Fractyl Health Reports Third Quarter 2024 Financial Results and Provides Business Updates

November 12, 2024

REMAIN-1 weight maintenance pivotal study enrollment progressing rapidly; mid-point data analysis expected in Q2 2025

Anticipate reporting data from REVEAL-1 open-label cohort beginning in Q4 2024

Topline data from REVITALIZE-1 pivotal study expected in mid-2025

Company presented compelling weight maintenance data from both Revita® and Rejuva® platforms at ObesityWeek® 2024

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

BURLINGTON, Mass, Nov. 12, 2024 (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), today reported its third quarter 2024 financial results and provided business updates.

"Fractyl is about to embark on what we believe is a catalyst-rich few quarters. At the end of this year, we expect to begin reporting data from the REVEAL-1 open-label cohort of the REMAIN-1 study, which we believe will demonstrate that the significant weight loss and weight maintenance we see in the real world setting in Germany can be replicated in our pivotal studies in the U.S. The strong demand from patients and clinical sites for the REMAIN-1 study underscores a critical unmet need for sustainable treatments for obesity, particularly for long-term weight maintenance," said Harith Rajagopalan, M.D., Ph.D., Co-Founder and Chief Executive Officer of Fractyl. "With our Rejuva platform, we are finalizing key in vivo studies to support the Clinical Trial Application (CTA) submission for RJVA-001 in T2D, and if the filing is approved, we plan to initiate a first-in-human study in the first half of 2025. Last week, we were excited to announce the nomination of our first smart GIP/GLP-1 pancreatic gene therapy lead candidate, RJVA-002, which is designed for the treatment of obesity. RJVA-002 is a locally administered AAV9 viral vector that expresses human GIP and GLP-1 hormones from a human insulin promoter. We are confident that our novel pipeline will position us among the leaders in addressing not just short-term weight loss, but also the underlying causes of obesity and T2D, offering patients options that could reduce the need for lifelong treatments."

Recent Highlights and Upcoming Milestones

Corporate Updates

- In November 2024, Fractyl presented compelling weight maintenance data from both the Revita and Rejuva platforms at The Obesity Society's Annual Meeting at ObesityWeek 2024 in San Antonio, Texas.
  - The oral presentation "Islet-Targeted GLP-1 Receptor Agonist Gene Therapy Reduces Fat and Improves Metabolism in Obese Mice" highlighted new preclinical data on sustained weight maintenance and lowering of blood sugar from Rejuva RJVA-001 for 13-weeks – the longest data to-date demonstrating the durable efficacy of RJVA-001.
  - The poster presentation "Duodenal Mucosal Resurfacing (DMR) Durably Maintains Weight Loss in Metabolic Disease" showcased compelling results from a pooled data analysis that demonstrated that the majority of patients durably maintained weight loss for one year post Revita procedure.

Revita®

- The Company has completed enrollment of a sufficient number of patients for the mid-point analysis of the REMAIN-1 pivotal study, which is evaluating Revita's efficacy in maintaining weight loss following discontinuation of GLP-1 therapy.
- Fractyl is currently enrolling patients in the REVEAL-1 open-label cohort of the REMAIN-1 study.
- In October 2024, Fractyl presented updated weight loss and blood glucose clinical results from the Company's German Real-World Registry at the Visceral Medicine 2024 meeting of the German Society for Gastroenterology, Digestive and Metabolic Diseases (DGVS) in Leipzig,

Germany. The clinical results and patient-reported outcomes further support the clinical potential of Revita to deliver sustainable weight loss and metabolic benefits. As of October 2024, 37 patients have been treated with Revita in Germany and 31 have enrolled in the Real-World Registry.

- Fractyl plans a controlled expansion in Germany in 2025. Revita has reimbursement authorization through the NUB reimbursement pathway for the treatment of T2D. At the end of October 2024, multiple hospitals had submitted applications for Revita reimbursement authorization from the German government.

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 reporting open-label data from the REVEAL-1 cohort of REMAIN-1 beginning in the fourth quarter of 2024 and anticipates a mid-point data analysis of REMAIN-1 in the second quarter of 2025.

- REVITALIZE-1: REVITALIZE-1 is a randomized, double-blind, multi-center pivotal study of Revita in patients with adequately controlled T2D on at least one glucose lowering agent (GLA). Fractyl continues to enroll patients in the study and expects to report topline results in mid-2025.

- Germany Real-World Registry Study: Fractyl plans to continue enrolling patients in its German Real-World Registry Study of Revita for T2D. The Company is planning to disclose additional registry data from a larger number of patients in the first quarter of 2025.

Rejuva®

- Fractyl has nominated its first smart GIP/GLP-1 pancreatic gene therapy lead candidate, RJVA-002, designed for the treatment of obesity. RJVA-002 is a locally administered AAV9 viral vector that expresses human GIP and GLP-1 hormones from a human insulin promoter. RJVA-002 is designed to activate both GIP and GLP-1 receptors, which together play crucial roles in regulating blood sugar and body weight.

Upcoming Milestones:

- Fractyl anticipates completing key in vivo studies to support the submission of a CTA for RJVA-001, Fractyl's first nominated GLP-1 pancreatic gene therapy candidate designed for the treatment of T2D, by the end of the year. If the CTA is approved, the Company intends to initiate its first-in-human study in the first half of 2025.

Third Quarter 2024 Financial Results

Revenue: Revenue in both quarters ended September 30, 2024 and 2023 was generated from the Company's pilot commercial launch in Germany.

R&D Expenses: Research and development expense was $19.0 million for the quarter ended September 30, 2024, compared to $9.4 million for the same period in 2023. The increase during the quarter was primarily due to the progress made in our REMAIN-1 and REVITALIZE-1 clinical studies, continued development of the Rejuva program and increased personnel-related expenses, including stock-based compensation.

SG&A Expenses: Selling, general and administrative expense was $4.8 million for the quarter ended September 30, 2024, compared to $4.5 million for the same period in 2023. The increase during the quarter was primarily due to professional service expenses and other costs associated with operating as a publicly traded company, and increased personnel-related expenses, including stock-based compensation.

Net Loss: Net loss was $23.2 million for the quarter ended September 30, 2024, compared to a net loss of $15.7 million for the same period in 2023. The increase in net loss was primarily attributed to a $9.9 million increase in operating expenses discussed above and a $1.5 million increase in non-cash loss from changes in fair value of notes payable, offset by a $3.3 million increase in non-cash gain from changes in fair value of warrant liabilities as well as a $0.7 million increase in net interest income.

Cash Position: As of September 30, 2024, Fractyl had approximately $84.7 million in cash and cash equivalents. Based on our current development plans, we believe that our existing cash and cash equivalents will be sufficient to fund our operations through expected key company milestones into the fourth quarter of 2025.

Webcast and Conference Call Information

Fractyl will host a conference call to discuss its third quarter 2024 financial results and provide business updates on Tuesday, November 12, 2024 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 or www.twitter.com/FractylHealth.

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 and T2D. Revita is designed to remodel the duodenal lining via hydrothermal ablation (i.e., duodenal mucosal resurfacing) to edit abnormal intestinal nutrient sensing and signaling mechanisms that are a potential root cause of metabolic disease. Revita has received a CE mark in Europe and, in January 2022, received reimbursement authorization through NUB in Germany for the treatment of T2D. In the United States, Revita is for investigational use only under US law. Revita has US FDA Breakthrough Device Designation in weight maintenance for people with obesity who discontinue GLP-1 based drugs, as well as in insulin-treated T2D. A pivotal study of Revita in patients with T2D who are inadequately controlled on any glucose lowering agent, REVITALIZE-1, is currently enrolling in the United States and Europe. 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 2024.

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.

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 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 IND-enabling studies, IND applications or Clinical Trial Applications, 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 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 November 12, 2024 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 Condensed Consolidated Balance Sheet Data
(in thousands)
(Unaudited)

	September 30, 2024	December 31, 2023
Cash and cash equivalents	$ 84,664	$ 33,209
Restricted cash	4,255	4,570
Working capital [1]	71,934	24,460
Total assets	126,924	76,212
Notes payable, long-term	30,317	55,152
Total liabilities	76,602	113,944
Convertible preferred stock	—	287,330
Total stockholders' equity (deficit)	50,322	(325,062)

(1) Working capital is defined as total current assets less total current liabilities.

Fractyl Health, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(in thousands)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Revenue	$ 14	$ 36	$ 90	$ 113
Cost of goods sold	7	25	50	75
Gross profit	7	11	40	38
Operating expenses:				
Research and development	19,004	9,382	50,190	27,872
Selling, general and administrative	4,797	4,502	18,171	10,021
Total operating expenses	23,801	13,884	68,361	37,893
Loss from operations	(23,794)	(13,873)	(68,321)	(37,855)
Other income (expense), net:				
Interest income, net	947	226	3,420	797
Change in fair value of notes payable	(2,610)	(1,065)	3,772	(19,676)
Change in fair value of warrant liabilities	2,293	(1,027)	17,442	(1,161)
Other expense, net	(9)	(8)	(37)	(16)
Total other income (expense), net	621	(1,874)	24,597	(20,056)
Net loss and comprehensive loss	(23,173)	(15,747)	(43,724)	(57,911)