Fractyl Health Announces Fourth Quarter and Full Year 2024 Financial Results and Business Updates

Mar 3, 2025

Strong patient and physician demand for pivotal REMAIN-1 study highlights urgent need for post-GLP-1 withdrawal weight maintenance solutions; midpoint data analysis anticipated in Q2 2025 and full study enrollment expected in summer 2025

Company plans to submit first Clinical Trial Application (CTA) module for RJVA-001 in type 2 diabetes to regulators in H1 2025, and if CTA is authorized, expects to report preliminary data in 2026

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

BURLINGTON, Mass., March 03, 2025 (GLOBE NEWSWIRE) -- Fractyl Health, Inc. (Nasdaq: GUTS) (“the Company”), a metabolic therapeutics company focused on pioneering new approaches that treat root causes of obesity and Type 2 Diabetes (T2D), is redefining the future of metabolic health by tackling one of obesity care’s most urgent challenges – sustaining weight loss after GLP-1 therapy. Today, the Company announced key anticipated milestones, growing patient and physician demand for its REMAIN-1 pivotal study, and fourth quarter and full year 2024 financial results, reinforcing its momentum for continued execution in 2025.

“The future of obesity care isn’t just about losing weight—it’s about keeping it off," said Harith Rajagopalan, M.D., Ph.D., Co-Founder and Chief Executive Officer of Fractyl Health. "At Fractyl, we are pioneering a new treatment paradigm that moves beyond short-term fixes to deliver lasting metabolic solutions. Our goal is to provide patients and physicians with something they don’t have today: a science-driven approach to long-term weight maintenance and metabolic health. With multiple key anticipated clinical milestones ahead in our REVEAL-1 and REMAIN-1 studies, and Rejuva advancing toward first-in-human studies, we believe 2025 will be a pivotal year – one that marks a major transformation in obesity and T2D treatment. We remain laser-focused on our efforts to deliver the innovations that will change the trajectory of these diseases for millions worldwide."

Recent Highlights and Upcoming Milestones

Revita®

- The Company reported significant progress in its ongoing REMAIN-1 pivotal study, which is evaluating weight maintenance after discontinuing GLP-1 drugs. In just six months since study initiation, more than 189 patients have enrolled across 13 clinical sites – reinforcing the urgent demand for a real off-ramp from GLP-1 drugs and the strong conviction among patients and physicians in Revita’s potential.

Upcoming Milestones:

- REMAIN-1: REMAIN-1 is a randomized, double-blind pivotal study of Revita versus sham in patients who have lost at least 15% total body weight on tirzepatide therapy, which was initiated in the third quarter of 2024. The Company anticipates a midpoint data analysis of REMAIN-1 in the second quarter of 2025 and full study enrollment in summer 2025.

- REVEAL-1: REVEAL-1 is the open-label cohort of the REMAIN-1 study. Additional data from the REVEAL-1 cohort is expected to be presented in the first quarter of 2025.

Rejuva®

- In December of 2024, Fractyl unveiled promising preclinical data demonstrating the safety and feasibility of local delivery of RJVA-001 Rejuva smart GLP-1 pancreatic gene therapy at the World Congress Insulin Resistance, Diabetes and Cardiovascular Disease (WCIRDC).

Upcoming Milestones:

- The Company anticipates submitting the first CTA module for RJVA-001 in T2D to regulators in the first half of 2025, and if the CTA is authorized, expects to report preliminary data in 2026.

Corporate Update

- In January, the Company announced a strategic decision to focus Revita exclusively on weight maintenance, prioritizing the REMAIN-1 pivotal study to address the most pressing need in obesity care, while advancing its novel Rejuva gene therapy platform into first-in-human studies. Fractyl paused investment in its Revita programs for T2D, which consisted of the REVITALIZE-1 study, and the Germany Real-World Registry study. This focused approach strengthens Fractyl's competitive positioning, ensures disciplined capital allocation, and extends its cash runway into 2026 – providing a clear path through multiple key anticipated clinical milestones.

Fourth Quarter and Full Year 2024 Financial Results

Revenue: Revenue in both quarters ended December 31, 2024 and 2023 was generated from the German Real-World Commercial Registry.

R&D Expenses: Research and development expense was $20.3 million for the quarter ended December 31, 2024, compared to $10.1 million for the same period in 2023. The increase during the quarter was primarily due to the progress made in the REMAIN-1 clinical study, the REVITALIZE-1 clinical study, continued development of the Rejuva program and increased personnel-related expenses, including stock-based compensation.

SG&A Expenses: Selling, general and administrative expense was $4.9 million for the quarter ended December 31, 2024, compared to $2.8 million for the same period in 2023. The increase during the quarter was primarily due to increased costs associated with operating as a publicly traded company, and increased personnel-related expenses, including stock-based compensation.

Net Loss: Net loss was $25.0 million for the quarter ended December 31, 2024, compared to a net loss of $19.2 million for the same period in 2023. The increase in net loss was primarily attributed to a $12.2 million increase in operating expenses discussed above, partially offset by a $6.1 million non-cash gain from changes in fair value of warrant liabilities as well as a $0.3 million increase in net interest income.

Cash Position: As of December 31, 2024, Fractyl had approximately $67.5 million in cash and cash equivalents. Based on current development plans, the Company believes existing cash and cash equivalents will be sufficient to fund operations through key anticipated company clinical milestones into 2026.

Webcast and Conference Call Information

Fractyl will host a conference call to discuss its fourth quarter and full year 2024 financial results and provide business updates on Monday, March 3, 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 Health'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 Health 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 is currently enrolling.

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 type 2 diabetes to regulators in H1 2025, and if the CTA is authorized, expects to 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, our strategic reprioritization and related workforce reduction, including its implementation and the expected costs and benefits, if any, 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, 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 Annual Report on Form 10-K filed with the Securities and Exchange Commission (the "SEC") on March 3, 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)

	December 31, 2024	December 31, 2023
Cash and cash equivalents	$ 67,464	$ 33,209
Restricted cash	4,255	4,570
Working capital [1]	51,988	24,460
Total assets	108,077	76,212
Notes payable, long-term	30,162	55,152
Total liabilities	79,653	113,944
Convertible preferred stock	—	287,330
Total stockholders' deficit	28,424	(325,062)

(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)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2024	2023	2024	2023
	(unaudited)	(unaudited)		
Revenue	$ 3	$ 7	$ 93	$ 120
Cost of goods sold	—	2	50	77
Gross profit	3	5	43	43
Operating expenses:				
Research and development	20,281	10,166	70,471	38,038
Selling, general and administrative	4,932	2,820	23,103	12,841
Total operating expenses	25,213	12,986	93,574	50,879
Loss from operations	(25,210)	(12,981)	(93,531)	(50,836)
Other income (expense), net:				
Interest income, net	726	463	4,146	1,260
Change in fair value of notes payable	(942)	(1,021)	2,830	(20,697)
Change in fair value of warrant liabilities	466	(5,633)	17,908	(6,794)
Other expense, net	(10)	(8)	(47)	(24)
Total other income (expense), net	240	(6,199)	24,837	(26,255)
Net loss and comprehensive loss	(24,970)	(19,180)	(68,694)	(77,091)
Accretion of dividends on convertible preferred stock	—	(4,330)	(1,737)	(17,180)
Net loss attributable to common stockholders	$ (24,970)	$ (23,510)	$ (70,431)	$ (94,271)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.52)	$ (11.18)	$ (1.62)	$ (45.29)
Weighted-average number of common shares outstanding, basic and diluted	48,445,979	2,102,410	43,541,527	2,081,328