

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 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 November 9, 2023, Better Therapeutics, Inc. issued a press release announcing financial results and other business updates for the quarter ended September 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	<a href="#">Press Release issued by Better Therapeutics, Inc., November 9, 2023.</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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**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: November 9, 2023

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

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## Better Therapeutics Reports Third Quarter 2023 Financial Results and Provides Business Updates

*Company obtained FDA authorization for AspyreRx™ to treat adults with type 2 diabetes and announced commercial launch*

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

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

"We made tremendous progress in Q3, which included the FDA authorization of AspyreRx and the completion of the work required for a commercial launch in early October. AspyreRx offers healthcare providers a clinically proven, convenient, and cost-effective treatment option that aligns with current diabetes treatment guidelines and is suitable for a broad range of people with type 2 diabetes," said Frank Karbe, Chief Executive Officer at Better Therapeutics. "Our current focus is on demonstrating commercial traction, primarily within our initial launch geographies. Securing payer coverage is a critical element for our success. We have advanced our discussions with multiple commercial payers, which gives us confidence that obtaining coverage for AspyreRx is achievable."

### Third Quarter and Recent Business Highlights

- **Obtained FDA Authorization:** In July 2023, Better Therapeutics announced that the U.S. Food and Drug Administration (FDA) authorized AspyreRx™ (formerly BT-001) as the first prescription-only digital therapeutic (PDT) treatment indicated to provide cognitive behavioral therapy (CBT) 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.
  - **Completed Enrollment in AspyreRx Real-world Evidence Program:** In September 2023, Better Therapeutics announced the completion of enrollment of 1,000 participants in its real-world evidence program evaluating the long-term effectiveness of AspyreRx in
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T2D.

- **New Patent Issued:** In September 2023, Better Therapeutics patent - "Managing lifestyle and health interventions with predictive analytics" - was issued in the European Union (EU). This is the Company's second patent issued of 4 patent families filed, covering the breadth of Better Therapeutics' novel method for delivering CBT, innovative use of patient engagement data, and AI methods such as machine learning to predict outcomes and adjust treatment.
  - **Commercially Launched AspyreRx:** In October 2023, Better Therapeutics announced the commercial launch of AspyreRx, with healthcare providers in the U.S. now able to prescribe the treatment for adults with T2D. Prescriptions are being written and patients are actively on treatment. If the patient's insurance does not cover AspyreRx, the Company is offering eligible patients a self-pay option, for a limited time, as payer coverage is established.
  - **LivVita Study Results Published:** In October 2023, Better Therapeutics announced the pre-print publication of the results of its LivVita Liver Study in *Gastro Hep Advances*, a peer-reviewed journal produced by the American Gastroenterological Association (AGA). Authors concluded the totality of positive efficacy, safety, and usability data indicates the potential of Better Therapeutics' digitally delivered CBT to help address the significant unmet clinical needs observed in metabolic dysfunction-associated steatotic liver disease (MASLD) and metabolic dysfunction-associated steatohepatitis (MASH).
  - **New Data Shows Superior Clinical Outcomes with Concurrent Use of AspyreRx and GLP-1 Receptor Agonists to Treat Type 2 Diabetes:** In October 2023, Better Therapeutics announced that new data from a subgroup analysis revealed that adjunctive use of AspyreRx with standard of care, including GLP-1 receptor agonists (GLP-1), leads to a substantially greater clinical improvement compared to control participants who used GLP-1s but did not incorporate AspyreRx into their regimen.
  - **Showcased AspyreRx at First Promotional Meeting:** In October 2023, Better Therapeutics announced its participation at the American College of Lifestyle Medicine's 2023 Annual Meeting. At this meeting, AspyreRx was presented for the first time,
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allowing over 2,000 medical professionals, healthcare executives, and researchers the opportunity to experience the product firsthand and attend the sponsored education session.

- **Additional Capital Raise:** In October 2023, Better Therapeutics raised \$2.9 million through its At-The-Market (ATM) facility, with an average price per share of \$0.42. This additional capital extends the Company's financial runway into the first quarter of 2024.

### Expected Upcoming Milestones

- **Obtain Commercial Payer Coverage for AspyreRx:** Better Therapeutics is currently engaged in advanced discussions with multiple commercial payers and expects to announce an agreement by the end of this year. The Company has submitted its Federal Supply Schedule (FSS) application and is awaiting to be assigned a contract negotiator. Once on the FSS, AspyreRx would be available to be prescribed to Veterans that receive care via the VA network.
  - **Request Breakthrough Device Designation:** Following the successful completion of the LivVita Liver Study and publication of the results in the peer-reviewed journal *Gastro Hep Advances*, Better Therapeutics intends to submit a request to the FDA for Breakthrough Device Designation for its investigational PDT in MASLD and MASH by the end of 2023. Currently, there is no FDA approved treatment for MASLD and MASH, 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.
  - **Announce a Business Development Partnership:** To support the commercialization of AspyreRx, Better Therapeutics expects to announce a business development partnership by the end of this year.
  - **Further Strengthen Financial Position:** Better Therapeutics expects to further strengthen its financial position in the fourth quarter to extend its financial runway.
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### Third Quarter 2023 Financial Results

**Research and development expenses** for the quarter ended September 30, 2023 were \$1.8 million, compared to \$5.5 million for the same period in 2022. The decrease was primarily due to a \$2.0 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 \$1.8 million decrease in personnel related costs as a result of savings from the restructuring in the first quarter of 2023 and other cost savings measures.

**Sales and marketing expenses** for the quarter ended September 30, 2023 were \$1.4 million, compared to \$1.6 million for the same period in 2022. Personnel related costs increased \$0.2 million as we prepared for the commercial launch of AspyreRx. This was offset by a \$0.3 million decrease in real world evidence costs as we completed enrollment in the study.

**General and administrative expenses** for the quarter ended September 30, 2023 were \$2.1 million, compared to \$4.0 million for the same period in 2022. The decrease was primarily related to a \$1.1 million decline in personnel and consulting costs related to the cost savings initiatives implemented earlier this year, and a \$0.7 million decrease in business insurance costs.

**Interest expense, net** for the quarter ended September 30, 2023 was \$0.5 million, compared to \$0.4 million for the same period in 2022. The increase was the result of higher interest rates associated with the Company's secured term loan agreement with Hercules Capital.

**Net loss** for the quarter ended September 30, 2023 was \$5.9 million, compared to \$11.4 million for the same period in 2022. On a per common share basis, net loss was \$0.15 and \$0.48 for the quarter ended September 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 the completion of the pivotal trial in the third quarter of 2022, and an increase in weighted average shares outstanding.

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**Capital resources:** Cash and cash equivalents were \$6.6 million on September 30, 2023, compared to \$15.7 million on December 31, 2022. In October 2023, the Company raised \$2.9 million in net proceeds from the utilization of our ATM facility at an average price of \$0.42 per share. The proceeds from the ATM and the lower operating expenses from the restructuring in the first quarter of 2023 will extend its runway into the first quarter of 2024.

### **Conference Call and Webcast**

Better Therapeutics will host a conference call and webcast today, November, 9, 2023, at 8:30 a.m. ET / 5:30 a.m. PT. To access the conference call, please register at: <https://register.vevent.com/register/BI7cccb1e37c44102b4f5ce26d785604d>. 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/dk6kxzaw>. 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.

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## **About AspyreRx**

AspyreRx (formerly 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 CBT via a smartphone to treat adults with type 2 diabetes (T2D). AspyreRx is backed by robust data demonstrating clinically meaningful and sustained reduction in A1c 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 from their smartphone. 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.

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For more information visit: [bettertx.com](https://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, including a request to the FDA for Breakthrough Device Designation for its investigational PDT in MASLD and MASH, and the timing of such submissions, plans related to the commercialization 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, Better Therapeutics’ plans regarding the research and advancement of its product candidates for additional treatments and other upcoming milestones, Better Therapeutics’ plans and expectations regarding the results of discussions with healthcare providers and payers and the interest of healthcare providers and payers in PDTs, the timing of and expectations related to Better Therapeutics’ engagement with Veterans Affairs and other government agencies, Better Therapeutics’ plans and expectations regarding potential financings and business development partnerships, 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 June 30, 2023 filed with the Securities and Exchange Commission (SEC) on August 9, 2023, and those that are included in any of Better Therapeutics’ subsequent filings with the SEC.*

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

	September 30 2023 (unaudited)	December 31, 2022 (audited)
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 6,598	\$ 15,740
Prepaid expenses	674	2,496
Other current assets	73	210
Total current assets	<u>7,345</u>	<u>18,446</u>
Capitalized software development costs, net	2,792	3,888
Property and equipment, net	102	121
Other long-term assets	483	488
Total Assets	<u>\$ 10,722</u>	<u>\$ 22,943</u>
<b>LIABILITIES AND STOCKHOLDERS' DEFICIT</b>		
Current liabilities:		
Accounts payable	\$ 2,308	\$ 3,035
Accrued payroll	1,886	2,301
Other accrued expenses	2,158	3,626
Current portion of long-term debt	6,586	4,532
Total current liabilities	<u>12,938</u>	<u>13,494</u>
Long-term debt, net of current portion and debt issuance costs	7,721	10,348
Total liabilities	<u>20,659</u>	<u>23,842</u>
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	4	2
Additional paid-in capital	124,370	110,602
Accumulated deficit	<u>(134,311)</u>	<u>(111,503)</u>
Total Stockholders' Deficit	<u>(9,937)</u>	<u>(899)</u>
Total Liabilities and Stockholders' Deficit	<u>\$ 10,722</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 September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	\$ 1,833	\$ 5,477	\$ 7,462	\$ 13,391
Sales and marketing	1,392	1,557	5,200	5,284
General and administrative	2,116	3,962	8,629	11,265
Total operating expenses	<u>5,341</u>	<u>10,996</u>	<u>21,291</u>	<u>29,940</u>
Loss from operations	(5,341)	(10,996)	(21,291)	(29,940)
Interest expense, net	(518)	(406)	(1,512)	(1,052)
Loss before provision for income taxes	(5,859)	(11,402)	(22,803)	(30,992)
Provision for income taxes	3	3	5	3
Net loss	<u>\$ (5,862)</u>	<u>\$ (11,405)</u>	<u>\$ (22,808)</u>	<u>\$ (30,995)</u>
Net loss per share, basic and diluted	<u>\$ (0.15)</u>	<u>\$ (0.48)</u>	<u>\$ (0.73)</u>	<u>\$ (1.32)</u>
Weighted-average shares used in computing net loss per share	<u>38,495,150</u>	<u>23,693,154</u>	<u>31,214,093</u>	<u>23,533,290</u>

**Investor Relations:**

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