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

May 13, 2024

Initiation of Remain-1 pivotal study for weight maintenance in patients with obesity after discontinuation of GLP-1 based drugs expected in the second half of 2024

Topline data from Revitalize-1 pivotal study in patients with inadequately controlled T2D anticipated in the fourth quarter 2024

Update from real-world Germany registry study of Revita in patients with T2D at DDG Annual Meeting

Appointed Adrian Kimber as Chief Commercial Officer to lead Revita launch readiness activities

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

BURLINGTON, Mass., May 13, 2024 (GLOBE NEWSWIRE) -- Fractyl Health, Inc. (Nasdaq: GUTS) (the "Company"), a metabolic therapeutics company focused on pioneering new approaches for the treatment of obesity and type 2 diabetes (T2D), today reported its first quarter 2024 financial results and provided business updates.

"As I reflect on our first quarter as a public company, I am incredibly excited about the progress we have made as an organization to provide potentially game-changing therapies to patients with obesity and T2D. In the second half of 2024 we expect to initiate the Remain-1 pivotal study for weight maintenance, as well as report study updates from the open-label cohort, Reveal-1. We also anticipate topline data from the Revitalize-1 pivotal study in patients with inadequately controlled T2D in the fourth quarter of 2024," said Harith Rajagopalan, M.D., Ph.D., co-founder and Chief Executive Officer of Fractyl. "And, as we look ahead to later-stage development, we strengthened our team with the addition of Adrian Kimber as Chief Commercial Officer. We believe we have the resources and leadership in place to advance our portfolio of product candidates that have the potential to help us achieve our mission of developing transformative therapies that can prevent and hopefully cure metabolic disease."

Recent Highlights and Upcoming Milestones

Revita®

The Revita DMR system is an endoscopic outpatient procedural therapy designed to durably modify duodenal dysfunction, and improve metabolic health, blood glucose levels, and weight in patients with inadequately controlled T2D.

- In May 2024, Fractyl provided a clinical update from its ongoing real-world registry study of Revita in patients with T2D at the German Diabetes Association (DDG) Annual Meeting in Berlin, Germany.

- As of April 15, 2024, the Company has treated 33 patients with DMR and enrolled 26 patients in the registry study with interim follow-up data from 19 patients. At three months post-procedure, the Company observed a reduction from median baseline HbA1c of greater than 1% and a reduction from baseline weight of greater than 15 pounds. Of the 19 patients, 95% remained stable or reduced their prescribed ADAs, 4 patients stopped at least one prescribed ADA, and of those, 2 patients discontinued all their previously prescribed ADAs. Patient related outcomes (PROs) questionnaires were provided to participants at 3 months follow up, with the majority responding that they would undergo the Revita DMR procedure again if it were necessary (90%) and would recommend the procedure to a friend or relative (95%). At 6 months post-DMR (n=14), average percent body weight loss was greater than 8% with median HbA1c falling from 9.2 at baseline to 7.6%. The Company believes these results suggest a significant overall improvement in metabolic health. No device or procedure-related serious adverse events have been reported to date.

- In March 2024, Fractyl received Investigational Device Exemption (IDE) approval from the U.S. Food and Drug Administration (FDA) to initiate a two-part, parallel cohort Remain-1 study for weight maintenance in patients with obesity who have lost at least 15% total body weight on GLP-1RA therapy and wish to discontinue their GLP-1RA without weight regain. In addition, the Company announced Reveal-1, an open-label cohort that will follow a similar patient population and management protocol with anticipated open-label data updates as the study

progresses.

Upcoming Milestones:

- Fractyl is currently enrolling patients in its pivotal Revitalize-1 study in patients with inadequately controlled T2D despite being on up to three ADAs and daily insulin. The Company anticipates completing enrollment in the second quarter of 2024 and expects to report topline data in the fourth quarter of 2024.

- Fractyl expects to initiate the Remain-1 randomized, double-blind pivotal study for weight maintenance and begin reporting updates for the open-label cohort, Reveal-1, in the second half of 2024.

- Fractyl plans to continue enrolling patients in its Germany Real-World registry and provide updates on an ongoing basis.

Rejuva®

Rejuva is a modular, physiologic gene therapy platform with three key elements designed to enable successful pancreatic gene therapy: (1) a proprietary delivery catheter designed to enable local, low dose therapeutic delivery directly to the pancreas via endoscopic access, (2) vectors with tropism for the pancreatic islet to enable successful transduction and gene delivery with limited biodistribution, and (3) transgenes with tissue-restricted promoters and metabolically active peptides that can durably impact glucose and weight control.

- In March 2024, Fractyl announced new results from its Rejuva platform demonstrating potent and durable effects of a single dose of a human GLP-1 pancreatic gene therapy transgene compared to semaglutide in the db/db mouse model, the standard rodent T2D efficacy model used for clinical development.

Upcoming Milestones:

- Fractyl intends to present new preclinical data on the potential of Rejuva for weight maintenance during the 2024 Digestive Disease Week (DDW) Annual Meeting taking place May 18-24, 2024 in Washington, D.C.

- Fractyl expects to complete IND-enabling studies, or its equivalent, for RJVA-001 in the second half of 2024. Pending regulatory clearance, the Company intends to initiate its first-in-human study in the first half of 2025.

- Fractyl plans to nominate its first GLP-1 PGTx candidate for obesity in the second half of 2024.

Corporate Updates

- In April 2024, Fractyl announced the appointment of Adrian Kimber as Chief Commercial Officer. Mr. Kimber brings over two decades of commercial and operational experience across both the biotechnology and medical device sectors, most recently serving as Global Vice President and Commercial Head at BioTronik Neuro, a leading provider of spinal cord stimulation devices.

First Quarter 2024 Financial Results

Revenue: Revenue in both quarters ended March 31, 2024 and 2023 was generated from the Company's pilot commercial launch in Germany that was initiated in the first quarter of 2023.

R&D Expenses: Research and development expense was $14.4 million for the quarter ended March 31, 2024, compared to $9.3 million for the same period in 2023. The increase during the quarter was primarily due to increased investment in Revitalize-1 Clinical Study, advancement of the Rejuva program and increased personnel-related expenses, including stock-based compensation.

SG&A Expenses: Selling, general and administrative expense was $7.1 million for the quarter ended March 31, 2024, compared to $2.8 million for the same period in 2023. The increase was primarily due to increased personnel-related expenses, including stock-based compensation and professional services expenses and other costs associated with operating as a publicly-traded company.

Net Loss: Net loss was $3.3 million for the quarter ended March 31, 2024, compared to a net loss of $11.9 million for the same period in 2023. The decrease in net loss was primarily related to a $17.1 million non-cash gain from a decrease in fair value of notes payable and warrants, and a $0.7 million increase in interest income earned, offset by an increase of $9.4 million in operating expenses.

Cash Position: As of March 31, 2024, Fractyl had approximately $121.4 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 through 2025.

Webcast and Conference Call Information

Fractyl will host a conference call to discuss its first quarter 2024 financial results and provide business updates on Monday, May 13, 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. A pivotal study of Revita in patients with inadequately controlled T2D despite multiple medicines and insulin, called 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, is anticipated to initiate in H2 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 trials or readouts, the potential launch or commercialization of any of our product candidates or products, the sufficiency of our cash, cash equivalents, and investments to fund our operating activities for any specific period of time, 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. 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 May 13, 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)

	March 31, 2024	December 31, 2023
Cash and cash equivalents	$ 121,441	$ 33,209
Restricted cash	4,570	4,570
Working capital [1]	111,200	24,460
Total assets	163,519	76,212
Notes payable, long-term	28,695	55,152
Total liabilities	79,341	113,944
Convertible preferred stock	—	287,330
Total stockholders' equity (deficit)	84,178	(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 March 31,	
	2024	2023
Revenue	$ 33	$ 5
Cost of goods sold	19	3
Gross profit	14	2
Operating expenses:		
Research and development	14,424	9,349
Selling, general and administrative	7,132	2,760
Total operating expenses	21,556	12,109
Loss from operations	(21,542)	(12,107)
Other income (expense), net:		
Interest income, net	1,098	417
Change in fair value of notes payable	6,686	(246)
Change in fair value of warrant liabilities	10,446	(5)
Other expense (income), net	(10)	9
Total other income (expense), net	18,220	175
Net loss and comprehensive loss	(3,322)	(11,932)