Better Therapeutics Announces Submission for FDA Breakthrough Device Designation for Digital Therapeutic Platform to Treat Liver Disease

January 2, 2024

SAN FRANCISCO--(BUSINESS WIRE)--Jan. 2, 2024-- Better Therapeutics, Inc. (NASDAQ: BTTX), a pioneer in developing prescription digital therapeutics (PDTs) to treat cardiometabolic diseases, today announced it has submitted a request to the U.S. Food and Drug Administration (FDA) for Breakthrough Device Designation for its novel PDT designed to treat metabolic dysfunction-associated steatotic liver disease (MASLD) and metabolic dysfunction-associated steatohepatitis (MASH), formerly known as NAFLD and NASH.

MASLD affects an estimated 25%–30% of adults in the U.S., including approximately 70% of individuals with type 2 diabetes and up to 90% of those with obesity. The more advanced form of this disease, MASH, affects approximately 5%–11% of American adults and has recently emerged as a leading indication for liver transplant. Despite growing rates of MASLD and MASH, there are currently no FDA approved drug or device treatments.

Behavioral modification is the recommended first-line treatment in clinical practice guidelines to help address many of the root causes and cardiometabolic comorbidities associated with MASLD and MASH. However, systemic accessibility barriers to in-person behavioral therapy exist, preventing a significant number of patients from receiving the care they need. PDTs offer the potential to address the growing need for a clinical tool that healthcare providers can offer patients living with these conditions.

This regulatory step for Better Therapeutics follows the completion of the Company's LivVita Liver Study and the subsequent publication of its results in *Gastro Hep Advances*. The study successfully met its primary endpoint by reducing liver fat within 90 days, while also achieving key secondary endpoints related to improved liver health without any device related adverse events. The study's authors concluded the totality of positive efficacy, safety and usability data indicates the potential of Better Therapeutics' digitally delivered CBT to help address the significant unmet clinical needs observed in MASLD and MASH.

"As a physician dedicated to addressing the complexities of metabolic disorders, witnessing the reduction in liver fat and enzymes within a short timeframe through this digital therapy is not only promising, but represents a groundbreaking advancement to use technology to help facilitate evidence-based treatment," said Naim Alkhouri, MD, Director of the Fatty Liver Program at Arizona Liver Health and Principal Investigator of the study. "This innovation has the potential to offer effective and scalable support that can make a meaningful impact on those living with MASLD and MASH."

The FDA's Breakthrough Device Designation is designed to expedite the development, assessment, and review of devices that demonstrate the potential to address life-threatening or irreversibly debilitating conditions where no approved or cleared alternative treatment options exist. The expected response timeline from the FDA is 60 days after receipt of a Breakthrough Device Designation application.

"Securing Breakthrough Device Designation from the FDA has the potential to accelerate the expansion of our digital therapeutics platform beyond type 2 diabetes," said Frank Karbe, President and CEO at Better Therapeutics. "The versatility of our therapeutic approach across a broad spectrum of cardiometabolic conditions is an exciting and unique aspect of our platform. Furthermore, the digital nature of our products allows for potential expansion in a fraction of the time and cost compared to traditional drug development."

Better Therapeutics ended its fiscal year 2023 with cash and cash equivalents of $4.2 million, compared to $6.6 million on September 30, 2023.

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' PDTs 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

About AspyreRx

AspyreRx (formerly BT-001) was granted marketing authorization by the FDA in July 2023 as the first prescription-only digital therapeutic to treat adults with type 2 diabetes (T2D). AspyreRx is backed by robust data demonstrating clinically meaningful and sustained reduction in A1c 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 from their smartphone. 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.

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’ expectations related to the efficacy and potential benefits of PDTs, including AspyreRx and CBT, and their potential treatment applications and their ability to improve clinical outcomes, expectations regarding the amendment to the Hercules debt facility and the outcome and success of cost saving initiatives, including salary reductions, and operational plans and their impact on Better Therapeutics’ financial position and cash runway, and expectations regarding the commercial traction of AspyreRx and partnering discussions, 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 fiscal quarter ended September 30, 2023 filed with the Securities and Exchange Commission (“SEC”) on November 09, 2023, and those that are included in any of the Company’s subsequent filings with the SEC.

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