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): July 30, 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

(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 7.01 Regulation FD Disclosure.

On July 30, 2024, Fractyl Health, Inc. (the "Company") issued a press release announcing that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Device Designation for the Company's Revita System for use in the maintenance of weight loss after discontinuation of GLP-1 drugs. The Company also announced that its REMAIN-1 pivotal study is underway with anticipated data readouts beginning in Q4 2024. 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 7.01 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 9.01 and shall be deemed to be furnished, and not filed:

Exhibit No.	Description
99.1	Fractyl Health, Inc. Press Release dated July 30, 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: July 30, 2024

By: /s/ Harith Rajagopalan

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

Fractyl Health Receives FDA Breakthrough Device Designation for Revita in Weight Maintenance for People with Obesity Who Discontinue GLP-1 Based Drugs

Breakthrough Device Designations are granted by the U.S. FDA to expedite review of promising technologies that address high unmet needs and may improve the lives of people with life-threatening or debilitating conditions

REMAIN-1 pivotal study underway to accelerate pathway for weight maintenance indication for Revita®, with anticipated data readouts beginning in Q4 2024

BURLINGTON, Mass., July 30, 2024 (GLOBE NEWSWIRE) – Fractyl Health, Inc. (Nasdaq: GUTS) (the "Company"), a metabolic therapeutics company focused on pioneering new approaches that treat the root cause of obesity and type 2 diabetes (T2D), today announced that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Device Designation for the Company's Revita System for use in the maintenance of weight loss after discontinuation of GLP-1 drugs. 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 Centers for Medicare & Medicaid Services (CMS).

Revita is an outpatient endoscopic procedure that involves resurfacing the mucosal lining of the duodenum, the first part of the small intestine just after the stomach, which is responsible for breaking down food into absorbable nutrients. Revita targets the duodenal lining, which can become thickened by high-fat and high-sugar diets, making it hard for the body to maintain a healthy metabolism and blood glucose levels. By resurfacing and reversing the pathology of the duodenal lining, Revita, if approved, has the potential to become the first disease-modifying therapy that targets a root cause of obesity and T2D.

Obesity is a highly prevalent, complex disease that is associated with multiple cardiometabolic complications, including T2D. GLP-1 agonists have become game-changers in the treatment of diabetes and obesity: over 40% of patients with diabetes in the U.S. have tried GLP-1s and over 12 million U.S. adults have used them just to lose weight,[1,2] yet they are not providing patients with sustained solutions to these chronic problems. Discontinuation rates are high due to gastrointestinal side effects, cost, access challenges, and other unexplained reasons. Clinical studies have highlighted the risk of substantial weight regain — as much as 66% — within one year of discontinuing GLP-1 drugs.[3,4]

To qualify for a Breakthrough Device Designation, a device technology must address an unmet need and show that it has the potential to provide for a more effective treatment of life-threatening diseases or irreversibly debilitating conditions. The goal of the program is to provide patients and clinicians with timely access to these Breakthrough treatments by accelerating their development, assessment and review while maintaining regulatory standards for pre-market approval.

"Patients who discontinue GLP-1 drugs need a reliable off-ramp that will allow them to maintain weight loss without having to continue taking these medicines. Breakthrough Device Designation from the FDA validates Revita's potential for these patients. We believe durable weight maintenance is the single largest unmet need in obesity today, and we believe Revita is one of the only investigational products that is being evaluated in a pivotal study to test its potential to provide sustained weight maintenance," said Harith Rajagopalan, M.D., Ph.D., Co-founder and Chief Executive Officer of Fractyl. "We look forward to reporting data from our open-label study in weight maintenance in the fourth quarter of this year and anticipate a mid-point randomized analysis of the REMAIN-1 pivotal study in Q2 2025. We believe these data will provide further proof that Revita stands alone in the crowded obesity landscape and has the potential to change the treatment paradigm for the majority of patients who want a sustainable solution for their obesity."

In prior clinical studies of Revita conducted in people with T2D in the U.S. and EU, pooled analyses of weight data provided evidence to support the potential for durable weight maintenance after a single Revita procedure. Revita is approved in Germany for the treatment of T2D and has both an FDA Breakthrough Device designation in insulin-treated T2D and reimbursement support from the CMS, meaning that CMS will cover routine costs and certain study-related expenses for participants.

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

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[1] https://www.kff.org/health-costs/poll-finding/kff-health-tracking-poll-may-2024-the-publics-use-and-views-of-glp-1-drugs/
[2] US Census Bureau data as of July 1, 2023
[3] Wilding JPH, et al. *Diabetes Obes Metab.* Weight regain and cardiometabolic effects after withdrawal of semaglutide: The STEP 1 trial extension(2022).
[4] Aronne LJ, et al. *JAMA*. Continued Treatment With Tirzepatide for Maintenance of Weight Reduction in Adults With Obesity: The SURMOUNT-4 Randomized Clinical Trial (2023).

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 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, 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 randomized analysis of the REMAIN-1 pivotal study in Q2 2025.

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 https://twitter.com/FractylHealth.

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 potential launch or commercialization of any of our product candidates or products, the potential treatment population 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. 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 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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