Fractyl Health Reports Positive One-Year REVEAL-1 Open-Label Results Showing Sustained Post-GLP-1 Weight Maintenance After a Single Revita® Procedure

Jun 4, 2026

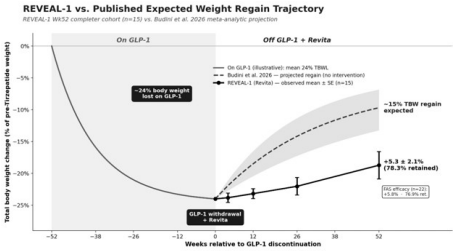
Participants retained ~78% of GLP-1 induced total body weight loss one year after discontinuation and a single Revita procedure

5.3% mean weight change observed with Revita (n=15); published third-party studies after GLP-1 withdrawal alone have shown ~15% weight regain at similar time points

33% of patients continued to lose further weight one year after discontinuing a GLP-1

Next anticipated Revita® clinical data readouts are one-year randomized data from the REMAIN-1 Midpoint Cohort in Q3 2026 and topline six-month randomized data from the REMAIN-1 Pivotal Cohort in early Q4 2026

Figure 1



REVEAL-1 vs. Published Expected Weight Regain Trajectory

BURLINGTON, Mass., June 04, 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 one-year results from its open-label REVEAL-1 Cohort. The REVEAL-1 Cohort is an open-label study in individuals with obesity who have lost at least 15% of their total body weight on a GLP-1 medication and who either need or choose to discontinue GLP-1 therapy. The REVEAL-1 data show that patients who underwent a single Revita procedure maintained approximately 78% of their prior GLP-1-induced weight loss at one year, with 33% of patients continuing to lose weight one year after discontinuing a GLP-1. The new results highlight Revita's potential to be a compelling procedural therapy for post-GLP-1 weight maintenance.

Key Findings:

- **Hard-to-treat GLP-1 responder population:** Participants lost ~24% total body weight (>50 lbs.) on GLP-1 drugs prior to enrollment (duration on GLP-1 therapy ranging from five months to five years.) Patients were enrolled who had lost at least 15% total body weight on GLP-1 medicines, with 17 of 22 participants having greater than 17.5% total body weight loss on GLP-1 drugs. Safety and complete efficacy data through one year are available for 22 and 15 participants, respectively.

- **Sustained weight maintenance through one year:** Participants maintained stable weight after a single Revita procedure, with a mean total body weight change of 5.3% ± 2.1% (LS means ± SE; n=15) at one year. An efficacy estimand in the full analysis set demonstrated similar results, with mean total body weight change of 5.8% ± 2.0% (LS means ± SE; n=22). Participants retained ~78% of their drug-induced weight loss at one year. 33% of participants continued to lose weight at one year. Published third-party studies[1,2] report ~15% weight regain by this time point after GLP-1 withdrawal alone (see Figure 1 below). Across this cohort, ablation length clustered narrowly around its median ablation length and the study therefore does not have power to detect an ablation length dose response.

- **100% of patients in the REVEAL-1 Cohort maintained at least 5% of GLP-1-induced weight loss through one year:** This ≥5% threshold is the responder definition used as the second co-primary endpoint in the REMAIN-1 Pivotal Cohort, which evaluates a responder rate among the Revita treated participants at one year to assess the durability of the Revita procedure for weight maintenance after GLP-1 discontinuation.

- **Sustained glycemic control through one year:** Minimal change in HbA1c levels was observed after the Revita procedure (0.08% ± 0.08%; LS means ± SE from MMRM; n=15), compared to the ~0.4% increase in HbA1c seen post-GLP-1 discontinuation in the STEP-1 trial extension[2] of GLP-1 withdrawal. This suggests Revita may help stabilize cardiometabolic parameters gained on GLP-1 therapy after the drug is stopped.

- **Excellent tolerability:** No procedure-related serious adverse events and no new treatment emergent adverse events were observed. Mild treatment-emergent adverse events occurred in eight of 22 participants (36%), were transient, self-limited, and all occurred within the first month of treatment. No late device-related adverse events were observed, and all adverse

events were consistent with prior Revita experience and similar to routine upper endoscopy findings.

- **Reproducible procedure performance:** As previously reported, average ablation length was approximately 16 cm (n=22), consistent with Revita European real-world experience and the ongoing REMAIN-1 Pivotal study, supporting the potential translatability of results and scalability of technique.

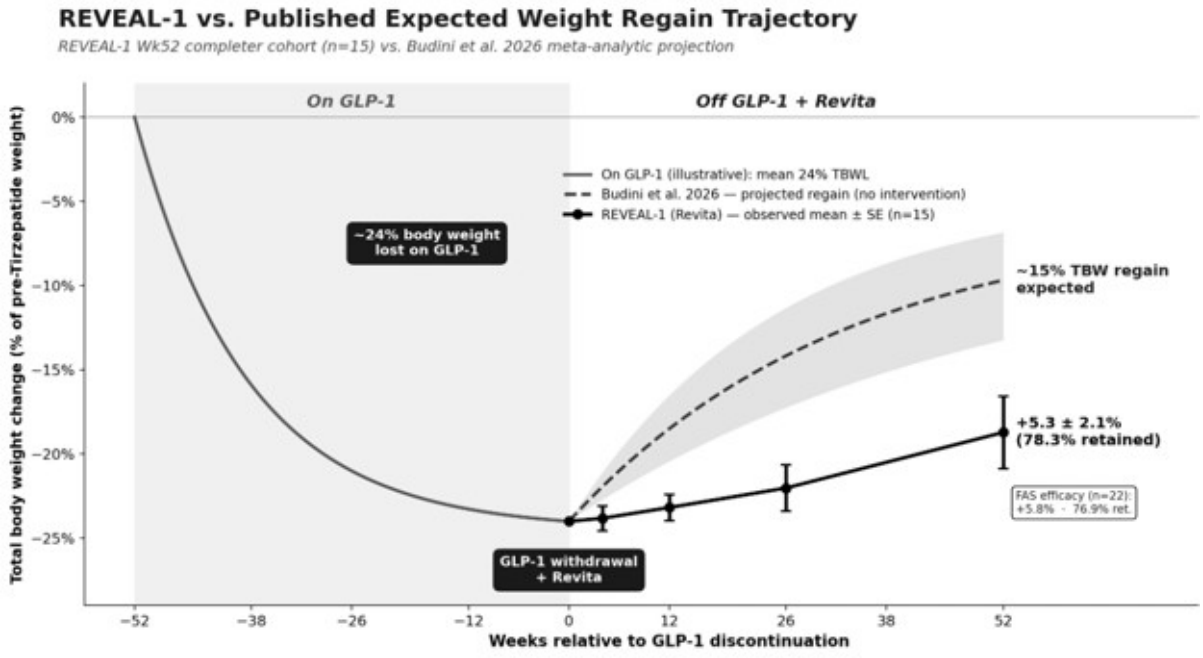


Figure 1: Total Body Weight Change Over Time Following GLP-1 Discontinuation and Revita Treatment. GLP-1 weight loss from weeks -52 to 0 are illustrative based on average weight loss and time on medication in REVEAL-1 subjects. Projected regain citation: Budini et al., eClinicalMedicine. 2026;93:103796. FAS = full analysis set, GLP-1 = glucagon-like peptide-1, TBW = total body weight.

“As a gastroenterologist, what's compelling here is the mechanism and the simplicity. Revita targets the duodenum, a root contributor to metabolic disease, through a single endoscopic procedure that fits within routine GI practice,” said Dr. Shailendra Singh, Director of Bariatric Endoscopy at West Virginia University. “Seeing patients sustain their weight loss a full year after one procedure, without staying on chronic medication, shows the potential for Revita to be a meaningfully different option than what we have today. And with a tolerability profile observed to date in line with a routine upper endoscopy, this is the kind of durable, procedure-based approach I could see fitting naturally into how we care for these patients.”

“GLP-1 medicines have transformed obesity care, but they were never designed to be taken forever, and the field's answer so far has been to keep patients on a drug indefinitely. Even the newest maintenance strategies ask people to switch from a weekly medication to a daily medication, live with ongoing side effects, and still regain some of the weight they worked so hard to lose. That is not the off-ramp patients are asking for,” said Harith Rajagopalan, M.D., Ph.D., Co-Founder and Chief Executive Officer of Fractyl. “With one-year REVEAL-1 data now showing durable weight maintenance after a single Revita procedure, and without any continued drug therapy, we believe Revita points to a fundamentally different path: a potentially one-time, root-cause approach to holding onto weight loss after GLP-1 discontinuation. We look forward to building on these open-label results with complementary one-year randomized data from our REMAIN-1 Midpoint Cohort in Q3 2026, followed by topline results from our REMAIN-1 Pivotal Cohort in early Q4 2026.”

About REVEAL-1

The REVEAL-1 Cohort (n=22) is an open-label study in individuals living with obesity who have lost at least 15% of their total body weight on a GLP-1 medication and who either need or choose to discontinue GLP-1 therapy. After stopping the GLP-1 based therapy, participants receive Revita treatment in an open-label setting and take part in a structured diet and lifestyle program. REVEAL-1 is designed to provide early, real-world insights on how Revita performs after GLP-1 discontinuation.

To date, 22 participants have been treated in the REVEAL-1 Cohort and are included in safety and efficacy analyses. Five participants withdrew or were lost to follow up and two participants experienced protocol deviations. The profile of the REVEAL-1 Cohort closely mirrors that of the REMAIN-1 Midpoint and Pivotal Cohorts, with an average age of 50 and a gender distribution of 86% women. All 22 participants had previously been treated with a GLP-1 therapy for durations ranging from approximately 5 months to 5 years, with a mean total body weight loss of 24% while on therapy and a mean body weight of 80 kg ± 3 kg (SEM) at the time of intervention.

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 Breakthrough Device designation from the U.S. Food and Drug Administration (FDA) 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 Health 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.

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 stabilize cardiometabolic parameters; the translatability of results and scalability of technique related to Revita; the design, initiation, timing and results of clinical enrollment and any clinical studies or readouts, including readouts from the REMAIN-1 Midpoint Cohort and the REMAIN-1 Pivotal Cohort; the potential launch or commercialization of any of our product candidates or products; 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 March 31, 2026, filed with the SEC on May 12, 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.

Contact

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[1] Aronne et al. JAMA. 2024;331(1):38–48. doi:10.1001/jama.2023.24945

[2] Wilding et al. Diabetes Obes Metab. 2022 Aug;24(8):1553-1564

A photo accompanying this announcement is available at https://www.globenewswire.com/NewsRoom/AttachmentNg/cfe8a68b-c93d-4766-9f1b-58dea83109bf