



Press Kit

Fractyl Health Inc.

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The Revita® System is for investigational use only in the United States, has received a CE mark in Europe, and NUB reimbursement in Germany.

About Fractyl Health

Addressing root causes of metabolic disease—in the gut

Fractyl Health is an organ editing metabolic therapeutics company pioneering a new approach to the treatment of type 2 diabetes (T2D). Our goal is to transform treatment from chronic blood glucose management to disease-modifying therapies that target the organ-level root causes of T2D.

We have assembled a mission-driven team of innovators, united in a passion to eradicate T2D and to develop breakthrough therapies—the type of therapies we would want for ourselves, our family members, and our loved ones with the disease.

Our approach involves identifying diseased metabolic organs at the root of the T2D disease process and designing disease-modifying treatments that aim to reverse the core pathology in these organs that is driving the disease process. We believe that addressing the diseased organs in a manner that is designed to restore their metabolic health and function offers the potential for disease eradication in a manner that current approaches, focused on lifestyle intervention or pharmacological management, have not been able to achieve. We call this approach “organ editing.”

About Revita[®]

Revita, our lead product candidate, aims to target duodenal dysfunction, which we believe to be a driver of insulin resistance in T2D, via a minimally invasive endoscopic procedure. In this outpatient procedure, the Revita catheter is introduced through the mouth and into the duodenum. The catheter is designed to first isolate the mucosa from the deeper layers beyond the submucosal space, then hydrothermally ablate the duodenal mucosa thought to be dysfunctional and driving insulin resistance. In the days following the ablation procedure, the duodenal mucosa regenerates, which we believe leaves a new duodenal lining revitalized and better able to function in a manner that has the potential to improve metabolic health.

About Revitalize

Led by our ongoing Revitalize-1 pivotal study, we have initiated a broad clinical program, Revitalize T2D, which is designed to evaluate Revita in multiple concurrent clinical studies across a range of patient populations from prediabetes to T2D patients on long-acting insulin. This program is built on previous studies conducted across Europe and in South America which have included a total of ~ 300 patients and delivered many years of invaluable follow up data. We are now enrolling patients in the Revitalize-1 clinical study. Revitalize-1 is evaluating the effectiveness and safety of Revita for people with inadequately controlled type 2 diabetes despite being on insulin and other antidiabetic agents.

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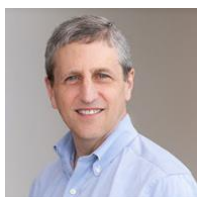
Leadership



HARITH RAJAGOPALAN, MD, PHD

CO-FOUNDER AND CEO

Harith Rajagopalan, M.D., Ph.D., is Co-founder and CEO of Fractyl Health, having started the company while serving as an Entrepreneur-in-Residence at General Catalyst Partners. Prior to founding Fractyl Health, Harith was an academic cardiologist and physician-scientist. He received his B.S. in chemistry from Stanford University and went on to obtain M.D. and Ph.D. degrees from Johns Hopkins School of Medicine. At Johns Hopkins, Harith did groundbreaking and award-winning research on intestinal cancers that was published in top medical journals including Nature and Science. After medical school, Harith trained in internal medicine and clinical cardiology at Brigham and Women's Hospital and completed a research fellowship at the Harvard Stem Cell Institute at Harvard Medical School.



JAY CAPLAN

CO-FOUNDER AND PRESIDENT

Jay Caplan is Co-founder and President of Fractyl Health and has held leadership positions in the medical device field for more than 20 years. Prior to founding Fractyl Health, Jay was the Chief Operating Officer of the Candela Corporation, a world leader in aesthetic devices. Previously, he was Chief Technology Officer and Vice President of Research and Development at InfraReDx, Inc. a venture-backed startup developing a novel cardiovascular imaging system to identify lipid-rich coronary plaques. Prior to InfraReDx, Jay was Vice President of Operations for Thermo Cardiosystems, where he led the team developing the HeartMate II left ventricular assist device. Jay holds a B.S. in electrical engineering from M.I.T. and an MBA from The Wharton School of the University of Pennsylvania.



LISA DAVIDSON

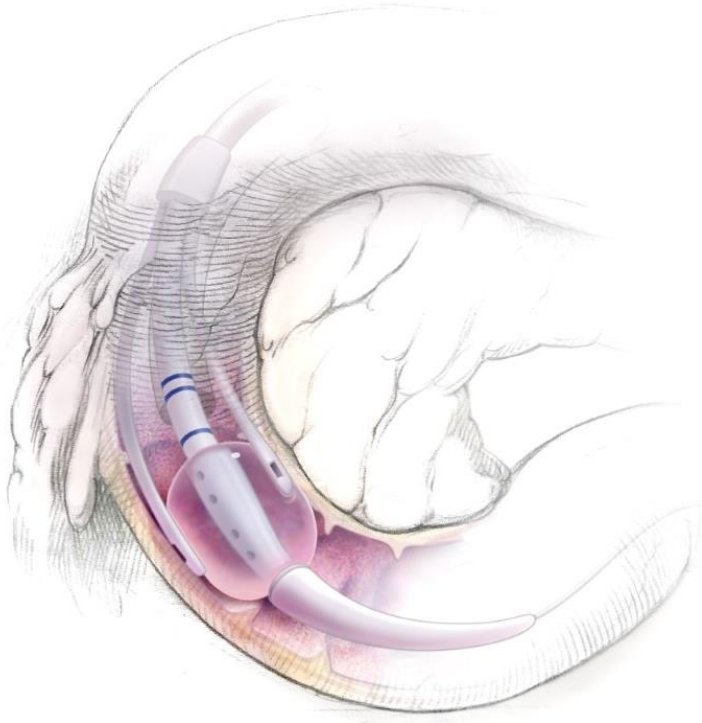
CHIEF FINANCIAL OFFICER

Lisa Davidson is Chief Financial Officer of Fractyl Health. Lisa has more than 25 years of broad corporate finance experience encompassing treasury management, strategic planning, operations finance, and controllership. She served as Vice President of Finance & Administration at Flexion Therapeutics, Inc. Prior to Flexion, Lisa served as Director of Finance at OmniSonics Medical Technologies, Inc. She previously served in various finance, strategy, and administration positions at PerkinElmer Inc., Pepsi Bottling Group, and Fisher Scientific International, Inc. (now part of ThermoFisher Scientific). Lisa has been involved in a number of M&A transactions, venture debt and equity financings, and numerous product launches. She holds both a B.A. and an MBA from the University of New Hampshire.

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Revita® Procedure Illustration



Revita Procedure Video

Revita DMR®
Procedure Overview

A potentially transformative approach
to Type 2 Diabetes treatment

The Revita® System is for investigational use only in the United States.
Revita DMR® has a CE mark from the European Union and is indicated for:
• Improvement of glycemic control in patients with Type 2 Diabetes who have preserved pancreatic beta cell function and whose diabetes is poorly controlled despite oral and/or injectable glucose lowering medications and/or long-acting insulin therapy

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