FRACTYL health

Fractyl Health Reports Fourth Quarter and Full Year 2023 Financial Results and Provides Business Update

April 1, 2024

Received IDE approval for the Revita® Remain-1 pivotal study for weight maintenance in patients with obesity after discontinuation of GLP-1 Based Drugs

Completion of enrollment in pivotal Revitalize-1 study in patients with inadequately controlled T2D expected in second quarter of 2024 and anticipated topline data in fourth quarter of 2024

Announced nomination of RJVA-001 as first clinical candidate in the Rejuva® GLP-1 gene therapy platform; completion of IND-enabling studies expected in second half of 2024

Completed initial public offering of common stock raising $110 million in gross proceeds; cash on hand expected to fund operations through 2025

BURLINGTON, Mass., April 01, 2024 (GLOBE NEWSWIRE) -- Fractyl Health (Nasdaq: GUTS), a metabolic therapeutics company focused on pioneering new approaches for the treatment of type 2 diabetes (T2D) and obesity, today reported its fourth quarter and full year 2023 financial results and provided a business update.

"2024 is shaping up to be a transformational year as we approach several key milestones across both our Rejuva and Revita platforms, bringing us closer towards our goal of enabling long-term control over type 2 diabetes and obesity without the burden of chronic therapies. We are thrilled to announce today the approval of our IDE for Revita's Remain-1 study in patients with obesity who wish to discontinue current GLP-1 treatment and look forward to initiating the study in the second half of the year," said Harith Rajagopalan, M.D., Ph.D., co-founder and Chief Executive Officer of Fractyl Health. "In addition, we expect to complete enrollment of our pivotal Revitalize-1 study and are excited to report topline data in the fourth quarter of 2024. In parallel, we recently announced the first candidate in our Rejuva GLP-1 pancreatic gene therapy platform, RJVA-001, and are on track to complete IND-enabling studies in the second half of the year. Following our recent initial public offering, we are now well-capitalized and positioned to execute across multiple key upcoming milestones for both our Revita and Rejuva platforms."

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.

- Today, the Company announced Investigational Drug 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. Based on the FDA IDA approval, Fractyl expects to initiate the Remain-1 randomized, double blind pivotal study and begin reporting updates for the open-label cohort, Reveal-1, in the second half of 2024.
- As of March 15, 2024, Fractyl treated 29 patients with DMR and enrolled 24 patients in the registry with interim follow-up data from 14 patients. At three months post-procedure, we observed a change in median baseline HbA1c of -1.9% (9.2% to 7.3%) and a median change in baseline weight of -17.6 pounds (244.7 pounds to 227.1 pounds). Of these 14 patients, two patients discontinued all their previously prescribed ADAs. We believe these results suggest a significant overall improvement in metabolic health.
- In December 2023, Fractyl announced new long-term weight maintenance data. A pooled analysis of data collected on secondary endpoints assessing weight in all of its controlled clinical studies across the U.S. and Europe demonstrated a 3.4% mean reduction in total body weight loss at four weeks in patients with T2D on multiple ADAs after undergoing a single Revita DMR Procedure and showed a sustained mean body weight loss of 4.0% at 48 weeks.
- The Revita system is approved in Europe as a medical device under a CE Mark and received reimbursement authorization through NUB in Germany in 2022 for the treatment of T2D. Fractyl has initiated a limited commercial pilot in a single center in Dusseldorf, Germany.

Upcoming Milestones:

- Fractyl is currently enrolling its pivotal Revitalize-1 study in patients with inadequately controlled T2D despite being on up to three ADAs and daily insulin. The Company expects to complete enrollment in the first half of 2024 and report topline data in the fourth quarter of 2024.
- Fractyl expects to initiate the Remain-1 randomized, double blind pivotal study and begin reporting updates for the open-label cohort, Reveal-1, in the second half of 2024.
- The Company 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 January 2024, Fractyl announced RJVA-001 as the first GLP-1 pancreatic gene therapy (GLP-1 PGTx) candidate in its Rejuva platform for the treatment of T2D. RJVA-001 is a locally administered AAV9 viral vector that expresses full-length GLP-1 hormone from the insulin promoter designed to improve upon known issues of treatment discontinuation and metabolic rebound typically seen with existing GLP-1 based therapies. Fractyl also announced that it has engaged with European regulators to align on an Investigational New Drug (IND)-enabling path for RJVA-001 for the treatment of T2D.
- In December 2023, Fractyl presented preclinical findings in an oral presentation at the World Congress of Insulin Resistance Diabetes and Cardiovascular Disease 2023 Annual Meeting. In the head-to-head preclinical *in vivo* study in a diet-induced obesity mouse model, a single administration of GLP-1 PGTx resulted in 27% total body weight loss at day 28, compared to 21% loss for chronic semaglutide. Animals that were subsequently withdrawn from semaglutide and received a single-dose of GLP-1 PGTx maintained initial body weight loss, while animals who did not crossover to GLP-1 PGTx regained 19% body weight by day 57.
- In November 2023, the Company announced the expansion of an academic-industry scientific partnership led by Professor Randy Seeley, Ph.D., of Michigan Medicine, the academic medical center of the University of Michigan, to explore mechanisms of metabolic improvement for weight loss from an intrapancreatic gene therapy leveraging GLP-1-based transgenes for long-duration treatment of type 2 diabetes and obesity.

Upcoming Milestones:

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

Corporate Updates

- In the first quarter of 2024, the Company completed an initial public offering (IPO), in which we issued and sold a total of 7,433,332 shares of common stock, inclusive of the partial exercise of the underwriters’ option to purchase additional shares, at a price to the public of $15.00 per share, resulting in aggregate net proceeds of approximately $100.3 million, after deducting the underwriting discounts and other offering expenses.
- In February 2024, Fractyl announced the appointment of Sam Conaway to its Board of

Directors. Mr. Conaway brings an extensive background in the commercialization of medical technologies and leadership in new product launches.

Fourth Quarter and Full Year 2023 Financial Results

Revenue: Fractyl initiated a limited commercial pilot in Germany in the first half of 2023. Due to the limited nature of the commercial pilot, revenue from sales and leasing of Revita in 2023 was insignificant, totaling $0.1 million for the year ended December 31, 2023.

R&D Expenses: Research and development expense was $10.2 million for the quarter ended December 31, 2023, compared to $8.6 million for the same period in 2022, and was $38.0 million for the year ended December 31, 2023, compared to $34.4 million for the same period in 2022. The increase was primarily due to increased personnel-related expenses, including stock based compensation, as well as clinical, medical and office lease expenditures, partially offset by decreased engineering, manufacturing, and preclinical study expenditures.

SG&A Expenses: Selling, general and administrative expense was $2.8 million for both quarters ended December 31, 2023 and December 31, 2022. It was $12.8 million for the year ended December 31, 2023, compared to $15.0 million for the same period in 2022. The decrease was primarily due to less professional services spending related to public relations, recruiting and marketing activities, offset by increased debt issuance cost incurred in 2023. In addition, in 2022 the Company wrote off $2.7 million capitalized offering costs related to its initial IPO plan that was delayed due to adverse market conditions. IPO offering costs incurred associated with the Company's IPO effort in 2023 were capitalized as deferred offering costs on the balance sheet.

Net Loss: Net loss was $19.2 million, or $(11.18) per share, for the quarter ended December 31, 2023, compared to a net loss of $10.9 million, or $(7.39) per share, for the same period in 2022. The increase in net loss was primarily related to $6.8 million increase in fair value of the notes payable and warrants, as well as an increase of $1.6 million in operating expenses. Net loss was $77.1 million, or $(45.29) per share, for the year ended December 31, 2023, compared to a net loss of $46.5 million, or $(31.97) per share, for the same period in 2022. The increase was primarily related to $30.0 million increase in fair value of the notes payable and warrants, as well as an increase of $1.5 million in operating expenses.

Cash Position: As of December 31, 2023, Fractyl had approximately $33.2 million in cash and cash equivalents. Based on its current business plans, Fractyl believes that its existing cash and cash equivalents, together with the approximately $100.3 million of aggregate net proceeds from the IPO, will be sufficient to fund its operating expenses and capital expenditures requirements through 2025.

About Fractyl Health

Fractyl Health is a metabolic therapeutics company focused on pioneering new approaches to the treatment of metabolic diseases, including T2D and obesity. Despite advances in treatment over the last 50 years, T2D and obesity 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.

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 T2D and obesity. 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, including without limitation the design, initiation, timing and results of clinical enrollment and any clinical trials or readouts, the content, information used for, timing or results of any IDE or IND-enabling studies or IND applications, the potential launch or commercialization of any of 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 type 2 diabetes and obesity 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; the Company's reliance on third parties to conduct certain aspects of the Company's preclinical studies and clinical studies; the regulatory approval process of the FDA, comparable foreign regulatory authorities and notified bodies, are 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 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 April 1, 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.

Fractyl Health, Inc.
Selected Condensed Consolidated Balance Sheet Data
(in thousands)
(Unaudited)

	December 31, 2023	December 31, 2022
Cash and cash equivalents	$ 33,209	$ 49,269
Restricted cash	4,570	4,255
Working capital [1]	24,460	44,318
Total assets	76,212	60,956
Notes payable, long-term	55,152	17,760
Total liabilities	113,944	25,945
Convertible preferred stock	287,330	287,330
Total stockholders' deficit	(325,062)	(252,319)

[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, except for share and per share information)
(Unaudited)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2023	2022	2023	2022
Revenue	$ 7	$ —	$ 120	$ —
Cost of goods sold	2	—	77	—
Gross profit	5	—	43	—
Operating expenses:				
Research and development	10,166	8,617	38,038	34,354
Selling, general and administrative	2,820	2,796	12,841	15,031
Total operating expenses	12,986	11,413	50,879	49,385
Loss from operations	(12,981)	(11,413)	(50,836)	(49,385)
Other income (expense), net:				
Interest income, net	463	411	1,260	797
Loss from debt extinguishment	—	—	—	(313)
Change in fair value of notes payable	(1,021)	130	(20,697)	2,315
Change in fair value of warrant liabilities	(5,633)	15	(6,794)	137
Other expense, net	(8)	(1)	(24)	(4)
Total other income (expense), net	(6,199)	555	(26,255)	2,932
Net loss and comprehensive loss	(19,180)	(10,858)	(77,091)	(46,453)
Accretion of dividends on convertible preferred stock	(4,330)	(4,330)	(17,180)	(17,180)
Net loss attributable to common stockholders	$ (23,510)	$ (15,188)	$ (94,271)	$ (63,633)
Net loss per share attributable to common stockholders, basic and diluted	$ (11.18)	$ (7.39)	$ (45.29)	$ (31.97)
Weighted-average number of common shares outstanding, basic and diluted	2,102,410	2,055,399	2,081,328	1,990,419

Contacts

Corporate Contact
Lisa Davidson, Chief Financial Officer
ir@fractyl.com, 781.902.8800

Media Contact
Beth Brett, Corporate Communications
bbrett@fractyl.com, 720.656.6544

Investor Contact
Stephen Jasper
Gilmartin Group
stephen@gilmartinir.com, 619.949.3681