



## Better Therapeutics Completes Enrollment in Real-World Evidence Program Evaluating Long-term Effectiveness of AspyreRx in Type 2 Diabetes

September 28, 2023

*1,000 participants enrolled across two studies, and six sites*

*Studies will evaluate clinical effectiveness beyond 6 months, impact on medication use and healthcare utilization*

SAN FRANCISCO--(BUSINESS WIRE)--Sep. 28, 2023-- [Better Therapeutics, Inc.](#) (NASDAQ: BTTX), a pioneer in developing prescription digital therapeutics (PDTs) to treat cardiometabolic diseases, today announced it has completed the enrollment of 1,000 participants across two studies as part of its ongoing clinical program to evaluate the long-term effectiveness of [AspyreRx](#)<sup>™</sup> (formerly BT-001). AspyreRx received [FDA authorization](#) in July 2023 as the first PDT to deliver Cognitive Behavioral Therapy (CBT) to treat adults with type 2 diabetes (T2D).

Better Therapeutics' ongoing clinical studies are designed to assess the long-term effectiveness of AspyreRx in diverse populations, as measured by change in HbA1c, and safety, as measured by severity and frequency of adverse events. The impact on medication use and healthcare utilization one year after beginning treatment with AspyreRx will also be evaluated, along with an advanced understanding of patient engagement patterns in a real-world setting. In addition, these studies intend to inform the durability of this digital therapeutic intervention.

Participants have been enrolled across Colorado Prevention Center (CPC), affiliated with the University of Colorado Anschutz Medical Campus, the Durham Veterans Association (VA) Health Care System, Ascension DePaul, and Mass General Brigham (MGB). All enrolled participants have been randomized and on-boarded onto AspyreRx or a control app.

"Ongoing studies like these are a critical compass needed in the implementation of healthcare innovation, and today we celebrate a significant milestone in the continued evaluation of digital therapies like AspyreRx," said [Marc Bonaca](#), MD, Executive Director of CPC Clinical Research. "These studies now extend experience with AspyreRx to participants of diverse geographies, health systems, and racial and ethnic groups for longer durations and in real-world settings and are poised to provide patients, clinicians, and others with a broad understanding of how a prescribable behavioral treatment can be best implemented."

Depending on adequate power, Better Therapeutics plans to share initial 6-month data by the end of 2023. This initial readout is expected to be followed by additional data releases in 2024.

"Behavioral changes to improve diet and lifestyle are critical for patients with diabetes, but few providers are trained to help patients make meaningful changes," said [Benjamin M. Scirica](#), MD, MPH, Director, Innovation, Cardiovascular Division, Brigham and Women's Hospital and Associate Professor, Harvard Medical School. "We are excited to be testing AspyreRx in a diverse population of patients with diabetes in order to understand how prescribable behavioral therapies can affect the management of metabolic diseases."

"As we announce completion of enrollment in these additional studies I am thrilled to share that we are on track for AspyreRx to be commercially available in Q4 of this year," said [Frank Karbe](#), Chief Executive Officer, Better Therapeutics. "Our launch will initially focus on geographies where innovative regional payers overlap with providers who are seeing the highest number of type 2 diabetes patients. Our latest healthcare provider research and feedback from our ongoing discussions with payers gives us confidence that we will be able to generate meaningful commercial traction, including payer coverage, within these initial launch geographies."

### About AspyreRx

[AspyreRx](#) (fka BT-001) was granted marketing authorization by the U.S. Food and Drug Administration (FDA) in July 2023 as the first prescription-only digital behavioral therapeutic device delivering a novel form of cognitive behavioral therapy (CBT) via smartphone to treat adults with type 2 diabetes (T2D). AspyreRx is backed by robust data demonstrating clinically meaningful and sustained reduction in HbA1c as well as improvements in other markers of cardiometabolic health when used up to 180 days. Using proven techniques that target the underlying psychological, behavioral, and cognitive factors that sustain or worsen T2D, AspyreRx is a self-paced, engaging experience that patients can access anytime/anywhere. It is prescribed by a healthcare provider in 90-day increments, with proprietary CBT delivered digitally in a weekly step-by-step process. Through interactive therapy lessons, skill-building modules, weekly goal setting and tracking, patients connect changes in behavior to improvements in blood sugar and other biometrics. Each step in the experience builds on the prior to enable and reinforce cognitive restructuring, building the emotional resilience and acceptance needed to make enduring changes.

### Indications for Use

AspyreRx is a prescription-only digital therapeutic device intended to provide cognitive behavioral therapy to patients 18 years or older with type 2 diabetes. The device targets behavior to aid in the management of type 2 diabetes in patients who are under the care of a healthcare provider. AspyreRx provides cognitive behavioral therapy as a treatment that should be used adjunctively with standard of care.

### About Better Therapeutics

[Better Therapeutics](#) is a prescription digital therapeutics company developing a novel form of cognitive behavioral therapy to address underlying factors that sustain or worsen cardiometabolic diseases. The Company has developed a proprietary platform for the development of FDA-regulated, software-based solutions for T2D, heart disease and other conditions. The CBT delivered by Better Therapeutics' PDT is designed to enable changes in neural pathways of the brain so lasting changes in behavior become possible. Addressing the underlying causes of these diseases has the potential to dramatically improve patient health while lowering healthcare costs. Better Therapeutics' clinically validated mobile applications are intended to be prescribed by physicians and reimbursed like traditional medicines.

For more information visit: [bettertx.com](https://bettertx.com)

### **Forward-Looking Statements**

Certain statements made in this press release are “forward-looking statements” within the meaning of the safe harbor provisions under the United States Private Securities Litigation Reform Act of 1995. Forward-looking statements are typically identified by words such as “plan,” “believe,” “expect,” “anticipate,” “intend,” “outlook,” “estimate,” “forecast,” “project,” “continue,” “could,” “may,” “might,” “possible,” “potential,” “predict,” “should,” “would” and other similar words and expressions, but the absence of these words does not mean that a statement is not forward-looking. The forward-looking statements in this press release include, but are not limited to, statements regarding Better Therapeutics’ plans related to the potential commercial launch of AspyreRx (formerly BT-001) for the treatment of T2D, expectations related to the efficacy and potential benefits of BT-001 and CBT and their potential treatment applications, the timing of results from, and Better Therapeutics’ plans for, its ongoing studies evaluating long-term effectiveness of AspyreRx in patients with T2D, Better Therapeutics’ plans regarding the research and advancement of its product candidates for additional treatments and Better Therapeutics’ plans and expectations regarding the results of discussions with healthcare providers and the interest of healthcare providers and payers in PDTs, among others. These forward-looking statements are based on the current expectations of the management of Better Therapeutics and are inherently subject to uncertainties and changes in circumstances and their potential effects and speak only as of the date of such statement. There can be no assurance that future developments will be those that have been anticipated. These forward-looking statements involve a number of risks, uncertainties or other assumptions that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements including: risks related to Better Therapeutics’ business, such as the willingness of the FDA to authorize PDTs, for commercial distribution and insurance companies to reimburse their use, market acceptance of PDTs, including AspyreRx, the risk that the results of previously conducted studies will not be interpreted favorably by the FDA or repeated or observed in ongoing or future studies involving Better Therapeutics’ product candidates and other risks and uncertainties included under the header “Risk Factors” in Better Therapeutics’ quarterly report on Form 10-Q for the quarter ended June 30, 2023 filed with the Securities and Exchange Commission (SEC) on August 9, 2023, and those that are included in any of Better Therapeutics’ subsequent filings with the SEC.

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