Better Therapeutics Reports Fourth Quarter and Full Year 2022 Financial Results and Provides Business Updates

March 30, 2023

Advanced preparations for potential commercial launch of BT-001 in U.S. in mid-2023

Reported positive topline results from exploratory trial for fatty liver disease

Announced restructuring and other cost saving actions to extend financial runway

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

SAN FRANCISCO--(BUSINESS WIRE)--Mar. 30, 2023-- Better Therapeutics, Inc. (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 fourth quarter and full year of 2022 and provided an update on progress toward achieving key corporate milestones.

"Better Therapeutics made significant progress in 2022 highlighted by the successful completion of our pivotal clinical trial of BT-001 in type 2 diabetes, the submission of our *de novo* classification request to the FDA seeking marketing authorization for BT-001 and the positive topline results from our exploratory trial for fatty liver disease," stated Frank Karbe, President and CEO of Better Therapeutics. "Despite our recent restructuring, the long-term outlook for the potential of our digital therapeutics' platform and our guidance for potential FDA authorization remains unchanged, and we continue to prepare for commercial launch."

Fourth Quarter and Recent Business Highlights

- **U.S. Food and Drug Administration (FDA) Accepted *De Novo* Request for BT-001:** In October 2022, Better Therapeutics' *de novo* classification request seeking marketing authorization of BT-001 for the treatment of adults with type 2 diabetes (T2D) was accepted for substantive review by the FDA. In February 2023, Better Therapeutics received a Request for Additional Information from the FDA, as expected, and is working to address the FDA's questions. If authorized by the FDA, BT-001 would be the first prescription solution intended to deliver highly scalable CBT to adults with T2D from a digital device.
- **Publication of BT-001 Pivotal Clinical Trial Results:** In October 2022, results from Better Therapeutics' pivotal clinical trial of BT-001 in adult patients with T2D were published in the American Diabetes Association-produced, peer-reviewed journal *Diabetes Care*. Data was also presented at the American Heart Association and in March 2023 it was presented at the American College of Cardiology.
- **Reported Positive Topline Results from Exploratory Trial for Fatty Liver Disease:** In December 2022, Better Therapeutics completed and reported positive results from a pilot study (the LivVita Liver Study) evaluating the feasibility of using a PDT to reduce fatty liver and improve liver disease biomarkers in Nonalcoholic Fatty Liver Disease (NAFLD) and Nonalcoholic Steatohepatitis (NASH). The LivVita Liver Study met its primary endpoint, showing a statistically significant positive signal with an average relative reduction in Magnetic Resonance Imaging – Proton Density Fat Fraction (MRI-PDFF) of 16% (p=0.01) in the intent-to-treat population (N=19).
- **Company Announces Restructuring To Preserve Cash Runway:** In March 2023, Better Therapeutics announced it would implement a reduction in force impacting 35% of the workforce. The company is also implementing other cost savings measures to further extend its financial runway.

Expected Upcoming Milestones

- **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 NAFLD and NASH and is expected to submit the application in the first half 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 having a prescription treatment option could be of significant benefit to millions of patients.
- **Potential FDA Authorization and Commercial Launch of BT-001:** Better Therapeutics is diligently advancing its preparations for the potential commercial launch of BT-001 in mid-2023. Upcoming milestones in market access include the submission of health economic outcomes research (HEOR) for publication and commencing pre-authorization information exchange meetings with Payers beginning in April.
- **First Dataset from BT-001 Real-World Evidence Program:** This randomized, controlled, multi-site program is designed to generate real-world evidence to provide payers and providers with long-term data related to usage and outcomes in a real-world setting. Interim study results are expected to be reported in the fourth quarter of 2023.

Fourth Quarter and Full Year 2022 Financial Results

Research and development expenses for the quarter ended December 31, 2022 were $3.0 million, compared to $6.4 million for the same period in 2021. The decrease primarily reflects a $1.8 million decrease in clinical study costs as a result of the completion of the BT-001 clinical trial in the third quarter of 2022 and a $1.6 million decrease in incentive compensation expense compared to the prior year. Research and development expenses for the year ended December 31, 2022 were $16.4 million, compared to $19.4 million for the same period in 2021. The decrease was primarily due to a $6.4 million decrease in clinical trial costs as the Company completed the BT-001 clinical trial, offset by a $2.5 million increase in personnel related costs related to expanding the Company's software development capabilities and $0.8 million increase in capitalized software amortization.

Sales and marketing expenses for the quarter ended December 31, 2022 were $1.7 million, compared to $1.2 million for the same period in 2021. The increase in sales and marketing expenses was primarily related to an increase of $0.3 million in personnel related costs and a $0.2 million increase in consulting expenses associated with commercial readiness activities to support the potential launch of BT-001, if authorized by the FDA. Sales and marketing expenses for the year ended December 31, 2022 were $7.0 million, compared to $2.3 million for the same period in 2021. The increase in sales and marketing expenses was primarily related to an increase of $1.2 million in personnel related costs and a $3.4 million increase in consulting expenses associated with commercial readiness activities to support the potential launch of BT-001, if authorized by the FDA.

General and administrative expenses for the quarter ended December 31, 2022 were $3.6 million, compared to $4.6 million for the same period in 2021. The decrease was primarily related to lower incentive compensation expenses compared to the prior year. General and administrative expenses for the year ended December 31, 2022 were $14.8 million, compared to $8.8 million for the same period in 2021. The overall increase in general and administrative expenses was primarily related to the increased costs of being a public company, including $3.4 million in business insurance, $1.6 million in personnel related costs and $1.6 million in outside services, including consulting, audit, and legal fees.

Interest expense, net for the quarter ended December 31, 2022 was $0.4 million, compared to $0.2 million for the same period in 2021. Interest expense, net for the year ended December 31, 2022 was $1.5 million, compared to $0.2 million 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 December 31, 2022 was $8.8 million, compared to $13.9 million for the same period in 2021. On a per common share basis, net loss was $0.37 and $0.71 for the quarter ended December 31, 2022 and 2021, respectively. Net loss for the year ended December 31, 2022 was $39.8 million, compared to $40.3 million for the same period in 2021. On a per common share basis, net loss was $1.69 and $3.11 for the year ended December 31, 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 Company's business combination in the fourth quarter of 2021.

Capital resources: Cash and cash equivalents were $15.7 million on December 31, 2022, compared to $40.6 million on December 31, 2021. As a result of the restructuring and other cost savings initiatives, we expect operating cash burn for 2023 to be lower than previously forecasted by approximately $10 million. The company is actively seeking additional sources of capital to extend its runway.

Conference Call and Webcast

Better Therapeutics will host a conference call and webcast today, March 30, 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/BI24e91f91597f4f97a40e32c908ac7be5. 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/cmdsh8s3. 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, 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 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 pricing 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 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 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 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.

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

	Three Months Ended December 31,		Year Ended December 31,	
	2022	2021	2022	2021
Operating Expenses:				
Research and development	$ 3,049	$ 6,354	$ 16,440	$ 19,436
Sales and marketing	1,695	1,177	6,979	2,336
General and administrative	3,578	4,573	14,843	8,788
Total operating expenses	8,322	12,104	38,262	30,560
Loss from operations	(8,322)	(12,104)	(38,262)	(30,560)
Interest expense, net	(439)	(182)	(1,491)	(185)
Change in fair value of SAFEs	—	(1,611)	—	(10,390)
Gain on loan forgiveness	—	—	—	647
Loss before provision (benefit) from income taxes	(8,761)	(13,897)	(39,753)	(40,488)
Provision (benefit) from income taxes	4	(3)	7	(153)
Net loss	$ (8,765)	$ (13,894)	$ (39,760)	$ (40,335)
Net loss per share attributable to common shareholders, basic and diluted	$ (0.37)	$ (0.71)	$ (1.69)	$ (3.11)
Weighted-average shares used in computing net loss per share	23,745,700	19,68,940	23,557,846	12,982,472

BETTER THERAPEUTICS, INC.
BALANCE SHEETS
(in thousands)

	Unaudited December 31, 2022	Audited December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 15,740	$ 40,566
Prepaid expenses	2,496	4,409
Other current assets	210	276
Total current assets	18,446	45,251
Capitalized software development costs, net	3,888	5,077

Property and equipment, net	121	82
Other long-term assets	488	548
Total Assets	$ 22,943	$ 50,958
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 3,035	$ 1,523
Accrued payroll	2,301	1,352
Other accrued expenses	3,626	1,858
Current portion of long-term debt	4,532	-
Total current liabilities	13,494	4,733
Long-term debt, net of current portion and debt issuance costs	10,348	9,505
Total liabilities	23,842	14,238
Stockholders' equity:		
Common stock	2	2
Additional paid-in capital	110,602	108,461
Accumulated deficit	(111,503)	(71,743)
Total Stockholders' Equity	(899)	36,720
Total Liabilities and Stockholders' Equity	$ 22,943	$ 50,958

View source version on businesswire.com: https://www.businesswire.com/news/home/20230330005285/en/

Investor Relations:
Mark Heinen
IR@bettertx.com

Media Enquiries:
Emma Williams
emma.williams@bettertx.com

Source: Better Therapeutics, Inc.