United States securities and exchange commission logo

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
FirstName LastNameHarith Rajagopalan, M.D., Ph.D.
support a successful PMA application for the applicable indication. To
the extent that the
Comapany
scopeNameFractyl Health,orInc.
of PMA approval commercialization is dictated or impacted
by the 24-week
timeframe, please
January 4, 2022 Page 2 revise to discuss.
FirstName LastName
Harith Rajagopalan, M.D., Ph.D.
FirstName LastNameHarith Rajagopalan, M.D., Ph.D.
Fractyl Health, Inc.
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January NameFractyl Health, Inc.
4, 2022
January
Page 3 4, 2022 Page 3
FirstName LastName
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