Filed by Mountain Crest Acquisition Corp. II
Pursuant to Rule 425 under the Securities Act of 1933
and deemed filed pursuant to Rule 14a-12
of the Securities Exchange Act of 1934
Subject Company: Mountain Crest Acquisition Corp. II
Commission File No. 001-39864

Company Name: Better Therapeutics, Inc.
Event: Canaccord Genuity 41st Annual Growth Conference
Date: August 12, 2021

<<Richard Close, Analyst, Canaccord Genuity Group, Inc.>>

Great. Good afternoon. I'm Richard Close with Canaccord Genuity covering digital and tech-enabled healthcare here at Canaccord. Sorry for being a couple minutes late, I had a broken Zoom link. But we got that under control. Really excited to have Better Therapeutics join us today for the Canaccord Genuity Growth Conference. Better Therapeutics is in the middle of a SPAC transaction. It's on the prescription digital therapeutics area. We've done a lot of work on PDTs over the last, call it, three years. And it's an extremely exciting space evolving rapidly. And glad to have Better Therapeutics introduce us to what they're doing on the digital therapeutic side. From the company, we have the CEO, Kevin Appelbaum. Thank you. CFO, Mark Heinen, if I'm pronouncing that correctly, I apologize. And then Chief Medical Officer, Mark Berman. So thank you all for joining us.

I'll turn it over to you. We got 25 minutes or I guess, a little less. But I'll let you guys introduce us to Better Therapeutics. Thank you.

<<Kevin Appelbaum, Co-Founder and Chief Executive Officer>>

Great. Thanks, Richard and thanks for everyone for your interest in listening to our story. We're excited to tell you about Better Therapeutics. At Better Therapeutics, we're developing a prescription digital therapeutics platform to treat a broad array of cardiovascular and metabolic diseases starting with type 2 diabetes. Earlier this year in April, we announced plans to merge with Mountain Crest Acquisition Corp. II, a special purpose acquisition company or SPAC. In addition to the $58 million held in the SPAC trust, we have also raised a $50 million pipe from leading biotech investors, including Farallon, RS, Sectoral and others.

These concurrent transactions will bring up to $100 million in cash to the Better balance sheet at a total equity value of about $300 million. We expect to close this transaction next month.

David Perry and I co-founded the company in 2015, and we continue to operate in our respective roles as Chairman and CEO. Over the past 25 years, David and I have individually started and led multiple disruptive companies, several of which grew to multi-billion dollar valuations. Together, we bring a combination of experiences uniquely suited to our work at Better, including a long history of working successfully with the FDA, conducting clinical trials for traditional pharmaceuticals and medical devices, developing highly engaging consumer facing software and bringing first-in-class products to market.

At Better, we're focused on doing two things that are fundamentally different. The first is that we use software instead of drugs to treat disease. And our treatments focus on the behaviors that are root causes instead of the symptoms or effects of disease. This is really important because as a nation, we spend almost $0.5 trillion each year treating the effects of cardiometabolic diseases, while doing very little about the causes.

We've created a therapeutics platform that delivers a new kind of cognitive behavioral therapy, which we call nutritional-CBT. We've conducted multiple clinical trials that have demonstrated positive results in type 2 diabetes and hypertension. And, because of the root causes of cardiometabolic diseases are common, a product that is effective at treating one is very similar to a product that would be effective at treating others. So with minimal product changes, we can use platform leverage to create a portfolio of therapeutics across a broad range of cardiometabolic conditions.

The problem we're addressing is unfortunately well established. These charts depict the increasing prevalence of certain cardiometabolic diseases in white, overlaid with the U.S. healthcare spending in blue. From left to right top to bottom, I've shown diabetes, hypertension, coronary artery disease. By looking at these charts and others across other cardiometabolic conditions, one key takeaway could be that we're spending more and more money to get worse and worse outcomes.

In fact, as a country, we spend almost $4 trillion a year on healthcare, and about 90% of that spend goes to address conditions that are caused by our behaviors. The behaviors that cause almost every cardiometabolic disease include poor diet, lack of exercise and related lifestyle factors. Looking at just these three common conditions, type 2 diabetes, hypertension and high cholesterol, we see that we're spending over $100 billion a year on drugs to treat their symptoms, while we're spending almost nothing to treat the underlying behaviors.

It would seem like we have a daunting task ahead with a problem that's almost too big to solve, but we actually know that there's a solution. And healthcare providers know it, too. The medical literature over the last 30 years contains numerous examples of cognitive behavioral therapy being delivered one-on-one to patients or in small groups to effectively treat cardiometabolic diseases. The obvious limitations are that the use of CBT as a treatment is neither scalable, nor affordable. And that matters a lot when there's over 150 million people in the U.S. with one or more cardiometabolic condition.

We founded Better Therapeutics on the hypothesis that we can create software to deliver cognitive behavioral therapy and treat disease by changing the patient behaviors that are the underlying closets. And we could do it using a scalable and affordable mobile application.

When we started the company, we weren't exactly sure what the business model would ultimately be, but that became clearer in 2017 when the FDA established a pathway for the approval of software as a direct treatment of disease. There have now been multiple companies that have successfully navigated this pathway, including Pear Therapeutics, Akili Interactive and Mahana Therapeutics. While there's always risk in working with the FDA, as we sit here today, we don't believe that risk to be significant.

On a macro basis, we're also experiencing significant tailwinds related to the acceleration in the adoption and use of digital solutions by both providers and patients. Undoubtedly, much of this is driven by the COVID 19 pandemic. In research we conducted last year, nearly 80% of providers indicated a high likelihood to prescribe and about 70% of patients indicated a high willingness to use Better's digital therapeutics for treating type 2 diabetes.

We also fielded the research last year with eight of the 10 largest payers to confirm our underlying assumptions around coverage and reimbursement. Payers indicated that type 2 diabetes remains a major concern. And in many cases is the largest line item in their budgets. They're open to new diabetes therapeutics and are especially receptive to the idea of treating behaviors as a solution. Part of this is driven by the fact that despite many new diabetes medications and advances in medical care over recent years, only about 50% of diabetics receiving treatment are able to achieve the clinical objective of glycemic control. So clearly what we have today isn't enough to do the job. And last, payers indicated a likelihood to cover our product as a pharmacy benefit and reimburse at prices within the range we have modelled.

So we think as we sit here today, we're at an inflection point where there's a clear opportunity to build a very valuable prescription digital therapeutics company. One that could change the way we treat a broad array of cardiometabolic diseases in the future. The problems well understood. The digital delivery of cognitive behavioral therapy to treat root causes is a promising solution. We've tested our software in multiple clinical trials with positive results and we have a clear relatively de-risked regulatory pathway to approval. And the acceptance and adoption of digital solutions is accelerating among all – among patients, payers and providers.

And with that, I will hand the communications baton to my partner Mark Berman, and he'll dig into some of the details.

<<Mark Berman, Chief Medical Officer>>

Thanks, Kevin. We have developed a digital therapeutics platform to deliver our form of cognitive behavioral therapy, which we call nutritional CBT. Our nutritional-CBT incorporates elements of behavioral therapy, lifestyle medicine and artificial intelligence to provide a highly personalized treatment that targets a broad but specific set of eating and related behaviors and over time promotes cognitive restructuring. It's designed to work within the context of standard medical care and concurrent medication use.

Early in development, we conducted feasibility studies to assess the impact of early versions of our software when paired with health coaches. And in those studies, we saw effect sizes that were comparable to first-line medications. In type 2 diabetes, we saw an average reduction in A1c, that's the measure of average blood sugar over the past two to three months, of 1.1%. And in hypertension, we saw an average reduction of 12 millimeters of mercury in systolic blood pressure. These are clinically meaningful changes that are associated with significant benefits for patients.

More recently, we conducted a pilot study to assess the impact of our software when used alone without any additional human support. Now, by this time we had incorporated our prior clinical learnings into a fully digital form of behavioral therapy, and we tested the software alone. In this 12 week study, we found comparable results with our earlier trials, observing meaningful changes in blood sugar over the entire duration of the study. This data was very encouraging to us, and it allowed us to proceed to a pivotal randomized controlled trial, which is now in progress. I'll tell you a little bit about that now.

Using input from several discussions with the FDA, we designed a pivotal randomized controlled trial to assess the safety and efficacy of BT-001, which is the version of our platform designed to treat type 2 diabetes. We believe the data from this study will be submission – will be sufficient to submit a De Novo application to the FDA for BT-001. This study will include a diverse set of adults with type 2 diabetes in six U.S. states so that we can evaluate BT-001 in a population that's representative of the U.S. type 2 diabetes patient population. We're enrolling 648 participants, this gives us 90% power to detect a clinically meaningful change in A1c between two treatment groups. We're including adults who have poor glycemic control, which is defined as a blood sugar level or A1c above 7% and the stable drug regimen prior to randomization.

And eligible participants will be randomized in a one-to-one fashion to a control arm, which consists of standard of care or an intervention arm, which consists of standard of care plus BT-001. The study is 180 days long. The primary efficacy endpoint being 90-day A1c and the primary safety endpoint is adverse events observed in the study. What's unique about this study is that it also gives us the opportunity to collect other measures of cardiometabolic health to advance development of our other indications.

<<Kevin Appelbaum, Co-Founder and Chief Executive Officer>>

Thanks, Mark. The pivotal trial Mark described is the first row here in our clinical development plan. And because of the high rates of co-morbidity with diabetes, as Mark just described, we expect this trial to generate randomized controlled data across as many as four additional indications. It's our intention to advance the most promising two of these indications into pivotal trials next year, which are likely to be studies in hypertension and hyperlipidemia. And over the next several years, we expect to advance multiple products, treating a range of cardio-metabolic conditions through the clinical and regulatory process at costs that would never be possible with traditional therapeutics.

Looking at BT-001, our first product for the treatment of Type 2 diabetes, let me start with this illustration that describes the current treatment paradigm for diabetes. The underlying assumption is that once a patient is diagnosed, they get progressively worse requiring more and more medications at a higher and higher costs for the remainder of their lives. We believe this conventional wisdom is fundamentally flawed. If we can instead use a prescription digital therapeutic to intervene and change the behaviors that are causing disease and prescribe it to patients when they're most receptive to making changes, for example, when they're first diagnosed or just prior to having to commence insulin, we have the opportunity to stop the progression of disease. And in many cases reverse it altogether.

This would obviously be good for patients, improving quality of life and overall health. It would be superior for the healthcare system, because as you can treat disease by changing the underlying behaviors or causes, you require far fewer medications and that takes costs out of the system. We need to do this.

As I mentioned earlier, only about 50% of diabetes patients are able to achieve the clinical goal of glycemic control. In the other 50% we're spending about $40 billion a year on prescription medications and failing to achieve our clinical objectives. Said differently, we're spending $40 billion a year on medications that do not achieve that the desired outcome, despite access to insurance and medical care and the latest innovations in diabetes treatment. This is a massive initial addressable market. It's also one that's changing quickly. That $40 billion dollars of drug spend is 2.5 times what it was 10 years ago. And current trends predict that it will be 2.5 times larger less than 10 years from today. With new therapeutics that can intervene and treat root causes, we have the opportunity to change this trajectory and begin to remove or take costs out of the system.

We made the decision to seek FDA authorization or clearance to all of our products so that we can fit seamlessly into the healthcare system and enable adoption at scale. While our form of therapy is new - using software instead of chemistry or biology, everything else works as designed. The physician diagnoses and prescribes treatment, payers reimburse that prescription, like they would a drug, and the patient remains in the care of their physician. We know that about 80% of all healthcare dollars originate with a physician's prescription. And we believe that to have the greatest impact on patients and build the most significant company we need our products to be incorporated into the system, keeping the physician - patient relationship whole.

Diabetes is a disease largely treated by primary care providers. And there's a whole bunch of them. Almost 400,000 providers wrote a prescription for a diabetes drug last year. While that's an enormous number of providers, a significant portion of diabetes patients - about 20% of them, are concentrated in a small subset, relatively small subset of providers, about 4%. These 17,000 providers will be our focus when we go-to-market. We intend to build the commercial organization and capability uniquely suited to launching prescription digital therapeutics into primary care in the U.S. By the end of our launch year in 2023, we expect our commercial team will number just over 100 individuals at an annualized cost of $30 million.

We also heard from payers in our earlier research is that while they will evaluate us like they would one of these branded diabetes medications, they will also hold us accountable to a comparable evidence threshold, demonstrating both clinical and economic impact in order to secure coverage and reimbursement. We plan to generate this evidence through both our ongoing pivotal trial and real-world evidence studies in larger patient populations conducted for a year or longer. On the left portion of this slide, we've shown our pilot data related to BT-001's ability to lower A1c relative to comparable branded medications. We intend to set price at a moderate discount to branded drugs, to optimize for coverage. And that's illustrated in the center panel here.

And last, the value that this alternative approach to treating diabetes can bring the payers is presented on the right side of this page. Behavioral therapy is a time limited treatment option and most patients will receive the optimal benefit after 1 or 2 90-day treatment cycles. This is not a form of therapy like medications where once patient is on a new drug, they're expected to be on it for the rest of their life. We've made some assumptions here about that number of treatment cycles a patient would get in the first year. Some portion of those patients undoubtedly would benefit from a second or third cycle in the following year or the year after that. But net, we believe a total cost of treatment to be around $4,500 for BT-001 compared to $10,000 to $20,000 over the same three-year period for some of these other medications.

If we look just at revenues generated from BT-001 in diabetes, we see an opportunity to build a very valuable company based only on diabetes revenues. We're projecting 2023 as our launch year and $88 million in net revenues in 2024. Our EBIT projections are fully burdened with anticipated operating expenses across our entire clinical development pipeline. And if we look at a slightly longer time period beyond 2025, we begin to see the benefits of our clinical pipeline come to fruition. As we launch our second and subsequent prescription digital therapeutics at the pace of about one per year thereafter.

I'll close on this last slide by laying out the milestones that we expect achieve between now and the end of 2022. We need about $50 million to execute this plan. As we mentioned at the onset, we're raising about $100 million through the SPAC PIPE transaction. We will get through our pivotal trial in diabetes and our FDA submission and likely approval in diabetes. We'll generate a robust set of data on additional indications, and we will advance the most promising second and third products into pivotal trials in the middle of next year.

So with that, I will pause because I think I am out of time.

<<Richard Close, Analyst, Canaccord Genuity Group, Inc.>>

Great. I'm just going to ask you one question, Kevin, I'm curious and Mark, maybe you can answer this as well. You guys did talk about AI. That's a little bit different than some of the other therapeutics, digital therapeutics that are I guess in the market are coming to market. Can you talk a little bit about the AI component in your offering?

<<Kevin Appelbaum, Co-Founder and Chief Executive Officer>>

Sure. Mark, you want to take that?

<<Mark Berman, Chief Medical Officer>>

Sure. Yes, happy to. Yes. So the unique opportunity that we have is to develop – to deliver behavioral therapy that is also simultaneously capturing data from the patient. We've a clear understanding of every engagement point with the therapeutic. And we also have access to data about the patient's current health status that gives us the ability to embed AI within the product to create a whole number of feedback loops to predict how well a patient is going to do. And if they're not going to do well steer them in the appropriate course and to give feedback to the patient. The great exciting thing about this is that well, we can do that on onset and guide patients using AI as we deploy into market and we get more and more patients on the system. There's a great capacity for that those algorithms to improve and become more robust over time.

<<Richard Close, Analyst, Canaccord Genuity Group, Inc.>>

Yes, thanks. That's very helpful. I do have a long list of questions, but we are out of time. So congratulations on it. I think diabetes is a great area. Obviously, we spend a lot of time on diabetes with other companies but on the prescription digital therapeutic, it seems like a no brainer and a huge market opportunity. Congratulations on the transaction and thank you for participating in our conference. And I look forward to following the progress and apologize for the two minutes being late there on my Zoom link. So thank you.

<<Kevin Appelbaum, Co-Founder and Chief Executive Officer>>

Appreciate it. Thanks for having us.

<<Mark Berman, Chief Medical Officer>>

Thanks everyone.