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): November 04, 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 November 4, 2024, Fractyl Health, Inc. (the "Company") issued a press release announcing the Company's nomination of RJVA-002 as its first GIP/GLP-1 pancreatic gene therapy lead candidate 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. 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 Company intends to present new preclinical data on sustained weight maintenance from its Rejuva RJV-001 single-administration GLP-1 pancreatic gene therapy candidate in an oral presentation on Tuesday, November 5, 2024, during The Obesity Society's Annual Meeting at ObesityWeek 2024 in San Antonio, Texas. The Company has posted a slide presentation from the oral presentation. The slide presentation can be found on the Company's website https://www.fractyl.com/our-science/presentations-publications/.

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 7.01 and shall be deemed to be furnished, and not filed:

Exhibit No.	Description
99.1	Fractyl Health, Inc. Press Release dated November 4, 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: November 4, 2024

By: /s/ Harith Rajagopalan

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

Exhibit 99.1

Fractyl Health to Present New Preclinical Data on Sustained Weight Maintenance and Blood Sugar from its Rejuva® RJVA-001 Single-Administration GLP-1 Pancreatic Gene Therapy Candidate at ObesityWeek® 2024

13-week follow-up represents the longest data to-date demonstrating durable efficacy of RJVA-001 on weight and blood sugar in the diet-induced obesity (DIO) mouse model

Company plans to use durable efficacy results as part of its FIH data package for RJVA-001

Fractyl also announces the nomination of RJVA-002, a GIP/GLP-1 dual agonist, as its first pancreatic gene therapy candidate for obesity

BURLINGTON, Mass., November 4, 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), will present new preclinical data on sustained weight maintenance from its Rejuva RJV-001 single-administration GLP-1 pancreatic gene therapy candidate in an oral presentation on Tuesday, November 5, 2024, during The Obesity Society's Annual Meeting at ObesityWeek 2024 in San Antonio, Texas. The presentation is titled "Islet-Targeted GLP-1 Receptor Agonist Gene Therapy Reduces Fat and Improves Metabolism in Obese Mice."

Rejuva is the Company's adeno-associated virus (AAV)-based pancreatic gene therapy program (PGTx), designed to enable durable pancreatic production of therapeutic peptides. RJVA-001 is the Company's gene therapy candidate encoding a Smart GLP-1™for the treatment of T2D. The presentation at ObesityWeek includes new results from preclinical studies in the well-validated DIO mouse model, providing independent confirmation of the efficacy of the RJVA-001 candidate in the laboratory of Dr. Randy J. Seeley at the University of Michigan Medical School.

"The new results in this model demonstrate the durability of our human GLP-1 expressing RJVA-001 candidate 13 weeks after treatment, which is the longest follow-up for Rejuva so far, and a considerable portion of the mouse lifespan,"said Harith Rajagopalan, M.D., Ph.D., Co-Founder and Chief Executive Officer of Fractyl. "This latest independent evaluation by a top academic researcher in obesity, Dr. Randy J. Seeley, validates and builds on results we previously reported in the DIO model at 8 weeks. Rejuva has the potential to be a pattern-breaking therapy that can finally deliver on the promise of the GLP-1 mechanism in the treatment of obesity and T2D – as shown by these results."

The ObesityWeek presentation will include new results demonstrating:

- Sustained maintenance of weight loss and blood sugar levels at week 13 in DIO mice receiving RJVA-001 and continuing a high fat diet.
- Over 10% of islet cells expressing immunoreactivity for GLP-1 protein following a single treatment of mice with PGTx.
- No safety signals observed.

"GLP-1 drugs have proven efficacious in obesity, but their durability remains a significant challenge because patients typically regain weight upon discontinuing treatment," said Dr. Randy J. Seeley, Professor of Surgery, Internal Medicine, and Nutritional Sciences at the University of Michigan Medical School, whose laboratory conducted the latest Rejuva study. "These efficacy data in obese mice suggest that RJVA-001, a human GLP-1 gene therapy targeting islets in the pancreas, has the potential to advance the treatment of obesity by offering a durable, single-dose off-ramp from GLP-1 receptor agonist drugs to help maintain weight loss."

The Company announces the nomination of RJVA-002 as its first Smart GIP/GLP-1 pancreatic gene therapy lead candidate 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.

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.

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, our participation and presentation at conferences, the potential benefits, 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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