



Fractyl Health's Revita Meets Six-Month Co-Primary Endpoint in Ongoing REMAIN-1 Pivotal Study, With Highly Statistically Significant Reduction in Weight Regain After GLP-1 Discontinuation

Oct 16, 2026

REMAIN-1 met its six-month co-primary endpoint with high statistical significance ($p=0.0023$; mITT population); demonstrated 80% retention of GLP-1 induced weight loss vs 67% for sham

32% of Revita® participants in primary analysis population (mITT) were either weight stable or had further weight loss at 6-months post GLP-1 discontinuation vs 18% for sham (post hoc; nominal $p=0.020$)

Post hoc analyses demonstrated that patients receiving a single complete duodenal ablation with Revita (≥ 20 cm length) regained 3.8% total body weight vs 8.2% in sham, reflecting a 53% reduction in weight regain between Month 1 and Month 6 (nominal $p=0.003$)

Revita has been generally well-tolerated with no device- or procedure-related serious adverse events

Revita received FDA Breakthrough Device Designation for Post-GLP-1 weight maintenance; De Novo marketing application submission to the FDA planned for late Q4 2026; anticipated topline one-year data from the REMAIN-1 Pivotal Cohort and second co-primary endpoint planned for Q1 2027

Dedicated CPT code 1122T for the Revita procedure takes effect January 1, 2027, well ahead of a potential U.S. launch in early 2028

Investor webcast today at 8:00 a.m. ET

BURLINGTON, Mass., Oct. 16, 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 positive topline six-month results from the Pivotal Cohort of its ongoing REMAIN-1 study (Pivotal Cohort), a 308-participant, multicenter, randomized, double-blind, sham-controlled study of the Revita DMR System (Revita) for weight maintenance in adults with obesity following discontinuation of GLP-1 therapy. REMAIN-1 met its pre-specified six-month co-primary endpoint of weight loss retention, as patients treated with a single Revita procedure demonstrated a highly statistically significant reduction in weight regain compared to sham ($p=0.0023$). The second prespecified co-primary endpoint, the percentage of participants who maintain 5% or greater total body weight loss, will be assessed at 12 months. We believe these 6-month results reinforce the potential of Revita to be the first durable procedural therapy for post-GLP-1 weight maintenance and support the Company's planned De Novo marketing application submission in late Q4 2026.

Key Findings

- **Six-month co-primary endpoint met:** In the modified intention-to-treat (mITT) population ($N=308$), Revita participants maintained approximately 80% of their GLP-1-induced weight loss after a single treatment at six months, compared with 67% in sham participants (least-squares mean weight regain of 5.1% versus 8.2% of body weight; $n=176$ versus 74), with high statistical significance ($p=0.0023$). 32% of Revita participants were either weight stable or had further weight loss at 6-months post GLP-1 discontinuation ($<2\%$ regain or incremental loss), versus 18% for sham (post hoc; nominal $p=0.020$).
- **Dose-dependent effect observed:** In a post hoc analysis by ablation length, participants who received 12 to 18 cm of duodenal ablation had 43% less regain than sham (observed mean weight regain of 4.7% versus 8.2%; $n=107$ versus 74). Participants who received 20 cm or more had 53% less regain than sham (mean regain of 3.8%; $n=47$). This is consistent with results from the REMAIN-1 Midpoint Cohort that indicated more complete duodenal ablation drove greater treatment effect.
- **Treatment effect grew over time:** The difference in weight regain between Revita and sham widened at each assessment, nearly doubling from Month 3 to Month 6.
- **Favorable interim safety data: Revita has been well-tolerated in this ongoing study.** There have been no device- or procedure-related serious adverse events, no deaths, and no unanticipated adverse device effects observed as of the September 24, 2026, data cut-off date. Related adverse events were predominantly mild and peri-procedural, with 94% occurring within seven days of the procedure and the vast majority within two days. Consistent with upper GI endoscopy, we believe these generally mild peri-procedural adverse events support potentially broad outpatient use for Revita, if approved.

"These REMAIN-1 randomized, sham-controlled results are a game changer for the treatment of obesity and offer the potential to change the standard of care in weight loss maintenance. Every day, patients in our clinics who have done well on a GLP-1 ask the same question: 'Do I have to stay on this forever?' Our patients are actively seeking an alternative to a lifetime of GLP-1 therapy," said Adrian Dan, M.D., FACS, FASMBS, DABS-MBS, DABOM, Medical Director of the Weight Management Institute at Summa Health, and Professor of Surgery at Northeast Ohio Medical University. "This is the kind of evidence our field has been waiting for. Revita DMR represents a new therapeutic category, and an important inflection point in obesity management. If authorized, Revita could provide an attractive alternative for patients who want to lock in the weight loss and health benefits achieved with medication."

"We started Fractyl with the simple premise that targeting duodenal dysfunction may enable scalable disease modification in obesity and metabolic disease for the very first time. The success of the REMAIN-1 pivotal study in its first co-primary endpoint establishes the thesis that targeting the duodenum may enable a durable metabolic reset for millions of patients who seek to treat the root cause of their obesity rather than rely on medicines to manage the disease," said Harith Rajagopalan, M.D., Ph.D., Co-Founder and Chief Executive Officer of Fractyl. "A randomized, double-blind trial of this size meeting its primary endpoint with this level of statistical significance signals the potential for a new therapeutic category in obesity care. We are grateful to the more than 300 participants, the investigators, and the site teams who made REMAIN-1 possible. With these data in hand, we intend to initiate our De Novo marketing application to the FDA in late Q4 2026, report 12-month results in the first quarter of 2027, and prepare for a potential U.S. launch that would make Revita the first procedural entrant into the single biggest unmet market need in obesity, the post-GLP-1 weight maintenance category."

Fractyl Forward: Path from Pivotal Readout to Potential Regulatory Submission and Launch

With positive topline six-month data now reported from the REMAIN-1 Pivotal Cohort, Fractyl is advancing toward its remaining anticipated 2026 milestone, a potential DeNovo regulatory submission, and preparing for a potential U.S. commercial launch.

- **Late Q4 2026:** Potential U.S. Food and Drug Administration (FDA) De Novo marketing application submission in post-GLP-1 weight maintenance.
- **January 1, 2027:** Category III CPT code 1122T for the Revita procedure takes effect.
- **Q1 2027:** Anticipated topline one-year 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.

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.

Webcast

Fractyl Health will host a webcast today, October 16, 2026, at 8:00 a.m. Eastern Time. The live webcast can be accessed by clicking [this link](#). This webcast can also be found 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 REMAIN-1 Weight Maintenance Program

REMAIN-1 is Fractyl's pivotal program evaluating Revita for weight maintenance in adults with obesity following discontinuation of GLP-1 therapy. The Pivotal Cohort (N=308) is a randomized, double-blind, sham-controlled study conducted at more than 30 U.S. sites in adults with obesity (BMI 30 to 45) without type 2 diabetes who had not previously received GLP-1 therapy. Participants received tirzepatide to achieve at least 15% total body weight loss and, after discontinuing the drug, were randomized 2:1 to a single Revita procedure or a sham endoscopic procedure. The study has two co-primary endpoints in the modified intention-to-treat (mITT) population: (i) percent total body weight regain at six months (Revita versus sham) and (ii) a responder rate defined as the proportion of Revita participants maintaining at least 5% total body weight loss relative to their pre-tirzepatide weight at one year, assessed against an FDA-mandated pre-specified performance goal of greater than 50%. Pre-specified key secondary endpoints include the Complete Ablation population (>14 cm of duodenal ablation), the higher run-in weight loss population (at least 17.5%), and the Optimized population (both). Per the pre-specified statistical analysis plan, key secondary endpoints are formally evaluated for statistical inference following assessment of the 12-month co-primary endpoint. The REMAIN-1 program also includes the open-label REVEAL-1 Cohort and the randomized, sham-controlled Midpoint Cohort (N=45), which reported one-year results in June and July 2026, respectively. Topline 12-month data from the Pivotal Cohort are expected in Q1 2027.

About Revita

The Revita® DMR System 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 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, an endoscopic procedural therapy in pivotal development for post-GLP-1 weight maintenance with positive pivotal six-month data, 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 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 promise and potential impact of our 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 translatability of results and scalability of technique related to Revita; the design, initiation, timing and results of clinical studies or readouts, including readouts from the REMAIN-1 Midpoint Cohort and the REMAIN-1 Pivotal Cohort, including 12-month data; the potential launch or commercialization of any of our product candidates or products; our 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); coding, coverage and payment for Revita, including the effectiveness and use of Category III CPT code 1122T and eligibility for or timing of Medicare transitional pass-through payment or other coverage, which are subject to AMA and CMS review and are not assured; the potential treatment population or benefits for any of our product candidates or products; 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 our 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 our filings with the Securities and Exchange Commission (the SEC), including the “Risk Factors” section of our Annual Report on Form 10-K for the year ended December 31, 2025, filed with the SEC on March 24, 2026, and other documents we subsequently file with or furnish to the SEC, including our 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 we may elect to update such forward-looking statements at some point in the future, we disclaim any obligation to do so, even if subsequent events cause our views to change.

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