draft Registration Statement on Form S-1

Our Solution: Revita, page 2

1. We note your response to prior comment 5 and revised disclosures identifying certain results as derived from "pooled, post-hoc" analysis. Please revise the Business section to present the complete results from all pooled and/or post-hoc analyses while discussing the protocols followed and any material limitations to these analyses. Please disclose the number of patients analyzed, indicate whether certain categories of patients were not analyzed and specify whether the findings were statistically significant. In this regard, we note that your disclosure on page 40 indicates that the observed reduction in HbA1c through 24 months was in "certain patients" who underwent the Revita DMR Procedure. Also, tell us whether you plan to include pooled, post-hoc analysis in your PMA

application to demonstrate durability beyond 48 weeks, if required. We may have further comment regarding this analysis, including the existing descriptions in the Prospectus Summary, after reviewing your response.

What Sets Us Apart, page 6

2. We note your response to prior comment 10 and re-issue. Please balance your disclosure that describes the advantages of your product candidates and approach with equally prominent disclosure regarding challenges, adverse results or disadvantages.

A Letter From Our Co-Founder, page 117

3. We note your response to prior comment 2. Please revise the prospectus, where appropriate, to identify the epidemiologists who have made the $2 trillion a year projection for 2030 and revise your disclosures to clarify whether this is a U.S. or a worldwide projection. Similarly revise the prospectus, where appropriate, to identify the epidemiologists who estimate that half of the individuals with T2D in the United States are not achieving targeted disease control.

Business, page 118

4. We note your response to prior comment 13 and re-issue in part. Please revise your Business section to discuss your plans for prospectively studying the safety and effectiveness of potential repeat procedures relative to your plans to file a PMA 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.

Ongoing Revitalize-1 Pivotal Clinical Study, page 147

5. We note your response to prior comment 16 and re-issue in part. Please revise your disclosure to discuss the rationale for establishing the pivotal trial endpoints at 24 weeks and your basis for determining, if true, that data at 24 weeks will support a finding of durable effectiveness. In this regard, please revise to discuss what feedback, if any, FDA staff has provided you with respect to the endpoints and what would be required to support a successful PMA application for the applicable indication. To the extent that the scope of PMA approval or commercialization is dictated or impacted by the 24-week timeframe, please revise to discuss.

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