Better Therapeutics Reports Second Quarter 2022 Financial Results and Provides Corporate Update

August 11, 2022

Completed pivotal trial of BT-001 for type 2 diabetes and reported positive secondary endpoint results after 180 days of treatment

On track to submit de novo classification request for BT-001 with FDA in third quarter of 2022

Completed enrollment in LivVita Liver Study for nonalcoholic fatty liver disease

Appointed Frank Karbe as President and Chief Executive Officer and member of Board of Directors

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

SAN FRANCISCO--(BUSINESS WIRE)--Aug. 11, 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 second quarter of 2022 and provided an update on progress toward achieving key corporate milestones.

“Better Therapeutics is poised to enter the next phase of its growth as a commercial company, with the recent completion of the BT-001 pivotal trial and, if authorized by the FDA, the potential launch of our first-in-class prescription digital therapeutic for the treatment of type 2 diabetes next year,” stated Frank Karbe, President and CEO of Better Therapeutics. “The pivotal trial of BT-001 met its primary and secondary endpoints and demonstrated a reassuring safety profile in a diverse and difficult to treat patient population, resulting in significant A1c reductions when compared with the current standard of care. We are on track to submit a *de novo* classification request for BT-001 with the FDA in the third quarter of 2022 and we believe we are well positioned to advance our digital therapeutic platform in type 2 diabetes and potentially other cardiometabolic conditions.”

Recent Business Highlights

- **Completed BT-001 Pivotal Clinical Trial:** Reported positive secondary endpoint results in July, following the announcement of positive primary endpoint results in March. The secondary endpoint evaluated the effectiveness and safety of the company’s investigational nCBT for the treatment of adult patients with uncontrolled type 2 diabetes (T2D) after 180 days of treatment. Among the encouraging results shown were:
    - Sustained and improved A1c levels in patients using BT-001, with average absolute A1c reduction improving from 0.3% at day 90 to 0.4% at day 180, supporting that the treatment effects of BT-001 were durable.
    - The difference in A1c levels after 180 days of treatment between BT-001 treated patients and Standard of Care (SOC) control group patients receiving standard of care remained statistically significant (p=0.01) even as more SOC patients increased blood sugar lowering medications.
    - Half of patients using BT-001 experienced clinically meaningful A1c reductions with a mean reduction of 1.3% in this subgroup at 180 days (SD 0.8%).
    - Results indicated that patients who did not use BT-001 were more likely to be placed on additional medications to improve A1c control. After the day 180 A1c draw, 1.7 times more SOC control patients increased their medications compared to BT-001 patients.
    - BT-001 demonstrated reassuring safety, with significantly fewer adverse (p<0.001) and serious adverse events (p=0.01) as compared to the SOC control group.
    - A clear dose-response between greater engagement in nCBT and greater reductions in A1c was found, supporting nCBT as a mechanism of action.
- **Completed Enrollment in the LivVita Liver Study for Nonalcoholic Fatty Liver Disease (NAFLD) and Nonalcoholic Steatohepatitis (NASH):** The company completed enrollment in a first ever clinical study evaluating the feasibility of nCBT to reduce liver fat and improve liver disease biomarkers as a potential treatment for fatty liver disease. This single arm interventional cohort study has now completed enrollment of 22 adult patients from two specialized liver treatment clinics based in Arizona. 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.
- **CEO Appointment:** Frank Karbe joined the company as President and Chief Executive Officer and as a member of the Board of Directors on July 5, 2022, succeeding Kevin Appelbaum. Frank is a widely experienced senior executive with extensive leadership and capital raising expertise, serving most recently as President and Chief Financial Officer of Myovant Sciences. Previously, he served for over a decade as Executive Vice President and Chief Financial Officer at Exelixis, Inc. Earlier in his career, he worked as an investment banker for Goldman Sachs & Co. focusing on the life sciences industry.
- **Granted Patent on Prescription Digital Therapeutics Platform:** In June 2022, the U.S. Patent and Trademark Office (USPTO) granted patent protection for several key features (methods and apparatus for generating and monitoring a therapy regimen) core to the company’s digital therapeutics platform, designed to help treat cardiometabolic diseases through the delivery of digital behavioral therapy as a PDT. Better Therapeutics’ patent coverage for its platform will extend

until at least September of 2039.

- **Publication of BT-001 Pivotal Clinical Trial Design:** A manuscript detailing the study design and methodology for the company's pivotal clinical trial of BT-001 in adult patients with T2D was published in the medical journal, Clinical Cardiology in July.

Expected Upcoming Milestones

- **BT-001 *De Novo* Submission:** Based on positive primary and secondary endpoint data from the BT-001 pivotal clinical trial, Better Therapeutics expects to submit a *de novo* classification request with the FDA in the third quarter of 2022, seeking marketing authorization of BT-001 for the treatment of adult patients with T2D.
- **Health Economic Model for BT-001 and Payer Coverage Discussions:** The company expects to complete its health economic models for BT-001 and plans to begin engaging payers in potential coverage discussions in the third quarter of 2022.
- **LivVita Liver Study:** Better Therapeutics is on track to complete the LivVita study and announce top-line results in the fourth quarter of 2022. The study is being conducted in collaboration with Arizona Liver Health and is evaluating the feasibility of investigational nCBT to reduce liver fat and improve liver disease biomarkers as a potential treatment for NAFLD and NASH.
- **BT-001 Real-World Evidence Program:** This randomized, controlled, multi-site program is designed to generate real-world evidence to provide additional support in the company's payer coverage and reimbursement discussions. The program is expected to enroll approximately 1,000 patients for a treatment period of at least 12 months. Interim data is expected in 2023.
- **Address Financing Needs:** Better Therapeutics has initiated a broad assessment of potential financing options. The company expects to address its financing needs within the next six months to ensure it has the financial resources to continue to prepare for a potential commercial launch of BT-001, if authorized by the FDA, and to potentially expand its digital platform into other cardiometabolic diseases.
- **Commercial Launch of BT-001:** The company is diligently advancing its preparations for the potential commercial launch of BT-001 upon FDA authorization.
- **Pipeline Expansion:** Better Therapeutics will gather pilot data from the BT-001 pivotal study and LivVita Liver Study to inform the potential initiation of an additional pivotal trial. Pending sufficient capital, the company is targeting 2023 for commencement of this study.

Second Quarter 2022 Financial Results

Research and development expenses for the three months ended June 30, 2022 were $4.2 million, compared to $5.0 million for the same period in 2021. The decrease primarily reflects lower clinical study costs due to the wind down of the pivotal trial for BT-001, partially offset by an increase in personnel and consulting costs related to preparing the *de novo* submission for BT-001 as well as expanding our clinical research and software development capabilities.

Sales and marketing expenses for the three months ended June 30, 2022 were $1.7 million, compared to $0.6 million for the same period in 2021. The increase was primarily due to higher personnel, marketing and consulting expenses associated with commercial readiness activities to support the potential launch of BT-001.

General and administrative expenses for the three months ended June 30, 2022 were $3.7 million, compared to $0.9 million for the same period in 2021. The increase was primarily related to higher personnel-related costs driven by an increase in headcount and additional costs of being a publicly traded company, including a $1.1 million increase in our business insurance.

Interest expense, net for the three months ended June 30, 2022 was $0.3 million, compared to $0 for the same period in 2021. The increase in interest expense, net 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 three months ended June 30, 2022 was $9.9 million, compared to $8.7 million for the same period in 2021. On a per common share basis, net loss was $0.42 and $0.84 for the three months ended June 30, 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 SPAC transaction in the fourth quarter of 2021.

Capital resources: Cash and cash equivalents were $29.7 million on June 30, 2022, compared to $40.6 million on December 31, 2021.

Conference Call and Webcast

Better Therapeutics will host a conference call and webcast today, August 11, 2022, at 8:30 a.m. ET / 5:30 a.m. PT. To access the conference call, please register at: https://register.vevent.com/register/BI6da59cc90fdb42a39adb1f216262cac7. 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/zcn84y83. 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 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). While CBT has been used for T2D and other cardiometabolic conditions before, until now the approach has not been scalable due to the need to deliver the therapy via a therapist. If authorized by FDA, BT-001 would be the first validated, prescription solution for delivering this therapeutic approach to T2D patients at scale, from their digital devices.

About the Better Therapeutics nCBT Platform

Better Therapeutics digital therapeutic platform is designed to delivers a novel form of CBT - nutritional CBT (nCBT) - to help people with cardiometabolic diseases potentially improve key measures related to T2D, nonalcoholic fatty liver disease, nonalcoholic steatohepatitis, hypertension, hyperlipidemia and other cardiometabolic conditions. By adapting the principles and mechanisms of cognitive behavioral therapy, the 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 (PDT) company developing a novel form of cognitive behavioral therapy (CBT) 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 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 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 clinical trial of BT-001 in patients with type 2 diabetes, Better Therapeutics' plans regarding FDA submissions, plans and expectations regarding the commercialization of BT-001, if authorized, expectations related to the 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 expectations related to the interest of healthcare providers and payers in PDTs, including BT-001, 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 repeated or observed in ongoing or future studies involving the company's product candidates and other risks and uncertainties included under the header "Risk Factors" in the 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, and those that are included in any of the company's future filings with the SEC.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Operating Expenses:				
Research and development	$ 4,241	$ 5,038	$ 7,914	$ 6,416
Sales and marketing	1,683	564	3,727	607
General and administrative	3,675	872	7,303	2,439
Total operating expenses	9,599	6,474	18,944	9,462
Loss from operations	(9,599)	(6,474)	(18,944)	(9,462)
Interest expense, net	(329)	(1)	(646)	(2)
Change in fair value of SAFEs	—	(2,821)	—	(5,313)
Gain on loan forgiveness	—	647	—	647
Loss before provision (benefit) from income taxes	(9,928)	(8,649)	(19,590)	(14,130)
Provision (benefit) from income taxes	—	1	—	(150)
Net loss	$ (9,928)	$ (8,650)	$ (19,590)	$ (13,980)
Cumulative preferred dividends allocated to Series A Preferred Shareholders	—	(394)	—	(782)
Net loss attributable to common shareholders, basic and diluted	$ (9,928)	$ (9,044)	$ (19,590)	$ (14,762)
Net loss per share attributable to common shareholders, basic and diluted	$ (0.42)	$ (0.84)	$ (0.83)	$ (1.38)
Weighted-average shares used in computing net loss per share	23,592,995	10,730,818	23,498,978	10,707,996

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

	June 30, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 29,685	$ 40,566
Prepaid expenses	2,380	4,409
Other current assets	72	276
Total current assets	32,137	45,251
Capitalized software development costs, net	4,364	5,077
Property and equipment, net	115	82
Other long-term assets	487	548
Total Assets	$ 37,103	$ 50,958
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,088	$ 1,523
Accrued payroll	2,074	1,352
Other accrued expenses	1,196	1,858
Current portion of long-term debt	1,783	—
Total current liabilities	6,141	4,733
Long-term debt, net of current portion and debt issuance costs	12,908	9,505
Total liabilities	19,049	14,238
Stockholders' equity:		
Common stock	2	2
Additional paid-in capital	109,385	108,461
Accumulated deficit	(91,333)	(71,743)
Total Stockholders' Equity	18,054	36,720
Total Liabilities and Stockholders' Equity	$ 37,103	$ 50,958

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