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): May 11, 2023

Better Therapeutics, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware (State or Other Jurisdiction of Incorporation) 001-39864 (Commission File Number) 85-3472546 (IRS Employer Identification No.)

548 Market Street #49404 San Francisco, California (Address of Principal Executive Offices)

94104 (Zip Code)

Registrant's Telephone Number, Including Area Code: 415 887-2311

(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	Symbol(s)	Name of each exchange on which registered
Common Stock	BTTX	The Nasdaq Stock Market LLC

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 \boxtimes

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 May 11, 2023, Better Therapeutics, Inc. issued a press release announcing financial results and other business updates for the quarter ended March 31, 2023. 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	Description
99.1	Press Release issued by Better Therapeutics, Inc., dated May 11, 2023
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 hereunto duly authorized.

Date: May 11, 2023

By: /s/ Mark Heinen

Mark Heinen Chief Financial Officer

Better Therapeutics Reports First Quarter 2023 Financial Results and Provides Business Updates

On track for an FDA decision mid-year

Announced restructuring to extend cash runway

Completed private placement financing

Company to host conference call and webcast today at 8:30 a.m. ET

SAN FRANCISCO--(BUSINESS WIRE)--May. 11, 2023-- <u>Better Therapeutics, Inc.</u> (NASDAQ: BTTX), a prescription digital therapeutics (PDT) company developing a clinically validated, software-based, novel form of cognitive behavioral therapy (CBT) to address the root causes of cardiometabolic diseases, today reported financial results for the first quarter 2023 and provided an update on progress toward achieving key corporate milestones.

"We successfully navigated several challenges in the first quarter of this year, laying the foundations for long-term success. The reduction in force, coupled with the completion of a private placement financing, extended our cash runway sufficiently to reach multiple significant milestones," stated Frank Karbe, President and CEO of Better Therapeutics. "We look forward to a decision from the FDA on our de novo submission within the next 90 days and remain focused on preparing for the potential commercial launch of BT-001 in type 2 diabetes."

First Quarter and Recent Business Highlights

- **Responded to FDA's Request for Information:** In February 2023, Better Therapeutics received a Request for Additional Information from the U.S. Food and Drug Administration (FDA) related to its de novo submission for BT-001, which is an expected part of the review process. The Company responded to the Request for Additional Information on April 17, 2023 and the FDA confirmed its review is progressing. If authorized by the FDA, BT-001 would be the first and only PDT delivering highly scalable CBT to adults with type 2 diabetes (T2D) from a digital device.
- Executives with Extensive Diabetes Experience Join Team: In March 2023, Better Therapeutics hired <u>Chip Amrein</u> as Head of Marketing, bringing with him two decades of experience in diabetes, most recently with Novo Nordisk. <u>Elizabeth Pash</u>, PhD, RDN, an accomplished leader with decades of cardiometabolic disease experience with Abbott and Medtronic, also joined Better Therapeutics as Head of Medical Affairs, bringing deep clinical insight, and product launch experience to the commercial organization.
- Announced Restructuring to Extend Runway Through Multiple Milestones: In March 2023, Better Therapeutics <u>implemented</u> a reduction in force impacting approximately 35% of the workforce. The Company also implemented other cost savings measures to further extend its cash runway.

• **Completed \$6.5 million Private Placement:** In April 2023, Better Therapeutics <u>announced</u> a private placement of 7,878,786 shares of the Company's common stock at a price of \$0.825 per share, which was the closing price of the Company's common stock on the Nasdaq Capital Market on April 5, 2023, for gross proceeds of approximately \$6.5 million before deducting offering expenses payable by the Company. There was strong participation in the transaction from certain officers and directors of the Company.

Expected Upcoming Milestones

- **Potential FDA Authorization and Commercial Launch of BT-001:** Better Therapeutics continues to expect the FDA's decision on the Company's de novo submission for marketing authorization of BT-001 by the middle of the year and is anticipating a commercial launch within a few months following such decision if the FDA approves the submission. Additional upcoming milestones include the submission of health economic data for peer review and publication.
- **Apply for Breakthrough Device Designation:** Following the successful completion of the LivVita Liver Study, Better Therapeutics commenced work on an application to the FDA for Breakthrough Device Designation for its investigational PDT in non-alcoholic fatty liver disease (NAFLD) and non-alcoholic steatohepatitis (NASH), and now expects to submit the application in the third quarter of 2023. Currently, there is no FDA approved treatment for NAFLD and NASH, which affect approximately one in four Americans. Behavioral change is foundational to addressing the root causes of the diseases and the Company believes that a prescription treatment option could be of significant benefit to millions of patients.
- **Complete Enrollment in BT-001 Real-world Evidence Program:** Better Therapeutics reported almost 75% of the target participant population has been enrolled in its real-world evidence program and expects to complete enrollment by the end of the third quarter. Following this milestone, the Company expects to share the first dataset from these long-term effectiveness studies in the fourth quarter of this year.
- **Further Strengthen Financial Position:** Better Therapeutics expects to deliver on multiple elements of its financing strategy to further enhance its financial position, including a potential business development partnership and / or royalty monetization transaction.

First Quarter 2023 Financial Results

Research and development expenses for the quarter ended March 31, 2023 were \$3.4 million, compared to \$3.7 million for the same period in 2022. The decrease was primarily due to an increase in capitalized software development costs, offset by a decrease in clinical study costs.

Sales and marketing expenses for the quarter ended March 31, 2023 were \$2.1 million, compared to \$2.0 million for the same period in 2022. The increase was primarily related to higher personnel related costs associated with commercial readiness activities, partially offset by slightly lower real world evidence study related expenses.

General and administrative expenses for the quarter ended March 31, 2023 were \$3.4 million, compared to \$3.6 million for the same period in 2022. The decrease was primarily related to a decrease in business insurance costs, offset somewhat by an increase in personnel and related costs.

Interest expense, net for the quarter ended March 31, 2023 was \$0.4 million, compared to \$0.3 million for the same period in 2022. The increase was primarily the result of an additional \$5.0 million borrowed under the Company's secured term loan agreement with Hercules Capital in the second quarter of 2022.

Net loss for the quarter ended March 31, 2023 was \$9.4 million, compared to \$9.7 million for the same period in 2022. On a per common share basis, net loss was \$0.39 and \$0.41 for the quarter ended March 31, 2023 and 2022, respectively. The decline in loss per share is primarily related to an increase in weighted average shares outstanding and a decline in net loss.

Capital resources: Cash and cash equivalents were \$6.1 million on March 31, 2023, compared to \$15.7 million on December 31, 2022. In April 2023, the Company completed a private placement of 7,878,786 shares of common stock for gross proceeds of approximately \$6.5 million, before deducting offering expenses payable by the Company. In addition, the Company amended its secured term loan agreement with Hercules Capital in April 2023, which provides for a delay in principal payments for up to six months. The Company believes the proceeds from the private placement combined with the amendment to the secured term loan agreement with Hercules Capital and the previously announced cost savings initiative will allow it to meet several key milestones included in its financing strategy.

Conference Call and Webcast

Better Therapeutics will host a conference call and webcast today, May 11, 2023, at 8:30 a.m. ET / 5:30 a.m. PT. To access the conference call, please register at: <u>https://register.vevent.com/register/BI5d9690c447df48b2b930b971560acd4f</u>. 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: <u>https://edge.media-server.com/mmc/p/khcj9g2y</u> A replay of the webcast may be accessed from the Presentations & Events page in the Investors section of the Better Therapeutics corporate website at: <u>https://investors.bettertx.com</u>.

Available Information

Better Therapeutics periodically provides other information for investors on its corporate website, <u>http://www.bettertx.com</u>, and its investor relations website, <u>https://investors.bettertx.com</u>. 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 has been used for T2D and other cardiometabolic conditions before, but until now the approach has not been scalable due to the need to deliver the therapy in-person via a therapist. If authorized by the FDA, BT-001 would be the first 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, NAFLD, NASH, hypertension, hyperlipidemia and other cardiometabolic conditions. By adapting the principles and mechanisms of CBT, Better Therapeutics' 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 company developing 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 T2D, 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 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 and in our earning conference call include, but are not limited to, statements regarding Better Therapeutics' plans and expectations regarding FDA submissions, including its application for Breakthrough Device designation for its investigational prescription digital therapy in NAFLD and NASH, plans and expectations related to potential marketing authorizations and the timing of and plans related to the potential commercial launch of BT-001 for the treatment of T2D, if authorized by the FDA, Better Therapeutics' plans and expectations regarding its real world evidence program for BT-001, including the timing of results, 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 pricina research and results and the interest of healthcare providers and payers in PDTs, Better Therapeutics' plans regarding publications, statements related to its financial outlook and cash runway and expectations 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 forwardlooking 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' annual report on Form 10-K for the year ended December 31, 2022 filed with the Securities and Exchange Commission (SEC) on March 30, 2023, and those that are included in any of Better Therapeutics' subsequent filings with the SEC.

BETTER THERAPEUTICS, INC. CONDENSED BALANCE SHEETS (in thousands, except share data)

ASSETS	March 31, 2023 (unaudited)		December 31, 2022 (audited)	
Current assets:	(u		<u> </u>	
Cash and cash equivalents	\$	6,068	\$	15,740
Prepaid expenses	Ψ	1,968	Ψ	2,496
Other current assets		406		210
Total current assets		8,442		18,446
Capitalized software development costs, net		3,752		3,888
Property and equipment, net		131		121
Other long-term assets		483		488
Total Assets	\$	12,808	\$	22,943
LIABILITIES AND STOCKHOLDERS' DEFICIT				
Current liabilities:				
Accounts payable	\$	2,513	\$	3,035
Accrued payroll		3,078		2,301
Other accrued expenses		2,510		3,626
Current portion of long-term debt		5,539		4,532
Total current liabilities		13,640		13,494
Long-term debt, net of current portion and debt issuance costs		9,001		10,348
Total liabilities		22,641		23,842
Commitments and contingencies				
Stockholders' deficit:				
Common stock		2		2
Additional paid-in capital		111,025		110,602
Accumulated deficit		(120,860)		(111,503)
Total Stockholders' Deficit		(9,833)		(899)
Total Liabilities and Stockholders' Deficit	\$	12,808	\$	22,943

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

		Three Months Ended			
	March 31,				
	2023		2022		
Operating expenses:					
Research and development	\$	3,389	\$	3,673	
Sales and marketing		2,104		2,044	
General and administrative		3,432		3,628	
Total operating expenses		8,925		9,345	
Loss from operations		(8,925)		(9,345)	
Interest expense, net		(431)		(317)	
Loss before provision for income taxes		(9,356)		(9,662)	
Provision for income taxes		1		—	
Net loss	\$	(9,357)	\$	(9,662)	
Net loss per share, basic and diluted	\$	(0.39)	\$	(0.41)	
Weighted-average shares used in computing net loss per share		23,826,594		23,413,213	

Investor Relations:

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