UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): September 22, 2022

BETTER THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-39864**	**85-3472546**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

548 Market Street #49404 **San Francisco, California**	**94104**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (415) 887-2311

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	**BTTX**	**Nasdaq Capital Market**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure.

On September 22, 2022, Better Therapeutics, Inc. (the "Company") announced that it has submitted a de novo classification request to the U.S. Food and Drug Administration seeking marketing authorization for BT-001, the Company's investigational prescription digital therapeutic designed to use nutritional cognitive behavioral therapy to treat type 2 diabetes. A copy of the press release is being furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information contained in Item 7.01 in this Current Report on Form 8-K and Exhibit 99.1 attached hereto is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release of Better Therapeutics, Inc., dated September 22, 2022.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Better Therapeutics, Inc.

Dated: September 22, 2022

By: /s/ Mark Heinen
Name: Mark Heinen
Title: Interim Chief Financial Officer

Exhibit 99.1

Better Therapeutics Submits De Novo Request to U.S. FDA for BT-001 Investigational Prescription Digital Therapy for Type 2 Diabetes

Submission follows completion of first-in-class trial demonstrating significant improvements in A1c reduction with investigational therapy targeting the root causes of type 2 diabetes.

SAN FRANCISCO, September 22, 2022 – Better Therapeutics, Inc. (NASDAQ: BTTX), a prescription digital therapeutics (PDT) company developing a novel form of cognitive behavioral therapy (CBT) to address the root causes of cardiometabolic diseases, today announced that it has submitted a *de novo* classification request to the U.S. Food and Drug Administration (FDA) seeking marketing authorization for BT-001, its potentially first-in-class digital therapeutic designed to use CBT to treat Type 2 Diabetes (T2D) in patients 18 years and older.

"Submitting this de novo request is not just a major milestone for our company but an important moment for patients, providers and payers. As the first digital therapeutic submitted to the FDA for the treatment of type 2 diabetes, BT-001 marks a new kind of treatment paradigm with the potential to address the root causes of this and other cardiometabolic diseases." said Mark Berman, MD, Chief Medical Officer of Better Therapeutics. "By providing people with convenient, personalized treatment rooted in decades of behavioral science, we aim to help them take back control and live healthier lives, instead of relying on increasingly costly pharmaceutical treatments that place undue burden on patients and fail to address the behavioral root causes of disease."

This submission follows positive results from the BT-001 pivotal trial, the largest randomized control study ever conducted of a digital therapeutic to evaluate glycemic response in T2D. The trial met both its primary and secondary endpoints demonstrating statistically and clinically meaningful reductions in A1c over the current standard of care, even as control group patients increased use of blood sugar lowering medications. The results achieved were sustainable and improved between day 90 and day 180 of the trial, demonstrating that BT-001 has the potential to deliver meaningful, durable improvements in blood sugar control for a complex range of patients with T2D already on standard of care blood sugar lowering medications.

In addition, exploratory data revealed a host of cardiometabolic improvements as well as lower medication utilization compared to the control group, supporting the potential for BT-001 to improve the overall health of patients with T2D and potentially reduce the usage of increasingly costly T2D medications associated with the progression of the disease.

If authorized by the FDA, BT-001 would be the first validated, prescription solution for delivering CBT to T2D patients at scale, from their digital devices. In addition to treating T2D with BT-001, if authorized, Better Therapeutics is exploring the potential to use CBT for other cardiometabolic conditions, including nonalcoholic fatty liver disease, nonalcoholic steatohepatitis, hypertension, and hyperlipidemia.

About BT-001

BT-001 is Better Therapeutics' investigational prescription digital therapy for the treatment of T2D. The investigational therapy is delivered via software that provides a tailored experience to patients designed to help them address the underlying causes of T2D by making meaningful, sustainable behavioral changes. The BT-001 investigational therapy is rooted in the well-studied, gold standard of behavioral modification therapies, cognitive behavioral therapy (CBT). While CBT has been used for T2D and other cardiometabolic conditions before, until now the approach has not been scalable due to the need to deliver the therapy via a therapist. If authorized by FDA, BT-001 would be the first validated, prescription solution for delivering this therapeutic approach to T2D patients at scale, from their digital devices.

About the Better Therapeutics nCBT Platform

Better Therapeutics digital therapeutic platform is designed to delivers a novel form of CBT to help people with cardiometabolic diseases potentially improve key measures related to T2D, nonalcoholic fatty liver disease, nonalcoholic steatohepatitis, hypertension, hyperlipidemia and other cardiometabolic conditions. By adapting the principles and mechanisms of CBT, the digital therapeutic platform is designed to address and modify the cognitive patterns that affect eating habits and other behavioral factors associated with cardiometabolic diseases.

About Better Therapeutics

Better Therapeutics is a prescription digital therapeutics (PDT) company developing a novel form of cognitive behavioral therapy (CBT) 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 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, if authorized for marketing, are intended to be prescribed by physicians and reimbursed like traditional medicines.

For more information visit: 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 the results of the completed trial of BT-001 in patients with type 2 diabetes, Better Therapeutics' plans and expectations regarding FDA submissions and the potential for marketing authorizations, expectations related to the potential benefits of BT-001 and CBT and their potential treatment applications, Better Therapeutics' plans regarding the research and advancement of its product candidates for additional treatments, expectations related to the interest of healthcare providers and payers in PDTs and legislative developments affecting PDTs, the potential to reduce healthcare and patient costs and the outcome of such developments, 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, including BT-001, for commercial distribution and insurance companies to reimburse their use, market acceptance of PDTs, including BT-001, 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, 2022 filed with the Securities and Exchange Commission (SEC) on August 11, 2022, and those that are included in any of Better Therapeutics' subsequent filings with the SEC.

Contact Information:

Investor Relations:

Mark Heinen
IR@bettertx.com

Media:

Ryan McKenna at Real Chemistry
rmckenna@realchemistry.com