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): May 13, 2022

BETTER THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-39864**	**85-3472546**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

548 Market Street #49404 **San Francisco, California**	**94104**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (415) 887-2311

Not Applicable
(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**	**Nasdaq Capital Market**

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 May 13, 2022, Better Therapeutics, Inc. (the "Company") issued a press release announcing financial results for the first quarter ended March 31, 2022. 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 8.01 Financial Statements and Exhibits.

On May 13, 2022 the Company issued a corporate presentation that it intends to utilize in various meetings with securities analysts, investors and others. A copy of the corporate presentation is filed as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release issued by Better Therapeutics, Inc., dated May 13, 2022
99.2	Corporate Presentation of Better Therapeutics, Inc., dated May 13, 2022.
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 thereunto duly authorized.

Better Therapeutics, Inc.

Dated: May 13, 2022

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

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

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 — 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

Investor Relations:
Mark Heinen
IR@bettertx.com

Media:
Peter Duckler at Real Chemistry
pduckler@realchemistry.com

Exhibit 99.2

Pioneering Prescription Digital Therapeutics for Cardiometabolic Diseases

MAY 2022

Better
THERAPEUTICS

Disclaimer

This presentation ("Presentation") is for informational purposes only. The information contained herein does not purport to be all-inclusive and neither Better Therapeutics, Inc. ("BetterTx" or the "Company") nor any of its respective affiliates nor any of its or their control persons, officers, directors, employees or representatives makes any representation or warranty, express or implied, as to the accuracy, completeness or reliability of the information contained in this Presentation. You should consult your own counsel and tax and financial advisors as to legal and related matters concerning the matters described herein, and, by accepting this Presentation, you confirm that you are not relying upon the information contained herein to make any decision. The reader shall not rely upon any statement, representation or warranty made by any other person, firm or corporation in making its investment or decision to invest in the Company. Neither the Company nor any of its respective affiliates nor any of its or their control persons, officers, directors, employees or representatives, shall be liable to the reader for any information set forth herein or any action taken or not taken by any reader, including any investment in shares of the Company.

Certain information contained in this Presentation relates to or is based on studies, publications, surveys and the Company's own internal estimates and research. In addition, all of the market data included in this Presentation involves a number of assumptions and limitations, and there can be no guarantee as to the accuracy or reliability of such assumptions. Finally, while the Company believes its internal research is reliable, such research has not been verified by any independent source. This meeting and any information communicated at this meeting are strictly confidential and should not be discussed outside your organization.

Forward-Looking Statements.

Certain statements in this Presentation may be considered forward-looking statements. Forward-looking statements generally relate to future events or the Company's future financial or operating performance. For example, these forward-looking statements include, but are not limited to, statements regarding the delivery of cognitive behavioral therapy and/or prescription digital therapeutics by the Company to address the root causes of type 2 diabetes and other cardiometabolic diseases; development of a proprietary platform and software-based solutions for treatment of type 2 diabetes, heart disease and other conditions; achievement of changes in neural pathways of the brain and lasting changes in behavior through cognitive behavioral therapy delivered by the Company's PDT; the capability of the Company to address the underlying causes of certain diseases and its related potential to improve patient health while lowering healthcare costs; the potential for Better Tx's clinically validated mobile applications to be prescribed by physicians and reimbursed like traditional medicines by insurance providers; potential and significance of the results of the pivotal study of BT-001 or any clinical or other trial; the potential success of BT-001 as a prescribed treatment used under physician supervision for people with uncontrolled type 2 diabetes; the possibility for the results of the pivotal study to support a regulatory submission for marketing authorization from the FDA; the potential timing of and the Company's expected progress towards developing and obtaining FDA approval for its products, related research and validation studies; the future financial stability, strength or success of Better Tx. In addition, any statements that refer to projections, forecasts or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. 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. Any forward-looking statements in this presentation are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to, the risk that the FDA may not be satisfied with the design of any of the Company's studies and trials, and even satisfied, payers may not reimburse BT-001, if approved, the risk that the results of previously conducted studies or interim results of ongoing studies will not be repeated or observed in ongoing or future studies involving our product candidates, the risk that the current COVID-19 pandemic will impact our platform validation, product testing, and the timing of the Company's submission of the BT-001 for marketing approval from the FDA. For a discussion of other risks and uncertainties, and other important factors, any of which could cause the Company's actual results to differ from those contained in the forward-looking statements, see the section entitled "Risk Factors" in BetterTx's filings on file with the Securities and Exchange Commission, available at the Securities and Exchange Commission's website at www.sec.gov, and as well as discussions of potential risks, uncertainties and other important factors in Better Tx's subsequent/future filings, if any, with the Securities and Exchange Commission. All information in this Presentation is as of the date of the release, and the Company undertakes no duty to update this information unless required by law.

Executive Team

David Perry
Co-Founder, Chairman

Kevin Appelbaum
Co-Founder, Chief Executive Officer

Mark Berman, MD
Chief Medical Officer

Mark Heinen
Chief Financial Officer

Kristin Wynholds
Chief Product Officer

Thiago Oliveira
Chief People Officer

Deepti Jaggi, PharmD
Chief Strategy & Commercial Officer

indigo · P&G · one medical · HARVARD MEDICAL SCHOOL · astellas · SEPHORA · Yale University School of Medicine · UCSF · Johnson & Johnson

Better Therapeutics is a prescription digital therapeutics (PDT) company founded on the hypothesis that we can create software to **treat cardiometabolic diseases by changing the patient behaviors that are root causes.**

Next Generation Therapeutics:
Using Software Instead of Drugs

A Digital Therapeutics Platform – delivering novel cognitive behavioral therapy targeting the root causes of cardiometabolic diseases

Demonstrated Results– clinically meaningful results in multiple trials for Type 2 Diabetes and Hypertension; completion of randomized, controlled pivotal trial expected in Q2 2022

Major Market Opportunities – $490 billion[1] spent in treating the effects of cardiometabolic diseases each year, while leaving the causes in place

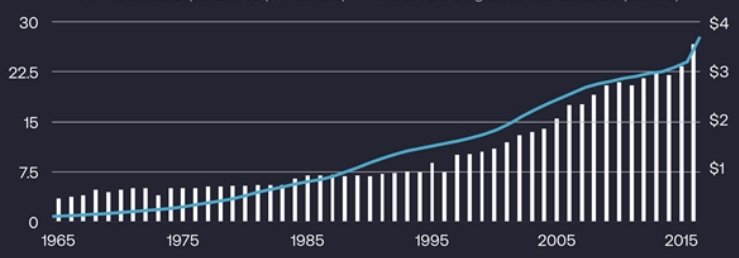
Platform Leverage – because we treat common root causes, we believe we can rapidly iterate our software and efficiently advance our pipeline with minimal product changes

Better

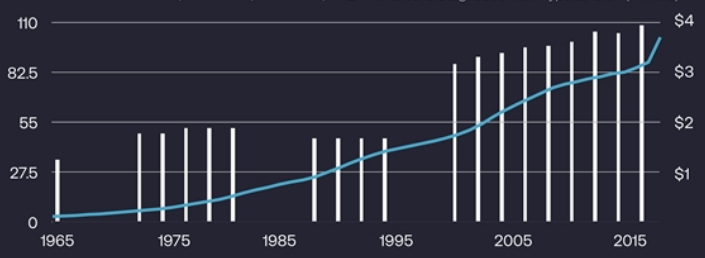
1. Milken Institute. 2017.

We are spending more and more money to get worse and worse outcomes

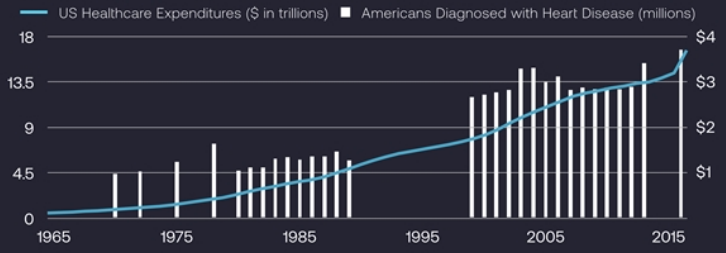
DIABETES



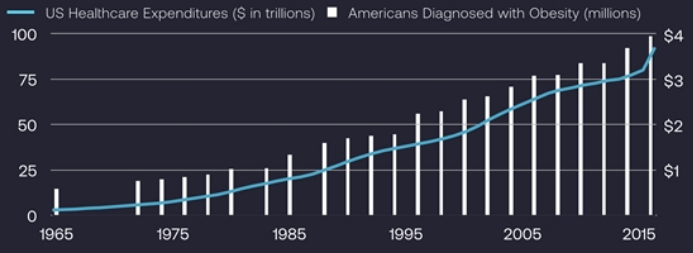
HYPERTENSION



CORONARY ARTERY DISEASE

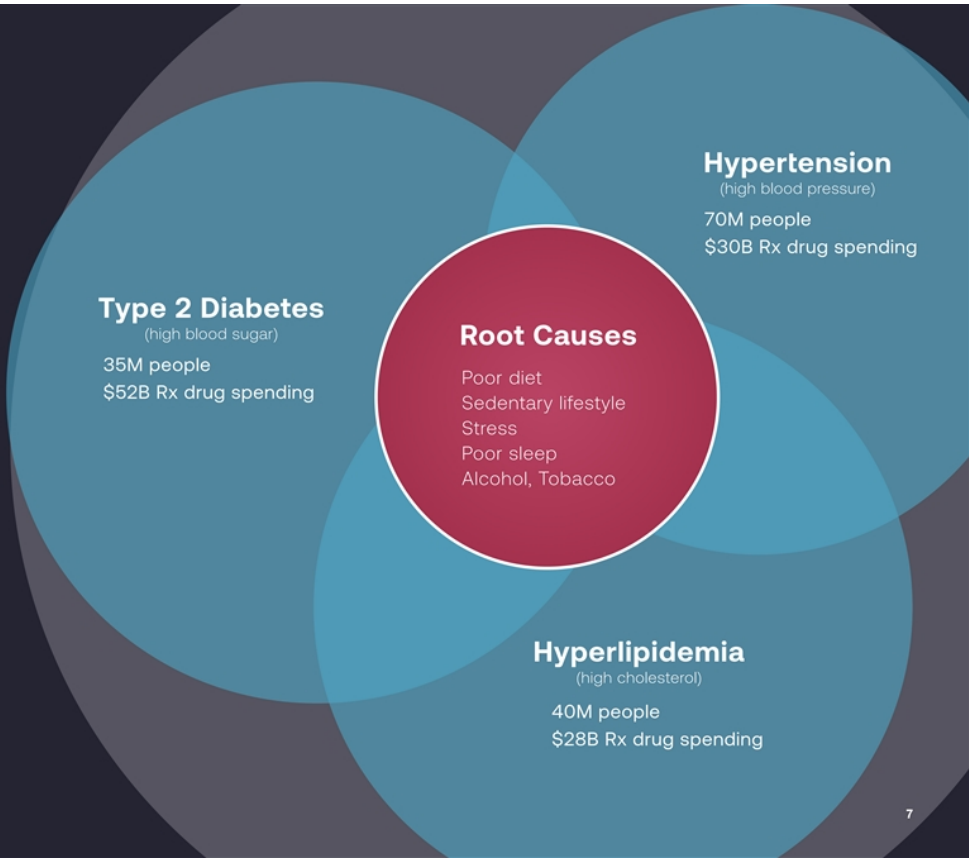


OBESITY

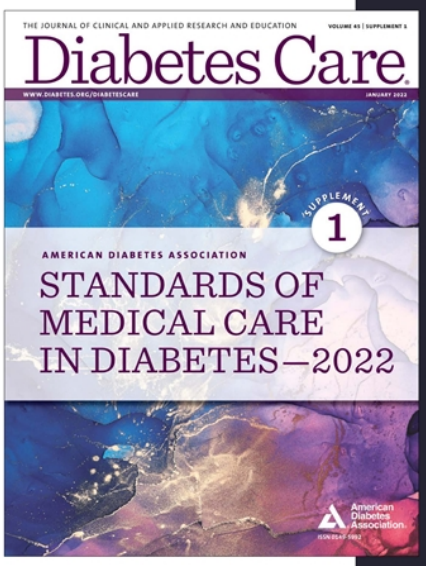


Better

That's because existing therapeutics treat symptoms but leave the common root causes untouched



Better



Current clinical guidelines highlight the importance of behavior change as the foundation of treatment, but physicians have no prescribable options

- Standard of Care guidelines emphasize the importance of behavior change in the management of disease
- Guidelines call for digital solutions to facilitate behavior change
- Reimbursement for solutions for behavior change is also encouraged in the latest guidelines
- However, there are no digital solutions available to be prescribed by physicians to help patients change the behaviors that cause diabetes and other cardiometabolic diseases

Better

Traditional Cognitive Behavioral Therapy (CBT) is effective at addressing the behavioral root causes of cardiometabolic diseases but is neither scalable nor affordable

Not Standardized

Treatment plans to treat cardiometabolic diseases with CBT are not standardized and different health professionals have different levels of success with their patients.

Not Scalable

Patients must commit to 8 - 20 CBT sessions with their healthcare professional.[3]

Not Affordable

Psychotherapists charge upwards of $100/hr and not all patients have insurance that covers treatment.[4]

"The results of this study show that PC-CBT lifestyle intervention [for patients with cardio-metabolic syndrome] leads to remarkable reductions in waist circumference, fasting serum-triglycerides levels, resting systolic blood tension, and improved quality of life when compared to the control group." [1]

"The results of this meta-analysis showed that CBT can be effective in reducing depression symptoms and fasting glucose in diabetes patients with comorbid depression as well as in improving quality of life and anxiety in the long-term." [2]

Sources: 1. Zhang, Y., Mei, S., Yang, R. et al. Effects of lifestyle intervention using patient-centered cognitive behavioral therapy among patients with cardio-metabolic syndrome: a randomized, controlled trial. BMC Cardiovasc Disord 16, 227 (2016) 2. Li C, Xu D, Hu M, Tan Y, Zhang P, Li G, Chen L. A systematic review and meta-analysis of randomized controlled trials of cognitive behavior therapy for patients with diabetes and depression. J Psychosom Res. 2017 Apr;95:44-54. 3. Turner, J. The use of cognitive behavioral therapy in diabetes care: A review and case study. Journal of Diabetes Nursing 14, 3 (2010); Mayo Clinic Cognitive Behavioral Therapy primer 4. Anxiety and Depression Association of America

We created nutritional CBT to treat the root causes of cardiometabolic diseases and can deliver it digitally to make it accessible, affordable and scalable

Targets eating and related behaviors

Given the importance of eating in survival, ideas that shape eating behavior are difficult to change and require direct targeting

nCBT is designed to go far beyond the typical “cognitive distortions” to address a broad but specific set of eating and lifestyle behaviors

Designed for cognitive restructuring

Therapy is delivered via Lessons and Skills that gradually advance, allowing time for cognitive restructuring before moving on to more deeply held beliefs

Includes Lessons and Skills to enhance emotional processing and help uncover the past experiences or cognitive origins of maladaptive beliefs. The intent is to create the emotional resilience and acceptance needed to make enduring changes

Enhances primary care

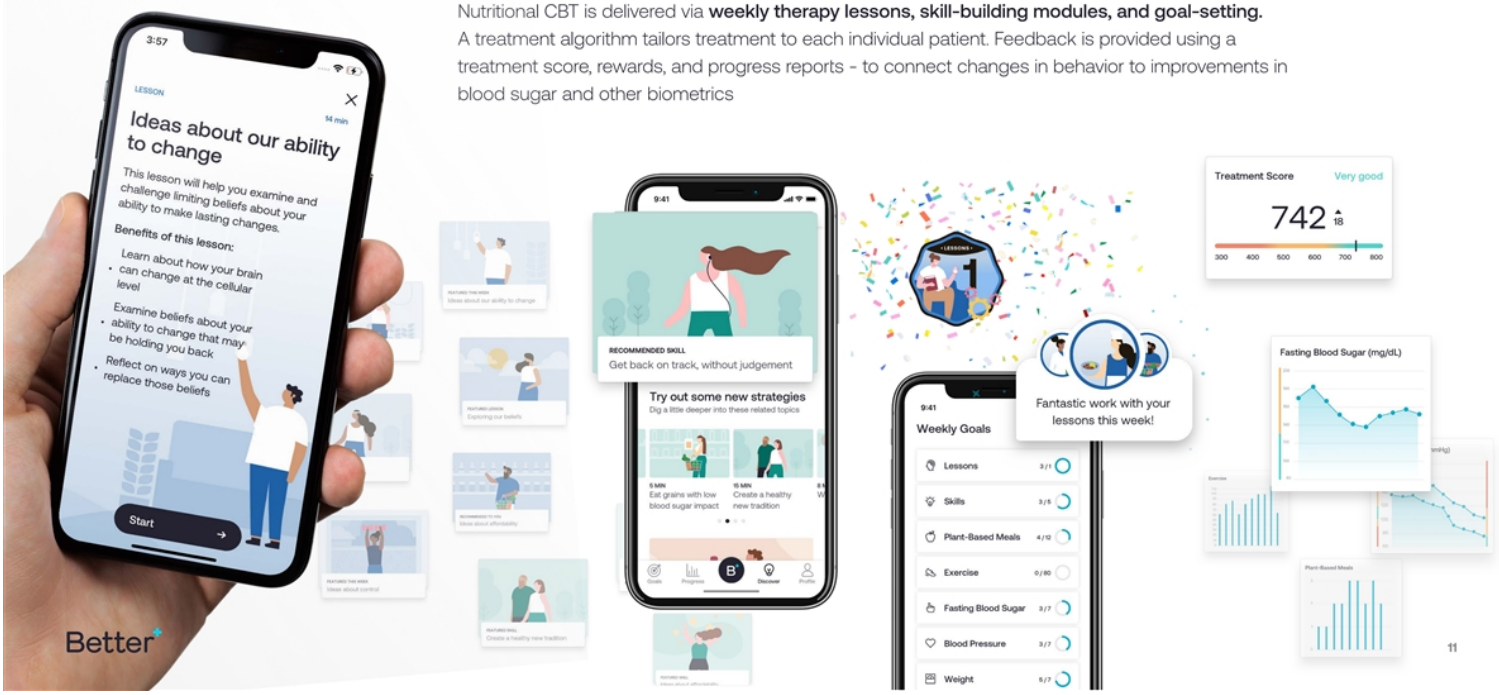
Designed to work within the existing framework of standard medical care and medication use. Lifts the burden of behavior change off of Physician’s plate

Unifies 3 distinct modalities — behavioral therapy, lifestyle medicine, AI into a single therapeutic experience

Can be applied to the broad set of cardiometabolic conditions and diverse patient panels typical of Primary Care

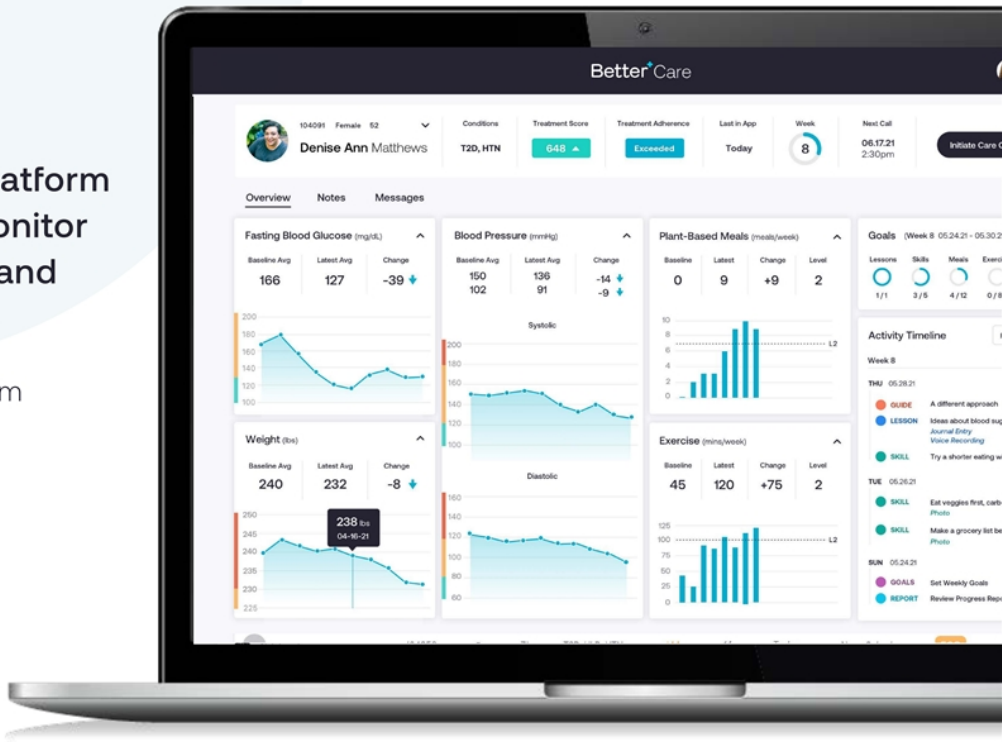
We deliver nutritional CBT using a mobile app prescribed by a physician

Nutritional CBT is delivered via **weekly therapy lessons, skill-building modules, and goal-setting.** A treatment algorithm tailors treatment to each individual patient. Feedback is provided using a treatment score, rewards, and progress reports - to connect changes in behavior to improvements in blood sugar and other biometrics

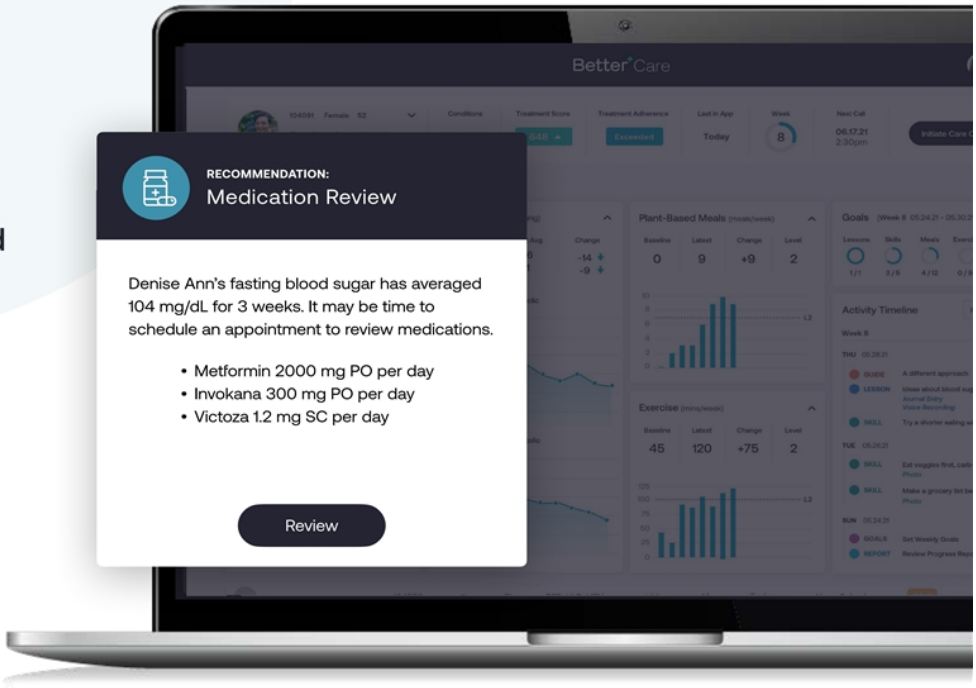


BetterCare is a software platform that allows providers to monitor patients during treatment and intervene when necessary

- Visualize treatment progress from prescription to refill
- Monitor activity and biometrics
- Identify patients at risk
- Enable early intervention



By using patient generated data, providers can make more informed clinical decisions and intervene early when needed



We are advancing a pipeline of PDT products using nCBT to treat multiple cardiometabolic diseases

Additional Scientific Areas of Interest

Increasingly, it is appreciated that there are shared pathways of pathophysiology, such as inflammation and immune activation that underlie the development of cardiometabolic conditions as well as conditions in other disease classes, such as Alzheimer's disease, multiple sclerosis and certain cancers.

- Chronic Kidney Disease
- Pre-Eclampsia
- Coronary Artery Disease
- Treatment-resistant Hypertension
- Familial Hypercholesterolemia
- Alzheimer's Disease
- Gestational Diabetes
- Peripheral Artery Disease

First in class, pivotal RCT demonstrating efficacy in type 2 diabetes

Half of BT-001 participants have clinically meaningful A1c reduction (mean 1.1%)

Clear dose-response signal observed

Favorable benefit to risk ratio...

...in diverse, nationally representative patient population with unmet medical needs

Primary Endpoint (Day 90)

BT-001 arm (n=296) improves A1c by 0.4% vs. Standard of Care Control (n=312) in Intent-to-treat (ITT) Analysis, p = 0.00003

45% of BT-001 participants have clinically meaningful response (A1c improves by ≥ 0.4%) vs. 27% of Control, p<0.00001

Average A1c reduction in responders is 1.1%

No adverse safety signal observed in BT-001

Secondary Endpoint (Day 180)

Changes in A1c between BT-001 and Control group

Changes in medications

Safety measures

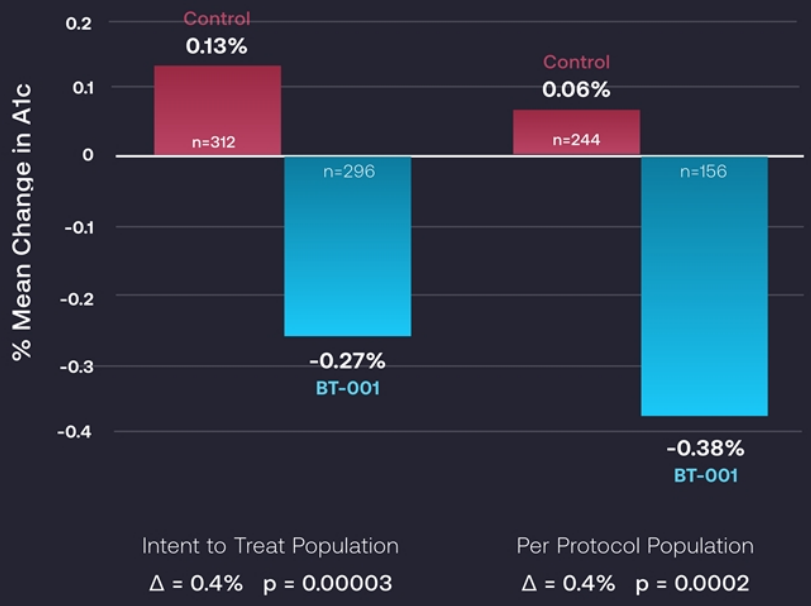
Subgroup analysis

BT-001 n=365 | Control n=360 | 669 Randomized & Onboarded
Powered at 90% to detect
clinically meaningful A1c change (0.4%)

Primary endpoint data at 90 days demonstrated clinically meaningful response with no serious adverse events

Glycemic improvements highly statistically significant. Important study context: COVID, seasonal impact, inconsistent timing of A1c draws.

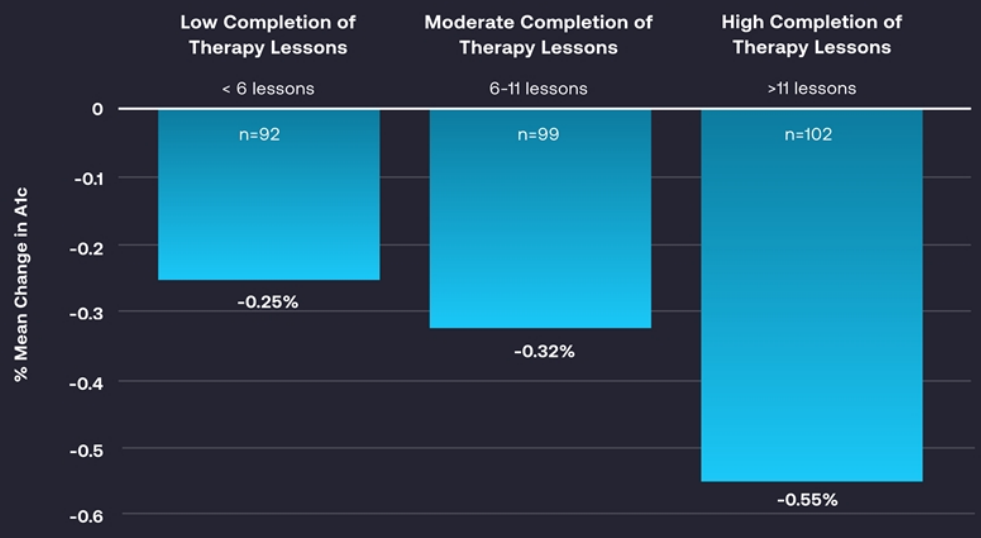
Trial population represented **racial, ethnic, geographic and socioeconomic diversity.** Participants had long-standing type 2 diabetes, high cardiovascular risk, high degree of co-morbidities and medication use.



Intent to Treat Population
Δ = 0.4% p = 0.00003

Per Protocol Population
Δ = 0.4% p = 0.0002

Greater engagement in nCBT linked to greater improvement in A1c, indicating a clear dose-response



During the first 90 days of use, patient engagement and persistence exceed that of consumer health & wellness apps*

*Apptentive | 2022 Mobile Customer Engagement Benchmark Report

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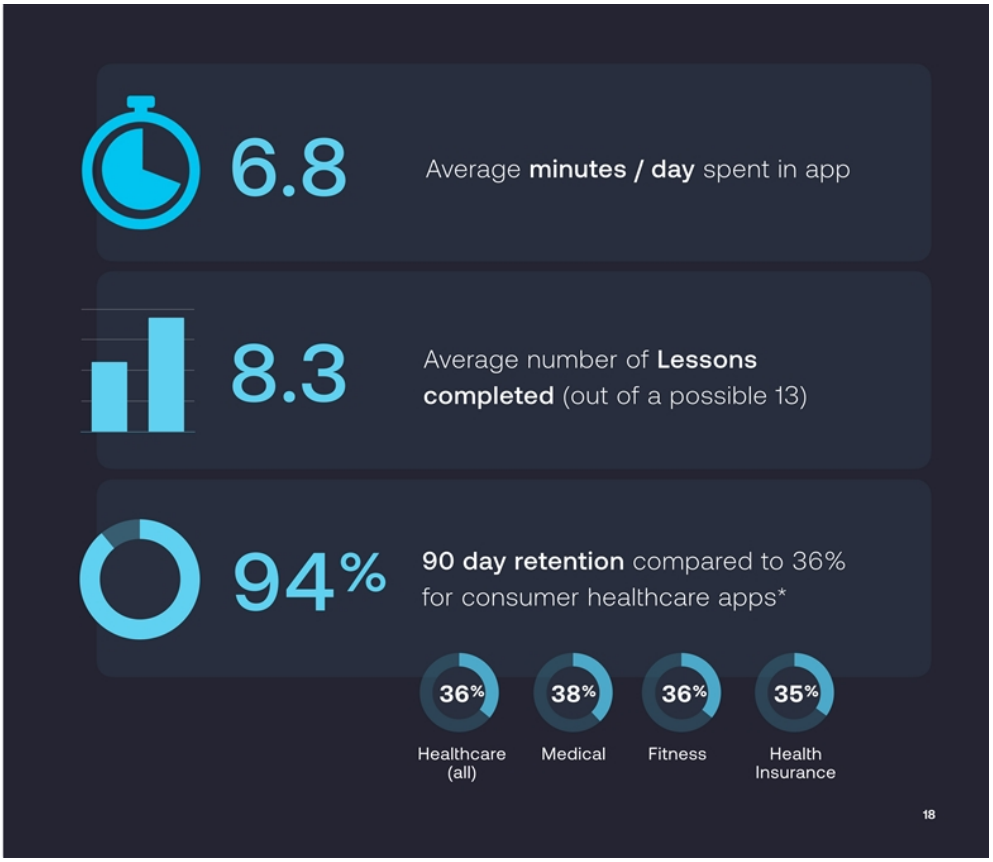


Potential claims based on primary endpoint and anticipated secondary endpoint data

Indications for Use

BT-001 is a prescription-only software program intended to help adult patients with type 2 diabetes improve glycemic control. The software delivers behavioral therapy via a mobile application that targets behaviors related to achieving glycemic control and is intended to reduce A1c.

Clinical Claims

BT-001 is designed to help patients with type 2 diabetes improve glycemic control by lowering A1c

Patients using BT-001 reduced A1c by an average amount of 0.4% when compared to a standard of care control group

45% reduced A1c by 0.4% or more (mean change 1.1%) compared to 27% in the control group receiving standard of care

Efficacy and safety has been evaluated in a diverse, clinically-complex and nationally-representative adult population with type 2 diabetes

> *"**I've got time** to change... this won't impact my life."*

> *"When my symptoms started – dizziness, blurred vision, getting up to go to the bathroom every hour at night, I went to the doctor and was diagnosed. **I'm shocked!** How did I get here?"*

> *"I'm exhausted. I can't sleep or seem to think straight. **I'm feeling worse** and now my vision is deteriorating. They tell me I have nerve and bone damage in my left foot. I've been taking 2 medications and now I have to take 3."*

> *"My doctor is talking about insulin...**I'm scared**. I feel like once you hit insulin you are on a downward slide to the end. There must be something else I can do."*

A BETTER START

A BETTER STEP UP

Pre-Diabetes	Diagnosis	Non-Insulin Treatment	Additional Non-Insulin Treatments	Insulin Treatment	Advanced Comorbidities
Incremental cost per patient per year		$2,000	$10,000	$19,000	
LIFESTYLE CHANGES	**FIRST LINE TREATMENT**	**DUAL THERAPY**	**TRIPLE THERAPY**	**STEP UP TO INSULIN**	
Changes to exercise and diet	Metformin	Metformin + Sulfonylurea	Metformin + GLP-1 + SGLT2	Metformin + GLP-1 + SGLT2 + Insulin	

Better+

Our value story is compelling to payers and we are substantiating it with robust evidence

Disease burden	Type 2 diabetes is among the largest expenses categories for payers (#1 in Medicare and VA; #5 in commercial insurance); patients with T2D cost an additional $11k per year than individuals without diabetes
Unmet need	Less than 50% of patients with T2D are able to achieve glycemic control with existing therapeutics Despite clinical guidelines that highlight behavior change as the foundation for treating T2D, providers currently have nothing to prescribe
Mechanism of Action	Cognitive Behavioral Therapy (CBT) is effective at changing the behaviors that cause T2D but is not scalable, affordable or accessible Nutritional CBT (nCBT) is an adaptation of CBT specifically designed to address the behavioral root causes of diabetes and can be delivered by a prescription digital therapeutic (PDT) If authorized by FDA, BT-001 will be the first and only way providers can prescribe CBT to their diabetes patients and address root causes
Target patient	Patients with uncontrolled T2D patients on a path to step up to insulin
Safety & effectiveness	BT-001 has shown a clinically meaningful benefit compared to standard of care alone in improving glycemic control by lowering A1c, and has shown no serious adverse events
Cost offsets	BT-001 can displace or delay more costly medications and has the potential to reduce hospitalizations and emergency room visits
Healthcare disparities	BT-001 is effective in populations of greatest need, including those that are racially, ethnically and socioeconomically diverse

Real-world evidence from a 1,000 participant randomized, controlled, multi-site study will inform our understanding of durability, impact on costs and medication use

	BT-001 Participants	Study Size	Duration
Mass General Brigham	500	750	18-month
CPC Clinical Research	250	500	24-month
Catalyst HEALTH NETWORK	250	250	12-month

Population: Participants with type 2 diabetes; A1c between 7.0% and 11.0%, not on prandial insulin

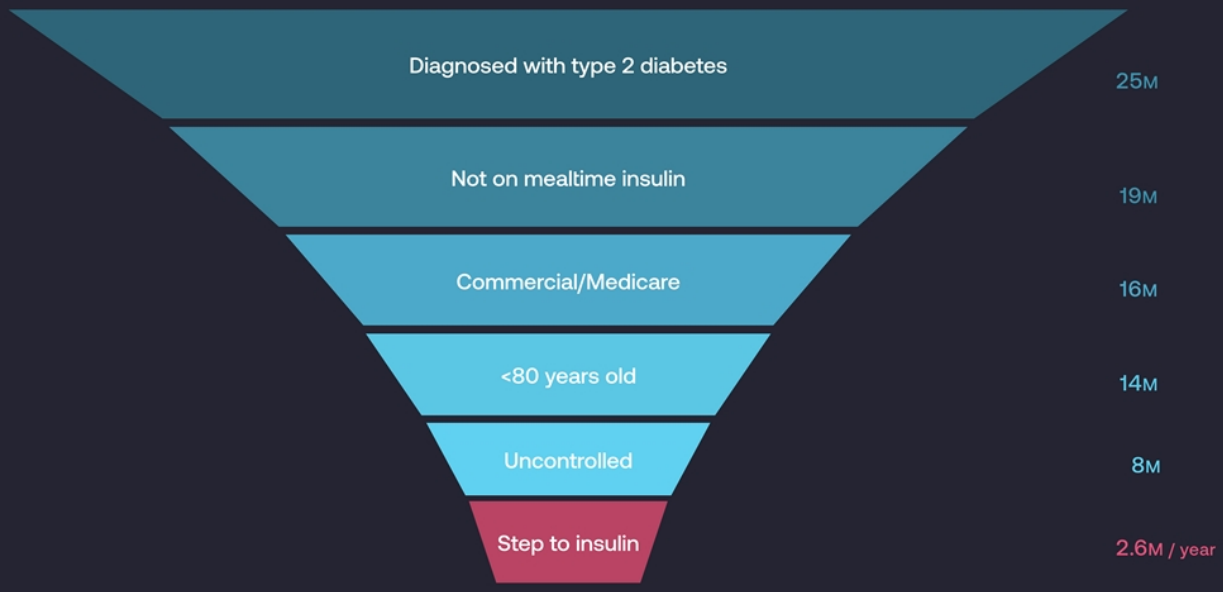
Design: Open-label, real world interventional studies using within participant comparison or control arm

Primary Measures: Mean change in A1c after 6 and 12-months (mean change within participant or compared to control)

Secondary Measures: Mean change in medication usage after 6 and 12-months (mean change within participant or compared to control)

Exploratory Endpoints: Changes in quality of life, diabetes treatment satisfaction, blood pressure, cholesterol, weight, lipids and HbA1c trends, medication use, diabetes related hospitalizations, emergency room visits, and outpatient visits at 12 months or more

If authorized by FDA, we will focus on patients who would otherwise step to insulin or other costly injectables at launch



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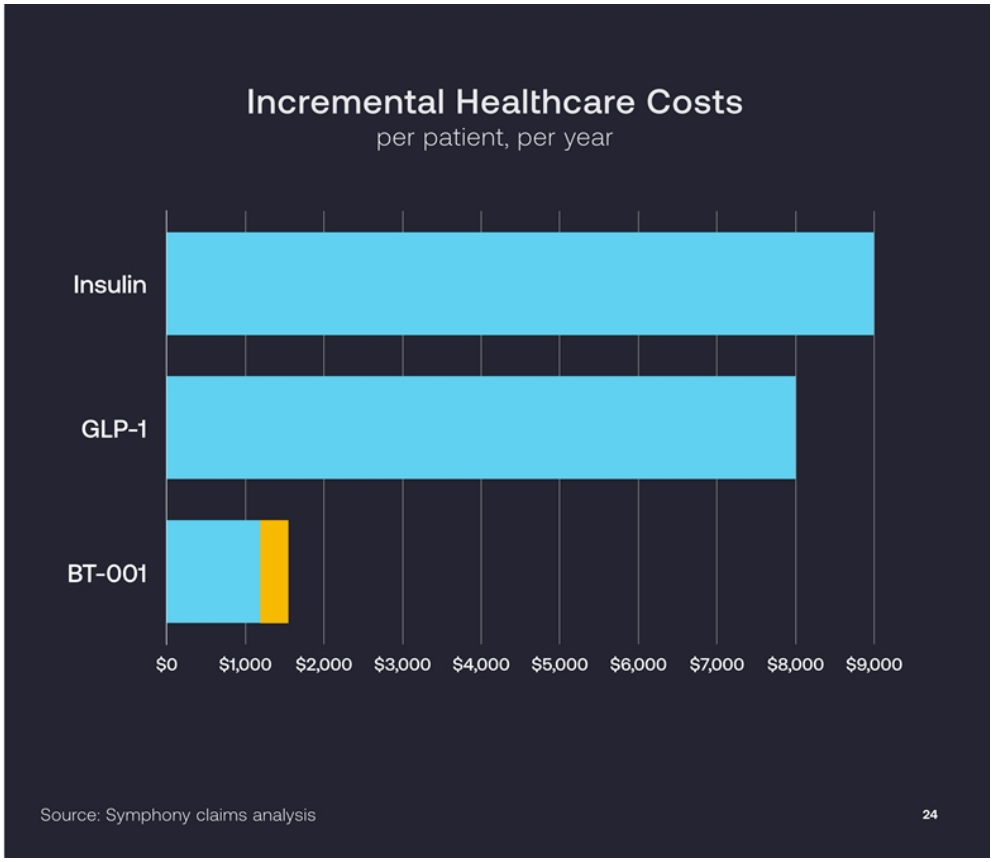
We intend to price in order to provide compelling value to payers and maximize access by minimizing controls such as prior authorizations and step edits



Source: Symphony claims analysis

At launch, we will focus on securing coverage from regionally dominant, early adopting commercial insurers and health systems.

A team of 20-40 FTEs will engage and educate approximately 4,000 primary care providers and endocrinologists practicing within large health systems and treating a disproportionate number of diabetes patients not well controlled by traditional medications.

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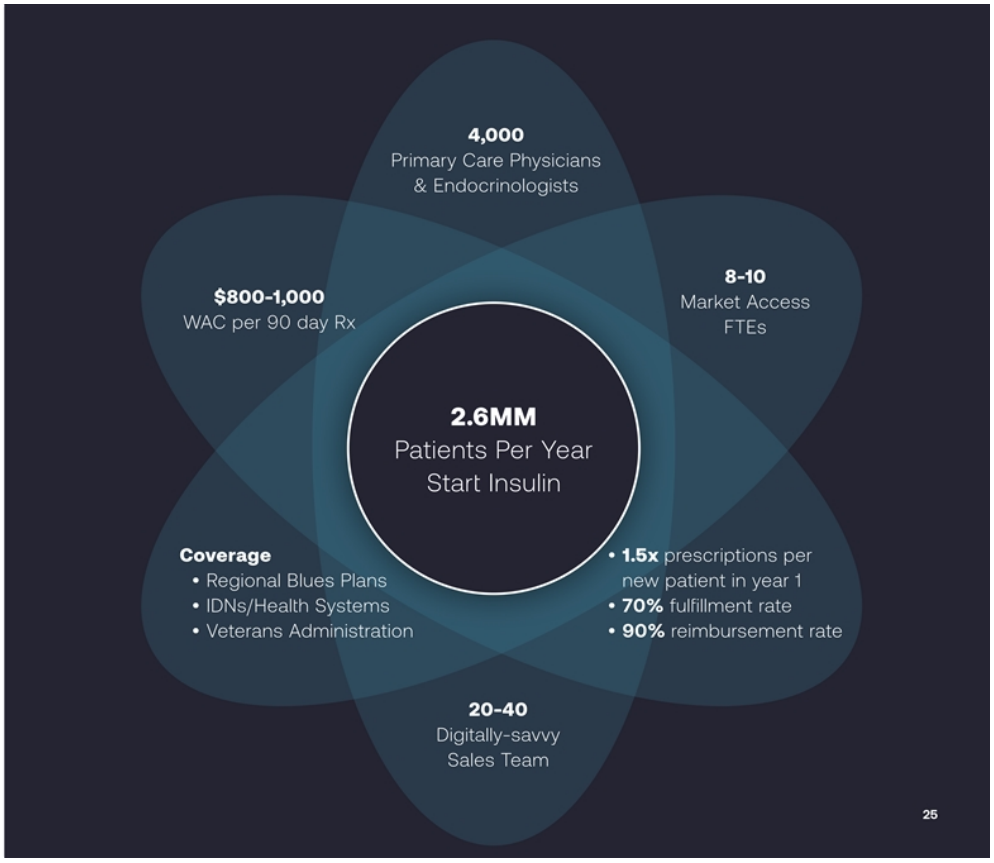
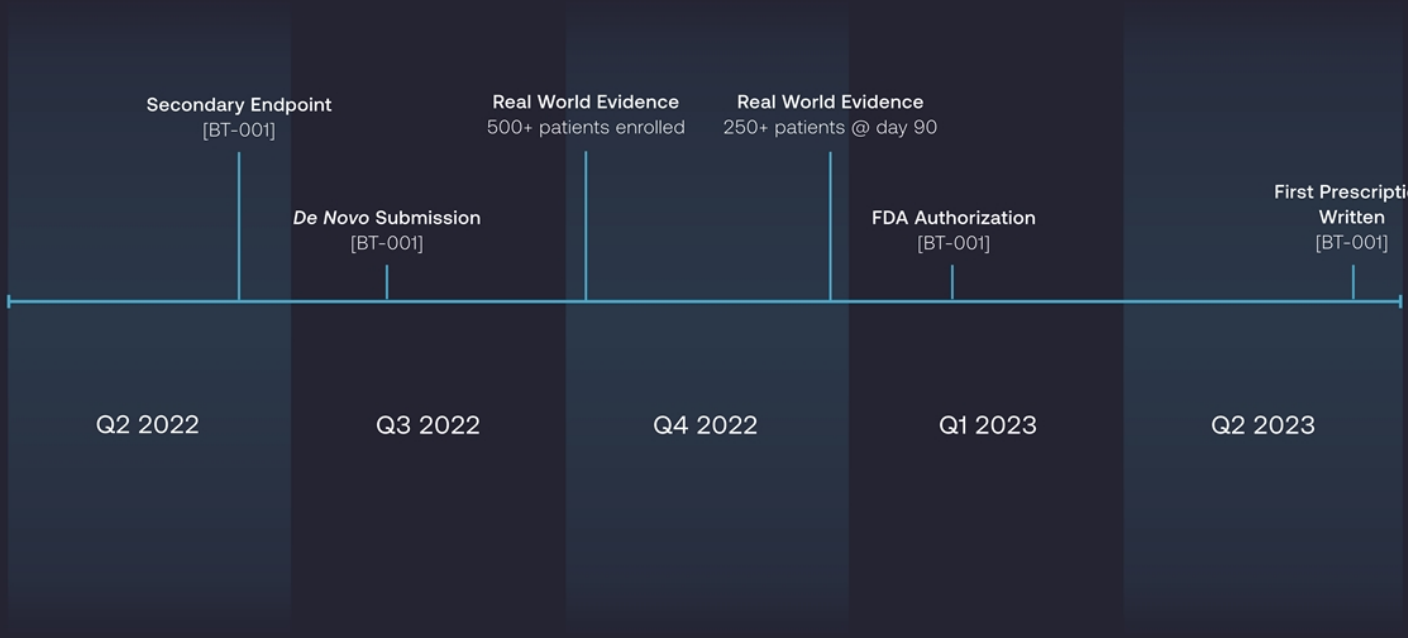


We expect to achieve multiple value creating milestones over the next 18 months



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Next Generation Therapeutics:
Using Software Instead of Drugs

A Digital Therapeutics Platform – delivering novel cognitive behavioral therapy targeting the root causes of cardiometabolic diseases

Demonstrated Results– clinically meaningful results in multiple trials for Type 2 Diabetes and Hypertension

Major Market Opportunities – $490 billion[1] spent in treating the effects of cardiometabolic diseases each year, while leaving the causes in place

Platform Leverage – because we treat common root causes, we believe we can rapidly iterate our software and efficiently advance our pipeline with minimal product changes

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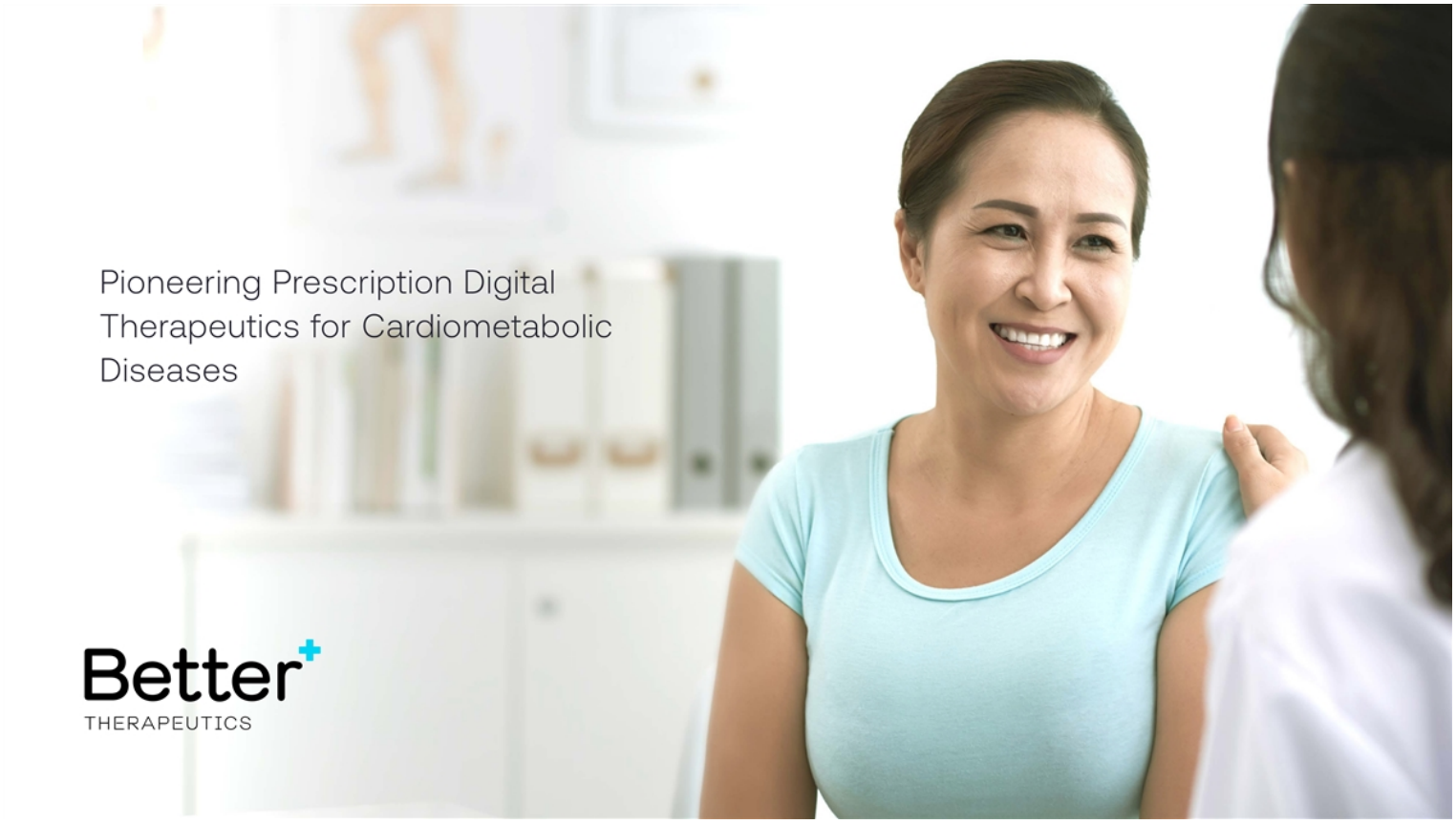
1. Milken Institute. 2017.


Pioneering Prescription Digital
Therapeutics for Cardiometabolic
Diseases
Better
THERAPEUTICS