Fractyl Health Expands Board of Directors with Appointments of Industry Leaders to Advance Clinical Execution and Strategic Growth

Sep 3, 2025

Appointments include Christopher Thompson, M.D. and Ian Sheffield as Independent Directors

BURLINGTON, Mass., Sept. 03, 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 the appointments of Christopher Thompson, M.D. and Ian Sheffield to its Board of Directors. These appointments build on Fractyl's recent momentum as it advances Revita ® through late-stage development and prepares for its first-in-human clinical study with Rejuva®.

"We are at a major inflection point for Fractyl, advancing two first-in-class products with the potential to transform the treatment of obesity and T2D," said Harith Rajagopalan, M.D., Ph.D., Co-Founder and Chief Executive Officer of Fractyl Health. "With randomized data from our Revita Midpoint Cohort expected this month and our Rejuva gene therapy platform moving toward the clinic, execution is critical to delivering on this next phase of growth. Chris's leadership in endoscopic approaches to tackling obesity and metabolic disease and Ian's deep expertise in healthcare investing will strengthen our ability to build on this momentum and position Fractyl as a late-stage, pre-commercial company poised to redefine metabolic care."

Christopher C. Thompson, M.D. is Professor of Medicine at Harvard Medical School and Director of Endoscopy at Brigham and Women's Hospital, where he also co-leads the Center for Weight Management and Wellness. Widely recognized as a pioneer in bariatric endoscopy, he has invented and advanced multiple procedures that have shaped the field. Dr. Thompson has led pivotal clinical trials, authored more than 300 peer-reviewed publications, and co-founded several start-ups in endoscopic technology including Bariendo, the first all-in-one obesity care platform with cost-effective and durable endoscopic treatments. He has held leadership positions in professional societies, including the American Society for Gastrointestinal Endoscopy, and is credited with establishing bariatric endoscopy as a discipline. Dr. Thompson's deep expertise in pioneering endoscopic therapies aligns with Fractyl's near-term Revita data milestones and the upcoming Rejuva first-in-human clinical study, strengthening clinical credibility as the Company advances its programs.

Ian Sheffield is an experienced healthcare investor and former medtech executive with a 20-year track record across public equities, private equity, and medical technology. He is Managing Partner at North Country Holdings, a private investment firm focused on acquiring and growing U.S.-based businesses. Previously, Mr. Sheffield held senior investment roles at Ashler Capital (Citadel), Bridger Capital, Great Point Partners, and Versant Ventures, leading or supporting investments across medical devices, diagnostics, healthcare services, and biotech. Earlier in his career, he held operating roles at Medtronic and Procter & Gamble, where he led teams in strategy, commercialization, and business management. He has served on the boards of both public and private medical technology companies. Mr. Sheffield holds a B.S. from Miami University and an M.B.A. from Harvard Business School. Mr. Sheffield's two decades of experience in healthcare investing and operations will be invaluable as Fractyl navigates late-stage development, capital allocation, and strategic partnerships to accelerate growth.

In conjunction with the new director appointments, Amy W. Schulman has stepped down from the Board of Directors.

"On behalf of the Board, I am pleased to welcome Chris and Ian to Fractyl and thank Amy for her important service to the Company and helping us arrive at this pivotal moment," said Ajay Royan, Chairman of the Board of Directors of Fractyl Health. "Chris and Ian's combined scientific and financial expertise arrives at precisely the right time as the Company accelerates toward key milestones and prepares for the next stage of growth. We are confident that their insights will help ensure we are strategically positioned to capture the extraordinary clinical and economic opportunity ahead of us to potentially transform metabolic care."

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 33 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 the third quarter of 2024 and has completed enrollment.

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. The Company has submitted the first Clinical Trial Application (CTA) module for RJVA-001 in T2D to regulators, and if the CTA is authorized, the Company expects to dose the first patients with RJVA-001 and report preliminary data in 2026.

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, timing and results of clinical enrollment and any clinical studies or readouts, 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, positioning our Company at the forefront of the global opportunity for metabolic care or a late-stage, pre-commercial company poised to redefine metabolic care, and the impact of changes in board composition on or 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; 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 sub-assembly components for Revita and for the materials for its Rejuva gene therapy platform for preclinical studies, and its ongoing clinical studies; the regulatory approval process of the FDA and comparable foreign regulatory authorities is 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 12, 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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