Fractyl Health Reports Fourth Quarter and Full Year 2025 Financial Results and Business Updates

Mar 24, 2026

Completed randomization in REMAIN-1 Pivotal Cohort; topline 6-Month data expected in early Q4 2026

Received favorable FDA feedback on De Novo classification request; De Novo submission expected in late Q4 2026

Reports new post-hoc analyses from REMAIN-1 Midpoint Cohort showing statistically significant ablation-length (i.e., dose)-dependent treatment effect on post-GLP-1 weight maintenance at 6 months

Patients with greater GLP-1-induced weight loss prior to randomization also exhibited larger sham-adjusted treatment effects at 6 months, with effect size increasing over time

New analyses provide further support for Revita mechanism of action and REMAIN-1 Pivotal Cohort design

Reiterates cash runway guidance into early 2027, beyond anticipated Pivotal data readout

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

BURLINGTON, Mass., March 24, 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 fourth quarter and full year 2025 financial results and provided business updates. The Company also reported new post-hoc analyses from the REMAIN-1 Midpoint Cohort showing a statistically significant ablation length (i.e., dose)-dependent treatment effect on post GLP-1 weight maintenance at 6 months that further strengthens the Company's belief in the REMAIN-1 Pivotal Cohort, with topline 6-month randomized data expected in early Q4 2026 and, if positive, potential De Novo marketing application submission expected in late Q4 2026.

“Completion of randomization in the REMAIN-1 Midpoint and Pivotal Cohorts marks a critical execution milestone, and today's new analyses from the Midpoint Cohort 6-month data gives us even greater anticipation for what the pivotal study might show. Revita® is a procedural therapy that appears to work very much like a drug: the effect of weight maintenance is larger in patients with greater GLP-1 weight loss and in those who receive longer lengths of duodenal ablation. The REMAIN-1 Pivotal Cohort was prospectively designed and statistically powered to demonstrate Revita's effect across these dimensions,” said Harith Rajagopalan, M.D., Ph.D., Co-Founder and Chief Executive Officer of Fractyl Health. “Approximately 30 million patients are projected to be on GLP-1s by 2035. The majority will face discontinuation and significant weight regain. Fractyl stands alone developing the first potential procedural option for post-GLP-1 weight maintenance with pivotal data expected this year.”

New Post-Hoc Analyses from REMAIN-1 Midpoint Cohort Demonstrating Dose-Dependent Treatment Effect at 6 months, Providing Further Confidence in REMAIN-1 Pivotal Cohort Design

Fractyl is reporting 6-month results from new post-hoc analyses of the REMAIN-1 Midpoint Cohort evaluating the relationship between treatment effect, procedural dose (defined as length of duodenal ablation) and degree of GLP-1-induced weight loss prior to Revita treatment. The analyses demonstrate that Revita's treatment effect is ablation length (i.e., dose)-dependent and greatest in participants with longer ablation length and higher run-in weight loss, consistent with the biological rationale for Revita and analogous to the dose-response relationships observed with drugs.

Key findings from the post-hoc analyses (N=45) include:

- A statistically significant correlation between ablation length and weight maintenance in the Revita arm demonstrates that more complete duodenal ablation drives greater treatment effect (n=29; p=0.048), reinforcing the view that the duodenal mucosa is a compelling target.
- Among participants with above median GLP-1-induced weight loss, the study observed a 70% reduction in weight regain with widening separation from sham from 1 to 6 months (p=0.004), providing supportive evidence for a potentially substantial clinically meaningful effect size over time in a large patient population. These results are consistent with the view that patients at greatest need may derive the greatest benefit from Revita.
- In participants with above median GLP-1-induced weight loss who received greater than 14 cm duodenal ablation, Revita participants retained 88% of GLP-1 induced weight loss at six months compared to only 60% in sham participants.

Blinded operational data from the Pivotal Cohort confirm that mean and median ablation length was 16 cm and mean total body weight loss was 18.3%, placing the Pivotal Cohort squarely within the optimal treatment zone identified in the Midpoint post-hoc analysis. Taken together, these data further support the design and statistical analysis of the REMAIN-1 Pivotal Cohort and reinforce the Company's confidence in the ongoing pivotal study's ability to demonstrate a clinically meaningful and lasting treatment effect.

Select Recent Revita® Clinical Highlights

The Company 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.

The following highlights represent key clinical milestones from the Germany Real-World Registry study and across the REMAIN-1 program. For complete data disclosures, please refer to the Company's previously issued press releases and SEC disclosures, available at ir.fractyl.com.

- In November 2025, Fractyl reported 2-year data from the Germany Real-World Registry study showing that a single Revita procedure led to an average 8.9% total body weight loss and a 1.7% reduction in HbA1c in participants with obesity and advanced T2D with no device- or procedure-related serious adverse events reported to date.
- In December 2025, Fractyl reported positive 6-month REVEAL-1 Cohort open-label results showing sustained post-GLP-1 weight maintenance after a single Revita procedure. Participants who lost 24% total body weight (>50 lbs.) on GLP-1 drugs maintained stable weight 6 months after GLP-1 discontinuation and a single Revita treatment, with a 1.5% mean weight change observed with Revita (n=17), compared to ~10% weight regain at similar time points reported in published third-party studies after GLP-1 withdrawal alone.
- In January 2026, Fractyl announced compelling 6-month randomized REMAIN-1 Midpoint data showing durable weight maintenance with Revita after GLP-1 discontinuation. Participants with above median GLP-1-associated weight loss experienced approximately 70% less post-GLP-1 weight regain with Revita versus sham at 6 months. These pilot study results support the pivotal study design and further substantiate Revita's potential to be the first durable procedural therapy for post-GLP-1 weight maintenance.
- In February 2026, Fractyl completed participant randomization in the REMAIN-1 Pivotal Cohort.

Fractyl Forward: Anticipated 2026 Revita Milestones

With randomization complete, Fractyl is advancing toward multiple anticipated clinical and regulatory milestones toward 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.

In connection with its regulatory strategy, the Company received pre-submission feedback from the U.S. Food and Drug Administration (FDA), in which it acknowledged that the safety profile of the Revita DMR System, based on clinical data from over 300 procedures, is consistent with a Class II device classification. 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.

- Q2 2026: 1-year REVEAL-1 Cohort data.
- Q3 2026: 1-year REMAIN-1 Midpoint Cohort randomized data.
- Early Q4 2026: Topline 6-month randomized data from REMAIN-1 Pivotal Cohort.
- Late Q4 2026: Potential FDA De Novo marketing application submission in post-GLP-1 weight maintenance.

Select Recent Rejuva® Development Progress

Rejuva is Fractyl's gene therapy platform designed to achieve 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 dual GIP/GLP-1 gene therapy designed to treat obesity.

- In October 2025, Fractyl announced potent new preclinical data from RJVA-002, its dual GIP/GLP-1 Smart GLP-1™ gene therapy candidate for obesity, showing approximately 30% weight loss after a single administration in a translational obesity model, with no observed adverse effects.
- In the second half of 2025, Fractyl submitted Clinical Trial Applications (CTAs) for RJVA-001 in T2D to regulators in the EU (Netherlands) and Australia, advancing the program toward its anticipated first-in-human study.

Fractyl Forward: Anticipated 2026 Rejuva Milestones

- **Q2 2026**: Regulatory feedback on CTAs for RJVA-001.
- **H2 2026:** First-in-human dosing of RJVA-001, subject to CTA authorization, and expected reporting of preliminary data.

Fourth Quarter 2025 Financial Results

- **Research and Development Expenses:** R&D expenses were $16.5 million for the quarter ended December 31, 2025, compared to $20.3 million for the same period in 2024. The decrease during the quarter was primarily due to our strategic reprioritization announced in the first quarter of 2025, which resulted in lower personnel related costs and reduced costs associated with the pausing of the REVITALIZE-1 study, partially offset by increases due to progress made in our REMAIN-1 study.
- **Selling, General and Administrative Expenses:** SG&A expenses were $6.8 million for the quarter ended December 31, 2025, compared to $4.9 million for the same period in 2024. The increase was primarily due to the underwriters' commissions paid in connection with our August 2025 financing.
- **Net Loss:** For the quarter ended December 31, 2025, Fractyl reported a net loss of $43.7 million, compared to $25.0 million for the same period in 2024. The increase was primarily driven by a $20.2 million non-cash accounting change in fair value related to our warrant liabilities and does not reflect a change in our underlying operating performance. Operating expenses for the quarter ended December 31, 2025 were $1.9 million lower compared to the same period in 2024.
- **Adjusted EBITDA:** Adjusted EBITDA was negative $21.2 million for the quarter ended December 31, 2025, compared to negative $22.1 million for the same period in 2024. The decrease was primarily due to the decrease in operating expenses.
- **Cash Position:** As of December 31, 2025, Fractyl had approximately $81.5 million in cash and cash equivalents. Based on current business plans, the Company believes its cash position as of December 31, 2025, combined with $4.1 million subsequent proceeds from warrant exercises received in January 2026, will fund operations into early 2027.

Webcast and Conference Call Information

Fractyl will host a conference call to discuss its fourth quarter financial results and provide business updates on Wednesday, March 24, 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 Health is a clinical stage metabolic therapeutics company focused on pioneering novel approaches to treat obesity and type 2 diabetes. Our Revita® and Rejuva® candidates are designed to target root causes of metabolic diseases, allowing us to advance metabolic disease treatment from chronic management towards prevention and reversal of disease. Fractyl is headquartered in Burlington, Massachusetts.

About Revita®

Revita is Fractyl Health'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 Health's Rejuva platform focuses on developing next-generation adeno-associated virus (AAV)-based, locally delivered gene therapies for the treatment of obesity and T2D. The Rejuva platform is in preclinical development and has not yet been evaluated by regulatory agencies for investigational or commercial use. Rejuva leverages advanced delivery systems and proprietary screening methods to identify and develop metabolically active gene therapy candidates targeting the pancreas. The program aims to transform the management of metabolic diseases by offering novel, disease-modifying therapies that address the underlying root causes of disease.

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 EBITDA and Adjusted EBITDA, which are non-GAAP financial measures as defined in Regulation G promulgated under the Securities Exchange Act of 1934. These non-GAAP financial measures are 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: our anticipated financial performance, including cash and cash equivalents, for any period of time, our strategic reprioritization and related workforce reduction, including its implementation and the expected costs and benefits, if any; our expected cash runway; the promise and potential impact of our 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 our product candidates or products, the REMAIN-1 Midpoint Cohort and the REMAIN-1 Pivotal Cohort; the potential treatment population or benefits for any of our product candidates or products; our 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); our 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 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 factors discussed under the caption "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2025 to be filed with the Securities and Exchange Commission (the SEC) on March 24, 2026 and in our other filings with the SEC. 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, the Company disclaims any obligation to do so, even if subsequent events cause its views to change.

Contact

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

	December 31, 2025	December 31, 2024
Cash and cash equivalents	$ 81,540	$ 67,464
Restricted cash, long-term	4,255	4,255
Working capital[(1)]	69,247	51,988
Total assets	121,402	108,077
Notes payable, long-term	30,586	30,162
Total liabilities	111,944	79,653
Total stockholders’ equity	9,458	28,424

(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)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2025	2024	2025	2024

	(unaudited)	(unaudited)		
Revenue	$ —	$ 3	$ —	$ 93
Cost of goods sold	—	—	—	50
Gross profit	—	3	—	43
Operating expenses:				
Research and development	16,493	20,281	74,536	70,471
Selling, general and administrative	6,791	4,932	22,280	23,103
Total operating expenses	23,284	25,213	96,816	93,574
Loss from operations	(23,284)	(25,210)	(96,816)	(93,531)
Other income (expense), net:				
Interest income, net	645	726	1,540	4,146
Change in fair value of notes payable	(900)	(942)	(4,724)	2,830
Change in fair value of warrant liabilities	(20,177)	466	(40,901)	17,908
Other expense, net	(11)	(10)	(53)	(47)
Total other income (expense), net	(20,443)	240	(44,138)	24,837
Net loss and comprehensive loss	$ (43,727)	$ (24,970)	$ (140,954)	$ (68,694)

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

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2025	**2024**	**2025**	**2024**
	(unaudited)	**(unaudited)**		
Net loss and comprehensive loss	$ (43,727)	$ (24,970)	$ (140,954)	$ (68,694)
Interest income, net	(645)	(726)	(1,540)	(4,146)
Depreciation	279	223	1,129	677
EBITDA	(44,093)	(25,473)	(141,365)	(72,163)
Stock-based compensation expense	1,855	2,899	6,684	14,426
Change in fair value of notes payable	900	942	4,724	(2,830)
Change in fair value of warrant liabilities	20,177	(466)	40,901	(17,908)
Adjusted EBITDA	$ (21,161)	$ (22,098)	$ (89,056)	$ (78,475)