Fractyl Health Announces Second Quarter 2025 Financial Results and Business Updates

Aug 12, 2025

Randomized 3-month REMAIN-1 Midpoint Cohort data expected in September 2025

Positive 3-month REVEAL-1 Cohort data showed single Revita® procedure sustained weight loss after GLP-1 discontinuation; incremental 6-month open-label data expected in Q4 2025

Top-line REMAIN-1 Pivotal Cohort 6-month data and PMA filing expected in H2 2026

$23M underwritten public offering expected to extend cash runway through key upcoming 3-and 6-month randomized data readouts from REMAIN-1 Midpoint Cohort

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

BURLINGTON, Mass., Aug. 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 second quarter 2025 financial results and provided business updates highlighting continued momentum across its Revita and Rejuva platforms. To support this clinical and strategic progress, the Company recently completed a $23 million underwritten public offering, which is expected to extend its cash runway through key upcoming 3-and 6-month randomized data readouts from the REMAIN-1 Midpoint Cohort.

"Fractyl is entering a critical time in the Company's growth. With enrollment complete in our REMAIN-1 Pivotal Cohort, randomized data in post-GLP-1 weight maintenance anticipated from the Midpoint Cohort next month, and the Rejuva gene therapy platform moving toward the clinic, we are making significant progress toward transforming the standard of care for people with chronic metabolic diseases like obesity and T2D," said Harith Rajagopalan, M.D., Ph.D., Co-Founder and Chief Executive Officer of Fractyl Health. "We believe Revita could pioneer a new therapeutic area in weight maintenance, helping patients sustain the hard-won benefits after discontinuing GLP-1 drugs. With our recent capital raise enhancing our financial position through key upcoming clinical milestones, we believe we're well-positioned to advance these category-defining platforms and bring much-needed solutions to patients in some of the most prevalent diseases in healthcare."

Recent Highlights and Upcoming Milestones

Revita®

The Company is evaluating Revita in the REMAIN-1 pivotal study, which 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 is an open-label cohort enrolling 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. After stopping the GLP-1 drug, participants receive the 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.

- In June, Fractyl reported positive 3-month data from the REVEAL-1 Cohort. Of the 22 participants treated, 13 had completed 3-month follow-up. Of these, 12 of 13 maintained or further reduced their weight after GLP-1 discontinuation and a single Revita procedure. Notably, 6 of 13 participants experienced additional weight loss. Median weight remained stable through 3 months (total body weight change of 0.46% or approximately 1 pound which was within the margin of error for daily weight measurement), versus the typical 5–6% (10–15 pounds) rebound seen in clinical studies such as SURMOUNT-4[1,2]. Only one participant experienced weight regain similar to that seen after tirzepatide withdrawal.
- Fractyl anticipates presenting incremental 6-month data from the REVEAL-1 Cohort in Q4 2025, and incremental 1-year data in Q2 2026.

REMAIN-1 Midpoint Cohort

The REMAIN-1 Midpoint Cohort is a randomized, double-blind cohort of 45 participants 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 initial efficacy analysis will be conducted after approximately 45 subjects have completed 12 weeks of follow-up. This Cohort is intended to provide an important early, randomized readout of Revita's potential to maintain weight loss following GLP-1 discontinuation.

- The Company completed enrollment of the 45 participants of the randomized REMAIN-1 Midpoint Cohort and remains on track to report 3-month data in September 2025.
- Fractyl anticipates presenting 6-month data from the REMAIN-1 Midpoint Cohort in Q1 2026.

REMAIN-1 Pivotal Cohort

The REMAIN-1 Pivotal Cohort is a randomized, double-blind cohort of 315 participants 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 second co-primary endpoint evaluates a responder rate among the Revita treated participants at 1 year to demonstrate the durability of the Revita procedure for weight maintenance following discontinuation of a GLP-1 based therapy.

- The Company has completed enrollment of the REMAIN-1 Pivotal Cohort and expects to complete randomization of 315 participants to Revita versus sham in the first half of 2026.
- Fractyl anticipates reporting with 6-month primary endpoint data from the REMAIN-1 Pivotal Cohort in H2 2026 and anticipates submitting a Premarket Approval application (PMA) 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. Participants had a baseline HbA1c between 7-10% (inclusive), a BMI of ≤45 kg/m^2, and were on at least one glucose-lowering agent (GLA).

- In August 2025, Fractyl reported data from the first 9 patients with 2 years of follow-up in the Germany Real-World Registry study, showing that a single Revita procedure led to a median 9.6% weight loss and a 1.6% reduction in HbA1c in participants with obesity and advanced T2D. These effects were sustained through two years, with no device- or procedure-related serious adverse events reported to date. These real-world findings build on prior clinical data and support Revita's potential as a durable, non-drug intervention for long-term metabolic control.

Rejuva®

Rejuva is Fractyl's gene therapy platform designed to deliver long-term remission of T2D and obesity by durably reprogramming metabolic hormone signaling within pancreatic islet cells. The lead product candidate from the platform, RJVA-001, is being advanced for patients with inadequately controlled T2D.

- In June 2025, Fractyl presented preclinical data at the American Diabetes Association's 85 th Scientific Sessions that showed a single dose of Rejuva prevented weight gain and hyperglycemia in healthy animals exposed to a high-fat diet. These results further validate the advancement of RJVA-001 toward first-in-human studies.
- In May 2025, the Company submitted the first module of its clinical trial application (CTA) in Europe for RJVA-001. The upcoming first-in-human Phase 1/2 study is designed as an open-label, multicenter, single ascending dose trial evaluating the safety, tolerability, and preliminary efficacy of a single, pancreas-targeted infusion of RJVA-001 in adults with inadequately controlled T2D.
- In May 2025, Fractyl presented new preclinical data on RJVA-001 at the American Society of Gene and Cell Therapy (ASGCT) 2025 Annual Meeting, demonstrating durable metabolic improvements, low systemic GLP-1 exposure, and targeted pancreatic expression via endoscopic ultrasound-guided delivery. These findings highlight Rejuva's potential to deliver potent, physiologic GLP-1 activity with improved tolerability compared to systemic GLP-1 drugs, and further support readiness for clinical translation.
- Pending regulatory authorization, the Company expects to dose the first patients with RJVA-001 and report preliminary data in 2026.

Business Updates

- In August 2025, Fractyl completed a $23 million underwritten public offering of common stock and accompanying warrants, including the full exercise of the underwriter's option to purchase additional shares. The offering drew participation from

both new and existing institutional investors, including Nantahala Capital, ADAR1 Capital Management, Second Line Capital, 683 Capital, and SilverArc Capital. If fully exercised for cash, the accompanying warrants issued with this offering could result in up to an additional $46 million in gross proceeds to the Company, for total potential proceeds of $69 million. The financing is expected to extend the Company's cash runway through key upcoming 3- and 6-month randomized data readouts from the REMAIN-1 Midpoint Cohort.

- In June 2025, Fractyl issued two new U.S. patents that expand protection for its duodenal mucosal resurfacing platform, reinforcing the Company's leadership in gut-targeted therapies for metabolic disease. The patents cover thermal and non-thermal electrical energy applications and strengthen Fractyl's robust IP portfolio, which now includes 32 granted U.S. patents and approximately 40 pending applications, along with numerous foreign issued patents and pending applications.
- In June 2025, Fractyl entered into a non-binding Letter of Intent (LOI) with Bariendo Inc. to evaluate a potential collaboration related to the use of Revita as a post–GLP-1 weight maintenance intervention, pending FDA approval. Bariendo is a U.S.-based obesity care platform focused on delivering minimally invasive endoscopic procedures through a national network of hospital and ambulatory endoscopy centers. Under the LOI, Bariendo has expressed its intent to work with Fractyl to assess operational readiness and support pre-commercial planning activities related to the potential integration of Revita into its clinical service offerings. These activities may include clinical workflow design, provider training, health economic analysis, and the development of referral pathways.

Second Quarter 2025 Financial Results

- **Research and Development Expenses:** R&D expenses were $21.2 million for the quarter ended June 30, 2025, compared to $16.8 million for the same period in 2024, primarily reflecting continued advancement of the REMAIN-1 clinical study and the Rejuva program.
- **Selling, General and Administrative Expenses:** SG&A expenses were $4.9 million, compared to $6.2 million in the second quarter of 2024, primarily driven by lower stock based compensation expenses.
- **Net Loss:** Net loss was $27.9 million for the quarter ended June 30, 2025, compared to $17.2 million for the same period in 2024, largely due to the fluctuation in the non-cash change in fair value of notes and warrants and partially driven by increase in operating expenses of $3.1 million.
- **Cash Position:** As of June 30, 2025, Fractyl had approximately $22.3 million in cash and cash equivalents. Based on current business plans, and after considering the net proceeds from its August 2025 underwritten offering, the Company believes its cash position will fund operations into 2026.

Webcast and Conference Call Information
Fractyl will host a conference call to discuss its second quarter financial results and provide business updates on Tuesday, August 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 32 granted U.S. patents and approximately 40 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.

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 the Company's August 2025 underwritten offering, including stockholder approval of Tranche B warrants or the potential exercise of any warrants, 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; 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 August 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)

	June 30, 2025	December 31, 2024
Cash and cash equivalents	$ 22,291	$ 67,464
Restricted cash	4,255	4,255
Working capital (1)	4,856	51,988
Total assets	62,006	108,077
Notes payable, long-term	29,985	30,162
Total liabilities	80,218	79,653
Total stockholders' equity (deficit)	(18,212)	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 June 30,		Six Months Ended June 30,	
	2025	**2024**	**2025**	**2024**
Revenue	$ —	$ 43	$ —	$ 76
Cost of goods sold	—	24	0	43
Gross profit	—	19	0	33
Operating expenses:				
Research and development	21,151	16,762	40,586	31,186
Selling, general and administrative	4,928	6,242	10,252	13,374
Total operating expenses	26,079	23,004	50,838	44,560
Loss from operations	(26,079)	(22,985)	(50,838)	(44,527)
Other income (expense), net:				
Interest income, net	226	1,375	729	2,473
Change in fair value of notes payable	(1,673)	(304)	(1,956)	6,382
Change in fair value of warrant liabilities	(348)	4,703	477	15,149
Other expense, net	(15)	(18)	(36)	(28)
Total other income (expense), net	(1,810)	5,756	(786)	23,976
Net loss and comprehensive loss	(27,889)	(17,229)	(51,624)	(20,551)

[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