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): July 28, 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** **(Address of principal executive offices)**	**94104** **(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 8.01 Other Information.

On July 28, 2022, Better Therapeutics, Inc. (the "Company") announced results from its clinical trial of BT-001, a prescription digital therapeutic platform that uses digitally delivered cognitive behavioral therapy to treat type 2 diabetes. A copy of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

On July 28, 2022, the Company expects to use a corporate presentation on secondary endpoint data from its clinical trial of BT-001 for its investor call. 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 July 28, 2022
99.2	Corporate Presentation of Better Therapeutics, Inc., dated July 28, 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: July 28, 2022

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

Exhibit 99.1

Better Therapeutics Completes Pivotal Trial of BT-001 for Type 2 Diabetes and Announces Positive Secondary Endpoint Results Following the Earlier Announcement of Positive Primary Endpoint Results

Data demonstrates BT-001 was durable with A1c reductions continuing to improve after 180 days of treatment

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

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

SAN FRANCISCO, July 28, 2022 – Better Therapeutics, Inc. ("Better Therapeutics", NASDAQ: BTTX), a prescription digital therapeutics company developing nutritional cognitive behavioral therapy (nCBT) to address the root causes of cardiometabolic diseases, today announced the completion of the pivotal clinical trial for BT-001, an investigational first-in-class prescription digital therapeutic that is designed to use nCBT to treat type 2 diabetes (T2D).

With the positive data reported by this pivotal clinical trial, Better Therapeutics intends to submit a *de novo* classification request to the U.S. Food and Drug Administration (FDA) in the third quarter of 2022, seeking marketing authorization for BT-001 for the treatment of patients with T2D. If granted, BT-001 would become the first prescription digital therapeutic for the treatment of T2D.

"Today's announcement is a moment to celebrate – not just for the team at Better Therapeutics – but for the patients and health care providers who know all too well that the way we treat T2D today simply isn't good enough given the magnitude of this epidemic disease," said Frank Karbe, president and CEO of Better Therapeutics. "We believe the data from this trial is remarkable, given we enrolled a diverse patient population with advanced disease already on rigorous blood sugar lowering regimens and who could self-select their dose of BT-001, unlike in traditional new drug pivotal trials. The positive data from this trial serves as an important stepping stone towards our goal of bringing BT-001 to patients and physicians in need of new therapies, and entering the next phase of our growth as a commercial-stage company."

This data follows the announcement in March that the trial had met its primary endpoint at day 90 with a p-value of < 0.0001. The secondary endpoint data assessed at day 180 continued this trend, showing statistically significant decreases in A1c levels when compared to a control group receiving standard of care (p-value = 0.01). The results achieved were sustainable and improved between day 90 and day 180 of the trial, demonstrating that BT-001 has the potential to deliver meaningful, durable improvements in blood sugar control for a complex range of patients with T2D already on standard of care blood sugar lowering medications. In addition, exploratory data revealed a host of cardiometabolic improvements as well as lower medication utilization compared to the control group, supporting the potential for BT-001 to improve the overall health of patients with T2D and potentially reduce the usage of increasingly costly T2D medications associated with the progression of the disease.

“As a physician focused on cardiometabolic conditions, it’s a rare and important moment to see an entirely new treatment paradigm emerge for patients with T2D, but that’s what we potentially have with this digital therapeutic approach,” said Mark Berman, MD, Chief Medical Officer of Better Therapeutics. “For too long, the treatment options available to people with T2D have largely been prescription medications that help reduce symptoms but do little to address the underlying causes of disease. This pivotal trial of digitally delivered nCBT in a complex patient population with advanced and difficult to treat disease generated results that were durable and a notable improvement over the current standard of care. The results also suggest that BT-001 has the potential to reduce the need for medications and lower healthcare utilization.”

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.

The open label, randomized, controlled, parallel group trial enrolled a nationally representative group of 668 adults with T2D and mean baseline A1c of 8.1%. Participants in the trial had long standing T2D (mean 11 years), multiple comorbidities, and were already on multiple diabetes medications, representing a difficult to treat patient population. Participants were randomized to receive standard of care with or without BT-001 and the primary efficacy endpoint was the difference in mean change from baseline in A1c after 90 days of treatment between the two groups. The trial was designed with a high bar to pass and to avoid artificial designs that could produce large outcomes that do not apply to all patients. This includes not constraining patients to a specific medication profile and not incentivizing patients to use the BT-001 therapy.

“The results of this trial are not just encouraging for patients with T2D mellitus but mark the start of a potential sea change in how we approach treatment of cardiometabolic diseases and their root causes,” said Marc Bonaca, MD, MPH, professor of medicine and director of vascular research, University of Colorado. “If we can deliver a scalable, sustainable and clinically validated way to make important and durable improvements in cardiometabolic disease, we can empower patients to take back control of their health from these costly, common chronic diseases.”

Conference Call and Webcast

Better Therapeutics will host a conference call and webcast today, July 28, 2022, at 8:30 a.m. ET to review the results from the pivotal clinical trial of BT-001 after 180 days of treatment for T2D. The live conference call may be accessed by dialing (800) 715-9871 (domestic) or (646) 307-1963 (international) and referring to conference ID: 4326594. All participants are encouraged to dial-in 10 minutes prior to the start time. The live webcast may be accessed by visiting the event page here. A replay of the webcast may be accessed from the Presentations & Events page in the Investors section of the Better Therapeutics corporate website: www.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 our 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.

Investor Relations:
Mark Heinen
IR@bettertx.com

Media:
Ryan McKenna at Real Chemistry
rmckenna@realchemistry.com

Exhibit 99.2

JULY 28, 2022

BT-001 Pivotal Clinical Trial Results

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, 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 Presentation include, but are not limited to, statements regarding the results of the trial of BT-001 in patients with type 2 diabetes, the Company's plans regarding FDA submissions, plans and expectations regarding the commercialization of BT-001, if approved, expectations related to the potential benefits of BT-001 and CBT and their potential treatment applications, the Company's 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, including BT-001, 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 the Company 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 the Company's 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 our product candidates and other risks and uncertainties included under the header "Risk Factors" in the Company's 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
Pioneering Prescription
Digital Therapeutics for
Cardiometabolic Diseases

BT-001 Pivotal Trial:
Statistically significant & clinically meaningful results in diverse patient population with advanced T2D

Primary Endpoint assessed at 90 days showed significant decrease in A1c as compared to control group receiving standard of care (p<0.0001)

Secondary Endpoint assessed at 180 days demonstrated sustained and improved response (p=0.01) Half of patients in BT arm achieved clinically meaningful changes with mean A1c reduction of 1.3% (SD 0.8%) in this subgroup

Robust safety data, with significantly fewer safety events in BT arm (p<0.001)

BT-001 use associated with **multiple additional cardiometabolic benefits**

Diverse & advanced patient population and unique trial design were setting a **high bar for success**

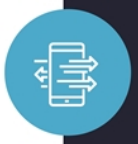
Using Software Instead of Drugs:
Unique Benefits of Digital Therapeutics

Opportunity to address healthcare inequities and access– Digital therapeutics can reach patients where they are and connect them to the best care despite the many barriers patients experience

Real-time insights into use and efficacy enables continuous improvement promising the potential for increasingly better efficacy without increased risk

Data generated offers greater insights enabling **better care and novel pricing models**

Potential to improve a broad range of health measures bears the promise to change - at scale - the course of a disease with **better overall long-term health outcomes and lower cost of care**



Development requires substantially less time and investment, enabling faster and more cost-efficient expansion into other potential indications or therapeutic areas

Next Generation Therapeutics: The Better Therapeutics Approach

Developing Digital Therapeutics that are cleared by the FDA for a specific indication and have labeled claims. If cleared, patients obtain access through a physician prescription that is reimbursed via health insurance

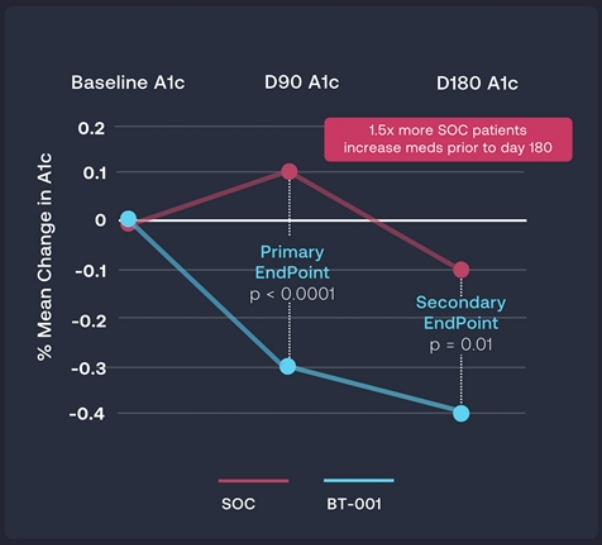
Initially focused on cardiometabolic diseases, which rank among the most common and costly chronic conditions that share lifestyle behaviors as a common root cause

Advancing principles of Cognitive Behavioral Therapy (CBT), a well proven, validated approach to improve behavior by developing a novel CBT protocol and making it digitally available to improve access and scalability

Rigorous product development incorporating patient & provider feedback into thoughtfully designed randomized controlled studies, backed up by Real World Evidence studies to support payer negotiations

Better

BT-001 Pivotal Trial Results



BT-001 demonstrated sustained and improved response at 180 days, with absolute A1c reduction advancing from 0.3% to 0.4%, highlighting potential for long-term improvements

- Both primary (A1c between group delta -0.4%, p<0.0001) and secondary endpoint (A1c delta -0.3%, p=0.01) were met
- Half of patients in BT arm achieved achieved clinically meaningful changes with absolute mean A1c reduction of 1.3% (SD 0.8%) in this subgroup

Robust safety data, with significantly fewer Adverse Events in BT arm (p<0.001)

BT-001 use associated with multiple additional cardiometabolic benefits and lower medication and lower healthcare utilization

BT-001 Pivotal Trial designed primarily for FDA de novo authorization

Nationally representative, diverse patient population

Investigators mirror real-world prescribers

Robust study design employed to minimize bias and set high comparison bar:

- Control arm is Standard of Care (i.e. gold standard care), not just treatment as usual
- Medication use and adjustment by investigators was not limited; only prandial insulin was excluded
- Patients were not mandated nor incentivized to use BT-001; instead were free to self-select dose

Nationally representative, diverse patient population recruited

Patient population recruited from 6 States, includes groups underrepresented in clinical trials, with historically poor access to care

Parameter / Category	Statistic	Standard of Care (n=343)	BT-001 (n=325)
Age (yrs)	Mean	58.1	58.0
% Female	%	56.3%	56.0%
Race	%		
White		61.2%	62.2%
Black or African American		29.2%	29.5%
Asian		5.2%	5.2%
American Indian or Alaskan Native		1.7%	1.2%
Native Hawaiian or Other Pacific Islander		0.6	0.3%
Ethnicity - Hispanic or Latino	%	14.0%	17.2%
Median Household Income by ZIP Code	Mean	$67,737	$69,789
% High School Degree or Some College but no Degree	%	42.0%	38.2%

Canonico, Mario Enrico, et al. "Cognitive behavioral therapy delivered via digital mobile application for the treatment of type 2 diabetes: Rationale, design, and baseline characteristics of a randomized, controlled trial." *Clinical Cardiology (2022).*

Participants had long-standing T2 diabetes, high cardiovascular risk, multiple comorbidities and extensive medication use

Parameter / Category	Statistic	Standard of Care (n=343)	BT-001 (n=326)
BMI (kg/m^2)	Mean	34.7	34.6
Baseline HbA1c (%)	Mean	8.1%	8.2%
Years Since Diagnosis	Mean	10.9	11.0
% on 2 or More Antihyperglycemic Medications	%	67.5%	68.4%
Using Antihypertensive Medications	%	71.7%	67.1%
% on 2 or More Number of Antihypertensive Medications [1]	%	66.5%	69.0%
10 Year CV Risk Score	Mean	15.1%	15.1%
Number of Comorbidities	Mean	2.7	2.8

[1] For those treated for hypertension (67.5% of participants)

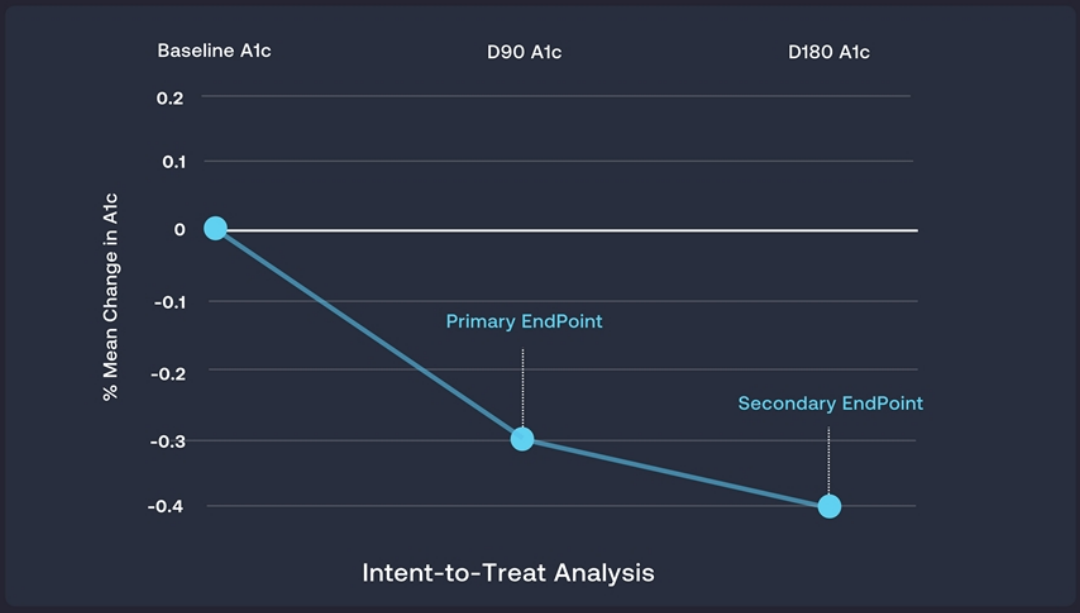
Canonico, Mario Enrico, et al. "Cognitive behavioral therapy delivered via digital mobile application for the treatment of type 2 diabetes: Rationale, design, and baseline characteristics of a randomized, controlled trial." *Clinical Cardiology (2022).*

Baseline diabetes medications reveal robust background therapy compared with general diabetes population

Medication Class	General Diabetes Population (2018) [1]	SOC	BT-001
All	82.7%	96.5%	96.0%
Metformin	59.5%	79.9%	80.1%
Sulfonylureas	24.4%	34.4%	36.2%
SGLT2 inhibitors	< 7.1%	24.8%	21.8%
GLP-1 analogues	< 7.1%	24.8%	19.0%
Insulin	25.6%	19.5%	17.8%
DPP-4 Inhibitors	10.8%	13.7%	17.2%
Thiazolidinediones	3.3%	5.0%	5.5%
Meglitinides	-	0.3%	0.9%

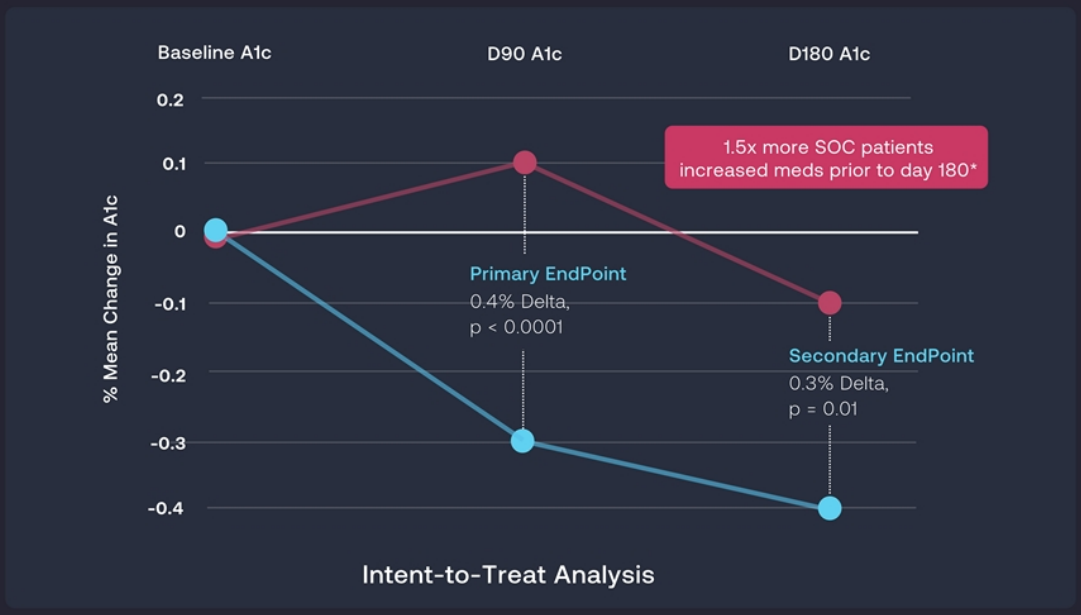
[1] Fang et al. Trends in Diabetes Treatment and Control in U.S. Adults, 1999-2018. *N Engl J Med* 2021;384:2219-28. DOI: 10.1056/NEJMsa2032271

BT-001 produced clinically meaningful and sustained reduction in A1c



Better+

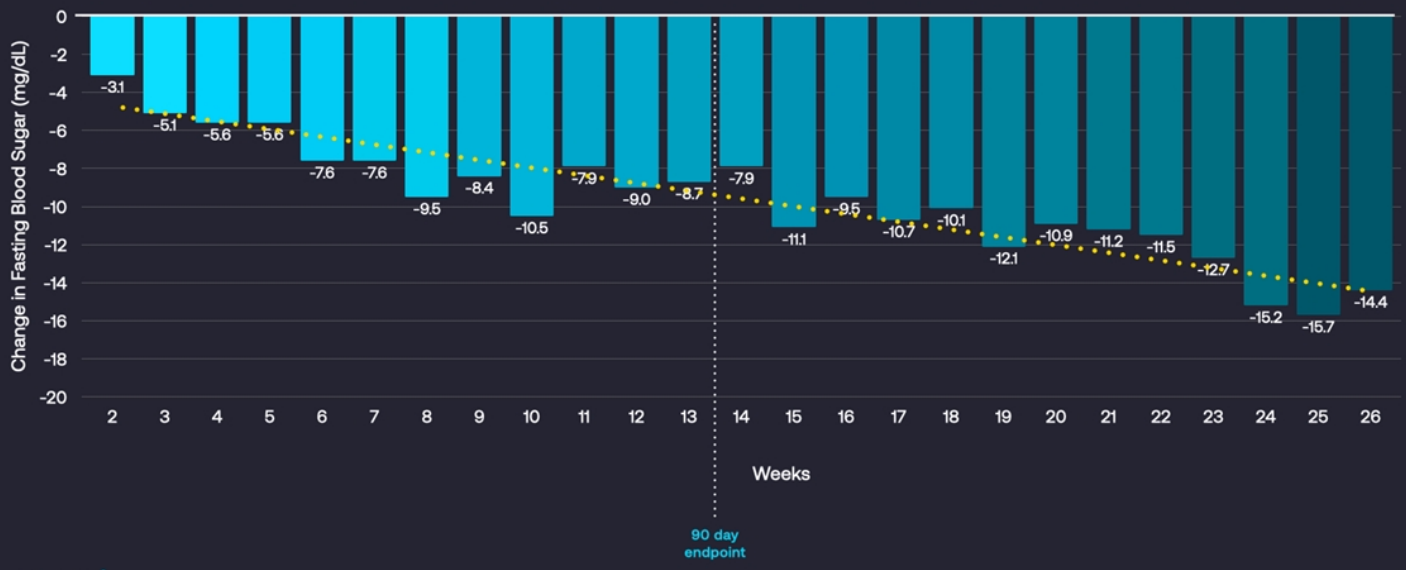
BT-001 reduced A1c despite on-study addition of more diabetes medication in the Standard of Care control group



** Prior to D180 A1c, comparable % of patients reduced antihyperglycemic medications (5.5% SOC; 4.3% BT-001)*

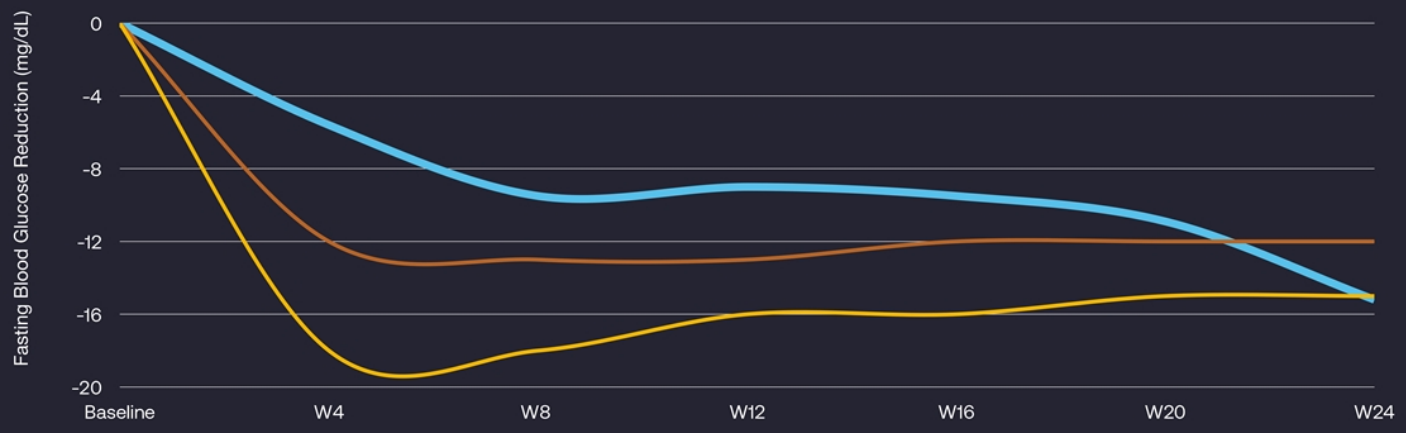
Better+

Trending average change in fasting blood glucose shows gradual and steady improvements, with no clear peak



Better+

Trends in fasting blood glucose in different therapies



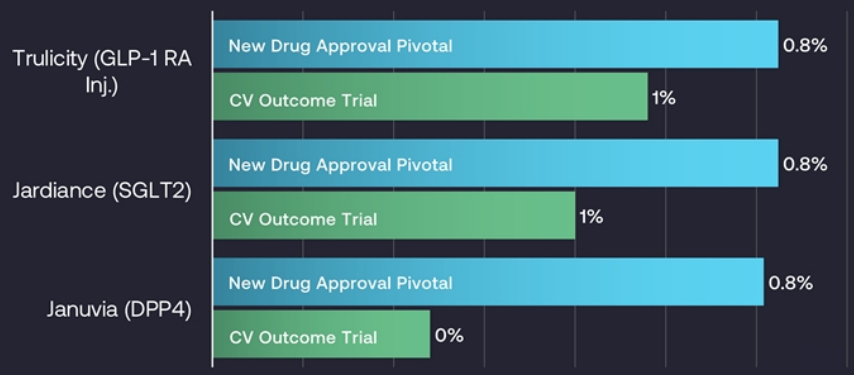
Ferrannini E et al. Dapagliflozin monotherapy in type 2 diabetic patients with inadequate glycemic control by diet and exercise: a randomized, double-blind, placebo-controlled, phase 3 trial. *Diabetes Care*. 2010;33:2217-2224.

Goldstein BJ, et al; for Sitagliptin 036 Study Group. Effect of initial combination therapy with sitagliptin, a dipeptidyl peptidase-4 inhibitor, and metformin on glycemic control in patients with type 2 diabetes. *Diabetes Care*. 2007;30(8):1979–1987.

Note: These results are from different studies with different trial designs and patient populations. No head-to-head studies between these candidates have been conducted.

Better

Cardiovascular Outcome Trials (CVOTs) show lower relative A1c reduction compared with new drug pivotal for same drug



Trulicity - Gerstein HC et al; Dulaglutide and cardiovascular outcomes in type 2 diabetes (REWIND): a double-blind, randomized placebo-controlled trial. Lancet. 2019;394(10193):121-130.

Umpierrez et al; Efficacy and Safety of Dulaglutide Monotherapy Versus Metformin in Type 2 Diabetes in a Randomized Controlled Trial (AWARD-3) *Diabetes Care* 2014;37(8):2168–2176.

Jardiance- Zinman B, et al. "Empagliflozin, Cardiovascular Outcomes, and Mortality in Type 2 Diabetes". The New England Journal of Medicine. 2015. 373(22):2117-28.

Roden M et al; on behalf of the EMPA-REG MONO trial investigators. Empagliflozin monotherapy with sitagliptin as an active comparator in patients with type 2 diabetes mellitus: a randomised, double-blind, placebo-controlled, phase 3 trial. Lancet Diabetes Endocrinol. 2013;1(3):208–19.

Januvia- Green JB, et al. "Effect of sitagliptin on cardiovascular outcomes in type 2 diabetes". *The New England Journal of Medicine*. 2015. 373(3):232-242.

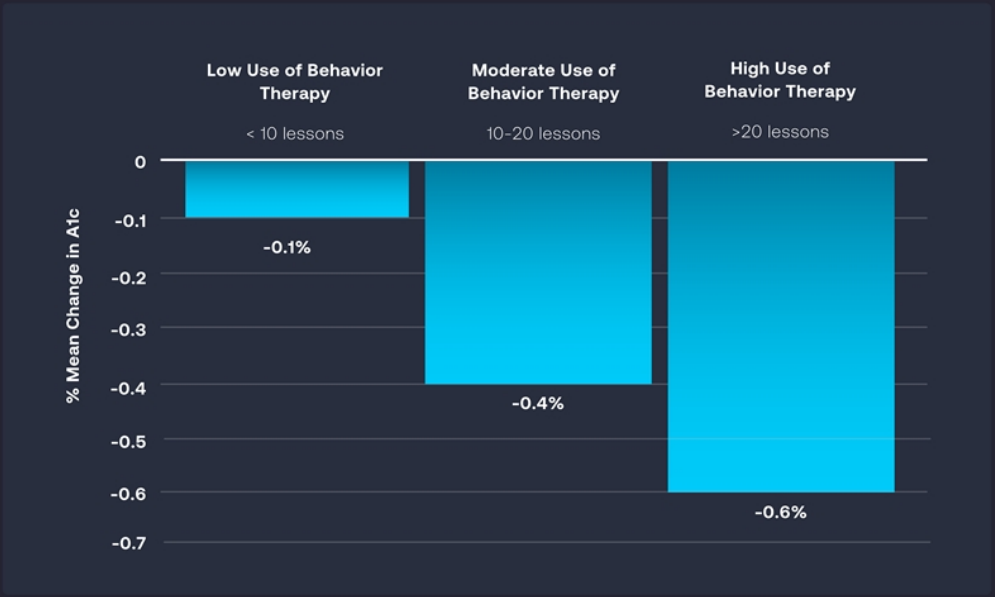
Aschner P, et al; Sitagliptin Study 021 Group. Effect of the dipeptidyl peptidase-4 inhibitor sitagliptin as monotherapy on glycemic control in patients with type 2 diabetes. Diabetes Care. 2006 Dec;29(12):2632-7.

Trial design may influence A1c reduction observed. BT-001 pivotal trial design is more similar to diabetes cardiovascular outcome trials

Trial Characteristic	New Drug Pivotal	CV Outcome Trial	BT-001 Pivotal
Poorly Controlled Diabetes at Baseline	Yes	Yes	Yes
Diabetes Disease Duration (mean)	< 10 yrs	> 10 yrs	> 10 yrs
Baseline Therapy Limited	Highly (e.g. Metformin monotherapy)	Moderately (e.g. Max of 2 drugs at Baseline)	Minimally (Only Prandial Insulin excluded)
Comparison Arm	Placebo or Single Agent	Standard of Care	Standard of Care
Dosage of Investigational Therapy Controlled	Yes	Yes	No

Patients who used BT-001 more had greater reduction in A1c

Participants self-selected dose of nCBT. Higher dose of nCBT lessons completed associated with larger A1c improvements at 180 days

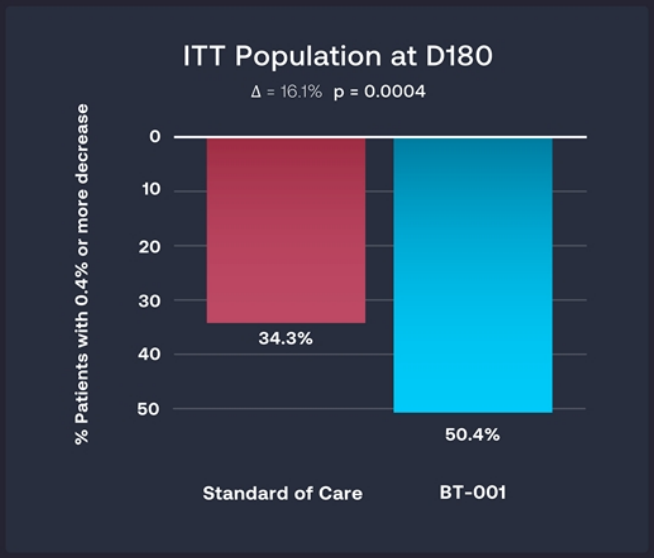


Better+

Higher dose subgroup shows substantially greater A1c improvement compared to Standard of Care control group

1.5x more BT-001 patients achieved meaningful A1c change

Significant improvements observed in BT-001 Group despite use of fewer diabetes medications

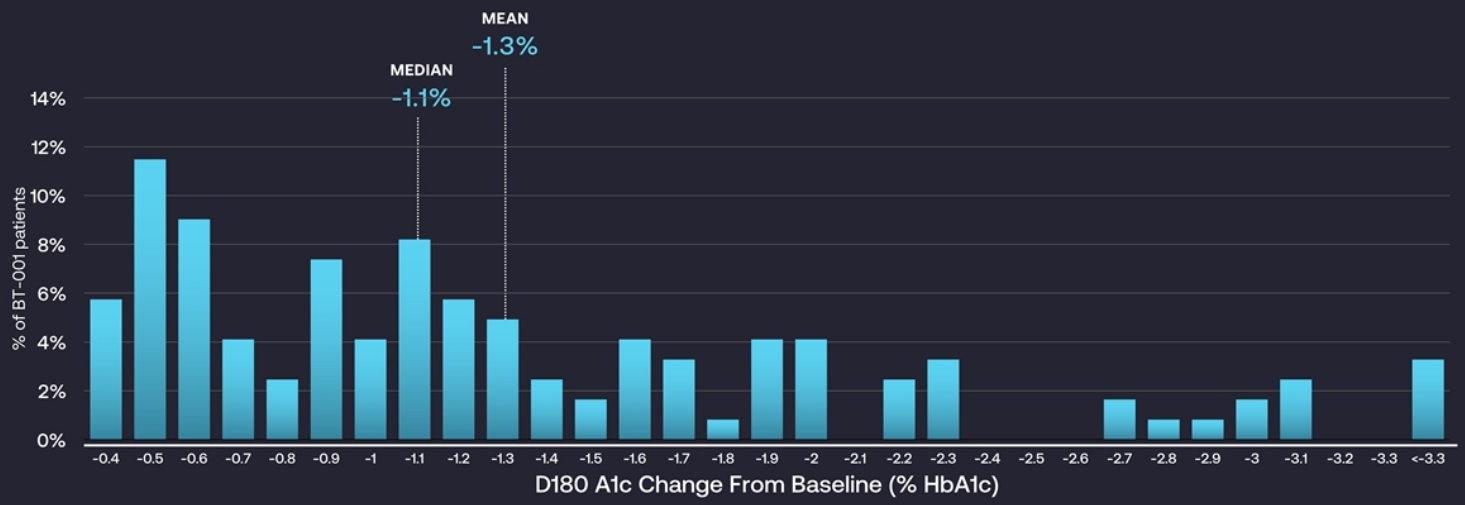


30 % Achieve 1% or more A1c reduction (vs 17%, p=0.001)

30 % Achieve blood sugar control target of A1c < 7% (vs 20% SOC, p=0.009)

BT-001 Meaningful Responders show range of large improvements at 180 days

"Meaningful Responders" defined as 0.4% or more A1c improvement



Better

180 Day safety data reveals significantly fewer Adverse Events

BT-001 patients had statistically significant fewer AEs and Serious AEs

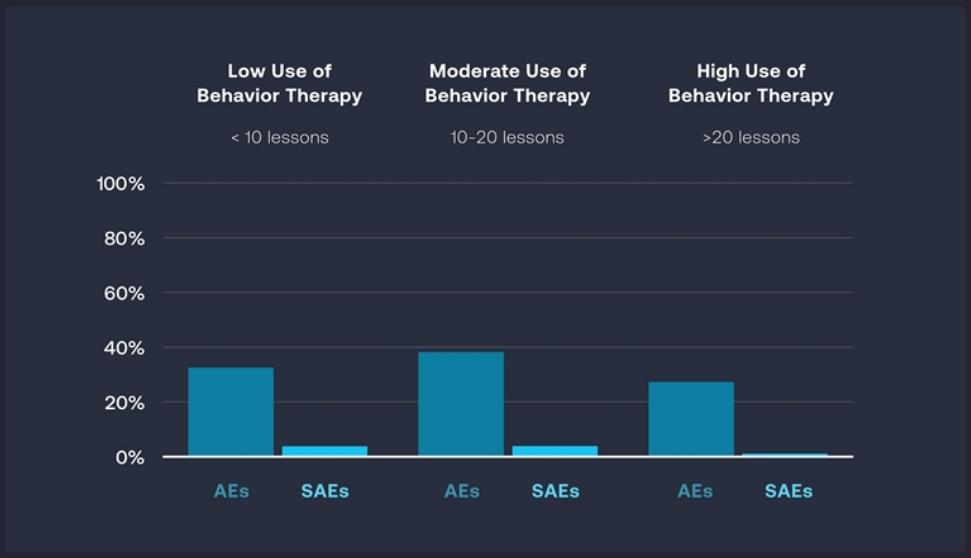
Number of subjects who experienced:	Standard of Care (n=343) Subjects n (%)	Standard of Care (n=343) Events n	BT-001 (n=325) Subjects n (%)	BT-001 (n=325) Events n	
An Adverse Event (AE)	188 (54.8%)	324	135 (41.5%)	265	p < 0.001
A Serious Adverse Event	24 (7.0%)	26	9 (2.8%)	9	p = 0.01
An AE Possibly/Probably Related to Study Intervention	0 (0.0%)	0	3 (0.9%)	4	
An AE that is Related to Medical Software	0 (0.0%)	0	0 (0.0%)	0	

BT-001 patients avoided more Serious Adverse Events (SAEs) commonly found in T2 diabetes

Number of subjects who experienced:	Standard of Care (n=343)		BT-001 (n=325)	
	Subjects n (%)	Events n	Subjects n (%)	Events n
A Serious Adverse Event (SAE)	24 (7.0%)	26	9 (2.8%)	9
SAEs Possibly Related to Diabetes / Cardiometabolic Health	14 (4.1%)	14	5 (1.5%)	5
Cardiovascular	6 (1.7%)	6	2 (0.6%)	2
Respiratory	2 (0.6%)	2	1 (0.3%)	1
Infectious	6 (1.7%)	6	2 (0.6%)	2
Other SAEs	12 (3.5%)	12	4 (1.5%)	4
Death	1 (0.3%)	1	0 (0.0%)	0

More Adverse Events (AEs and SAEs) are not observed with more use of BT-001

Participants self-selected dose. Higher dose associated with larger improvements, but not higher rates of AEs.



Safety profiles of top performing diabetes drugs differ from BT-001

Adverse Reaction (>/= 5%)	GLP1	SGLT2	BT-001 Pivotal
Nausea	**Yes**	No	No
Vomiting	**Yes**	No	No
Diarrhea	**Yes**	No	No
Abdominal pain	**Yes**	No	No
Constipation	**Yes**	No	No
Female genital mycotic infections	No	**Yes**	No
Urinary track infections	No	**Yes**	No
Devise related adverse events	N/A	N/A	< 1%

Note: These results are from different studies with different trial designs and patient populations. No head-to-head studies between these candidates have been conducted.

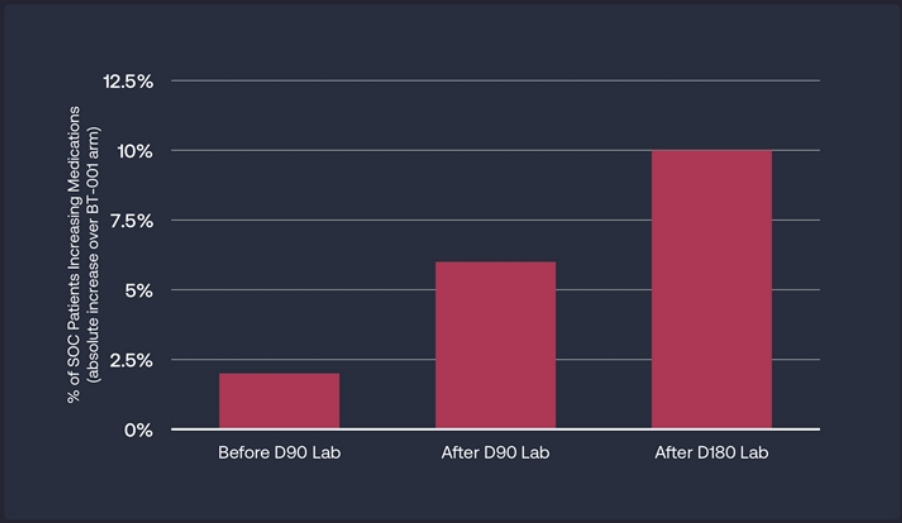
Data reveals statistically significant changes in multiple exploratory endpoints, underscoring potential for broad-based benefits

Statistically significant findings in:

- **Systolic Blood Pressure**
- **Weight Reduction**
- **Mood Scores**
- **Quality of Life Scores (Physical Health-Related)**
- **Adverse Event and Serious Adverse Event Rates**

Data to be submitted for peer-review publications.

Antihyperglycemic medication utilization and healthcare utilization increased more in Standard of Care control group patients with a widening gap over 6-months



BT-001 patients experienced fewer hospitalizations, ER visits, and outpatient visits over length of study

During 180 days of use, patient engagement and persistence exceed benchmarks for consumer health & wellness apps*

5.9

Average minutes / day spent in app

81%

Percentage of patients using the app at 180 days

61

NPS Score after 180 days

Better+

*Apptentive | 2022 Mobile Customer Engagement Benchmark Report - % retention at 90 days. *Retention was 94% in BT-001 group at 90 days*

Marc Bonaca, MD, MPH

Executive Director, CPC Clinical Research
Associate Professor of Medicine, Cardiology, and Vascular Medicine
Director of Vascular Research, University of Colorado School of Medicine

Addressing the unmet needs in Type 2 Diabetes requires new therapies

Qualities of an ideal new therapy in T2 Diabetes

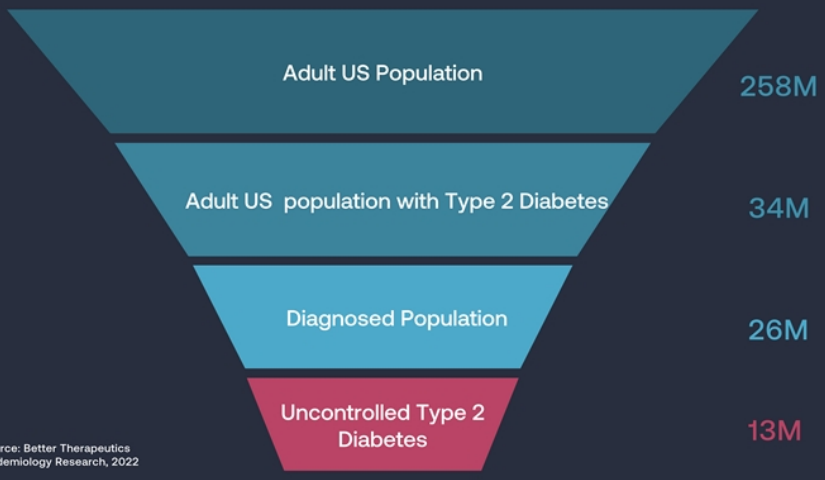
1. Non-pharmacologic
2. Can be prescribed and data tracked in medical record
3. Additive effects on top of evidence-based therapy
4. Potential to decrease need for medication and/or healthcare utilization
5. Safe
6. Sustained effect

Addressing the unmet needs in Type 2 Diabetes requires new therapies

Qualities of an ideal new therapy in T2 Diabetes

- Non-pharmacologic
- Can be prescribed and data tracked in medical record
- Additive effects on top of evidence-based therapy
- Potential to decrease need for medication and/or healthcare utilization
- Significantly fewer AEs and SAEs in BT-001 group
- Sustained and improved A1c reduction at 180 days

We intend to go to market with a focus on patients whose blood sugar remains uncontrolled despite the use of medications



Source: Better Therapeutics Epidemiology Research, 2022

COST IN 2020*

~$490B

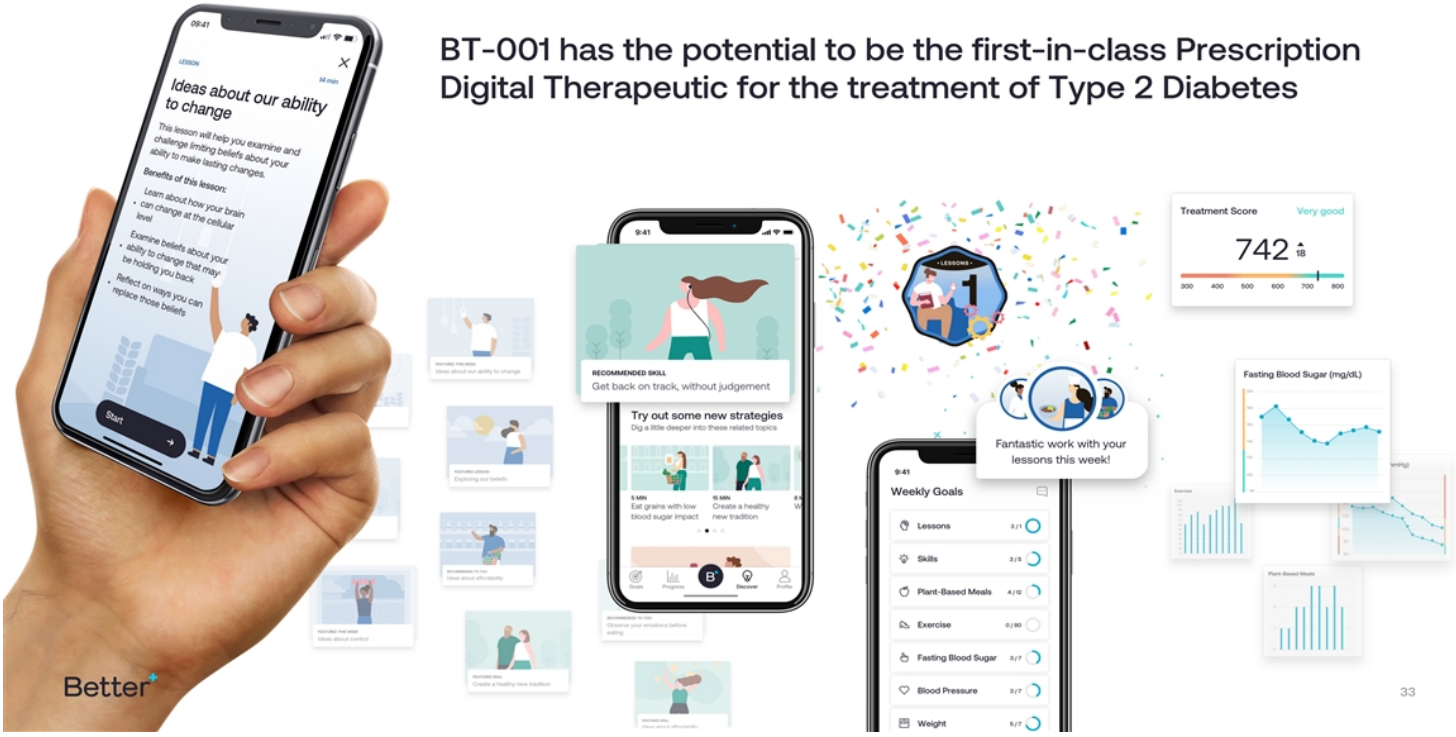
COST IN 2030*

~$600B

*Source: Projected costs from Rowley et al, Diabetes 2030: Insights from Yesterday, Today and Future Trends. *Population Health Management* 2017; Vol 20,1:6-12

Better

BT-001 has the potential to be the first-in-class Prescription Digital Therapeutic for the treatment of Type 2 Diabetes



CPT Codes:

New for 2022/2023 CPT Editorial Panel accepted the use of temporary codes to identify supplying a device, reporting and interpretation of CBT applications.

0702T - Remote therapeutic monitoring of a standardized online digital cognitive behavioral therapy program ordered by a physician or other qualified health care professional; supply and technical support, per 30 days

0703T - Management services by physician or other qualified health care professional, per calendar month

Bipartisan Bill Introduced:

March 10, 2022 Reps. Mike Thompson (CA-05) and David McKinley (WV-01) and Sens. Jeanne Shaheen (D-NH) and Shelly Moore Capito (R-WV) introduced the bipartisan legislation, *Access to Prescription Digital Therapeutics Act of 2022*

HCPCS Code:

CMS established a new HCPCS code Level II Code A9291, effective April 1, 2022, for Prescription Digital Behavioral Therapy, FDA cleared, per course of treatment

We plan to focus on securing coverage from regionally dominant, early adopting commercial payers, IDNs/health systems

	PAYERS	HEALTH SYSTEMS
LEADING INDICATORS OF ADOPTION:	• Population health focused • History of adopting new technologies	• Centralized decision-making • Accountable Care Organization (ACO) affiliations

Real-world evidence from randomized, controlled, multi-site program 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 Ascension VA U.S. Department of Veterans Affairs	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

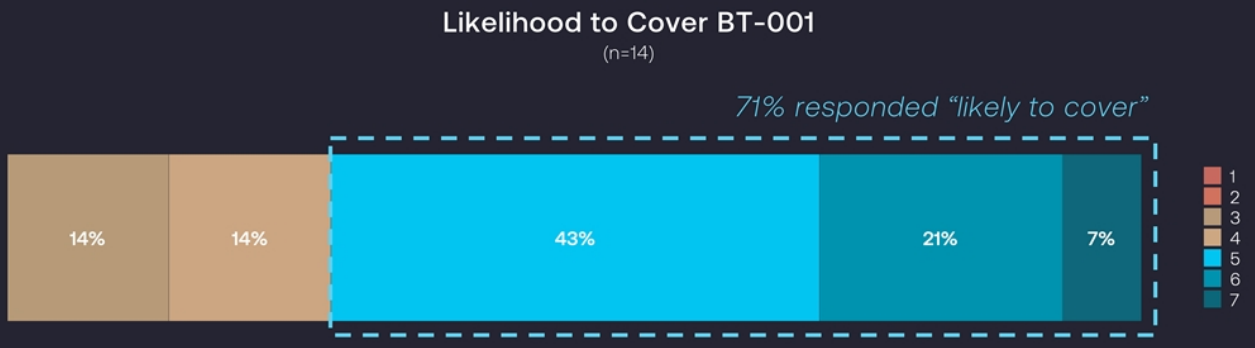
Primary Measures: Mean change in A1c after 6 and 12-months (mean change within participant or compared to control)

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

Payer Survey

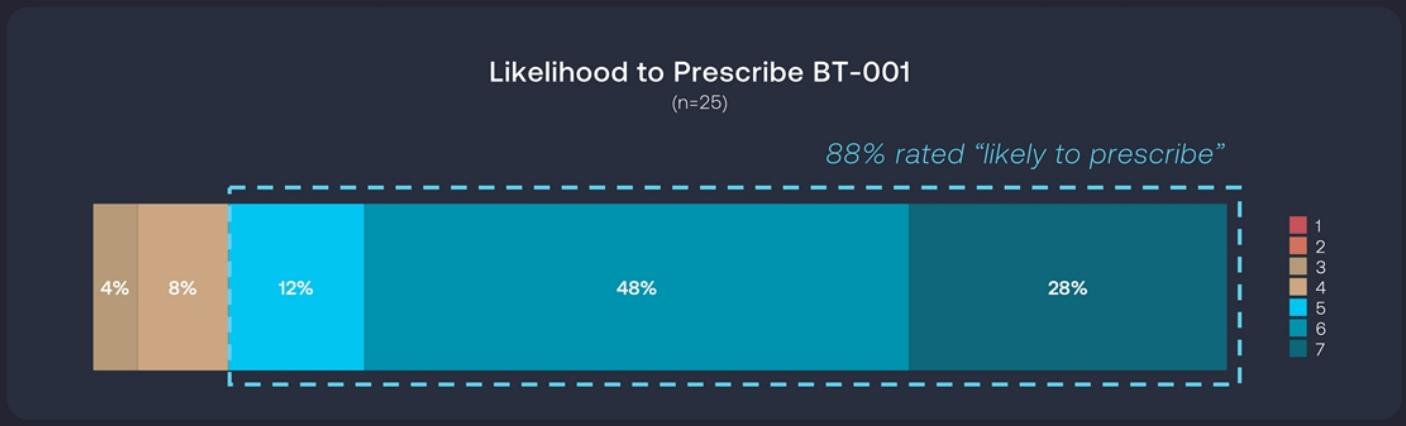
National and regional payers, as well as PBMs reacted positively to BT-001's Target Product Profile



Source: Better Therapeutics Quantitative Market Research, June 2022. The 1 to 7 scale represents the likelihood of the payer to cover BT-001, where 1 was "not at all likely" and 7 was "extremely likely."

Provider Survey

Providers have expressed a willingness to prescribe BT-001 based on Target Product Profile



Source: Better Therapeutics Quantitative Market Research, Mar 2022. The 1 to 7 scale represents the likelihood of the provider to prescribe BT-001 to at least some of their patients, where 1 was "not at all likely" and 7 was "extremely likely."


Better
THERAPEUTICS
Pioneering Prescription
Digital Therapeutics for
Cardiometabolic Diseases

Key Priorities

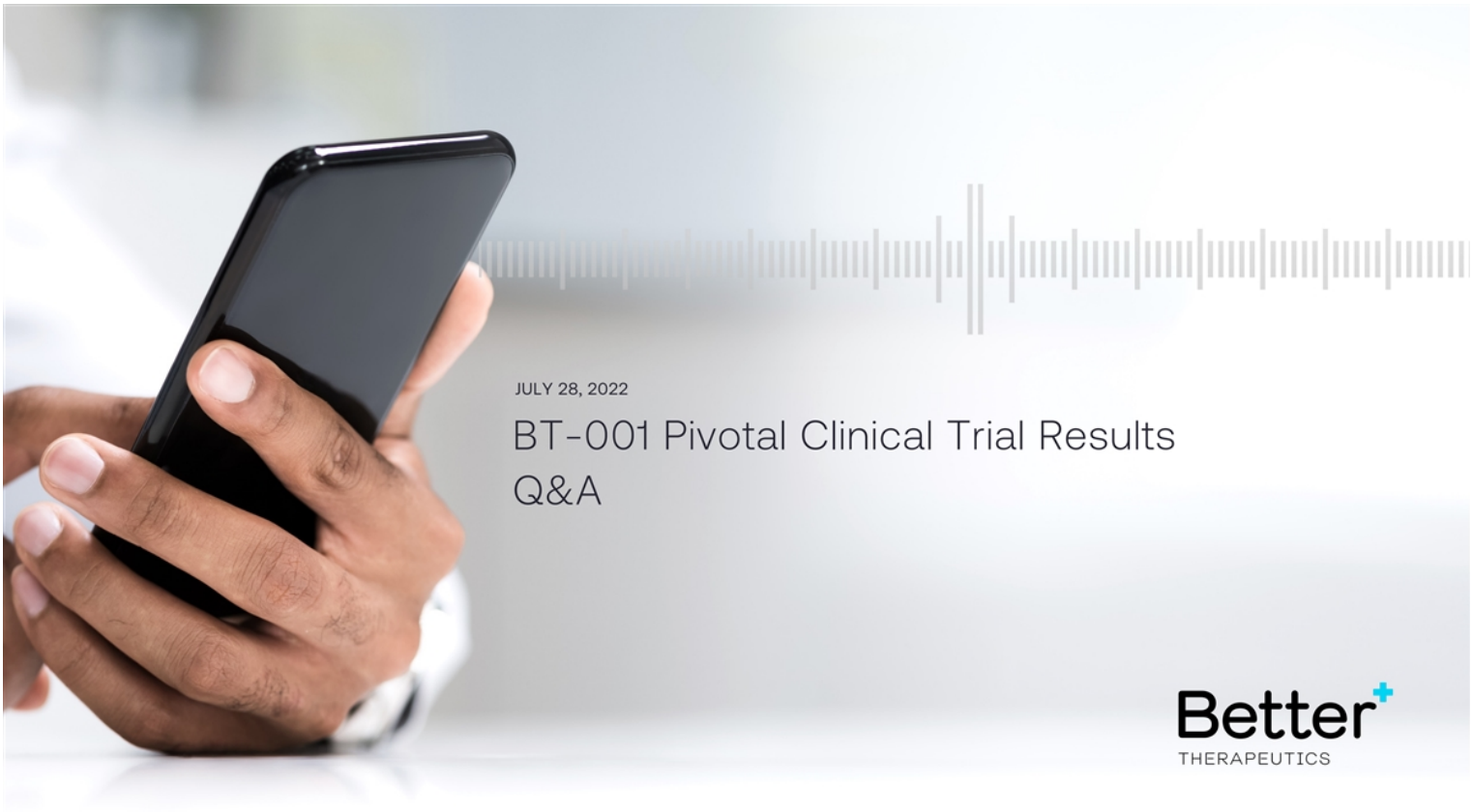
Financing – initiated a broad assessment of potential financing options to support our commercial launch and potentially expand into other cardiometabolic diseases.

De Novo Submission - Submit a de novo classification request with the FDA seeking marketing authorization of BT-001 for the treatment of patients with Type 2 diabetes in the third quarter of 2022.

Commercial Launch - Advance our preparations for the potential commercial launch of BT-001

Upcoming Milestones

Q3 2022	De Novo Submission
Q3 2022	Health economic model for BT-001 and payer coverage discussions
Q4 2022	Completion of LivVita Liver Study for NAFLD and NASH
Q4 2022/ Q1 2023	Address financing needs
Pending FDA Authorization	Commercial launch
2023	Pipeline Expansion / Next Pivotal Study



JULY 28, 2022

BT-001 Pivotal Clinical Trial Results Q&A

Better THERAPEUTICS