UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): August 14, 2024

Fractyl Health, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-41942**	**27-3553477**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
3 Van de Graaff Drive Suite 200 Burlington, Massachusetts		**01803**
(Address of Principal Executive Offices)		**(Zip Code)**

Registrant's Telephone Number, Including Area Code: (781) 902-8800

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.00001 par value per share	GUTS	The Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On August 14, 2024, Fractyl Health, Inc. announced its financial results for the quarter ended June 30, 2024 and provided a corporate update. A copy of the press release in connection with the announcement is being furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information contained in Item 2.02 of this Current Report (including Exhibit 99.1 attached hereto) shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly provided by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

The following exhibit relates to Item 2.02 and shall be deemed to be furnished, and not filed:

Exhibit No.	Description
99.1	Fractyl Health, Inc. Press Release dated August 14, 2024
104	Cover Page Interactive Data File (embedded within the inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Fractyl Health, Inc.

Date: August 14, 2024

By: /s/ Harith Rajagopalan

Harith Rajagopalan, M.D., Ph.D.
Chief Executive Officer

Exhibit 99.1

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

Updated clinical results from German Real-World Registry demonstrate potential for Revita® to meaningfully sustain weight loss and lower blood sugar for at least one-year post-treatment in a real-world setting

Granted U.S. FDA Breakthrough Device designation for Revita in weight maintenance after discontinuation of GLP-1 based drugs

REMAIN-1 pivotal study for Revita in weight maintenance now initiated with anticipated data readouts beginning in Q4 2024

REVITALIZE-1 on-track to report topline data in mid-2025 in expanded Type 2 Diabetes patient population

Presented head-to-head preclinical data comparing Rejuva® versus semaglutide in #1 abstract at ADA 2024

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

BURLINGTON, Mass, August 14, 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 second quarter 2024 financial results and provided business updates.

"GLP-1 drugs have demonstrated impressive results in clinical studies. However, we are seeing that a majority of patients stop taking GLP-1 drugs within one year of starting them and are at risk of rapid weight regain and loss of hard-won benefits," said Harith Rajagopalan, M.D., Ph.D., Co-founder and Chief Executive Officer of Fractyl. "These limitations extend to almost all drugs in the class and has created an urgent need for a durable solution to weight maintenance for a growing number of patients. We are proud to be pioneers in addressing this unmet need, which led us to accelerate our Revita weight maintenance study, REMAIN-1. We believe the recent FDA Breakthrough Device designation for Revita underscores our differentiated approach to the weight maintenance problem and provides further validation for this platform. This quarter we were also pleased to share new preclinical data showing that our Rejuva GLP-1 pancreatic gene therapy platform can durably improve body composition and blood sugar compared to semaglutide, and prevent weight regain after stopping semaglutide. This abstract was chosen as the top submission at this year's American Diabetes Association (ADA)'s meeting."

Dr. Rajagopalan continued, "Across the Company, we have had strong execution through the first half of the year and are now entering what we believe to be a transformational period for Fractyl. We have significant upcoming milestones across both Revita and Rejuva which will be foundational to our goal of developing potentially one-time, disease-modifying solutions in the pursuit of durable improvement in obesity and T2D."

Recent Highlights and Upcoming Milestones

Revita®

- In August 2024, Fractyl announced new weight maintenance and blood sugar clinical results from the Company's German Real-World Registry for the first 11 patients who have completed at least 12 months of post-Revita procedure follow-up. At baseline, prior to Revita, these patients were a median age of 62 years, with obesity and advanced T2D, a median body weight of 111 kilograms (245 pounds; BMI 32 kg/m2), and median baseline HbA1c of 9.6% despite using up to three glucose lowering agents. Approximately two-thirds of these patients were male. At 12 months, the patient's median weight decreased from 111

kilograms (245 pounds) to 97 kilograms (214 pounds), representing a nearly 13% total body weight loss, and their median HbA1c decreased from 9.6% to 7.2%. In addition, the number of glucose lowering medications remained stable or decreased for 10 out of the 11 patients at 12 months. It is important to note that weight loss was observed as early as 1-month post-Revita procedure, and weight loss was generally maintained through 1 year of follow-up, which demonstrates in a real-world setting the potential for a single Revita procedure to be a durable weight maintenance solution. Revita was well tolerated in these patients, and no procedure-related adverse safety events were observed. The Company plans to share additional registry data from a larger number of patients at a scientific congress later this year. To date, 37 patients have been treated with Revita in Germany and 31 have consented to participate in the Real-World Registry.

- In July 2024, Fractyl received Breakthrough Device designation from the U.S. Food and Drug Administration ("FDA") for Revita for use in the maintenance of weight loss after discontinuation of GLP-1 based drugs. The Breakthrough Device designation will enable priority regulatory review with the FDA upon successful completion of the REMAIN-1 study, as well as the potential for an early or accelerated decision on reimbursement by the Centers for Medicare & Medicaid Services (CMS). Revita has already been granted FDA Breakthrough Device designation in insulin-treated T2D.

- In June 2024, Fractyl announced its plans to accelerate its REMAIN-1 clinical study, which is evaluating Revita's efficacy in maintaining weight loss following the discontinuation of GLP-1 therapy.

- In June 2024, the FDA approved an amendment to the protocol of the REVITALIZE-1 study of Fractyl's Revita device, which expands eligibility to patients with T2D who are inadequately controlled on any glucose lowering agent (GLA), including GLP-1 drugs and/or insulin. Previously, the protocol included T2D patients who are inadequately controlled on insulin and up to three non-insulin drugs, including GLP-1 therapies. The updated protocol expands the potential U.S. treatment population by nearly six-fold to ~25 million patients.

Upcoming Milestones:

- REMAIN-1: REMAIN-1 is a randomized, double-blind pivotal trial of Revita versus sham in patients who have lost at least 15% total body weight on tirzepatide therapy. REMAIN-1 was initiated in the third quarter of 2024. The Company anticipates reporting open label data from the REVEAL-1 cohort of REMAIN-1 in the fourth quarter of 2024 and anticipates a mid-point data analysis of the REMAIN-1 cohort 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 GLA. Fractyl is currently enrolling the REVITALIZE-1 study and anticipates reporting topline data 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 and provide quarterly updates on clinical outcomes.

Rejuva®

- In June 2024, Fractyl presented new head-to-head preclinical data on sustained weight maintenance and improved body composition from its Rejuva pancreatic gene therapy program in an oral presentation at the ADA's 84th Scientific Sessions. The data demonstrated that a single administration of a Rejuva GLP-1 candidate reduced fat mass and improved glycemia in the well-validated diet-induced obesity (DIO) mouse model. DIO mice were randomized 1:1:1 to receive a single administration of Rejuva GLP-1-based gene therapy candidate, daily semaglutide injections, or placebo. After the initial 4-week period, semaglutide was discontinued for mice and those animals were further randomized 1:1 to receive either a single

administration of the Rejuva gene therapy candidate or placebo and followed for an additional 4 weeks. At week 8, fat mass rebounded to 1% below baseline in the semaglutide withdrawal group, whereas semaglutide-withdrawn mice treated with Rejuva maintained fat reduction of 17% and weight loss of 22%. In addition, the data provide the first demonstration that Rejuva treatment has potential to mimic natural release of GLP-1 from the intestine. The abstract was selected as the #1 abstract of the conference.

- In May 2024, Fractyl presented new preclinical Rejuva data as part of an oral presentation at Digestive Disease Week 2024 (DDW). The data demonstrated that Rejuva reduced liver weight by 42% and liver triglyceride content by 67% compared to placebo two months after administration. The data also showed a reduction of 36% in total cholesterol and 51% in low density lipoprotein (LDL) cholesterol compared to placebo two months after administration. These results indicate the potential impact of Rejuva to alleviate cardiovascular risk associated with increased levels of cholesterol and highlight the potential for profound, durable, and broad metabolic benefit that can be achieved from single-administration GLP-1-based pancreatic gene therapy.

Upcoming Milestones:

- Fractyl remains on-track to complete an Investigational New Drug (IND)-enabling study, or its equivalent, for RJVA-001, its first nominated GLP-1 pancreatic gene therapy candidate designed for the treatment of T2D, 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 pancreatic gene therapy candidate for obesity in the second half of 2024.

Corporate Updates

- In August 2024, Fractyl announced that, after twelve years of distinguished service, Allan Will has stepped down as Chairman of the Board and as a member of the Company’s board of directors, effective immediately. Mr. Will will serve as an advisor to Ajay Royan, who has been appointed as the new Chair of the Board. Mr. Royan has served as a member of the board of directors since 2014.

Second Quarter 2024 Financial Results

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

R&D Expenses: Research and development expense was $16.8 million for the quarter ended June 30, 2024, compared to $9.1 million for the same period in 2023. The increase was primarily due to the initiation of REMAIN-1, the progress made in REVITALIZE-1, continued development of the Rejuva program and increased personnel-related expenses, including stock-based compensation.

SG&A Expenses: Selling, general and administrative expenses were $6.2 million for the quarter ended June 30, 2024, compared to $2.8 million for the same period in 2023. The increase 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 $17.2 million for the quarter ended June 30, 2024, compared to a net loss of $30.2 million for the same period in 2023. The decrease in net loss was primarily attributed to the change in fair value of notes payable and warrant liabilities as well as increased interest income, offset by the increase of in operating expenses discussed above.

Cash Position: As of June 30, 2024, Fractyl had approximately $102.4 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 into the fourth quarter of 2025.

Webcast and Conference Call Information

Fractyl will host a conference call to discuss its second quarter 2024 financial results and provide business updates on Wednesday, August 14, 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 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. It 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 weight maintenance for patients with obesity after discontinuation of GLP-1-based drugs, called REMAIN-1, is underway with anticipated data readouts from the open-label study in weight maintenance in the fourth quarter of 2024 and an anticipated mid-point analysis of the REMAIN-1 in the second quarter of 2025. 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.

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, and results of clinical enrollment and any clinical studies or readouts, the content, information used for, timing or results of any IND-enabling studies or IND applications, the potential launch or commercialization of any of our product candidates or products, the potential treatment population for any of our product candidates or products, 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 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 August 14, 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)

	June 30, 2024	December 31, 2023
	(Unaudited)	
Cash and cash equivalents	$ 102,439	$ 33,209
Restricted cash	4,570	4,570
Working capital [1]	92,274	24,460
Total assets	146,437	76,212
Notes payable, long-term	28,368	55,152
Total liabilities	75,682	113,944
Convertible preferred stock	—	287,330
Total stockholders' equity (deficit)	70,755	(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 June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Revenue	$ 43	$ 72	$ 76	$ 77
Cost of goods sold	24	47	43	50
Gross profit	19	25	33	27
Operating expenses:				
Research and development	16,762	9,141	31,186	18,490
Selling, general and administrative	6,242	2,759	13,374	5,519
Total operating expenses	23,004	11,900	44,560	24,009
Loss from operations	(22,985)	(11,875)	(44,527)	(23,982)
Other income (expense), net:				
Interest income, net	1,375	154	2,473	571
Change in fair value of notes payable	(304)	(18,365)	6,382	(18,611)
Change in fair value of warrant liabilities	4,703	(129)	15,149	(134)
Other expense (income), net	(18)	(17)	(28)	(8)
Total other income (expense), net	5,756	(18,357)	23,976	(18,182)
Net loss and comprehensive loss	(17,229)	(30,232)	(20,551)	(42,164)