

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): August 09, 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	Trading 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 ☒

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 August 9, 2023, Better Therapeutics, Inc. issued a press release announcing financial results and other business updates for the quarter ended June 30, 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., August 9, 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: August 9, 2023

By: /s/ Mark Heinen

Mark Heinen
Chief Financial Officer

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

Obtained FDA Authorization for AspyreRx™ to treat adults with type 2 diabetes

Established price and launch metrics in preparation for expected launch in Q4

Completed financing transactions totaling \$12.5 million in net proceeds

Company to host conference call and webcast today at 4:30pm ET

SAN FRANCISCO--(BUSINESS WIRE)--August. 9, 2023-- Better Therapeutics, Inc. (NASDAQ: BTTX), a pioneer in developing prescription digital therapeutics to treat cardiometabolic diseases, today reported financial results for the second quarter 2023 and provided an update on progress towards achieving key corporate milestones.

"Obtaining FDA authorization for AspyreRx was a pivotal milestone for our company and a catalyst for strengthening our financial position and advancing business development discussions," said Frank Karbe, Chief Executive Officer at Better Therapeutics. "With a commercial release of AspyreRx anticipated later this year, gaining broad payer coverage and building awareness amongst targeted healthcare providers is a key priority for us."

Second Quarter and Recent Business Highlights

- **Announced FDA Authorization of AspyreRx:** In July 2023, Better Therapeutics announced that the U.S. Food and Drug Administration (FDA) authorized AspyreRx™ (formerly BT-001), a prescription-only digital therapeutic (PDT) treatment indicated to provide cognitive behavioral therapy to patients 18 years or older with type 2 diabetes (T2D). AspyreRx was reviewed through the FDA's De Novo pathway and its authorization creates a new class of diabetes digital behavioral therapeutic devices.
 - **Set Price for AspyreRx:** In July 2023, Better Therapeutics completed final pricing research and set the Wholesale Acquisition Cost (WAC), or list price, for AspyreRx at \$750.00 for a 90-day script. The Company also plans to offer the product on a cash-pay basis at a discounted price, for a limited period of time, to provide patients who are not covered by insurance at launch with an affordable out-of-pocket option.
 - **Completed Multiple Financing Transactions:** In April 2023, Better Therapeutics announced a private placement financing for gross proceeds of approximately \$6.5 million before deducting offering expenses payable by the Company. In July 2023, Better Therapeutics announced the completion of an additional \$6.7 million in net proceeds from multiple equity transactions. There was strong participation in both financings from certain officers and directors of the Company.
-

Expected Upcoming Milestones

- **Commercial Launch of AspyreRx:** AspyreRx is expected to launch commercially in the fourth quarter of 2023. With FDA authorization in hand, the Company is continuing to pursue payer coverage as well as finalizing SAM registration, the System for Award Management, a government-wide registry for vendors doing business with the Federal government. Registration is followed by negotiation for access via the Federal Supply Schedule.
- **Complete Enrollment in BT-001 Real-world Evidence Program:** As of July 31st, 2023, Better Therapeutics has enrolled approximately 90% of the target participant population in its real-world evidence program and expects to complete enrollment by the end of the third quarter. Pending sufficient power, the Company expects to share the first dataset from these long-term effectiveness studies in the fourth quarter of this year.
- **Request Breakthrough Device Designation:** Following the successful completion of the LivVita Liver Study, Better Therapeutics intends to submit a request to the FDA for Breakthrough Device Designation for its investigational PDT in non-alcoholic fatty liver disease (NAFLD) and non-alcoholic steatohepatitis (NASH) by the end 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.
- **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, by the end of this year.

Second Quarter 2023 Financial Results

Research and development expenses for the quarter ended June 30, 2023 were \$2.2 million, compared to \$4.2 million for the same period in 2022. The decrease was primarily due to a \$1.0 million decrease in clinical study costs as a result of the completion of the BT-001 pivotal trial in the third quarter of 2022 as well as a \$0.7 million decline in personnel related costs as a result of savings from the restructuring in the first quarter of 2023.

Sales and marketing expenses for the quarter ended June 30, 2023, were \$1.7 million, compared to \$1.7 million for the same period in 2022. Personnel related costs increased \$0.3 million as we continue to prepare for the commercial launch of AspyreRx. This was offset by \$0.3 million in severance related costs in the prior year.

General and administrative expenses for the quarter ended June 30, 2023, were \$3.1 million, compared to \$3.7 million for the same period in 2022. The decrease was primarily related to a decrease in business insurance costs.

Interest expense, net for the quarter ended June 30, 2023, was \$0.6 million, compared to \$0.3 million for the same period in 2022. The increase was primarily the result of higher interest rates and 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 June 30, 2023 was \$7.6 million, compared to \$9.9 million for the same period in 2022. On a per common share basis, net loss was \$0.24 and \$0.42 for the quarter ended June 30, 2023 and 2022, respectively. The decline in loss per share is related to a decline in net loss in the second quarter of 2023 compared to the prior year as a result of savings from the restructuring in the first quarter of 2023, and an increase in weighted average shares outstanding.

Capital resources: Cash and cash equivalents were \$6.2 million on June 30, 2023, compared to \$15.7 million on December 31, 2022. In July 2023, the Company raised \$6.7 million in net proceeds from additional financings. The Company believes the proceeds from the financings and the previously announced amendment to the secured term loan agreement with Hercules Capital will extend its runway into the fourth quarter.

Conference Call and Webcast

Better Therapeutics will host a conference call and webcast today, August 9, 2023, at 4:30 p.m. ET / 1:30 p.m. PT. To access the conference call, please register at: <https://register.vevent.com/register/BI614fa4bfabc545808e507d9f77a536a6>. 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/2drr9dwx>. A replay of the webcast may be accessed from the Presentations & Events page in the Investors section of the Better Therapeutics corporate website at: <https://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, <https://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 AspyreRx

AspyreRx (fka BT-001) was granted marketing authorization by the U.S. Food and Drug Administration (FDA) in July 2023 as the first prescription-only digital behavioral therapeutic device delivering a novel form of cognitive behavioral therapy (CBT) via smartphone to treat adults with type 2 diabetes (T2D). AspyreRx is backed by robust data demonstrating clinically meaningful and sustained reduction in HbA1c as well as improvements in other markers of cardiometabolic health when used up to 180 days. Using proven techniques that target the underlying psychological, behavioral, and cognitive factors that sustain or worsen T2D, AspyreRx is a self-paced, engaging experience that patients can access anytime/anywhere. It is prescribed by a healthcare provider in 90-day increments, with proprietary CBT delivered digitally in a weekly step-by-step process. Through interactive therapy lessons, skill-building modules, weekly goal setting and tracking, patients connect changes in behavior to improvements in blood sugar and other biometrics. Each step in the experience builds on the prior to enable and reinforce cognitive restructuring, building the emotional resilience and acceptance needed to make enduring changes.

Indications for Use

AspyreRx is a prescription-only digital therapeutic device intended to provide cognitive behavioral therapy to patients 18 years or older with type 2 diabetes. The device targets behavior to aid in the management of type 2 diabetes in patients who are under the care of a healthcare provider. AspyreRx provides cognitive behavioral therapy as a treatment that should be used adjunctively with standard of care.

About Better Therapeutics

Better Therapeutics is a prescription digital therapeutics company developing a novel form of cognitive behavioral therapy to address underlying factors that sustain or worsen 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 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 Better Therapeutics’ plans and expectations regarding FDA submissions, plans related to the potential commercial launch of AspyreRx (formerly BT-001) for the treatment of T2D, expectations related to the efficacy and potential benefits of BT-001 and CBT and their potential treatment applications, the timing of results from, and Better Therapeutics’ plans for, its Real-world Evidence Program, Better Therapeutics’ plans regarding the research and advancement of its product candidates for additional treatments, expectations related to pricing, research and its plans regarding offering AspyreRx at a discounted price, Better Therapeutics’ plans and expectations regarding the results of discussions with healthcare providers and the interest of healthcare providers and payers in PDTs, Better Therapeutics’ plans and expectations regarding its financing and business developments strategy, and statements related to its cash runway and long-term 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, for commercial distribution and insurance companies to reimburse their use, market acceptance of PDTs, including AspyreRx, 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 March 31, 2023 filed with the Securities and Exchange Commission (SEC) on May 11, 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)

	June 30, 2023 (unaudited)	December 31, 2022 (audited)
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 6,196	\$ 15,740
Prepaid expenses	1,166	2,496
Other current assets	60	210
Total current assets	7,422	18,446
Capitalized software development costs, net	3,584	3,888
Property and equipment, net	115	121
Other long-term assets	483	488
Total Assets	<u>\$ 11,604</u>	<u>\$ 22,943</u>
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	\$ 2,985	\$ 3,035
Accrued payroll	2,747	2,301
Other accrued expenses	2,448	3,626
Current portion of long-term debt	5,693	4,532
Total current liabilities	13,873	13,494
Long-term debt, net of current portion and debt issuance costs	8,519	10,348
Total liabilities	22,392	23,842
Commitments and contingencies (Note 8)		
Stockholders' deficit:		
Common stock, \$0.0001 par value per share, 200,000,000 shares authorized as of June 30, 2023 and December 31, 2022 and 31,797,101 and 23,851,022 shares issued and outstanding as of June 30, 2023 and December 31, 2022, respectively	3	2
Additional paid-in capital	117,658	110,602
Accumulated deficit	(128,449)	(111,503)
Total Stockholders' Deficit	(10,788)	(899)
Total Liabilities and Stockholders' Deficit	<u>\$ 11,604</u>	<u>\$ 22,943</u>

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	\$ 2,240	\$ 4,241	\$ 5,629	\$ 7,914
Sales and marketing	1,704	1,683	3,808	3,727
General and administrative	3,081	3,675	6,513	7,303
Total operating expenses	7,025	9,599	15,950	18,944
Loss from operations	(7,025)	(9,599)	(15,950)	(18,944)
Interest expense, net	(563)	(329)	(994)	(646)
Loss before provision for income taxes	(7,588)	(9,928)	(16,944)	(19,590)
Provision for income taxes	1	—	2	—
Net loss	\$ (7,589)	\$ (9,928)	\$ (16,946)	\$ (19,590)
Net loss per share, basic and diluted	\$ (0.24)	\$ (0.42)	\$ (0.62)	\$ (0.83)
Weighted-average shares used in computing net loss per share	31,215,194	23,592,995	27,541,308	23,498,978

Investor Relations:

Mark Heinen
IR@bettertx.com

Media Enquiries:

Emma Williams
emma.williams@bettertx.com

