Fractyl Health and Bariendo Sign Letter of Intent to Prepare for Potential Offering of Revita® Across its Bariatric and Metabolic Endoscopy Centers Nationwide

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Collaboration is designed to implement a highly scalable clinical pathway for Revita in post GLP-1 weight maintenance, pending FDA approval, potentially benefiting millions of eligible patients

Rising interest from patients and payers for an off-ramp from GLP-1 drugs is fueling significant demand for endoscopic alternatives designed to restore health rather than manage disease

BURLINGTON, Mass. and SAN FRANCISCO, June 04, 2025 (GLOBE NEWSWIRE) -- Fractyl Health, Inc. (Nasdaq: GUTS) (the Company or Fractyl), a metabolic therapeutics company focused on pattern-breaking approaches that treat root causes of obesity and type 2 diabetes (T2D), and Bariendo Inc. (Bariendo), the first all-in-one obesity care platform with cost-effective and durable endoscopic treatments for the rising obesity epidemic, today announced the signing of a non-binding Letter of Intent (the LOI) to explore a future collaboration centered on Fractyl's investigational Revita procedure as a durable off-ramp for weight maintenance following GLP-1 drug discontinuation.

This agreement comes as Fractyl prepares for three key data readouts from its ongoing pivotal study of Revita: REVEAL-1 Cohort open-label data expected in June 2025; REMAIN-1 Midpoint Cohort data expected in the third quarter of 2025; and 6-month primary endpoint data from the REMAIN-1 Pivotal Cohort expected in the second half of 2026. Together, these clinical milestones are designed to demonstrate Revita's potential to help maintain weight loss after GLP-1 discontinuation and inform its possible role in supporting durable metabolic outcomes.

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, altering key nutrient sensing and signaling mechanisms in the gut and driving obesity and metabolic disease. By resurfacing and reversing the pathology of the duodenal lining, if approved by the U.S. Food and Drug Administration (FDA), Revita has the potential to become the first disease-modifying therapy that targets a root cause of obesity.

Bariendo brings to the partnership a scalable, physician-driven platform designed to deliver a holistic approach to obesity, including metabolic endoscopic solutions at the nation's largest network of high-volume hospital and ambulatory endoscopy centers across the United States. Bariendo's mission is to commercialize and scale long-term solutions to obesity that don't require ongoing medication use, empowering people to live healthier lives free from the burden of chronic disease. This model is well-aligned with the purpose of Revita, which is being developed as potentially the first outpatient endoscopic procedure targeting post-GLP-1 weight maintenance.

The explosion of GLP-1 usage has led to the observation that most patients rapidly discontinue drug therapy and face the risk of rapid weight regain after stopping their drugs. Fractyl and Bariendo see an urgent need for an effective "off-ramp" solution that may enable patients to maintain their hard-won weight loss without chronic pharmacology. Under the terms of the LOI, Bariendo has expressed its intent to work with Fractyl to develop its operational readiness and planning for potential integration of Revita into its clinical offerings, pending FDA approval. The collaboration will focus on pre-commercial preparation, including clinical workflow design, provider education, health economic analysis, and the development of referral pathways.

"Obesity is one of the most prevalent diseases in America [1], and a major contributor to the nation's leading causes of death, like heart attacks, diabetes, and cancer. Bariendo is aiming to address this global health crisis with patient-centric, science-based solutions, combining the latest in endoscopic procedures, anti-obesity medicine and concierge care," said Dr. Christopher Thompson, Co-Founder of Bariendo. "We have observed tremendous inbound interest from patients and payers for an off ramp from GLP-1s and are excited to partner with Fractyl as they develop Revita, which we believe has the potential to address the largest remaining unmet need in obesity: weight maintenance."

"This agreement reflects growing recognition of Revita's potential to address a major unmet need in post-GLP-1 care, as reflected in recruitment velocity in our REMAIN-1 pivotal study," said Harith Rajagopalan, M.D., Ph.D., Co-Founder and Chief Executive Officer of Fractyl. "In the study, we have observed extraordinary interest from patients and providers in a holistic approach to durable weight maintenance that includes a time-limited period of weight loss 'induction therapy' with GLP-1 drugs followed by

weight maintenance with Revita and diet/lifestyle intervention. Bariendo is an ideal partner to enable the translation of this care pathway in the REMAIN-1 study to accelerate widespread clinical adoption of Revita pending FDA approval. We believe this collaboration with Bariendo is an important early step toward shaping how durable metabolic interventions will be delivered at scale."

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'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 is based in Burlington, MA. For more information, visit www.fractyl.com.

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. Revita is designed to remodel the duodenal lining via hydrothermal ablation (i.e. duodenal mucosal resurfacing) to reverse damage to intestinal nutrient sensing and signaling mechanisms caused by chronic high-fat and high-sugar diets that are a root cause of metabolic disease. In the U.S., Revita is for investigational use only under U.S. law. Revita has U.S. FDA Breakthrough Device designation in weight maintenance for people with obesity who discontinue GLP-1 based drugs. A pivotal study of Revita in patients with obesity after discontinuation of GLP-1 based drugs, called REMAIN-1, was initiated in the third quarter of 2024 and has completed enrollment.

About Bariendo
Bariendo is the first direct-to-consumer platform to curate, personalize and scale cost-effective, long-term solutions to obesity, offering advanced endoscopic weight loss procedures like ESG Stomach Tightening™. With a national network of advanced obesity management providers and upscale facilities, Bariendo delivers minimally invasive treatments, providing significant and lasting weight loss. The platform also provides comprehensive follow-up care, remote monitoring, and personalized coaching. Backed by a prestigious scientific advisory board, including endobariatric experts from Harvard Medical School and other renowned institutions, Bariendo provides streamlined access to cutting-edge interventions. For more information, visit www.bariendo.com.

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 intent, plans and expected benefits of a collaboration with Bariendo, 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 content, information used for, timing or results of any Investigational New Drug (IND)-enabling studies, communications with regulators, the potential launch or commercialization of any of our product candidates or products, the potential treatment population or benefits 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, redefining the future of metabolic disease treatment, and with respect to providing the first outpatient endoscopic procedure targeting post-GLP-1 weight maintenance, positioning our Company at the forefront of the global opportunity for metabolic care, 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 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 Company's reliance on third parties for the manufacture of sub-assembly components for Revita, 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 May 13, 2025 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, except as required by law.

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[1] Chronic Disease Prevalence in the US: Sociodemographic and Geographic Variations by Zip Code Tabulation Area