

NEWS RELEASE

FOR IMMEDIATE RELEASE

Launchit DTx Inc.

May 9, 2023

Regulora[®], a Digital Therapeutic for abdominal pain caused by IBS, is now available in Canada.

Hamilton, ON, May 9, 2023 – Launchit DTx announces that they have received Health Canada authorization to market Regulora[®], and the treatment is now available in Canada to adults living with Irritable Bowel Syndrome (IBS).

The Regulora[®] app was developed by metaMe Health, a U.S. company that develops Digital Therapeutics for the treatment of common chronic conditions. Regulora[®] is an FDA-cleared Prescription Digital Therapeutic in the U.S., and Launchit DTx has sublicensed the technology for the Canadian market.

Patients and doctors can learn more by visiting www.regulora.ca. Patients are required to obtain a referral from their doctor to ensure the treatment is right for them.

IBS is a chronic condition that affects 10-15% of adults in the United States, roughly 25 to 45 million people.¹ Notably, an estimated 13-20% of the population (approximately 5 to 7.5 million people) are living with IBS in Canada. On average, Canadians with IBS miss an average of 13 days of work per year, leading to \$8 billion in lost productivity. Published data estimates the economic burden of IBS is \$6.5 billion annually in Canada.²

metaMe Health's Regulora is the first U.S. FDA-authorized Prescription Digital Therapeutic specifically for abdominal pain associated with IBS in adults. It provides self-administered Gut-Directed Hypnotherapy (GDH) through a convenient iOS and Android app that can be used at home along with other IBS treatments.

Until now, the availability of GDH has been limited, as it required in-person administration by specialized therapists. Now, with Regulora, patients no longer have to drive to a clinic for

¹ IBS Facts and Statistics. Accessed September 19, 2022. Learn more: <https://aboutibs.org/what-is-ibs/facts-about-ibs/>.

² Gastrointestinal Society and Canadian Society of Intestinal Research. IBS Facts. Accessed September 19, 2022. Learn more: <https://badgut.org/information-centre/a-z-digestive-topics/ibs-awareness/>

therapy or wait for a referral that is weeks out. They can get gut-directed hypnotherapy digitally through the App Store or Google Play.

Tim Rudolphi, CEO at metaMe Health, says, “We’re excited to expand the availability of our first digital therapeutic, Regulora® outside of the U.S. It is great to have a trusted partner like Launchit DTx to manage the complexities of the Canadian commercialization and regulatory processes that are required to take Regulora to market.”

Jamie Harsevoort, CEO at Launchit Ventures, adds, “We are excited to further enable metaMe Health’s mission to provide an innovative treatment option to patients with abdominal pain due to IBS. With an estimated 5 to 7.5 million IBS patients in Canada, we have a tremendous opportunity to make a difference in patients’ lives by providing a proven therapy that they can access easily at home.”

Prescription Digital Therapeutics deliver evidence-based therapeutic interventions through high-quality software programs to prevent, manage, or treat a medical disorder or disease. PDTs incorporate advanced technology, design best practices, clinical evaluation, usability studies, and data security, and are developed under the same rigorous conditions as pharmaceuticals – complete with clinical trials, regulatory clearance, and availability through a physician’s referral.

About metaMe Health, Inc.

metaMe Health, Inc. is a U.S. company that develops Prescription Digital Therapeutics (PDT) for the treatment of common chronic conditions. metaMe Health’s initial digital solutions aim to relieve the pain and disruption of everyday life experienced by millions suffering from gastrointestinal disorders. By allowing patients to be prescribed treatment confidentially and to undergo treatment privately at home, metaMe Health offers non-drug options that provide relief in a familiar, comfortable environment. For additional information, please visit <https://www.metamehealth.com/> or follow @metaMeHealth on Twitter and metaMe Health on LinkedIn.

About Launchit Ventures, Inc.

Launchit Ventures, Inc. is a HealthTech venture studio that offers a new model for entrepreneurship, combining company building with venture funding, to develop new businesses faster and with less risk. Launchit Ventures partners with researchers, entrepreneurs, industry veterans, and others who have great ideas but need support and expertise to commercialize them. The Launchit Ventures team and its partners bridge the gap between a founder with an idea and the actual reality of getting a HealthTech start-up product or service into the market. For additional information, please visit <https://launchitventures.com>.

Learn more about Regulora® at <https://regulora.ca>.

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