Fractyl Health Appoints Samuel Conaway to Its Board of Directors, Bolstering New Product Commercial Expertise During Revita® Pivotal Clinical Trials

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LEXINGTON, Mass., Feb. 20, 2024 (GLOBE NEWSWIRE) -- Fractyl Health, Inc. (Nasdaq: GUTS) (“Fractyl Health” or the “Company”), a metabolic therapeutics company focused on pioneering new approaches for the treatment of Type 2 Diabetes (T2D) and obesity, today announced the appointment of Samuel Conaway to its Board of Directors. Mr. Conaway's extensive background in the commercialization of medical technologies and leadership in new product launches will provide valuable insight and experience as Fractyl Health advances through pivotal clinical studies for T2D and weight loss maintenance and continues its ongoing pilot launch and real-world registry study of Revita in Germany.

"Sam Conaway's proven track record in the successful launch of novel products and therapeutic procedures is a critical addition to our Board of Directors at this juncture," said Dr. Harith Rajagopalan, Co-Founder and CEO of Fractyl Health. "As we progress with our pivotal trials and look towards the future, Sam's strategic vision and commercial acumen will be invaluable, and his appointment underscores our commitment to developing and commercializing new treatment options for people with T2D and obesity."

Mr. Conaway currently serves as President of U.S. Sales in the Cardiology Group at Boston Scientific Corporation and as Chairman of Close the Gap, the Boston Scientific Health Equity initiative. His leadership roles have cemented his reputation as a driving force in the medical device sector.

"I am deeply honored and excited to join the Board of Directors at Fractyl Health, a company at the cutting edge of addressing some of the most pressing healthcare challenges of our time," said Mr. Conaway. "Fractyl Health's novel approach has the potential to significantly impact patient lives, and I look forward to contributing my experience to support Revita through its clinical milestones and as the company seeks approval for this innovative technology."

Mr. Conaway's expertise is expected to play a key role in Fractyl Health's ongoing efforts to complete its pivotal clinical studies in T2D and weight loss maintenance.

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 Lexington, 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. 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 Fractyl Health's ongoing efforts to complete its pivotal clinical studies in T2D and weight loss maintenance, Fractyl Health’s expectations regarding its lead product candidate, Revita, the status of its studies of Revitalize-1, and Mr. Conaway’s expected impact on the Company. 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 fact that there can be no guarantee that Revita’s Breakthrough Device designation will benefit the development and regulatory approval process; additional time may be required to develop and obtain regulatory approval or certification for the Company’s Rejuva gene therapy candidates; the Company’s dependence on the success of its lead product candidate, Revita; 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 sub-assembly components for Revita and for the materials for its Rejuva gene therapy platform for preclinical studies and its ongoing clinical studies; the Company’s dependence on third-party sole-source suppliers for certain sub-assembly components of Revita; and changes in methods of the Company’s Rejuva gene therapy candidate manufacturing or formulation. These and other important factors discussed under the caption "Risk Factors" in the Company’s prospectus filed with the Securities and Exchange

Commission (the “SEC”) on February 2, 2024, and its other filings with the SEC, could cause actual results to differ materially from those indicated by the forward-looking statements made in this press release. Any such forward-looking statements represent management's estimates as of the date of this press release. 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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