



Fractyl Health Strengthens Revita Patent Portfolio as It Advances Toward FDA Submission and Potential Commercialization

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- Patent milestones build on positive REMAIN-1 six-month pivotal results and patient research supporting interest in a one-time procedure for post-GLP-1 weight maintenance
- New catheter patent provides protection extending to 2042; broader portfolio includes issued duodenum treatment-method claims not limited to any specific energy modality
- Fractyl's IP portfolio includes 39 granted U.S. patents, approximately 40 pending U.S. applications and more than 50 issued international patents

BURLINGTON, Mass., Oct. 30, 2026 (GLOBE NEWSWIRE) -- Fractyl Health, Inc. (Nasdaq: GUTS) (the Company or Fractyl), a clinical-stage metabolic therapeutics company focused on pioneering novel approaches to treat obesity and type 2 diabetes (T2D), today announced additions to its U.S. patent portfolio that strengthen the intellectual property foundation for investigational Revita® as the Company advances toward a planned U.S. Food and Drug Administration (FDA) De Novo marketing submission for post-GLP-1 weight maintenance.

The patent developments build on positive six-month results from the REMAIN-1 Pivotal Cohort and recently announced market research identifying patient interest in a one-time procedural approach to maintaining weight loss after GLP-1 therapy. Together, these advances support Fractyl's strategy to develop Revita as a potential new treatment option for patients seeking to preserve the weight loss they achieved with medication.

The U.S. Patent and Trademark Office (USPTO) has issued a patent covering aspects of Revita's single-use catheter and allowed a patent application covering how the system controls thermal energy during treatment. These developments complement an existing console patent and broader issued treatment-method claims that are not limited to any specific energy modality.

"The positive six-month REMAIN-1 results and our patient research strengthen our confidence in Revita's potential to address a substantial unmet need in post-GLP-1 weight maintenance by targeting the duodenum," said Harith Rajagopalan, M.D., Ph.D., Co-Founder and Chief Executive Officer of Fractyl Health. "As we build the clinical evidence and prepare for potential commercialization, we are also strengthening protection for the innovations behind Revita. Our portfolio spans key device components and duodenal treatment methods, including claims that are not limited to any specific energy modality. We believe this breadth is an important foundation for Revita's potential long-term commercial value."

Protecting the technology behind a potential one-time treatment

U.S. Patent No. 12,740,821, issued September 22, 2026, covers specific design features of the Revita catheter designed to help it navigate the duodenum—the first part of the small intestine—and position the treatment element for duodenal ablation

The single-use catheter is a key component of the Revita system. The patent's term extends to November 28, 2042, adding long-term protection for the claimed catheter technology.

The USPTO has also issued a Notice of Allowance for U.S. Patent Application No. 18/988,800, directed to Revita's thermal dosing method. The allowed claims cover separately controlling heated and cooling fluids within the treatment element to regulate the thermal dose delivered to the duodenal lining. This method is part of the hydrothermal ablation approach being evaluated in the ongoing REMAIN-1 Pivotal Cohort.

Treatment-method claims not limited to any specific energy modality

Fractyl's intellectual property strategy extends beyond the specific hardware and hydrothermal technology used in Revita to include methods of treating duodenal tissue that are not limited to a particular ablation modality.

U.S. Patent No. 12,471,979 includes an independent method claim that is not limited to any specific energy modality. The claim addresses a defined sequence of positioning an expandable treatment device, delivering energy to duodenal mucosal tissue, and repeating treatment at additional locations. Dependent claims expressly address electrical or thermal energy.

These claims provide an additional layer of treatment-method protection alongside patents covering Revita's catheter, console and

thermal dosing technology. Their scope is defined by the device features and procedural steps required by the claims.

Building the foundation for potential commercialization

The catheter patent and allowed thermal-dosing application complement U.S. Patent No. 12,690,909, issued July 28, 2026, which covers a heater design for the Revita console.

Together, these recent patent developments strengthen issued and allowed claims across the system that powers the procedure, the single-use catheter and the treatment method. Fractyl believes this combination supports its preparations for potential commercialization while protecting innovations developed through years of investment in duodenal treatment technology.

Fractyl's intellectual property portfolio currently includes 39 granted U.S. patents, approximately 40 pending U.S. applications, and more than 50 issued patents outside the United States. The portfolio includes patents with terms extending into 2042, although individual patent terms vary.

About Revita

The Revita® DMR System is Fractyl's lead product candidate, designed to remodel the duodenal lining via a single, minimally invasive endoscopic procedure intended to restore healthy nutrient sensing and signaling disrupted by chronic metabolic disease. By targeting duodenal dysfunction, Revita is designed to address an underlying driver of obesity and enable durable weight maintenance following GLP-1 discontinuation. Revita has received FDA Breakthrough Device Designation for weight maintenance in people with obesity who discontinue GLP-1 therapies. Revita is for investigational use only in the United States and is CE marked in the European Union and United Kingdom.

About Fractyl Health

Fractyl is a clinical-stage metabolic therapeutics company focused on pioneering novel approaches to treat obesity and type 2 diabetes. The Company's lead product candidate, Revita, is an endoscopic procedural therapy in pivotal development for post-GLP-1 weight maintenance. Fractyl's goal is to change the course of metabolic disease, advancing treatment from chronic management toward prevention and reversal of disease. Fractyl is headquartered in Burlington, Massachusetts.

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 are forward-looking statements. These statements may be identified by words such as "aims," "anticipates," "believes," "could," "estimates," "expects," "forecasts," "goal," "intends," "may," "plans," "possible," "potential," "seeks," "will" and variations of these words or similar expressions that are intended to identify forward-looking statements, although not all forward-looking statements contain these words.

Forward-looking statements in this press release include, without limitation, statements regarding: the scope, duration, enforceability and potential benefits of the Company's intellectual property protection, including the potential application of treatment-method claims to technologies using different energy modalities; the anticipated issuance of allowed patent applications and growth of the Company's patent portfolio; the potential protection afforded by patents covering the Revita console, catheter and treatment methods; the potential contribution of the Company's intellectual property portfolio to Revita's long-term commercial value; the promise and potential impact of the Company's clinical trial data, market research and product candidates, including Revita's potential for maintaining weight loss following GLP-1 therapy discontinuation; the potential patient population, patient interest and commercial opportunity for Revita; the Company's regulatory strategy, including the timing of any potential De Novo marketing application submission and the potential use and benefits of the De Novo pathway; the potential receipt of FDA marketing authorization; the potential launch or commercialization of the Company's product candidates; the Company's strategic and product development objectives and goals; 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. These risks include, without limitation, the risk that pending or allowed patent applications may not issue as patents; that issued patents may be challenged, invalidated, circumvented or found unenforceable, or may not provide the anticipated scope or duration of protection; that the Company may be unable to obtain or maintain adequate intellectual property protection for its product candidates; that clinical results may not support regulatory authorization or commercial adoption; that stated patient preferences may not translate into actual demand; and risks related to clinical development, regulatory review, financing and commercialization. These and other risks are discussed more fully in the Company's filings with the Securities and Exchange Commission (the SEC), including the "Risk Factors" section of its Annual Report on Form 10-K for the year ended December 31, 2025, filed with the SEC on March 24, 2026, and other documents it subsequently files with or furnishes to the SEC, including its Quarterly Report on Form 10-Q for the quarter ended June 30, 2026, filed with the SEC on August 10, 2026.

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, it disclaims any obligation to do so, even if subsequent events cause its views to change.

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