# Fractyl Health Reinforces Intellectual Property Leadership in Metabolic Disease with Two New U.S. Patents Directed to Duodenal Resurfacing

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*Robust intellectual property portfolio, built over more than a decade, designed to protect core innovations for treating metabolic diseases*

*New U.S. patents strengthen Fractyl's leadership in metabolic innovation by expanding its patent coverage of duodenal resurfacing, including thermal and non-thermal electrical energy applications*

BURLINGTON, Mass., June 18, 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), today announced that the United States Patent and Trademark Office has issued two new patents that further strengthen the Company's extensive intellectual property (IP) portfolio protecting its duodenal resurfacing innovations.

Fractyl has built its patent portfolio since 2011, and its IP estate now includes 31 granted U.S. patents and approximately 40 pending U.S. applications, along with numerous foreign issued patents and pending applications. The two newly issued patents further reinforce the Company's leadership position in duodenal resurfacing applications.

U.S. Patent No. 12,329,439, issued June 17, 2025, and U.S. Patent No. 12,303,185, issued May 20, 2025, both titled *"Electrical energy ablation systems, devices and methods for the treatment of tissue,"* are directed to ablating duodenal mucosa with various forms of energy, including thermal and non-thermal electrical energy.

"These new patents reinforce our leadership in gut-targeted therapies for metabolic disease," said Sarah Toomey, General Counsel and Corporate Secretary of Fractyl Health. "We created this category of duodenal mucosal resurfacing more than a decade ago and continue to expand an IP portfolio that supports our vision for the Company. Revita® represents a first-in-class and potentially breakthrough treatment in this category with a compelling clinical profile in hundreds of treated patients with obesity and type 2 diabetes. As the pioneers in this field, we believe that continued innovation, along with proactive protection of our inventions, will allow us to deliver the best therapies possible to patients and physicians."

"The idea that ablating a segment of the duodenal mucosa could drive clinically meaningful metabolic improvements emerged as a compelling and important insight from Fractyl's early clinical studies," said John Amatruda, M.D., Adjunct Professor of Medicine at Yale University School of Medicine. "These early findings informed foundational design principles at Fractyl that have led to a category of devices and techniques for duodenal mucosal resurfacing. This progress represents a significant step toward the creation of potentially disease-modifying metabolic therapies."

These IP developments come 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.

**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. The Company has a robust and growing IP portfolio, with 31 granted U.S. patents and approximately 40 pending U.S. applications, along with numerous foreign issued patents and pending applications. 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 Q3 2024 and has completed enrollment.

**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 potential launch or commercialization of any of our product candidates or products, the status, breadth and strength of our intellectual property portfolio and its ability to protect our innovations, our ability to obtain patent coverage for our products, our ability to successfully defend litigation and other similar complaints and to establish and maintain intellectual property rights covering our products, the potential treatment population for or benefits of 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, redefining the future of metabolic disease treatment, positioning our Company at the forefront of the global opportunity for metabolic care, and the timing of any of the foregoing. These statements do not purport to limit the scope of any issued patents. 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 scope of protection we and/or any future licensors are able to establish and maintain for intellectual property rights covering our innovations or our product candidates; 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 lengthy and unpredictable regulatory approval process for the Company's product candidates; uncertainty regarding its 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.

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