Better Therapeutics Reports First Quarter 2022 Financial Results and Provides Update on Key Corporate Milestones

May 13, 2022

Reported positive primary endpoint results from pivotal trial of BT-001 after 90 days of treatment for type 2 diabetes

> *Represents a first-in-class randomized, controlled clinical trial of a prescription digital therapeutic (PDT) for treating a cardiometabolic disorder*
>
> *Data supports filing of a de novo classification request with the FDA, which is expected in the third quarter of 2022, subject to supportive secondary endpoint data and study completion in the second quarter of 2022*

Initiated first-ever clinical study evaluating nutritional Cognitive Behavior Therapy (nCBT) as potential treatment for Nonalcoholic Fatty Liver Disease (NAFLD) and Nonalcoholic Steatohepatitis (NASH)

Expanded real-world evidence study of BT-001 through collaboration with Mass General Brigham and Durham Veterans Administration to further establish durability of effect and impact on healthcare costs

SAN FRANCISCO--(BUSINESS WIRE)--May 13, 2022-- Better Therapeutics, Inc. (NASDAQ: BTTX), a prescription digital therapeutics (PDT) company developing nutritional cognitive behavioral therapy (nCBT) to address the root causes of cardiometabolic diseases, today reported financial results for the first quarter of 2022 and provided an update on progress toward achieving key corporate milestones.

“Better Therapeutics has made significant progress in advancing the clinical development of its first-in-class digital therapeutic platform for the treatment of cardiometabolic diseases,” stated Kevin Appelbaum, Co-Founder and CEO of Better Therapeutics. “Our pivotal trial of BT-001, evaluating the use of nCBT for the treatment of patients with uncontrolled type 2 diabetes achieved its primary endpoint, supporting the filing of a *de novo* classification request with the FDA for potentially the first ever PDT in this widespread indication. nCBT has the potential to treat a broad range of other cardiometabolic conditions and our team has achieved key pipeline milestones with the initiation of a feasibility study evaluating nCBT as a potential treatment for Nonalcoholic Fatty Liver Disease (NAFLD) and Nonalcoholic Steatohepatitis (NASH). Together, these initiatives reflect an emerging standard of care for the treatment of cardiometabolic diseases, built on a foundation of behavioral therapy delivered as prescription digital therapeutics.”

First Quarter 2022 Financial Results

Research and development expenses for the quarter ended March 31, 2022 were $3.7 million, compared to $1.4 million for the comparable period in 2021. The increase was primarily related to the costs of advancing research in conjunction with the company's prescription digital therapeutic, BT-001.

Sales and marketing expenses for the quarter ended March 31, 2022 were $2.0 million, compared to $43 thousand for the comparable period in 2021. The increase primarily reflects personnel, marketing and consulting expenses associated with pre-launch preparations of BT-001.

General and administrative expenses for the quarter ended March 31, 2022 were $3.6 million, compared to $1.6 million for the comparable period in 2021. The increase was primarily related to personnel costs to support company growth and additional costs of being a publicly traded company.

Capital resources: Cash and cash equivalents were $31.7 million on March 31, 2022, compared to $40.6 million on December 31, 2021. Borrowing capacity on the company's secured loan agreement with Hercules Capital, Inc. was $5 million on March 31, 2022.

Recent Business Highlights

Clinical Programs

- **BT-001 Pivotal Clinical Trial Results:** Reported positive primary endpoint data at day 90 evaluating the use of nCBT for the treatment of patients with uncontrolled type 2 diabetes. The study met its primary efficacy endpoint and demonstrated an excellent safety profile. Patients who received BT-001 demonstrated clinically meaningful and statistically significant improvement in A1c compared to control (mean improvement 0.4%; p-value < 0.0001). 45% of patients receiving BT-001 demonstrated a reduction in A1c of at least 0.4% (mean improvement 1.1%) vs. 27% of the patients in the control group.

- **BT-001 Real-World Evidence Study:** The Durham Veterans Administration (VA) Medical Center joined Mass General Brigham, Colorado Prevention Center, and Catalyst Health System in an ongoing randomized, controlled, multi-site study to generate evidence supporting payer coverage and reimbursement. These centers are expected to enroll approximately 1,000 patients for a treatment period of at least 12 months. Change in A1c and healthcare resource utilization will be evaluated and compared to usual care. Study results will be reported on a rolling basis as cohorts of 250 patients complete an incremental 90 days of treatment.

- **LivVita Liver Study:** Initiated first-ever clinical study evaluating the feasibility of nCBT to reduce liver fat and improve liver disease biomarkers as a potential treatment for NAFLD and NASH. The study is being conducted in collaboration with Arizona Liver Health, a leading liver clinical research center. This single arm interventional cohort study is expected to

enroll approximately 20 patients for a treatment period of 90 days. The primary endpoint is the mean change in percent liver fat, as measured by Magnetic Resonance Imaging Proton Density Fat Fraction (MRI-PDFF). The study is expected to be completed in the third quarter of 2022. NAFLD/NASH affects over 64 million adults in the U.S., resulting in over $100 billion in direct healthcare costs annually. There are currently no FDA approved therapeutics for treating NASH/NAFLD.

Treatment Guidelines and Reimbursement

- **Evolution of Treatment Guidelines:** The American Diabetes Association (ADA) added a recommendation for using mobile apps and digital solutions to facilitate behavior change in treating type 2 diabetes to its 2022 Standard of Care Guidelines (SOC). Upon FDA-authorization, BT-001 has the potential to become the first prescription digital therapeutic available to physicians for use in the treatment of patients with diabetes.

- **Coverage:** The Centers for Medicare & Medicaid Services (CMS) established a new Healthcare Common Procedure Coding System (HCPCS) code to become effective in the second quarter of 2022, creating a new pathway for the reimbursement of PDTs. In addition, the *Access to Prescription Digital Therapeutics Act of 2022*, was introduced and, if enacted, will expand Medicare coverage to include PDTs as a benefit class.

Expected Upcoming Milestones

- **Completion of BT-001 Pivotal Trial and De Novo Submission:** Secondary endpoint data following 180 days of treatment are expected at the end of the second quarter of 2022. In addition to the secondary endpoint which compares the mean change in A1c between the treated group to the control group, exploratory endpoints will include a comparison of the change in medications of the two groups. With continued positive data, the company expects to file a *de novo* classification request with the FDA in the third quarter of 2022, seeking marketing authorization of BT-001 for the treatment of patients with type 2 diabetes.

- **Real World Evidence Study:** Data are expected on the first 250 patients to complete 90 days of treatment in the fourth quarter of 2022.

- **BT-002 and BT-003 Pivotal Trials:** The company will gather pilot data from the BT-001 study that will inform the initiation of pivotal trials of BT-002 and BT-003 for the treatment of hypertension and hyperlipidemia, respectively. Pending favorable data and sufficient capital, these studies will commence as soon as the first half of 2023.

- **Key Opinion Leader (KOL) Webinar:** The company will host a key opinion leader webinar concurrent with the ADA annual meeting being held June 3-7, 2022. The webinar will explain the use of nCBT as a mechanism of action, the intersection of clinical intent, behavioral science and designing software for behavior change. It will then connect the dots and demonstrate how nCBT can fill the gap in current standard of care guidelines. Participating KOL's will be announced at a later date.

Conference Call and Webcast

Better Therapeutics will host a conference call and webcast today, May 13, 2022, at 8:30 a.m. ET to provide a business update. The conference call may be accessed by dialing (833) 945-2463 (domestic) or (678) 825-8211 (international) and referring to conference ID: 9776049. The live webcast may be accessed by visiting the event link at: https://edge.media-server.com/mmc/p/xqrnp5by. Following the webcast, 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.

About Better Therapeutics

Better Therapeutics is a prescription digital therapeutics (PDT) 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 type 2 diabetes, heart disease and other conditions. The cognitive behavioral therapy 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 the timing and results of the ongoing trial of BT-001 in patients with type 2 diabetes, Better Therapeutics' plans regarding FDA submissions, the timing of and expectations regarding receipt of marketing authorization and the commercial launch of BT-001, expectations related to the potential benefits of BT-001 and nCBT 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 legislative developments affecting PDTs and the outcome of such

developments, 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, the risk that the results of previously conducted studies will not be repeated or observed in ongoing or future studies involving our product candidates and other risks and uncertainties included under the heading "Risk Factors" in Better Therapeutics' annual report on form 10-K for the year ended December 31, 2021 filed with the Securities and Exchange Commission (SEC) on March 28, 2022, available at the SEC's website at www.sec.gov, and those that are included in any of Better Therapeutics' future filings with the SEC. Should one or more of these risks or uncertainties materialize, or should any of Better Therapeutics' assumptions prove incorrect, actual results may vary in material respects from those projected in these forward-looking statements.

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

	March 31, 2022 (Unaudited)	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 31,673	$ 40,566
Prepaid expenses	3,242	4,409
Other current assets	264	276
Total current assets	35,179	45,251
Capitalized software development costs, net	4,526	5,077
Property and equipment, net	98	82
Other long-term assets	488	548
Total Assets	$ 40,291	$ 50,958
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 735	$ 1,523
Accrued payroll	862	1,352
Other accrued expenses	1,666	1,858
Current portion of long-term debt	304	-
Total current liabilities	3,567	4,733
Long-term debt, net of current portion and debt issuance costs	9,299	9,505
Total liabilities	12,866	14,238
Stockholders' equity:		
Common stock	2	2
Additional paid-in capital	108,828	108,461
Accumulated deficit	(81,405)	(71,743)
Total Stockholders' Equity	27,425	36,720
Total Liabilities and Stockholders' Equity	$ 40,291	$ 50,958

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

	Three Months Ended March 31,	
	2022	2021
Operating Expenses:		
Research and development	$ 3,673	$ 1,378
Sales and marketing	2,044	43
General and administrative	3,628	1,566
Total operating expenses	9,345	2,987

Loss from operations	(9,345)	(2,987)
Interest expense, net	(317)	(2)
Change in fair value of SAFEs	—	(2,492)
Loss before benefit from income taxes	(9,662)	(5,481)
Benefit from income taxes	—	(151)
Net loss	$ (9,662)	$ (5,330)
Cumulative preferred dividends allocated to Series A Preferred Shareholders	—	(388)
Net loss attributable to common shareholders, basic and diluted	$ (9,662)	$ (5,718)
Net loss per share attributable to common shareholders, basic and diluted	$ (0.41)	$ (0.54)
Weighted-average shares used in computing net loss per share	23,413,213	10,684,920

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