



## Fractyl Health Announces First Quarter 2025 Financial Results and Business Updates

May 13, 2025

*REVEAL-1 Cohort 3-month open-label data update expected in June 2025; early clinical signals reinforce Revita's potential to maintain weight loss after GLP-1 discontinuation in the real world*

*REMAIN-1 Midpoint Cohort data expected in Q3 2025; first randomized data on post-GLP-1 weight maintenance*

*REMAIN-1 Pivotal Cohort has completed enrollment ahead of schedule; 6-month primary endpoint data anticipated in H2 2026*

*Rejuva gene therapy platform advancing toward first-in-human studies; first CTA module submission for RJVA-001 expected in June 2025*

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

BURLINGTON, Mass., May 13, 2025 (GLOBE NEWSWIRE) -- Fractyl Health, Inc. (Nasdaq: GUTS) ("the Company"), a metabolic therapeutics company focused on pattern breaking approaches that treat root causes of obesity and type 2 diabetes (T2D), today announced first quarter 2025 financial results and provided business updates highlighting rapid clinical and operational momentum.

"At Fractyl, we are answering one of the most urgent questions in obesity care: how to maintain weight loss after patients discontinue GLP-1 therapy," said Harith Rajagopalan, M.D., Ph.D., Co-Founder and Chief Executive Officer of Fractyl Health. "We are accelerating on our bold ambition to create lasting, disease-modifying therapies. With the REMAIN-1 Pivotal Cohort fully enrolled ahead of schedule, early REVEAL-1 Cohort data demonstrating promising weight stability, and Rejuva advancing toward the clinic, we are executing with urgency and precision. Our momentum reflects the tremendous demand for new solutions in metabolic care and could position Fractyl at the forefront of what we believe will be a \$175 billion global opportunity for weight maintenance solutions. 2025 is shaping up to be a transformational year for Fractyl as we work to redefine the future of metabolic disease treatment."

### **Recent Highlights and Upcoming Milestones**

#### **Revita®**

The Company is evaluating Revita in the REMAIN-1 pivotal study, which is designed to include 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 April, the Company [announced](#) that 15 participants had been treated in the REVEAL-1 Cohort, with 1-month data available for the first 7 participants. These data showed encouraging weight maintenance after GLP-1 discontinuation, with average weight regain of just 1.2%, compared to approximately 3% typically observed post-GLP-1 cessation<sup>1</sup>.
- Fractyl anticipates presenting incremental 3-month data from the REVEAL-1 Cohort in June 2025, which the Company believes will provide additional early validation of Revita's potential.

#### **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.

The randomized Midpoint Cohort serves as an important early randomized readout to assess Revita's potential to maintain weight loss after GLP-1 discontinuation.

- The Company completed enrollment of the 45 participants of the randomized REMAIN-1 Midpoint Cohort in the fourth quarter of 2024 and remains on track to report the first randomized 3-month data from this cohort in the third quarter of 2025.

### **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. 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 a 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 after discontinuation of a GLP-1 based therapy.

- The Company announced today that it has completed enrollment of the REMAIN-1 Pivotal Cohort ahead of schedule. Fractyl expects to complete randomization of 315 participants to Revita versus sham in the first half of 2026, with 6-month primary endpoint data anticipated in the second half of 2026.

### **Rejuva®**

- Fractyl's pancreatic gene therapy platform, Rejuva, continues to advance toward the clinic. Following regulatory alignment with European authorities in Q1 2025, Fractyl plans to submit its first Clinical Trial Application (CTA) module for RJVA-001, targeting patients with inadequately controlled T2D, in June 2025, with additional filings shortly thereafter.
- Pending regulatory authorization, Fractyl expects to dose the first patients with RJVA-001 and report preliminary data in 2026, which the Company believes could lead to a potentially first-in-class, smart, durable gene therapy designed to reprogram the pancreas to deliver natural metabolic control.

### **First Quarter 2025 Financial Results**

- **Research and Development Expenses:** R&D expenses were \$19.4 million for the quarter ended March 31, 2025, compared to \$14.4 million for the same period in 2024, reflecting continued advancement of REMAIN-1, the Rejuva program, and related personnel costs.
- **Selling, General and Administrative Expenses:** SG&A expenses were \$5.3 million, compared to \$7.1 million in the first quarter of 2024, primarily driven by lower stock based compensation expense, partially offset by increased public company costs.
- **Net Loss:** Net loss was \$23.7 million for the quarter ended March 31, 2025, compared to \$3.3 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 \$3.2 million.
- **Cash Position:** As of March 31, 2025, Fractyl had approximately \$42.1 million in cash and cash equivalents. Based on current operating plans, the Company believes its cash position will fund operations into the fourth quarter of 2025.

### **Webcast and Conference Call Information**

Fractyl will host a conference call to discuss its first quarter financial results and provide business updates on Tuesday, May 13, 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](http://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. Fractyl is based in Burlington, MA. For more information, visit [www.fractyl.com](http://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 plans to submit the first Clinical Trial Application (CTA) module for RJVA-001 in T2D to regulators in June 2025, 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 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, comparable foreign regulatory authorities and 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 May 13, 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**  
*(in thousands)*

	<b>March 31, 2025</b>	<b>December 31, 2024</b>
Cash and cash equivalents	\$ 42,108	\$ 67,464
Restricted cash	4,255	4,255
Working capital <sup>(1)</sup>	28,244	51,988
Total assets	83,040	108,077
Notes payable, long-term	29,385	30,162

Total liabilities	76,665	79,653
Total stockholders' equity	6,375	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**  
*(in thousands)*

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2025</b>	<b>2024</b>
Revenue	\$ —	\$ 33
Cost of goods sold	—	19
Gross profit	—	14
Operating expenses:		
Research and development	19,435	14,424
Selling, general and administrative	5,324	7,132
Total operating expenses	24,759	21,556
Loss from operations	(24,759)	(21,542)
Other income (expense), net:		
Interest income, net	503	1,098
Change in fair value of notes payable	(283)	6,686
Change in fair value of warrant liabilities	825	10,446
Other expense, net	(21)	(10)
Total other income, net	1,024	18,220
Net loss and comprehensive loss	(23,735)	(3,322)

<sup>1</sup> Aronne LJ, Sattar N, Horn DB, et al. Continued Treatment with Tirzepatide for Maintenance of Weight Reduction in Adults with Obesity. *Jama* 2023;331(1):38–48.