

LATHAM & WATKINS LLP

September 21, 2023

VIA EDGAR

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

Attention: Tyler Howes
Alan Campbell
Michael Fay
Brian Cascio

**Re: Fractyl Health, Inc.
Amendment No. 5 to Draft Registration Statement on Form S-1
Submitted August 22, 2023
CIK 0001572616**

To the addressees set forth above:

On behalf of our client, Fractyl Health, Inc. (the “**Company**”), set forth below is the Company’s response to the comment of the Staff (the “**Staff**”) of the Division of Corporation Finance of the Securities and Exchange Commission (the “**Commission**”) in its letter dated September 15, 2023, relating to the Company’s Amendment No. 5 to the draft registration statement on Form S-1 submitted on August 22, 2023 (the “**Registration Statement**”).

The Company has confidentially submitted today Amendment No. 6 to the Registration Statement (“**Amendment No. 6**”), together with this letter, via EDGAR submission. For convenience of reference, the text of the comment in the Staff’s letter has been reproduced in bold and italics herein. The Company has also provided its response immediately after the comment. Capitalized terms used but not otherwise defined herein have the meanings assigned to such terms in Amendment No. 6.

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Amendment No. 5 to Draft Registration Statement on Form S-1

Prospectus Summary

Overview, page 1

1. *We note your statements here and elsewhere regarding your expected timing to initiate a first-in-human clinical study of Rejuva. Please remove this disclosure as it appears to be premature given your disclosure indicates that you have yet to nominate a candidate, complete preclinical studies and submit an IND for this program.*

Response: In response to the Staff's comment, the Company has revised the disclosure on pages 2, 6, 9, 121, 124, 130, 133 and 162 of Amendment No. 6.

Our Development Pipeline, page 2

2. *Please revise the Revita section of your pipeline table so that the same indication does not appear twice. In that regard, we note that you have included arrows for both "Germany Real World Registry" and "Insulin-Treated T2D", which appear to be duplicative. Please also revise your pipeline table with respect to Rejuva to show Phase 1, Phase 2 and Phase 3 columns to clearly represent what development stages must be completed prior to commercialization of this candidate.*

Response: In response to the Staff's comment, the Company has revised the disclosure on pages 2 and 121 of Amendment No. 6. In addition, the Company respectfully advises the Staff that it obtained a CE mark from the EU and UK in 2016 for Revita for the improvement of glycemic control in patients with inadequately controlled T2D despite oral and/or injectable glucose lowering medications and/or long-acting insulin, as the Company has updated and indicated in Footnote 1 of the pipeline table. The "Germany Real World Registry" study is an ongoing post-approval study in real-world patients with inadequately controlled T2D on at least one ADA and the Revitalize-1 "Insulin-Treated T2D" study is a pivotal Phase 3 clinical study in patients with inadequately controlled T2D despite being on up to three ADAs and 20 to 100 units of insulin daily, and, therefore, these studies are not duplicative. The Company respectfully advises the Staff that it has also revised its pipeline table with respect to Rejuva to show Phase 1, Phase 2 and Phase 3 columns.

3. *Please revise this subsection or elsewhere in the Prospectus Summary, as appropriate, to disclose why you did not commercially launch Revita in Europe prior to the first half of 2023.*

Response: In response to the Staff's comment, the Company has revised the disclosure on pages 1, 120 and 162 of Amendment No. 6.

What Sets Us Apart, page 3

4. *We note that your disclosure here and elsewhere indicates that your product candidates are designed to target dysfunction with “one-time” treatments. However, your disclosure throughout the prospectus also indicates that the Revita system is designed to enable “repeatable” metabolic improvement. Please reconcile your disclosure.*

Response: In response to the Staff’s comment, the Company has revised the disclosure on pages 3, 5, 122, 129 and 156 of Amendment No. 6. In addition, the Company respectfully advises the Staff that “one-time” treatments of Revita and Rejuva are designed to provide long-term metabolic benefits with fewer interventions needed between subsequent administrations of Revita and/or Rejuva unlike the current pharmacotherapy standard of care, which requires chronic dosing (e.g., daily, weekly or monthly). For clarity, the Company has replaced the phrase “one-time treatments” with “single administration.”

We hope that the foregoing has been responsive to the Staff’s comment 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

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