Fractyl Health Reports Third Quarter 2025 Results; Revita® Clinical Momentum Builds Toward 2026 Pivotal Readout and PMA Filing, Cash Runway Extended into Early 2027

Nov 12, 2025

Positive randomized 3-month REMAIN-1 Midpoint Cohort data showed single Revita procedure maintained weight loss after GLP-1 discontinuation; 6-month data expected in Q1 2026

6-month data from open-label REVEAL-1 Cohort expected in Q4 2025

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

$83M in underwritten offerings expected to extend cash runway through upcoming clinical and regulatory milestones and into early 2027

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

BURLINGTON, Mass., Nov. 12, 2025 (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 announced third quarter 2025 financial results and provided business updates highlighting continued momentum across its Revita and Rejuva® platforms. During the third quarter, the Company reported positive randomized data from the REMAIN-1 Midpoint Cohort, expanded its Rejuva Smart GLP-1™ platform into obesity with potent preclinical results from RJVA-002, strengthened its Board of Directors with industry leaders, and completed $83M in underwritten offerings, which it expects will extend its cash runway through upcoming clinical and regulatory milestones and into early 2027.

“The third quarter marked a major inflection point for Fractyl,” said Harith Rajagopalan, M.D., Ph.D., Co-Founder and Chief Executive Officer of Fractyl Health. “With positive randomized data from our Revita program showing that durable, drug-free weight maintenance may be attainable, we are pushing the boundaries of what is possible in metabolic disease. We aim to move beyond chronic management and toward durable remission, potentially transforming care for the hundreds of millions of people living with obesity and T2D. With pivotal Revita data and our first-in-human Rejuva study ahead, we believe Fractyl is well positioned for a series of meaningful catalysts that could reshape the future of metabolic medicine.”

Recent Highlights and Upcoming Milestones

Revita®

The Company is studying Revita in the REMAIN weight maintenance program, which is designed to evaluate Revita’s potential to sustain weight loss following GLP-1 discontinuation. The REMAIN program includes three distinct patient cohorts: the REVEAL-1 Cohort, the REMAIN-1 Midpoint Cohort, and the REMAIN-1 Pivotal Cohort.

REVEAL-1 Cohort

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 drug, participants receive the Revita treatment in an open-label setting. REVEAL-1 is designed to provide early, real-world insights on how Revita performs after GLP-1 discontinuation.

- Fractyl expects to report 6-month data from the REVEAL-1 Cohort in Q4 2025, and 1-year data in Q2 2026.

REMAIN-1 Midpoint Cohort

The REMAIN-1 Midpoint Cohort (n=45) is a randomized, double-blind, sham-controlled pilot study to assess the potential of Revita to maintain weight loss after GLP-1 discontinuation. Participants are individuals with obesity who have not yet taken GLP-1 drugs, are initiated on tirzepatide at the time of enrollment, and treated with the drug to achieve at least 15% total body weight loss. Participants then discontinue tirzepatide and are randomized to undergo either Revita or a sham procedure with a 2:1 treatment allocation. The key efficacy endpoint was total body weight change in Revita versus sham at 3 months. This Cohort is intended to provide an important early, randomized readout of Revita’s potential to maintain weight loss after GLP-1 discontinuation.

- In September 2025, Fractyl reported positive 3-month randomized data from the REMAIN-1 Midpoint Cohort. The study met its key efficacy endpoint, showing that Revita-treated patients lost an additional 2.5% of total body weight after stopping tirzepatide, while sham-treated patients regained 10% (p=0.014). The Revita procedure was well-tolerated with no related serious adverse events reported, consistent with prior clinical studies. These data provide the first randomized, blinded evidence that drug-free, durable weight maintenance is possible and strengthens confidence in the ongoing REMAIN-1 Pivotal Cohort.
- Fractyl expects to report 6-month randomized data from the REMAIN-1 Midpoint Cohort in Q1 2026.

REMAIN-1 Pivotal Cohort

The REMAIN-1 Pivotal Cohort (n=315) is a randomized, double-blind, sham-controlled pivotal study to evaluate the safety and efficacy of Revita in maintaining weight loss after GLP-1 discontinuation. The first co-primary endpoint is defined as the percent of total body weight regain from the time of tirzepatide discontinuation in Revita versus sham patients through 6-month follow-up. The primary objective is to demonstrate the benefit of Revita versus sham for weight maintenance after GLP-1 discontinuation.

- The Pivotal Cohort is fully enrolled, and as of October 31, 2025, randomization was complete in over 60% of 315 planned participants. The procedure was well-tolerated, with no unanticipated or device/procedure related serious adverse effects reported, and no new safety concerns were observed. The Company expects to complete randomization in early 2026.
- Fractyl anticipates reporting 6-month primary endpoint data from the REMAIN-1 Pivotal Cohort in H2 2026 and potentially filing a Premarket Approval (PMA) application with the U.S. Food and Drug Administration (FDA) in H2 2026.

Germany Real-World Registry Study

The Germany Real-World Registry study is a prospective, post-market, clinical follow-up study to evaluate the Revita procedure in patients with inadequately controlled T2D. Entry criteria included a baseline Hemoglobin A1c (HbA1c) between 7-10% (inclusive), a BMI of ≤45 kg/m^2, and use of at least one glucose-lowering agent (GLA).

- As of October 31, 2025, the first 30 participants have now reached one year of follow-up, and 14 participants have reached two years of follow-up. The first 14 participants with two-year follow-up maintained an average total body weight loss of 8.9% and a 1.7% reduction in HbA1c. 3-month results were highly predictive of outcomes at 6, 12, and 24 months.

Rejuva®

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 address obesity.

- In October 2025, Fractyl announced potent new preclinical data from RJVA-002, its dual GIP/GLP-1 gene therapy candidate for obesity, at the Cell & Gene Meeting on the Mesa 2025. A single administration of RJVA-002 led to approximately 30% weight loss over five weeks in a translational obesity model in male mice, with weight loss not yet plateaued and no observed adverse effects. These findings highlighted the potential for a durable, one-time gene therapy approach to obesity that could match or exceed best-in-class chronic drug therapy. Results from this ongoing study at longer time points and with associated metabolic measurements will be presented at an upcoming scientific congress.
- Fractyl has completed preclinical chemistry, manufacturing, and controls (CMC) activities and lot release for its RJVA-001 drug product.
- Fractyl 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 2026.

Business Updates

- In September 2025, Fractyl announced a $60 million underwritten offering of common stock. The financing, together with the Company's $23 million underwritten public offering in August, further strengthens its balance sheet and extends its estimated cash runway through upcoming clinical and regulatory milestones into early 2027.
- In September 2025, Fractyl expanded its Board of Directors with the appointment of Christopher Thompson, M.D., Professor of Medicine at Harvard Medical School and a pioneer in bariatric endoscopy, and Ian Sheffield, an experienced healthcare investor and former medtech executive. Their combined clinical and financial expertise strengthens the Company's leadership as it advances Revita through late-stage development and prepares for its first-in-human Rejuva study.

Third Quarter 2025 Financial Results

- **Research and Development Expenses:** R&D expenses were $17.5 million for the quarter ended September 30, 2025, compared to $19.0 million for the same period in 2024, primarily due to reduced spending on the REVITALIZE-1 study and lower stock-based compensation expenses.
- **Selling, General and Administrative Expenses:** SG&A expenses were $5.2 million, compared to $4.8 million in the third quarter of 2024, primarily driven by costs incurred related to the issuance of the warrants in connection with the underwritten public offering in August 2025.
- **Net Loss:** For the quarter ended September 30, 2025, Fractyl reported a net loss of $45.6 million, compared to $23.2 million for the same period in 2024. The variance was driven by a $23.5 million non-cash accounting change in fair value related to the warrants and does not reflect a change in underlying operating performance. Operating expenses this quarter were $1.1 million lower compared to the same period in 2024.
- **Cash Position:** As of September 30, 2025, Fractyl had approximately $77.7 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 third quarter financial results and provide business updates on Wednesday, November 12, 2025, 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 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 33 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 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, for any period of time, the impact of our August 2025 underwritten offering, including the potential exercise of any Tranche A and Tranche B warrants, the September 2025 underwritten offering, 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 or products, the potential treatment population or benefits for any of our product candidates or products, 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 following: the Company's limited operating history; the incurrence of significant net losses and the fact that the Company expects to continue to incur significant net losses for the foreseeable future; the Company's need for substantial additional financing; the Company's ability to continue as a going concern; the restrictive and financial covenants in the Company's credit agreement; the lengthy and unpredictable regulatory approval process for the Company's product candidates; uncertainty regarding its clinical studies; the fact that the Company's product candidates may cause serious adverse events or undesirable side effects or have other properties that may cause it to suspend or discontinue clinical studies, delay or prevent regulatory development, prevent their regulatory approval, limit the commercial profile, or result in significant negative consequences; additional time may be required to develop and obtain regulatory approval or certification for the Company's Rejuva gene therapy candidates; the Company's reliance on third parties to conduct certain aspects of the Company's preclinical studies and clinical studies; the Company's reliance on third parties for the manufacture of sub-assembly components for Revita and for the materials for its Rejuva gene therapy platform for preclinical studies, and its ongoing clinical studies; the regulatory approval process of the FDA and comparable foreign regulatory authorities is lengthy, time-consuming and inherently unpredictable, and even if we complete the necessary clinical studies, we cannot predict when, or if, we will obtain regulatory approval or certification for any of our product candidates, and any such regulatory approval or certification may be for a more narrow indication than we seek; we may experience delays, interruptions or additional costs in obtaining and maintaining government regulatory approvals, licenses, certifications or reimbursements as a result of federal government shutdowns, reduced staffing or funding lapses; and the potential launch or commercialization of any of Company's product candidates or products and our strategic and product development objectives and goals, and the other 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.

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

	September 30, 2025	December 31, 2024
Cash and cash equivalents	$ 77,657	$ 67,464
Restricted cash	4,255	4,255
Working capital (1)	61,021	51,988
Total assets	114,272	108,077
Notes payable, long-term	30,770	30,162
Total liabilities	117,450	79,653
Total stockholders' equity (deficit)	(3,178)	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
(unaudited, in thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Revenue	$ —	$ 14	$ —	$ 90
Cost of goods sold	—	7	—	50
Gross profit	—	7	—	40
Operating expenses:				
Research and development	17,457	19,004	58,043	50,190

Selling, general and administrative	5,237	4,797	15,489	18,171
Total operating expenses	22,694	23,801	73,532	68,361
Loss from operations	(22,694)	(23,794)	(73,532)	(68,321)
Other income (expense), net:				
Interest income, net	166	947	895	3,420
Change in fair value of notes payable	(1,868)	(2,610)	(3,824)	3,772
Change in fair value of warrant liabilities	(21,201)	2,293	(20,724)	17,442
Other expense, net	(6)	(9)	(42)	(37)
Total other income (expense), net	(22,909)	621	(23,695)	24,597
Net loss and comprehensive loss	(45,603)	(23,173)	(97,227)	(43,724)