



Fractyl Raises \$55 Million in Series E Financing to Advance Revita DMR for Type 2 Diabetes

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Revita® DMR is the first and only procedural therapy for type 2 diabetes; Revita DMR has been shown to durably improve blood sugar control without the need for escalating drug therapy and to reduce liver fat in NAFLD/NASH in clinical studies to date.

LEXINGTON, Mass., August 6, 2020 – [Fractyl Laboratories Inc.](#) (Fractyl), a life sciences company dedicated to novel therapeutic interventions that can reverse the metabolic disease epidemic, today announced a first close of \$55 million in a Series E financing. The financing was led by new investor Taiwania Capital Management Corporation and included returning investors Bessemer Venture Partners, General Catalyst, Domain Associates, Mithril Capital Management, Emergent Medical Partners, True Ventures, and GV. New investors, Catalio Capital Management, CDIB Venture Capital Corp., and YJ Capital, also participated in the round. Michael Huang, Managing Partner at Taiwania, will join Fractyl's Board of Directors in conjunction with the financing.

The proceeds from the financing will be used to support the Revita T2Di pivotal clinical trial of Revita DMR (duodenal mucosal resurfacing) for the treatment of patients with type 2 diabetes (T2D). Revita T2Di aims to examine the effect of Fractyl's Revita DMR treatment on glycemic control and insulin requirements. The primary endpoint of the study will be the percentage of patients who are able to achieve target glycemic control (HbA1c less than or equal to 7%) without the need for insulin at 24 weeks post procedure, comparing Revita DMR to the sham arm. Secondary endpoints will assess the impact of Revita DMR on additional glycemic, hepatic, and cardiovascular endpoints.

"Type 2 diabetes and NAFLD/NASH are eroding our global health and are responsible for a large portion of global healthcare costs," said Huang. "Fractyl has established through rigorous clinical studies that Revita, a breakthrough non-drug, non-surgical treatment, has the potential to significantly improve type 2 diabetes outcomes."

"Fractyl's founding mission was to find a better way to treat type 2 diabetes by addressing the root cause of disease that can reverse the disease process rather than manage its symptoms. We now have data from hundreds of patients with type 2 diabetes showing the durable benefits of a single Revita treatment," said Harith Rajagopalan, M.D., Ph.D., co-founder and CEO of Fractyl. "We welcome our new investors and the continued support of our returning investors, who recognize that we are at a pivotal moment in fundamentally redefining the treatment paradigm for metabolic diseases, including type 2 diabetes and NAFLD/NASH. We look forward to initiating our pivotal U.S. clinical trial later this year."

The Revita DMR treatment harnesses breakthrough insights in intestinal biology and aims to reset key metabolic pathways, including insulin resistance, to reverse metabolic disease. This same-day, outpatient endoscopic procedure uses heat to resurface the lining of the upper intestine (duodenal mucosa) in a minimally invasive, outpatient procedure.

Data from clinical trials, involving close to 300 patients at more than 20 centers across three continents, has demonstrated that one Revita treatment can create long-lasting improvements in both T2D and fatty liver disease to help patients with type 2 diabetes avoid further medication escalation. Revita DMR has been shown to be safe and well-tolerated with no long-term adverse events in clinical studies to date.

In April 2016, the Revita DMR System received a CE mark in the European Union. In March 2020, the CE Mark label for Revita DMR was expanded from its original label for patients with poorly controlled type 2 diabetes on oral medications to include insulin withdrawal for patients with T2D, improvements in NAFLD/NASH in patients with T2D, and improvements in insulin sensitivity in patients with polycystic ovary syndrome (PCOS). In the United States, Revita is approved for investigational use only by the U.S. Food and Drug Administration. The Revita DMR System may be available for investigational use in other regions.

About Fractyl

Fractyl Laboratories is applying unparalleled insights into intestinal biology to advance treatments and potential cures for metabolic diseases. Fractyl is developing Revita DMR, a same-day, minimally invasive procedure to treat highly prevalent metabolic diseases, resulting from insulin resistance, including type 2 diabetes (T2D) and nonalcoholic fatty liver disease (NAFLD), of which the more serious condition is nonalcoholic steatohepatitis (NASH). The company's unique treatment approach offers the potential to restore health to millions of patients worldwide and reduce the global economic and healthcare burden of metabolic disease. Fractyl is a private life sciences company based in Lexington, Mass. For more information, visit www.fractyl.com or www.twitter.com/FractylLabs.

CORPORATE CONTACT:

Lisa Davidson, Chief Financial Officer,
17 Hartwell Avenue, Lexington, MA 02421,
lisa@fractyl.com, +1.781.902.8800

MEDIA CONTACT:

Jessica Yingling, Ph.D.,
Little Dog Communications Inc.,
+1.858.344.8091

jessica@litldog.com,