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

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): October 21, 2026

Fractyl Health, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-41942
(Commission File Number)

27-3553477
(IRS Employer
Identification No.)

**3 Van de Graaff Drive
Suite 200
Burlington, Massachusetts**
(Address of Principal Executive Offices)

01803
(Zip Code)

Registrant's Telephone Number, Including Area Code: (781) 902-8800

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.00001 par value per share	GUTS	The Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.05 Costs Associated with Exit or Disposal Activities.

On October 21, 2026, Fractyl Health, Inc. (the “*Company*”) adopted a plan to sharpen its strategic focus on its Revita[®] program in connection with a strategic reprioritization. As part of the plan, the Company will reduce its workforce by approximately 45% of the Company’s current headcount. The reduction in force is expected to be completed during the fourth quarter of 2026.

The Company estimates that it will incur charges of approximately \$2 million for severance and other employee termination-related costs, with the majority of such costs to be incurred in the fourth quarter of 2026. The estimated costs that the Company expects to incur, and the timing thereof, are subject to a number of assumptions and actual results may differ. The Company may also incur other charges or cash expenditures not currently contemplated due to events that may occur as a result of, or associated with, the workforce reduction, including potential impairment charges, if any. If required, the Company will amend this Current Report on Form 8-K at such time as its management is able in good faith to estimate the amount, or range of amounts, of these additional charges.

Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

Retirement of Executive Officer

In connection with the workforce reduction, on October 21, 2026, Jay Caplan announced his retirement. effective October 30, 2026 (the “*Separation Date*”), from his executive roles as the Company’s President and Chief Product Officer. Mr. Caplan will be entitled to severance benefits as set forth in his employment agreement. Mr. Caplan’s Employment Letter Agreement, dated January 26, 2024, by and between the Company and Mr. Caplan (the “*Caplan Agreement*”), is filed as Exhibit 10.7 to the Company’s Registration Statement on Form S-1/A (File No. 333-276046), filed with the Securities and Exchange Commission (the “*SEC*”) on January 29, 2024. Mr. Caplan is expected to continue to support the Company as a senior advisor to the leadership team following the Separation Date.

In connection with Mr. Caplan’s retirement, the Company intends to enter into separation and consulting agreements with Mr. Caplan that will provide for the terms of Mr. Caplan’s cessation of employment. Such separation and consulting agreements have not yet been finalized. The Company will provide a description of the material terms of the separation and consulting agreements by filing a Current Report on Form 8-K after the information is determined or becomes available.

Appointment Of President

In connection with Mr. Caplan’s departure, on October 21, 2026, the Board of Directors of the Company appointed Harith Rajagopalan, M.D., Ph.D., the Company’s Co-Founder, Chief Executive Officer and a member of the Board, to serve as President of the Company, effective as of the Separation Date, in addition to his continuing roles as Chief Executive Officer and as a director of the Company. Dr. Rajagopalan will continue to serve as the Company’s principal executive officer.

Item 8.01 Other Events.

On October 22, 2026, the Company issued a press release announcing its sharpened strategic focus on Revita, the workforce reduction, and that the Company is discontinuing internal development of its Rejuva gene therapy program and is seeking strategic alternatives for the program, a copy of which is filed as Exhibit 99.1 hereto.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Description
99.1	Press Release dated October 22, 2026.
104	Cover Page Interactive Data File (embedded with the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Fractyl Health, Inc.

Date: October 22, 2026

By: /s/ Harith Rajagopalan

Harith Rajagopalan, M.D., Ph.D.

Co-Founder, Chief Executive Officer and Director
(Principal Executive Officer)



Fractyl Health Sharpens Focus on Revita Following Positive Pivotal Results, Advancing Toward Planned FDA De Novo Submission in Post-GLP-1 Weight Maintenance

Following positive topline six-month REMAIN-1 pivotal results, Revita advancing toward planned FDA De Novo submission in late Q4 2026 and anticipated 12-month pivotal data readout in Q1 2027

Workforce reduction aligns organization behind Revita's near-term clinical and commercial opportunity

Company discontinuing development of Rejuva candidates and seeking strategic alternatives to maximize the value of its Rejuva gene therapy program

Cash runway extended into Q2 2027; quarterly operating cash burn expected to be reduced by ~50% to approximately \$8 million by end of Q2 2027

BURLINGTON, Mass., October 22, 2026 (GLOBE NEWSWIRE) – Fractyl Health, Inc. (Nasdaq: GUTS) (the Company or Fractyl), a clinical-stage metabolic therapeutics company focused on pioneering novel approaches to treat obesity and type 2 diabetes (T2D), today announced that it is sharpening its focus and concentrating its financial and operational resources on advancing Revita®, its lead product candidate, toward potential U.S. Food and Drug Administration (FDA) marketing authorization and commercialization in post-GLP-1 weight maintenance.

The decision follows the Company's recent announcement of positive topline six-month results from the REMAIN-1 Pivotal Cohort, which met its prespecified six-month co-primary endpoint with high statistical significance in weight regain compared to sham ($p=0.0023$). The Company believes these results reinforce Revita's potential to become the first durable procedural therapy for post-GLP-1 weight maintenance, addressing what the Company believes is one of the largest unmet needs in obesity care as millions of patients seek sustainable solutions to maintain weight loss following GLP-1 discontinuation.

To support this sharpened focus, Fractyl will implement a reduction in force affecting approximately 45% of its workforce. These actions are intended to create a streamlined, Revita-focused organization, reduce quarterly cash burn by approximately 50% by the end of Q2 2027 and concentrate resources on realizing Revita's clinical and commercial potential.

Fractyl will also discontinue internal development of its Rejuva gene therapy program and is seeking strategic alternatives to maximize the value of the program.

In conjunction with these organizational changes, Jay Caplan, Co-Founder, President and Chief Product Officer of Fractyl, will retire from his executive roles with the Company, effective October 30, 2026. Mr. Caplan is expected to continue to support the Company as a senior advisor to the leadership team.

"We believe the positive pivotal results from REMAIN-1 represent a defining moment for Fractyl and represent an enormous opportunity for Revita potential to fundamentally change how obesity is treated and offer a durable approach to weight maintenance," said Harith Rajagopalan, M.D., Ph.D., Co-Founder and Chief Executive Officer of Fractyl. "A million patients per month in the United States face the challenge of weight regain after discontinuing GLP-1 therapies. Our goal is for Revita to establish an entirely new therapeutic category by aiming to reverse years of diet-induced damage to the gut. We expect the capital we have today to be sufficient to fund our planned De Novo submission and upcoming

12-month pivotal data, and we are excited to focus our attention and align our resources behind our near-term opportunity.

"While these decisions are difficult, particularly those impacting our colleagues, we believe this focused strategy will position Fractyl to operate more efficiently and advance Revita toward its clinical and commercial potential. I also want to personally thank my fellow co-founder, Jay Caplan, for his leadership, partnership and invaluable contributions to Fractyl over the years. Jay has been instrumental in building the Company. We are deeply grateful for his dedication and lasting contributions, as well as those of all our colleagues affected by this transition."

Strategic Actions to Advance Revita, Reduce Cash Burn and Extend Runway

The Company is implementing the following measures to support execution through upcoming potential clinical and regulatory milestones.

- **Workforce Reduction:** The Company will reduce its workforce by approximately 45%, with the reduction expected to be substantially completed by November 2026.
- **Extended Cash Runway:** Based on its current operating plan and anticipated expense reductions, including the expected cash costs associated with the reprioritization, the Company expects its existing cash and cash equivalents to fund operations into Q2 2027.
- **Reduced Quarterly Cash Burn:** As cost reductions take effect and REMAIN-1 Pivotal Cohort expenditures decline, the Company expects operating quarterly cash burn to be reduced by approximately 50%, to approximately \$8 million, by end of Q2 2027.
- **Rejuva Strategic Alternatives:** The Company will discontinue internal development of its Rejuva gene therapy program and seek strategic alternatives to maximize the value of the program. There can be no assurance that the Company's review of strategic alternatives for Rejuva will result in any transaction, and the Company does not intend to disclose further developments unless and until it determines that disclosure is appropriate or required.

Fractyl Forward: Advancing Revita Toward a New Therapeutic Category in Obesity Care

The Company continues to anticipate the following anticipated milestones:

- **Late Q4 2026:** Planned FDA De Novo marketing application submission for Revita in post-GLP-1 weight maintenance.
- **Q1 2027:** Anticipated topline 12-month data from the REMAIN-1 Pivotal Cohort, including the second co-primary endpoint.
- **Late 2027:** Potential FDA marketing authorization.
- **Early 2028:** Potential U.S. commercial launch.

About Revita

The Revita® DMR System is Fractyl's lead product candidate, designed to remodel the duodenal lining via a single, minimally invasive endoscopic procedure intended to restore healthy nutrient sensing and signaling disrupted by chronic metabolic disease. By targeting duodenal dysfunction, Revita is designed to address an underlying driver of obesity and enable durable weight maintenance following GLP-1 discontinuation. Revita has received FDA Breakthrough Device Designation for weight maintenance in people with obesity who discontinue GLP-1 therapies. Revita is for investigational use only in the United States and is CE marked in the European Union and United Kingdom.

About Fractyl Health

Fractyl is a clinical-stage metabolic therapeutics company focused on pioneering novel approaches to treat obesity and type 2 diabetes. The Company's lead product candidate, Revita, is an endoscopic procedural therapy in pivotal development for post-GLP-1 weight maintenance. Fractyl's goal is to change

the course of metabolic disease, advancing treatment from chronic management toward prevention and reversal of disease. Fractyl is headquartered in Burlington, Massachusetts.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release that do not relate to matters of historical fact are forward-looking statements. These statements may be identified by words such as “aims,” “anticipates,” “believes,” “could,” “estimates,” “expects,” “forecasts,” “goal,” “intends,” “may,” “plans,” “possible,” “potential,” “seeks,” “will” and variations of these words or similar expressions that are intended to identify forward-looking statements, although not all forward-looking statements contain these words. Forward-looking statements in this press release include, without limitation, statements regarding: the potential benefits of the Company's sharpened strategic focus and reprioritization, including the proposed workforce reduction and its anticipated impact on the Company's expenditures and financial runway; the promise and potential impact of the Company's clinical trial data and product candidates, including Revita's potential for maintaining weight loss after GLP-1 based therapy discontinuation and its potential to be the first procedural therapy for post-GLP-1 weight maintenance; the design, initiation, timing and results of clinical studies or readouts, including readouts from the REMAIN-1 Pivotal Cohort, including 12-month data; the potential launch or commercialization of any of the Company's product candidates or products; the Company's regulatory strategy, including the timing of any potential De Novo marketing application submission and the potential use and benefits of the De Novo pathway (FDA pre-submission feedback is advisory and non-binding, or as to the timing of any such authorization); the potential treatment population or benefits for any of the Company's product candidates or products; the Company's strategic and product development objectives and goals; the Company's expected quarterly cash burn and cash runway; the Company's exploration of strategic alternatives for Rejuva and the potential benefits thereof; and the timing of any of the foregoing. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause the Company's actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including, but not limited to, the risks that are discussed more fully in its filings with the Securities and Exchange Commission (the SEC), including the “Risk Factors” section of its Annual Report on Form 10-K for the year ended December 31, 2025, filed with the SEC on March 24, 2026, and other documents it subsequently files with or furnishes to the SEC, including its Quarterly Report on Form 10-Q for the quarter ended June 30, 2026, filed with the SEC on August 10, 2026. These forward-looking statements are based on management's current estimates and expectations. While the Company may elect to update such forward-looking statements at some point in the future, it disclaims any obligation to do so, even if subsequent events cause its views to change.

Contact

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