



DIVISION OF  
CORPORATION FINANCE

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

September 15, 2023

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

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

Dear Harith 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. 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.

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

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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.

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.

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.

You may contact Michael Fay at 202-551-3812 or Brian Cascio at 202-551-3676 if you have questions regarding comments on the financial statements and related matters. Please contact Tyler Howes at 202-551-3370 or Alan Campbell at 202-551-4224 with any other questions.

Sincerely,

Division of Corporation Finance  
Office of Industrial Applications and  
Services

cc: Nathan Ajiashvili, Esq.