Fractyl Health Appoints Mike Zumdahl as Senior Vice President, Market Access and Commercial Strategy

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Experienced market access leader joins to build reimbursement and health economic infrastructure for Revita® ahead of anticipated REMAIN-1 Pivotal Cohort topline data in early Q4 2026

BURLINGTON, Mass., June 01, 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 the appointment of Mike Zumdahl as Senior Vice President, Market Access and Commercial Strategy. Mr. Zumdahl served as Vice President of Global Health Economics, Market Access, and Government Affairs at Inari Medical, where he led the function through the company's growth and 2025 acquisition by Stryker. He joins Fractyl as the Company prepares for the anticipated REMAIN-1 Pivotal Cohort topline readout in early Q4 2026 and a potential De Novo marketing application submission for Revita® in late Q4 2026.

“We are thrilled to welcome Mike to the Fractyl team at this critical inflection point. With nearly one million people per month discontinuing GLP-1 therapy in the U.S. and actively seeking a durable off ramp, building robust reimbursement and health economic infrastructure is essential for commercial success. Mike’s track record building market access for breakthrough procedural therapies at Inari and for helping launch the GLP-1 category at Novo Nordisk makes him the ideal leader to help define the post-GLP-1 weight maintenance category ahead of our REMAIN-1 pivotal data and potential De Novo marketing application later this year,” said Harith Rajagopalan, M.D., Ph.D., Co-Founder and Chief Executive Officer of Fractyl.

Most recently, Mr. Zumdahl was President of Commercial Access Partners, advising medtech companies on go-to-market strategy, health economics, and reimbursement. Prior to that, he led Global Health Economics, Market Access, and Government Affairs at Inari Medical before its acquisition by Stryker for approximately $4.9 billion in February 2025, helping create one of medtech’s most successful market access build-outs for a novel procedural category. Earlier in his career, he started as a sales representative at GSK, and then spent nearly a decade at Novo Nordisk in roles of increasing responsibility, including National Accounts and Government Payers, where he contributed to the company's Health Economics and Outcomes Research strategy and value-based contracting for GLP-1 therapies.

“The post-GLP-1 weight maintenance problem represents the largest unmet need I have seen in metabolic disease in the last twenty years. I joined Fractyl to build the reimbursement architecture for a novel procedure in this category, and the commercial strategy to help more patients access the therapy,” said Mr. Zumdahl. “I’m energized to be working on this critically important unmet patient need, alongside Harith and the team, at this pivotal moment for the Company.”

About Revita

Revita is Fractyl Health’s lead product candidate, designed to remodel the duodenal lining via a one-time, minimally invasive endoscopic procedure intended to restore healthy nutrient sensing and signaling disrupted by chronic metabolic disease. Revita has received Breakthrough Device designation from the U.S. Food and Drug Administration (FDA) 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 Health is a clinical stage metabolic therapeutics company advancing two differentiated candidates designed to target the root causes of obesity and T2D: Revita, a procedural therapy in pivotal development for post-GLP-1 weight maintenance, and Rejuva, an AAV-based gene therapy platform with its lead candidate RJVA-001 entering first-in-human clinical studies. Fractyl’s goal is to advance metabolic disease 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 regarding the Company’s executive leadership hire, including the anticipated contributions of the Company’s Senior Vice President, Market Access and Commercial Strategy. 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. These and other risks are discussed more fully in our filings with the Securities and Exchange Commission (the SEC) including the “Risk Factors” section of our Annual Report on Form 10-K for the year ended December 31, 2025, filed with the SEC on March 24, 2026, and other documents we subsequently file with or furnish to 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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