

LATHAM & WATKINS LLP

January 11, 2022

VIA EDGAR AND KITEWORKS

Division of Corporation Finance
Office of Life Sciences
U.S. Securities and Exchange Commission
100 F Street, N.E.
Washington, DC 20549-6010

Attention: Alan Campbell
Joe McCann
Michael Fay
Daniel Gordon

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

FIRM / AFFILIATE OFFICES

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To the addressees set forth above:

On behalf of our client, Fractyl Health, Inc. (the “*Company*”), set forth below are the Company’s responses to the comments of the Staff (the “*Staff*”) of the Division of Corporation Finance of the Securities and Exchange Commission (the “*Commission*”) in its letter dated January 4, 2022, relating to the Company’s Amendment No. 1 to the draft registration statement on Form S-1 submitted on December 20, 2021 (the “*Registration Statement*”).

The Company has confidentially submitted today Amendment No. 2 to the Registration Statement (“*Amendment No. 2*”), together with this letter, via EDGAR submission. For the Staff’s reference, we are providing to the Staff copies of this letter as well as both a copy of Amendment No. 2 and a copy marked to show all changes from the Registration Statement submitted on December 20, 2021.

For convenience of reference, the text of the comments in the Staff’s letter has been reproduced in bold and italics herein. The Company has also provided its response immediately after each numbered comment. Capitalized terms used but not otherwise defined herein have the meanings assigned to such terms in Amendment No. 2.

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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.*

Response: In response to the Staff’s comment, the Company has revised the disclosure on pages 2, 3, 4, 40, 119, 120, 140, 149, 150, 153 and 154 of Amendment No. 2.

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 disadvantage.*

Response: In response to the Staff’s comment, the Company has revised the disclosure on pages 6, 7 and 122 of Amendment No. 2.

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.*

Response: In response to the Staff’s comment, the Company has revised the disclosure on pages 1, 117, 118 and 125 of Amendment No. 2.

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*

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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.

Response: In response to the Staff's comment, the Company has revised the disclosure on pages 3, 40, 119, 140, 148 and 157 of Amendment No. 2. In addition, the Company respectfully advises the Staff that the Company may conduct post-approval studies evaluating the safety and effectiveness of potential repeat procedures of Revita. In correspondence with the FDA, the Company has been advised that its study design for Revitalize-1 is adequate and may support a future marketing approval or clearance if the study is successfully executed and meets its stated endpoints.

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 application 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.*

Response: In response to the Staff's comment, the Company has revised the disclosure on pages 147 and 148 of Amendment No. 2. In addition, the Company respectfully advises the Staff that in correspondence with the FDA, the Company has been advised that its study design for Revitalize-1 is adequate and may support a future marketing approval or clearance if the study is successfully executed and meets its stated endpoints. The Company plans to have pre-submission discussions with the FDA leading up to its PMA submission for Revita.

We hope that the foregoing has been responsive to the Staff's comments and look forward to resolving any outstanding issues as quickly as possible. Please do not hesitate to contact me at (212) 906-2916 with any questions or further comments you may have regarding this filing or if you wish to discuss the above.

Sincerely,

/s/ Nathan Ajiashvili

Nathan Ajiashvili
of LATHAM & WATKINS LLP

Enclosures
cc: (via e-mail)

Harith Rajagopalan, M.D., Ph.D., Chief Executive Officer, Fractyl Health, Inc.
Johan Brigham, Latham & Watkins LLP
Evan Smith, Latham & Watkins LLP
Edwin O'Connor, Goodwin Procter LLP
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