## LATHAM & WATKINS LLP

December 14, 2023

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## **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. 6 to Draft Registration Statement on Form S-1

Submitted September 21, 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 October 3, 2023, relating to the Company's Amendment No. 6 to the draft registration statement on Form S-1 submitted on September 21, 2023.

The Company has publicly filed today the registration statement on Form S-1 (the "*Registration Statement*"), 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 the Registration Statement.

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## LATHAM&WATKINS LLP

## Amendment No. 6 to Draft Registration Statement on Form S-1

**Prospectus Summary** 

Our Development Pipeline, page 2

1. We note your response to prior comment 2 and reissue in part. Please further clarify if both the "CE Mark" approval arrow and "Insulin-Treated T2D" arrow are for separate indications. To the extent both of these arrows are targeting the same indication, revise the Revita section of your pipeline table so that the same indication does not appear twice.

Response: In response to the Staff's comment, the Company has revised the pipeline table on pages 3 and 123 of the Registration Statement. The Company respectfully advises the Staff that the "CE Mark" approval arrow and the "Insulin-Treated T2D" arrow are for separate indications. As disclosed in the Registration Statement, the Company 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 indicated in Footnote 1 of the pipeline table on pages 3 and 123 of the Registration Statement. The "Germany Real World Registry" study is evaluating Revita in 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 evaluating Revita in 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, a separate indication to the CE Mark approval.

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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 Evan Smith, Latham & Watkins LLP Jonathan Sarna, Latham & Watkins LLP Edwin O'Connor, Goodwin Procter LLP Alicia Tschirhart, Goodwin Procter LLP