

# Better Therapeutics Commences Pivotal Study of Prescription Digital Therapeutic for the Treatment of Type 2 Diabetes

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Randomized, controlled, parallel-group study will evaluate the product's cognitive behavioral therapy approach to changing behaviors that are the root cause of type 2 diabetes

Geographically diverse study seeks to enroll 650 people in Texas, Illinois, Florida, California and New York

Data on primary endpoint expected in Q4 2021

SAN FRANCISCO--(BUSINESS WIRE)--Better Therapeutics, Inc., ("Better Therapeutics") a prescription digital therapeutics company delivering cognitive behavioral therapy to address the root causes of cardiometabolic diseases, today announced the enrollment of the first patient in its pivotal study to evaluate the safety and efficacy of BT-001 for the treatment of type 2 diabetes. The study began screening patients in February and the first of those patients have now completed the run-in period. BT-001 is an FDA-regulated, prescription digital therapeutic that delivers a novel form of cognitive behavioral therapy to patients with uncontrolled type 2 diabetes. The study adopts a fully virtual model and is actively recruiting patients across five states: Texas, Illinois, Florida, California and New York.

"Each year, hundreds of billions of dollars are poured into our healthcare system to treat cardiometabolic diseases – including type 2 diabetes – without addressing the underlying causes, which are behaviors," said Kevin Appelbaum, co-founder and chief executive officer of Better Therapeutics. "Cognitive behavioral therapy targets the root cause of these conditions and delivering this therapy via a prescription mobile app has the potential to transform the treatment paradigm for a broad range of diseases. I eagerly anticipate results from this pivotal study that could support a regulatory submission for BT-001."

The Better Therapeutics platform blends clinical, behavioral and psychological inputs into a series of therapy lessons and skill-building modules. These are designed to isolate and shift the underlying thoughts and beliefs which guide diet and lifestyle behaviors that cause a wide range of cardiometabolic diseases, including type 2 diabetes. BT-001 is being evaluated as a prescribed treatment used under physician supervision for people with uncontrolled type 2 diabetes.

"We have designed and are now enrolling a fully virtual clinical trial. It is complete with telemedicine patient visits and the use of mobile phlebotomists dispatched to patient homes to collect blood samples and biometric health measures including weight, blood pressure and pulse," said Mark Berman, M.D., chief medical officer of Better Therapeutics. "Not only could data from this pivotal study support submission for an FDA approval in type 2 diabetes, but we expect we will also collect data that could accelerate the development of our other product candidates."

The randomized, controlled, parallel-group study will enroll 650 individuals with type 2 diabetes and baseline A1c greater than 7% in Texas, Illinois, Florida, California and New York. Participants will be randomized to receive standard of care with or without BT-001. The primary efficacy endpoint of the study is difference in the mean change from baseline in A1c between the two groups after 90 days of treatment. The secondary efficacy endpoint is difference in mean change from baseline in A1c between the two groups at 180 days since treatment initiation.

If positive, study results may support a regulatory submission for marketing authorization from the U.S. Food & Drug Administration (FDA). Exploratory endpoint data captured during this study, including change in insulin resistance, blood lipids, inflammation, blood pressure and weight, could accelerate the development of Better Therapeutics' product candidates to treat other cardiometabolic conditions.

BT-001 is the company's lead candidate among their pipeline of FDA-regulated, prescription digital therapeutics designed to treat the underlying cause of a range of cardiometabolic conditions. It is anticipated that upon marketing authorization, primary care providers will prescribe, and insurers will reimburse the company's therapeutics, much like they would a traditional medication.

Clinical data demonstrating the efficacy and safety of Better Therapeutics developmental product candidates has been published in multiple peer-review journals including <u>Journal of the Endocrine Society</u>, <u>JMIR Cardio</u>, <u>JMIR Diabetes</u> and more.

## **About Better Therapeutics**

Better Therapeutics is a prescription digital therapeutics (PDT) company delivering a novel form of cognitive behavioral therapy to address the root causes of cardiometabolic diseases. The company has developed a proprietary platform for the development of FDA-regulated, software-based solutions for type 2 diabetes, heart disease and other conditions. The cognitive behavioral therapy delivered by Better Therapeutics' PDT enables 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.

#### **Additional Information**

On April 6, 2021 Better Therapeutics entered into a definitive merger agreement with Mountain Crest Acquisition Corp. II (Nasdaq: MCAD) ("Mountain Crest II"), a special purpose acquisition company for a proposed business combination.

In connection with the proposed business combination between Mountain Crest II and Better Therapeutics, Mountain Crest II will file a registration statement on Form S-4 containing a proxy statement/prospectus (the "Form S-4") with the Securities and Exchange Commission (the "SEC"). The Form S-4 will include a proxy statement to be distributed to holders of Mountain Crest II's common stock in connection with Mountain Crest II's solicitation of proxies for the vote by Mountain Crest II's shareholders with respect to the proposed transaction and other matters as described in the

Form S-4, as well as the prospectus relating to the offer of securities to be issued to Better Therapeutics' stockholders in connection with the proposed business combination. After the Form S-4 has been filed and declared effective, Mountain Crest II will mail a definitive proxy statement, when available, to its stockholders. Investors and security holders and other interested parties are urged to read the Form S-4, any amendments thereto and any other documents filed with the SEC carefully and in their entirety when they become available because they will contain important information about Mountain Crest II, Better Therapeutics and the proposed business combination. Additionally, Mountain Crest II will file other relevant materials with the SEC in connection with the business combination. Copies of these documents may be obtained free of charge at the SEC's web site at <a href="https://www.sec.gov">www.sec.gov</a>. Securityholders of Mountain Crest II are urged to read the Form S-4 and the other relevant materials when they become available before making any voting decision with respect to the proposed business combination because they will contain important information. The information contained on, or that may be accessed through, the website referenced in this press release is not incorporated by reference into, and is not a part of, this press release.

### **About Mountain Crest Acquisition Corp. II**

Mountain Crest Acquisition Corp. II is a blank check company formed for the purpose of effecting a merger, share exchange, asset acquisition, share purchase, reorganization or similar business combination with one or more businesses. Mountain Crest II is efforts to identify a prospective target business will not be limited to a particular industry or geographic region, although the company intends to focus on operating businesses in North America.

## Participants in the Solicitation

Mountain Crest and Better Therapeutics and their respective directors and executive officers may be deemed participants in the solicitation of proxies with respect to the proposed business combination under the rules of the SEC. Securityholders may obtain more detailed information regarding the names, affiliations, and interests of certain of Mountain Crest's executive officers and directors in the solicitation by reading Mountain Crest's Form S-4 and other relevant materials filed with the SEC in connection with the proposed business combination when they become available. Information about Mountain Crest II's directors and executive officers and their ownership of Mountain Crest II common stock is set forth in Mountain Crest II's annual report on Form 10-K for the year ended December 31, 2020, dated March 30, 2021, as modified or supplemented by any Form 3 or Form 4 filed with the SEC since the date of that filing. Other information regarding the interests of Mountain Crest II's participants in the proxy solicitation, which in some cases, may be different than those of their stockholders generally, will be set forth in the Form S-4 relating to the proposed business combination when it becomes available. These documents can be obtained free of charge at the SEC's web site at <a href="https://www.sec.gov">www.sec.gov</a>.

Better Therapeutics and its directors and executive officers may also be deemed to be participants in the solicitation of proxies from the stockholders of Mountain Crest II in connection with the proposed business combination. A list of the names of such directors and executive officers and information regarding their interests in the proposed business combination will be included in the Form S-4 for the proposed business combination.

#### Non-Solicitation

This press release shall not constitute a solicitation of a proxy, consent, or authorization with respect to any securities or in respect of the proposed business combination. This press release shall also not constitute an offer to sell or the solicitation of an offer to buy any securities, nor shall there be any sale of securities in any states or jurisdictions in which such offer, solicitation, or sale would be unlawful prior to registration or qualification under the securities laws of any such jurisdiction. No offering of securities shall be made except by means of a prospectus meeting the requirements of Section 10 of the Securities Act of 1933, as amended, or an exemption therefrom.

# **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, including statements about the parties' ability to close the proposed business combination and related transactions, the anticipated benefits of the proposed business combination, and the financial condition, results of operations, earnings outlook and prospects of Mountain Crest II and/or the proposed business combination and related transactions and may include statements for the period following the consummation of the proposed business combination and related transactions. In addition, any statements that refer to projections (including EBITDA, adjusted EBITDA, EBITDA margin and revenue projections), forecasts or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. 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 are based on the current expectations of the management of Mountain Crest II and Better Therapeutics, as applicable, 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' strategies and its PDTs, such as the willingness of the FDA to approve PDTs and insurance companies to reimburse their use; the ability to complete the proposed business combination due to the failure to obtain approval from Mountain Crest II's stockholders or satisfy other closing conditions in the definitive merger agreement; the amount of any redemptions by existing holders of Mountain Crest II's common stock; the ability to recognize the anticipated benefits of the business combination; other risks and uncertainties included under the header "Risk Factors" in the registration statement on Form S-4 to be filed by Mountain Crest II, in the final prospectus of Mountain Crest II for its initial public offering dated January 7, 2021 and its annual report on Form 10-K for the year ended December 31, 2020; and in Mountain Crest II's other filings with the SEC.

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