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): August 10, 2026

Fractyl Health, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-41942**	**27-3553477**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

3 Van de Graaff Drive **Suite 200** **Burlington, Massachusetts**	**01803**
(Address of Principal Executive Offices)	**(Zip Code)**

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

Not Applicable
(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 2.02 Results of Operations and Financial Condition.

On August 10, 2026, Fractyl Health, Inc. (the "Company") announced its financial results for the quarter ended June 30, 2026 and provided a corporate update. A copy of the press release in connection with the announcement is being furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information contained in Item 2.02 of this Current Report on Form 8-K (including Exhibit 99.1 attached hereto) shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended (the "Securities Act"), or the Exchange Act, except as expressly provided by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

The following exhibit and shall be deemed to be furnished, and not filed:

Exhibit No.	Description
99.1	Fractyl Health, Inc. Press Release dated August 10, 2026
104	Cover Page Interactive Data File (embedded within 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: August 10, 2026

By: /s/ Harith Rajagopalan

Harith Rajagopalan, M.D., Ph.D.
Co-Founder, Chief Executive Officer and Director
(Principal Executive Officer)

Exhibit 99.1

Fractyl Health Reports Second Quarter 2026 Financial Results and Business Updates

One-year REMAIN-1 Midpoint Cohort data show Revita patients maintained up to 84% of prior GLP-1-induced weight loss versus 46% with sham in patients receiving complete duodenal ablations — the first randomized evidence of durable, drug-free weight maintenance

One-year open-label REVEAL-1 Cohort data provide real-world evidence of durable weight maintenance, with patients maintaining approximately 78% of their prior GLP-1-induced weight loss after a single Revita procedure

REMAIN-1 Pivotal Cohort topline data on track for early Q4 2026, paving the way for potential FDA De Novo submission in post-GLP-1 weight maintenance in late Q4 2026

Cash runway guidance into early 2027, beyond anticipated Pivotal data readout and FDA De Novo Submission

Conference call today at 4:30 p.m. ET

BURLINGTON, Mass., August 10, 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 second quarter 2026 financial results and provided business updates. The Company also reiterated all previously disclosed 2026 Revita® clinical and regulatory milestones, including topline 6-month randomized data from the REMAIN-1 Pivotal Cohort expected in early Q4 2026, and its cash runway guidance into early 2027.

“With one-year randomized data for the REMAIN-1 Midpoint Cohort and open label data for REVEAL-1 Cohort, we have the clearest evidence yet that a single Revita procedure can meaningfully reduce weight regain after GLP-1 discontinuation, with the greatest benefit observed in patients who received an adequate dose of duodenal ablation,” said Harith Rajagopalan, M.D., Ph.D., Co-Founder and Chief Executive Officer of Fractyl. “Together with a favorable one-year safety profile and cash runway into early 2027, these results give us continued confidence in the design and execution of our ongoing REMAIN-1 Pivotal Cohort, with topline six-month data on track for early Q4 2026 and a potential FDA De Novo submission to follow later in the quarter. As we approach these anticipated milestones, we are also building the commercial infrastructure needed to bring Revita to the patients with the greatest need.”

Select Recent Revita Clinical Highlights

Fractyl is studying Revita in the REMAIN-1 weight maintenance program, which is designed to evaluate Revita's potential to maintain weight loss following GLP-1 based therapy discontinuation. The REMAIN-1 program includes three distinct participant cohorts that are conducted under a single IDE: the REVEAL-1 Cohort, the REMAIN-1 Midpoint Cohort and the REMAIN-1 Pivotal Cohort.

- In June 2026, Fractyl reported one-year data from the open-label REVEAL-1 Cohort, showing that participants who underwent a single Revita procedure experienced a mean total body weight change of 5.3% after GLP-1 discontinuation (n=15), maintaining approximately 78% of their prior GLP-1-induced weight loss. These findings provide real-world evidence and support Revita’s potential to be a compelling procedural therapy for post-GLP-1 weight maintenance.
- In July 2026, Fractyl reported one-year randomized data from the REMAIN-1 Midpoint Cohort demonstrating durable weight maintenance after a single Revita procedure. The treatment effect was greatest in a pre-specified optimized population, combining complete duodenal ablation (>14 cm) with higher GLP-1-induced run-in weight loss (≥17.5%), where Revita-treated participants maintained approximately 84% of their GLP-1-induced weight loss compared to 46% in sham participants (least squares mean weight regain of 4.1% versus 13.5% of body weight; n=10 versus 8 for Revita versus sham). No device- or procedure-related serious adverse events occurred through one year, and no new device-related treatment-emergent adverse events were observed between six and 12 months. These randomized,

sham-controlled results provide direct read-through to the REMAIN-1 Pivotal Cohort ahead of its topline six-month readout in early Q4 2026.

Commercial Readiness

In June 2026, Fractyl strengthened its commercial leadership team with the appointment of Mike Zumdahl as Senior Vice President, Market Access and Commercial Strategy. Mr. Zumdahl brings experience building reimbursement and health economic infrastructure for breakthrough procedural therapies, most recently at Inari Medical, and joins Fractyl as the Company prepares for the anticipated REMAIN-1 Pivotal Cohort topline readout in early Q4 2026. Fractyl plans to provide additional detail on its commercial strategy and market opportunity at an upcoming Investor Day in September.

Fractyl Forward: Reiterating Path to Pivotal Readout and Potential Regulatory Submission

With one-year data now reported from both the REVEAL-1 Cohort and the REMAIN-1 Midpoint Cohort, and randomization of the REMAIN-1 Pivotal Cohort complete, Fractyl is advancing toward its two remaining anticipated 2026 milestones: pivotal readout and potential U.S. regulatory submission. The Company reiterates its previously announced cash runway into early 2027, beyond the anticipated pivotal data readout.

- **Early Q4 2026**: Topline 6-month randomized data from the REMAIN-1 Pivotal Cohort.
- **Late Q4 2026**: Potential U.S. Food and Drug Administration (FDA) De Novo marketing application submission in post-GLP-1 weight maintenance.
- **Q1 2027:** Topline one-year data from the REMAIN-1 Pivotal Cohort.

As in all applications, the FDA indicated that final pathway determinations will be made following review of the complete safety dataset, which the Company intends to include in its potential De Novo marketing application submission.

Rejuva® Development Progress and Anticipated 2026 Rejuva Milestones

Rejuva is Fractyl's gene therapy platform designed to enable long-term remission of T2D and obesity by durably reprogramming pancreatic islet cells to endogenously produce metabolic hormones. The lead product candidate, RJVA-001, is being advanced for patients with inadequately controlled T2D. The second candidate, RJVA-002, is a preclinical-stage dual GIP/GLP-1 gene therapy designed to treat obesity. In April 2026, Fractyl received clinical trial application (CTA) authorization for RJVA-001 in the Netherlands. Fractyl also plans to conduct the clinical trial for RJVA-001 at sites in Australia. In July 2026, Fractyl received ethics committee approval in Australia.

Fractyl reiterates its anticipated 2026 Rejuva milestone:

- **H2 2026:** First-in-human dosing of RJVA-001, subject to site activation, and expected reporting of preliminary data.

Second Quarter 2026 Financial Results

- **Research and Development Expenses:** R&D expenses were $13.8 million for the quarter ended June 30, 2026, compared to $21.2 million for the same period in 2025. The decrease of $7.3 million was primarily related to reduced spending on Fractyl's Revita and Rejuva programs.
- **Selling, General and Administrative Expenses:** SG&A expenses were $5.3 million for the quarter ended June 30, 2026, compared to $4.9 million for the same period in 2025. The increase of $0.4 million was primarily driven by higher stock compensation expenses.
- **Net Loss:** For the quarter ended June 30, 2026, Fractyl reported a net loss of $25.5 million, compared to net loss of $27.9 million for the same period in 2025. The decrease in net loss of $2.4 million was driven by a $7.0 million reduction in operating expenses, $0.3 million lower non-cash loss from change in fair value of debt, $0.2 million higher interest income, partially offset by $5.1 million higher non-cash loss from change in fair value of warrant liabilities.
- **Adjusted EBITDA:** Adjusted EBITDA was negative $16.3 million for the quarter ended June 30, 2026, compared to negative $24.0 million for the same period in 2025. The decrease in the non-GAAP adjusted

loss of $7.7 million was primarily due to reduced operating expenses excluding stock compensation expenses.

- **Cash Position:** As of June 30, 2026, Fractyl had approximately $47.1 million in cash and cash equivalents. Based on current business plans, the Company believes its cash position will fund operations into early 2027.

Webcast and Conference Call Information

Fractyl will host a conference call to discuss its second quarter financial results and provide business updates on Monday, August 10, 2026, at 4:30 p.m. ET. A live webcast of the conference call can be accessed in the "Events" section of Fractyl's website at ir.fractyl.com. The webcast will be archived and available for replay for at least 30 days after the event.

About Fractyl Health

Fractyl is a clinical-stage metabolic therapeutics company advancing two differentiated candidates designed to target the root causes of obesity and T2D: Revita, a procedural therapy in pivotal development for post-GLP-1 weight maintenance, and Rejuva, an AAV-based gene therapy platform with its lead candidate RJVA-001 entering first-in-human clinical studies. Fractyl's goal is to advance metabolic disease treatment from chronic management toward prevention and reversal of disease. Fractyl is headquartered in Burlington, Massachusetts.

About Revita

Revita is Fractyl's lead product candidate, designed to remodel the duodenal lining via a one-time, minimally invasive endoscopic procedure intended to restore healthy nutrient sensing and signaling disrupted by chronic metabolic disease. 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 Rejuva

Fractyl's Rejuva platform is developing next-generation AAV-based, locally delivered gene therapies for the treatment of obesity and T2D. Rejuva leverages advanced delivery systems and proprietary screening methods to identify and develop metabolically active gene therapy candidates targeting the pancreas, with the goal of offering novel, disease-modifying therapies that address the underlying root causes of disease.

The platform's lead candidate, RJVA-001, has received Clinical Trial Authorization in the Netherlands to initiate a Phase 1/2 first-in-human clinical trial in T2D, the first clinical-stage program from the Rejuva platform. Fractyl expects to dose the first patient with RJVA-001 and report preliminary data in the second half of 2026, subject to site activation. Fractyl also plans to conduct the clinical trial for RJVA-001 at sites in Australia and has received ethics committee approval in Australia. Additional Rejuva candidates, including RJVA-002 (a dual GIP/GLP-1 gene therapy candidate designed to treat obesity), remain in preclinical development. In the United States, Rejuva is in preclinical development. No Investigational New Drug (IND) application has been filed with the U.S. Food and Drug Administration (the FDA), and Rejuva has not been approved or authorized by the FDA for use in humans.

Non-GAAP Financial Measures

This press release contains certain financial information that is not presented in conformity with U.S. generally accepted accounting principles (GAAP), including Adjusted EBITDA, which is a non-GAAP financial measure as defined in Regulation G promulgated under the Securities Exchange Act of 1934. This non-GAAP financial measure is provided as supplemental information to Fractyl's financial measures presented in this press release in accordance with GAAP.

The Company defines Adjusted EBITDA as net loss adjusted to exclude (i) interest income, net, (ii) depreciation expense, (iii) stock-based compensation expense, (iv) change in fair value of notes payable and (v) change in fair value of warrant liabilities.

Management believes Adjusted EBITDA provides useful supplemental information to investors regarding the Company's core operating performance and facilitates period-to-period comparisons by excluding items that are

non-cash or non-operational in nature and may vary in magnitude. Adjusted EBITDA is also used by management in evaluating the Company's operating performance and in planning and forecasting activities.

The non-GAAP financial measures used by Fractyl may not be the same or calculated in the same manner as those used and calculated by other companies. Non-GAAP financial measures have limitations as analytical tools and should not be considered in isolation or as a substitute for Fractyl's financial results prepared and reported in accordance with GAAP. This non-GAAP measure should not be construed as an inference that the Company's future results will be unaffected by unusual or non-recurring items. A reconciliation of Adjusted EBITDA reported in this press release to the most comparable GAAP measure for the respective periods appears in the table captioned "Reconciliation of GAAP Net Loss to Adjusted EBITDA" later in this press release.

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 expected initiation, timing, design, endpoints, site activation, and conduct of the RJVA-001 first-in-human clinical trial in the Netherlands and the RJVA-001 clinical trial in Australia; the timing and results of first-in-human dosing and reporting of preliminary data; Fractyl's regulatory strategy, including submissions to and communications with regulators in the European Union, Australia, and other jurisdictions; the promise, potential impact, and mechanism of action of RJVA-001 and Fractyl's Rejuva platform; Fractyl's anticipated financial performance, including cash and cash equivalents, for any period of time; Fractyl's expected cash runway; the promise and potential impact of Fractyl's preclinical or clinical trial data and product candidates, including Revita's potential for maintaining weight loss after GLP-1 based therapy discontinuation; the design, initiation, timing and results of clinical enrollment and any clinical studies or readouts, including readouts from the REVEAL-1 Cohort, the REMAIN-1 Midpoint Cohort and the REMAIN-1 Pivotal Cohort; the content, information used for, timing or results of any Investigational New Drug (IND)-enabling studies, IND applications, or CTAs; communications with regulators regarding the REVEAL-1 Cohort, the potential launch or commercialization of any of Fractyl's product candidates or products, the REMAIN-1 Midpoint Cohort and the REMAIN-1 Pivotal Cohort; the potential treatment population or benefits for any of Fractyl's product candidates or products; Fractyl's regulatory strategy, including potential use and benefits of the De Novo pathway (FDA pre-submission feedback is advisory and non-binding, and there is no assurance that FDA will accept a De Novo marketing application submission or that the Revita DMR System will receive marketing authorization); Fractyl's commercial readiness activities and the development of commercial infrastructure; the timing and content of any planned Investor Day or similar event; Fractyl's strategic and product development objectives and goals; 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 Fractyl'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 Fractyl's filings with the Securities and Exchange Commission (the SEC) including the "Risk Factors" section of Fractyl's Annual Report on Form 10-K for the year ended December 31, 2025, filed with the SEC on March 24, 2026, and other documents Fractyl subsequently files with or furnishes to the SEC, including Fractyl's 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 Fractyl may elect to update such forward-looking statements at some point in the future, Fractyl disclaims any obligation to do so, even if subsequent events cause Fractyl's views to change.

Contact

Brian Luque, Head of Investor Relations and Corporate Development

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Fractyl Health, Inc.
Selected Consolidated Balance Sheet Data
(in thousands)
(unaudited)

	June 30, 2026	December 31, 2025
Cash and cash equivalents	$ 47,140	$ 81,540
Restricted cash	4,255	4,255
Working capital [1]	33,866	69,247
Total assets	81,976	121,402
Notes payable, long-term	30,446	30,586
Total liabilities	83,641	111,944
Total stockholders' equity (deficit)	(1,665)	9,458

(1) Working capital is defined as total current assets less total current liabilities.

Fractyl Health, Inc.
Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except for share and per share information)
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
Operating expenses:				
Research and development	$ 13,812	$ 21,151	$ 29,410	$ 40,586
Selling, general and administrative	5,284	4,928	10,506	10,252
Total operating expenses	19,096	26,079	39,916	50,838
Loss from operations	(19,096)	(26,079)	(39,916)	(50,838)
Other income (expense), net:				
Interest income, net	431	226	1,024	729
Change in fair value of notes payable	(1,382)	(1,673)	(1,992)	(1,956)
Change in fair value of warrant liabilities	(5,484)	(348)	24,571	477
Other expense, net	(7)	(15)	(7)	(36)
Total other income (expense), net	(6,442)	(1,810)	23,596	(786)
Net loss and comprehensive loss	$ (25,538)	$ (27,889)	$ (16,320)	$ (51,624)
Net loss per share, basic and diluted	$ (0.16)	$ (0.57)	$ (0.10)	$ (1.05)
Weighted-average number of common shares outstanding, basic and diluted	158,648,963	49,042,926	158,570,993	48,952,525

Fractyl Health, Inc.
Reconciliation of GAAP Net Loss to Adjusted EBITDA
(in thousands)
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2026	2025	2026	2025
Net loss	$ (25,538)	$ (27,889)	$ (16,320)	$ (51,624)
Interest income, net	(431)	(226)	(1,024)	(729)
Depreciation	278	270	559	560
EBITDA	(25,691)	(27,845)	(16,785)	(51,793)
Stock-based compensation expense	2,496	1,785	5,027	3,191
Change in fair value of notes payable	1,382	1,673	1,992	1,956
Change in fair value of warrant liabilities	5,484	348	(24,571)	(477)
Adjusted EBITDA	$ (16,329)	$ (24,039)	$ (34,337)	$ (47,123)