Fractyl Health Enters a Catalyst-Rich 2026 Positioned to Define the Post-GLP-1 Weight Maintenance Therapeutic Category

Jan 5, 2026

Randomized 6-month data from the REMAIN-1 Midpoint Cohort expected in late January 2026

Topline 6-month data from the REMAIN-1 Pivotal Cohort and potential PMA submission expected in H2 2026

Approximately $85.6 million in cash and cash equivalents on hand, supporting execution across planned 2026 milestones

Received gross proceeds of $23.0 million from exercises of Tranche A warrants from August 2025 financing, with cash runway into early 2027

BURLINGTON, Mass., Jan. 05, 2026 (GLOBE NEWSWIRE) -- Fractyl Health, Inc. (Nasdaq: GUTS) (the Company or Fractyl), a metabolic therapeutics company focused on pattern-breaking approaches that treat root causes of obesity and type 2 diabetes (T2D), today outlined its strategic outlook for 2026, highlighting anticipated clinical and regulatory milestones across its Revita® and Rejuva® programs.

“As we enter 2026, we believe Fractyl is positioned for a definitional year, and our focus is on disciplined execution with an accelerating cadence of clinical and regulatory milestones and progress,” said Harith Rajagopalan, M.D., Ph.D., Co-Founder and Chief Executive Officer of Fractyl Health. “We are rapidly advancing Revita as an outpatient endoscopic therapy designed to address a root cause of obesity. This year, we expect to deliver pivotal data and potential PMA filing in what we see as the single biggest problem in obesity today: post-GLP-1 weight maintenance. With millions of patients expected to start and then stop taking a GLP-1 this year, we believe weight loss maintenance is the new unmet need in obesity care, and is clearly what patients, prescribers, payers, and the broader health economic community are looking for.”

Revita®

In 2026, the Company plans to advance Revita through a series of important clinical and regulatory milestones, building on continued progress across the REVEAL-1, REMAIN-1 Midpoint, and REMAIN-1 Pivotal Cohorts as the program moves through pivotal validation in post-GLP-1 weight maintenance. In parallel, Fractyl is aligning clinical development with regulatory strategy and real-world implementation considerations for Revita as the Company advances through a registrational year.

Anticipated 2026 Revita Milestones

- **Late January 2026:** 6-month randomized data from the REMAIN-1 Midpoint Cohort
- **Early 2026:** Complete randomizations for the REMAIN-1 Pivotal Cohort
- **Q2 2026:** 1-year REVEAL-1 Cohort data
- **Q3 2026:** 1-year REMAIN-1 Midpoint Cohort data
- **H2 2026:** Topline 6-month randomized data from the REMAIN-1 Pivotal Cohort
- **H2 2026:** Potential Revita PMA filing in post-GLP-1 weight maintenance

Rejuva®

Fractyl plans to continue advancing its Rejuva gene therapy platform toward clinical validation in 2026, with progress expected toward first-in-human (FIH) evaluation of its lead program, RJVA-001, in patients with inadequately controlled T2D, subject to regulatory authorization. In H2 2025, Fractyl completed Clinical Trial Applications (CTA) for a RJVA-001 FIH study in EU and Australia, setting the stage for expected dosing of first patients and preliminary data in 2026.

Anticipated 2026 Rejuva Milestones

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

Financial Guidance and Cash Runway

As of December 31, 2025, Fractyl had approximately $81.5 million, in preliminary unaudited cash and cash equivalents. In connection with exercises of Tranche A warrants from Fractyl’s August 2025 financing, an additional $4.1 million of proceeds were

received on January 2, 2026, resulting in a balance of $85.6 million in cash and cash equivalents as of such date. Fractyl's current cash and cash equivalents are expected to fund its operations through early 2027 and support execution across planned 2026 clinical and regulatory milestones.

About Fractyl Health
Fractyl Health is a metabolic therapeutics company focused on pioneering new approaches to the treatment of metabolic diseases, including obesity and T2D. Despite advances in treatment over the last 50 years, obesity and T2D continue to be rapidly growing drivers of morbidity and mortality in the 21st century. Fractyl's goal is to transform metabolic disease treatment from chronic symptomatic management to durable disease-modifying therapies that target the organ-level root causes of disease. The Company has a robust and growing IP portfolio, with 35 granted U.S. patents and approximately 45 pending U.S. applications, along with numerous foreign issued patents and pending applications. Fractyl is based in Burlington, MA. For more information, visit www.fractyl.com.

About Revita®
Fractyl Health's lead product candidate, Revita, is based on the company's insights surrounding the potential role of the gut in obesity. Revita is designed to remodel the duodenal lining via hydrothermal ablation (i.e. duodenal mucosal resurfacing) to reverse damage to intestinal nutrient sensing and signaling mechanisms caused by chronic high-fat and high-sugar diets that are a root cause of metabolic disease. In the U.S., Revita is for investigational use only under U.S. law. Revita has U.S. FDA Breakthrough Device designation in weight maintenance for people with obesity who discontinue GLP-1 based drugs. A pivotal study of Revita in patients with obesity after discontinuation of GLP-1 based drugs, called REMAIN-1, was initiated in the third quarter of 2024 and has completed enrollment.

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. The Company has submitted the first Clinical Trial Application (CTA) module for RJVA-001 in T2D to regulators, and if the CTA is authorized, the Company expects to dose the first patients with RJVA-001 and report preliminary data in H2 2026. RJVA-002, the Company's second candidate from the Rejuva platform, is a dual GIP/GLP-1 gene therapy for obesity that has demonstrated approximately 30% weight loss in preclinical studies after a single administration, underscoring its potential to deliver durable, well-tolerated metabolic benefits from a one-time intervention.

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 should be considered forward-looking statements, including, without limitation, statements regarding our anticipated financial performance, including cash and cash equivalents, our expected cash runway, the promise and potential impact of our preclinical or clinical trial data, the design, initiation, timing and results of clinical enrollment and any clinical studies or readouts, the content, information used for, timing or results of any Investigational New Drug (IND)-enabling studies, IND applications or Clinical Trial Applications, communications with regulators, the potential launch or commercialization of any of our product candidates, the potential treatment population or benefits for any of our product candidates, and our strategic and product development objectives and goals, including with respect to enabling long-term control over obesity and type 2 diabetes without the burden of chronic therapies, redefining the future of metabolic disease treatment, positioning our Company at the forefront of the global opportunity for metabolic care, 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 Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (the SEC) on November 12, 2025 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.

Preliminary Financial Information

The Company's audited consolidated financial statements at and for the year ended December 31, 2025 are not yet available. As a result, the financial information described in this press release is preliminary and unaudited, represents management's estimate as of the date hereof and is subject to completion of the Company's financial closing procedures for the fourth quarter and fiscal year ended December 31, 2025. This preliminary financial information may materially differ from the actual results that will be reflected in the Company's audited consolidated financial statements when such financial statements are completed and publicly disclosed. The Company's independent registered public accounting firm has not conducted an audit or review of, and does not express an opinion or any other form of assurance with respect to, the Company's preliminary results.

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