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): November 14, 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 2.02. Results of Operations and Financial Condition.

On November 14, 2022, Better Therapeutics, Inc. (the "Company") issued a press release announcing financial results and other business updates for the third quarter ended September 30, 2022. 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 2.02 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 issued by Better Therapeutics, Inc., dated November 14, 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: November 14, 2022

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

Better Therapeutics Reports Third Quarter 2022 Financial Results and Provides Business Updates

U.S. FDA accepted the company's submission of its de novo request for BT-001 investigational prescription digital therapy for type 2 diabetes in adults

BT-001 pivotal clinical trial 90-day results published in peer-reviewed journal Diabetes Care

Appointed highly experienced healthcare executive as Chief Commercial Officer

On track to report topline results from LivVita study in fourth quarter of 2022

Company to host conference call and webcast today at 4:30 p.m. ET

SAN FRANCISCO — November 14, 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 reported financial results for the third quarter of 2022 and provided an update on progress toward achieving key corporate milestones.

"Better Therapeutics continued its strong momentum in the third quarter, with the completion of the BT-001 pivotal clinical trial and acceptance of its *de novo* classification request to the U.S. Food and Drug Administration seeking marketing authorization for BT-001," stated Frank Karbe, President and CEO of Better Therapeutics. "We believe the publication of our trial results in a leading peer-reviewed journal further highlights the quality of our data and novelty of our approach as does the encouraging feedback we have received from our payer interactions to date. Additionally, we significantly advanced our financing discussions, and our team is laser-focused on preparing for the potential launch of our first-in-class prescription digital therapeutic for the treatment of type 2 diabetes (T2D) in adults next year, if authorized by FDA."

Third Quarter and Recent Business Highlights

- **Completed BT-001 Pivotal Clinical Trial:** Better Therapeutics reported positive secondary endpoint results from the BT-001 pivotal trial in July, following the announcement of positive primary endpoint results in March. 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, supporting our belief that BT-001 has the potential to deliver meaningful, durable improvements in blood sugar control for adults with T2D already on standard of care blood sugar lowering medications.
- **Submitted *De Novo* Request to U.S. Food and Drug Administration (FDA) for BT-001:** In October, our de novo classification request, seeking marketing authorization of BT-001 for the treatment of adults with T2D, was accepted for substantive review by the FDA. If authorized by

the FDA, BT-001 would be the first validated, prescription solution for delivering highly scalable cognitive behavioral therapy to adults with T2D from a digital device.

- **Published BT-001 Pivotal Clinical Trial Results:** The encouraging 90-day results from the company's pivotal clinical trial of BT-001 in patients 18 years and older with T2D were published in the American Diabetes Association-produced, peer-reviewed journal Diabetes Care in October 2022.
- **Presented BT-001 Pivotal Clinical Trial Results:** The pivotal trial results were presented by independent physician experts to the medical community at the Society for Vascular Medicine's Annual Scientific Sessions as well as at a late breaking featured science session at the American Heart Association's annual meeting in November 2022.
- **Began Payer Coverage Discussions:** Better Therapeutics initiated its health economic models for BT-001 and began engaging payers to share data from the BT-001 pivotal trial and inform its approach to gaining coverage.
- **Appointed Diane J. Gómez-Thinnes as Chief Commercial Officer:** Ms. Gómez-Thinnes brings more than two decades of experience in the healthcare industry, leading the commercialization and launch of prescription and consumer health products for companies, including Johnson & Johnson and Galderma.

Expected Upcoming Milestones

- **LivVita Liver Study:** Better Therapeutics is on track to report topline results from the LivVita study in the fourth quarter of 2022. The study is being conducted in collaboration with Arizona Liver Health and is evaluating the feasibility of CBT to reduce liver fat and improve liver disease biomarkers as a potential treatment for nonalcoholic fatty liver disease (NAFLD) and nonalcoholic steatohepatitis (NASH).
- **Address Financing Needs:** Better Therapeutics has initiated a broad assessment of potential financing options. The company expects to address its financing needs in the coming months to ensure it has the financial resources to continue to prepare for a potential commercial launch of BT-001, if authorized by the FDA, and to potentially expand its digital platform into other cardiometabolic diseases.
- **Commercial Launch of BT-001:** The company is diligently advancing its preparations for the potential commercial launch of BT-001, which, if authorized by the FDA, is anticipated in 2023.

Third Quarter 2022 Financial Results

Research and development expenses for the quarter ended September 30, 2022 were $5.5 million, compared to $6.7 million for the same period in 2021. The decrease primarily reflects lower clinical study costs as a result of the winddown of the clinical trial for BT-001, partially offset by an increase in personnel and consulting costs related to preparing the *de novo* submission for BT-001 as well as an expansion of the company's software development capabilities.

Sales and marketing expenses for the quarter ended September 30, 2022 were $1.6 million, compared to $0.6 million for the same period in 2021. The increase was primarily due to higher personnel, marketing and consulting expenses associated with commercial readiness activities to support the potential launch of BT-001, if authorized by FDA.

General and administrative expenses for the quarter ended September 30, 2022 were $4.0 million, compared to $1.8 million for the same period in 2021. The increase was primarily related to higher personnel-related costs driven by an increase in headcount and additional costs of being a publicly traded company, including a $1.1 million increase in business insurance.

Interest expense, net for the quarter ended September 30, 2022 was $0.4 million, compared to $0 for the same period in 2021. The increase was the result of the interest incurred on the company's secured term loan agreement with Hercules Capital, which commenced in the fourth quarter of 2021.

Net loss for the quarter ended September 30, 2022 was $11.4 million, compared to $12.5 million for the same period in 2021. On a per common share basis, net loss was $0.48 and $1.20 for the quarter ended September 30, 2022 and 2021, respectively. The decline in loss per share is primarily related to an increase in weighted average shares outstanding as a result of the deSPAC transaction in the fourth quarter of 2021.

Capital resources: Cash and cash equivalents were $22.3 million on September 30, 2022, compared to $40.6 million on December 31, 2021.

Conference Call and Webcast

Better Therapeutics will host a conference call and webcast today, November 14, 2022, at 4:30 p.m. ET / 1:30 p.m. PT. To access the conference call, please register at: https://register.vevent.com/register/BI2c729f96a5894042b72aa89ac43ae0c8. Upon registering, each participant will be provided with call details and access codes. All participants are encouraged to join 10 minutes prior to the start time. The live webcast may be accessed by visiting the event link at: https://edge.media-server.com/mmc/p/uritguso. A replay of the webcast may be accessed from the Presentations & Events page in the Investors section of the Better Therapeutics corporate website at: investors.bettertx.com.

Available Information

Better Therapeutics periodically provides other information for investors on its corporate website, http://www.bettertx.com, and its investor relations website, http://www.investors.bettertx.com. This includes press releases and other information about financial performance, information on corporate governance, and details related to its annual meeting of stockholders. Better Therapeutics intends to use its website as a means of disclosing material non-public information and for complying with its disclosure obligations under Regulation FD. Accordingly, investors should monitor Better Therapeutics' website, in addition to following its press releases, SEC filings, and public conference calls and webcasts.

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 in-person 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 CBT Platform

Better Therapeutics' investigational digital therapeutic platform is designed to deliver 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 treating cardiometabolic 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 and related comments in our earnings conference call 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 efficacy and 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 statements regarding its financing needs, plans and expectations, 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 our 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 September 30, 2022 filed with the Securities and Exchange Commission (SEC) on November 14, 2022, and those that are included in any of Better Therapeutics' subsequent filings with the SEC.

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BETTER THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands, except share and per share data)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Operating Expenses:				
Research and development	$ 5,477	$ 6,667	$ 13,391	$ 13,082
Sales and marketing	1,557	552	5,284	1,159
General and administrative	3,962	1,776	11,265	4,215
Total operating expenses	10,996	8,995	29,940	18,456
Loss from operations	(10,996)	(8,995)	(29,940)	(18,456)
Interest expense, net	(406)	—	(1,052)	(3)
Change in fair value of SAFEs	—	(3,466)	—	(8,779)
Gain on loan forgiveness	—	—	—	647
Loss before provision (benefit) from income taxes	(11,402)	(12,461)	(30,992)	(26,591)
Provision (benefit) from income taxes	3	—	3	(150)
Net loss	$ (11,405)	$ (12,461)	$ (30,995)	$ (26,441)
Cumulative preferred dividends allocated to Series A Preferred Shareholders	—	(403)	—	(1,185)
Net loss attributable to common shareholders, basic and diluted	$ (11,405)	$ (12,864)	$ (30,995)	$ (27,626)
Net loss per share attributable to common shareholders, basic and diluted	$ (0.48)	$ (1.20)	$ (1.32)	$ (2.58)
Weighted-average shares used in computing net loss per share	23,693,154	10,752,790	23,533,290	10,723,091

BETTER THERAPEUTICS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands)

	(unaudited) September 30, 2022	(audited) December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 22,305	$ 40,566
Prepaid expenses	1,123	4,409
Other current assets	62	276
Total current assets	23,490	45,251
Capitalized software development costs, net	4,121	5,077
Property and equipment, net	122	82
Other long-term assets	488	548
Total Assets	$ 28,221	$ 50,958
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,255	$ 1,523
Accrued payroll	2,477	1,352
Other accrued expenses	2,451	1,858
Current portion of long-term debt	3,129	—
Total current liabilities	9,312	4,733
Long-term debt, net of current portion and debt issuance costs	11,657	9,505
Total liabilities	20,969	14,238
Stockholders' equity:		
Common stock	2	2
Additional paid-in capital	109,988	108,461
Accumulated deficit	(102,738)	(71,743)
Total Stockholders' Equity	7,252	36,720
Total Liabilities and Stockholders' Equity	$ 28,221	$ 50,958