

**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): September 13, 2022

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

Delaware
(State or other jurisdiction
of incorporation)

001-39864
(Commission
File Number)

85-3472546
(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 7.01 Regulation FD Disclosure.

On September 13, 2022, Better Therapeutics, Inc. (the “Company”) presented a corporate presentation at the H.C. Wainwright 24th Annual Global Investment Conference. A copy of the corporate presentation is filed as Exhibit 99.1 to this Current Report on Form 8-K. The corporate presentation will also be available on the Company’s website in the Investors section at <https://investors.bettertx.com/news-events/events-presentations>.

The information contained in Item 7.01 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 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Corporate Presentation of Better Therapeutics, Inc., dated September 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: September 13, 2022

By: /s/ Mark Heinen

Name: Mark Heinen

Title: Interim Chief Financial Officer



Pioneering Prescription Digital Therapeutics for Cardiometabolic Diseases

SEPTEMBER 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, 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 delivery of cognitive behavioral therapy and/or prescription digital therapeutics by the Company to address the root causes of type 2 diabetes and other cardio metabolic 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 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, the future financial stability, strength, or success of the Company, 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 quarterly report on Form-10-Q for the fiscal quarter ended June 30, 2022 filed with the Securities and Exchange Commission ("SEC") on August 11, 2022, and those that are included in any of the Company's subsequent filings with the SEC.

Contents

The Problem

Better Therapeutics Approach

How our Product Works

BT-001 Pivotal Trial

Go-to-Market Plan

Investment Summary



\$4.1 Tn

US National Health
Expenditure in 2020¹

86%

of healthcare dollars are spent on
chronic disease maintenance²

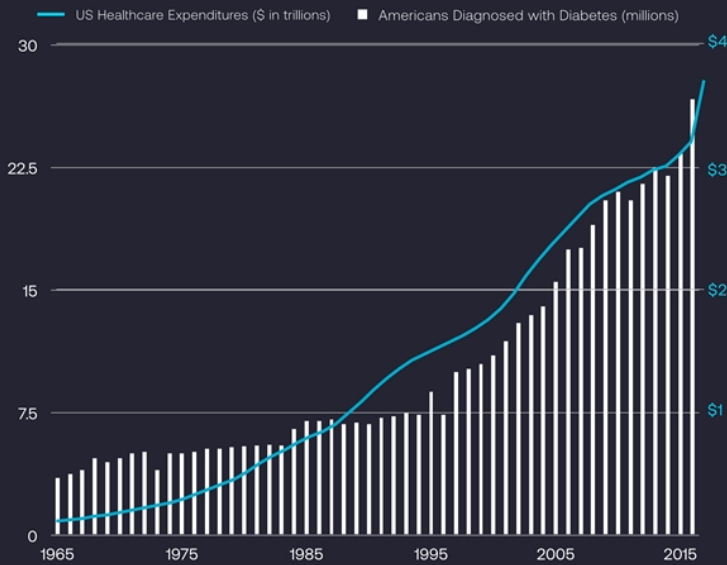
50%

of adults in the US
have a chronic disease²

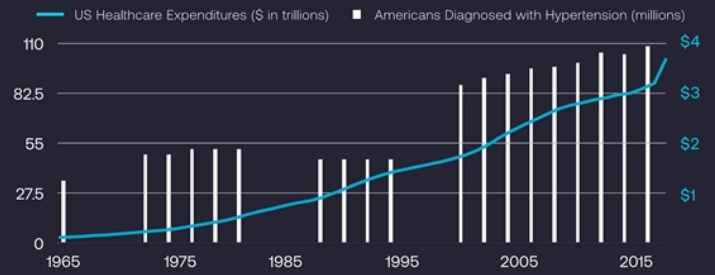
Currently available **drugs treat symptoms** but do not
impact the root cause of disease. **Most patients get worse**
over time despite being on multiple prescription drugs

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

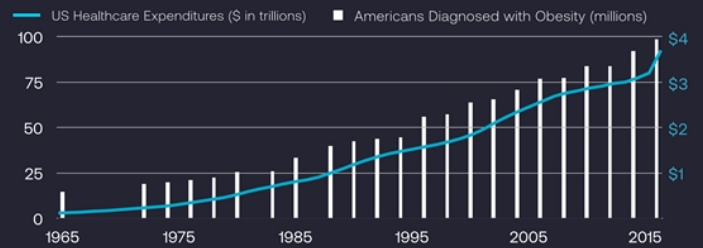
DIABETES



HYPERTENSION



OBESITY





The vast majority of patients diagnosed with cardio metabolic diseases progress in their disease, leading to more costly complications and interventions over time



Example: Type 2 Diabetes Typical Disease Progression



LIFESTYLE CHANGES
Changes to exercise and diet

FIRST LINE TREATMENT
Metformin

DUAL THERAPY
Metformin + Sulfonylurea

TRIPLE THERAPY
Metformin + GLP-1 + SGLT2

STEP UP TO INSULIN
Metformin + GLP-1 + SGLT2 + Insulin

Contents

The Problem

Better Therapeutics Approach

How our Product Works

BT-001 Pivotal Trial

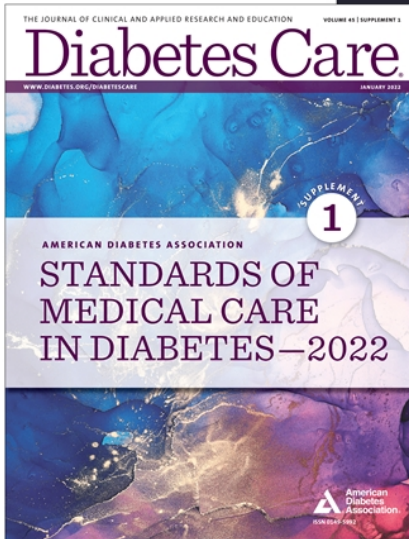
Go-to-Market Plan

Investment Summary



Many of the most common (and costly) chronic diseases share **lifestyle behaviors** as a **common root cause**.

Better Therapeutics combines medical, behavioral and digital/data science to create software based therapeutics that are designed to improve human health by **targeting behavior change**.



CURRENT CLINICAL GUIDELINES highlight behavior change as the foundation of treatment, but physicians have no options to prescribe it

- ✓ Emphasize importance of behavior change
- ✓ Call for digital solutions to facilitate behavior change
- ✓ Encourage reimbursement for solutions for behavior change
- ✗ No digital solutions available to prescribe behavioral therapy to treat root causes of diabetes and other cardiometabolic conditions



Next Generation Therapeutics: The Better Therapeutics Approach



Developing Digital Therapeutics that are authorized by the FDA for a specific indication and have labeled claims. If authorized or 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

Using Software: 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



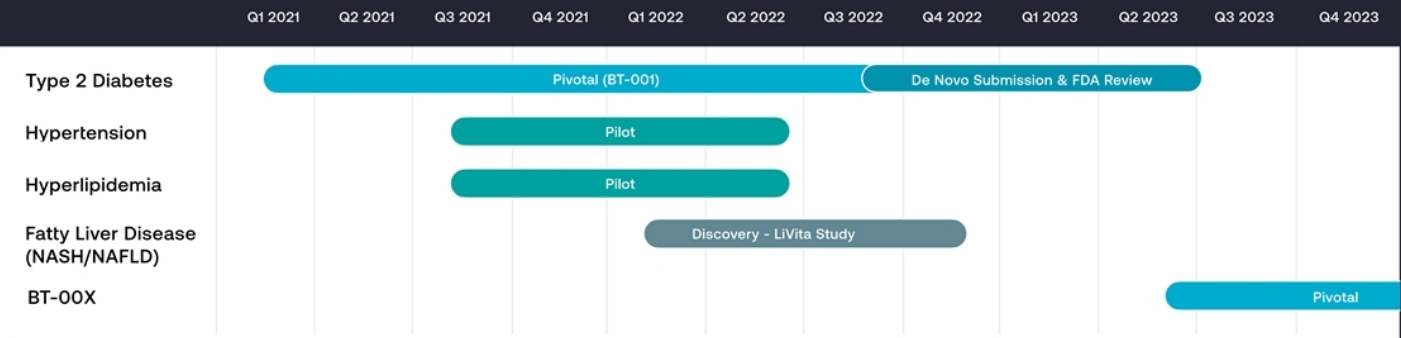
Data generated offers greater insights enabling **better care, novel pricing models and continuous product improvement**



Development requires substantially less time and investment,

enabling faster and more cost-efficient expansion into other potential indications or therapeutic areas

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.

Contents

The Problem

Better Therapeutics Approach

How our Product Works

BT-001 Pivotal Trial

Go-to-Market Plan

Investment Summary



Cognitive Behavioral Therapy

Developed in the 1960s, it is considered the gold standard for evidence-based therapy to help patients make lasting behavior changes by **changing neural pathways in the brain**

Traditional Cognitive Behavioral Therapy (CBT) is effective at addressing the behavioral root causes of cardiometabolic diseases but has limitations



Not Standardized

Treatment plans to treat cardiometabolic diseases with CBT are selected by individual health professionals who have different levels of success with their patients.



Not Scalable

Patients must commit to 8 - 20 CBT sessions with their healthcare professional.¹



Not Accessible

Time and geographic constraints make in-person sessions with a therapist impossible for many patients



Not Affordable

Psychotherapists charge upwards of \$100/hr and not all patients have insurance that covers treatment.²

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



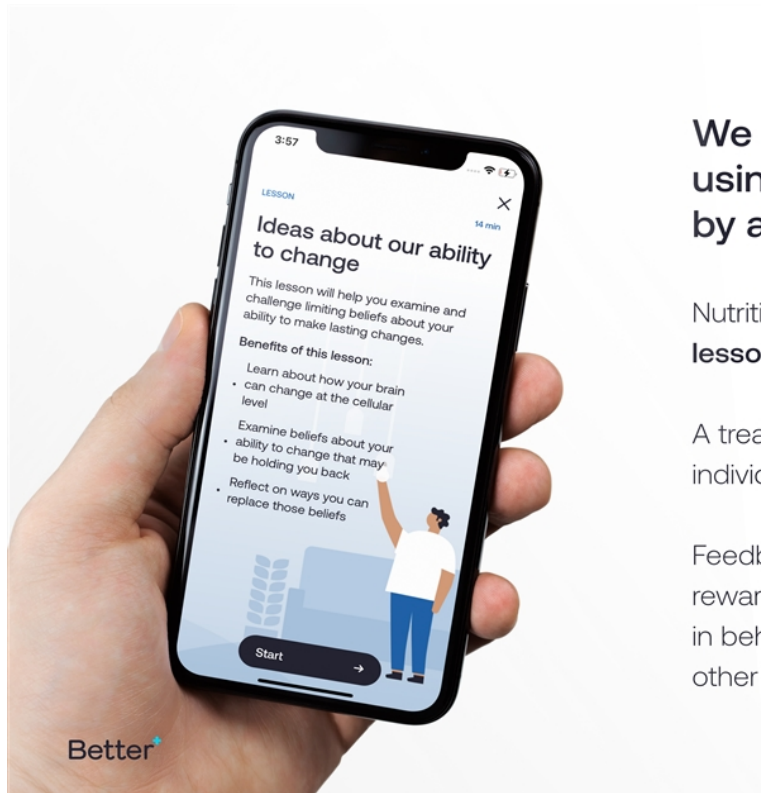
Goes far beyond the typical “cognitive distortions” in traditional CBT to address eating and lifestyle behaviors



Works within the existing framework of standard medical care and medication use.



Unifies behavioral therapy, lifestyle medicine, and AI into a single therapeutic experience



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



COGNITIVE BEHAVIORAL THERAPY

Changes thoughts
and beliefs so that
difficult behavior
changes are
possible.

Better⁺



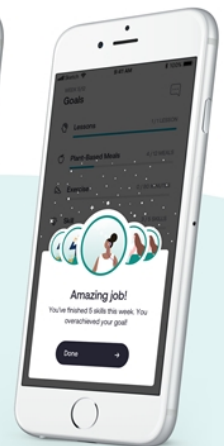
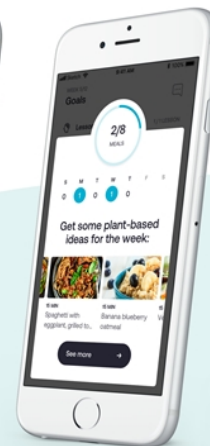
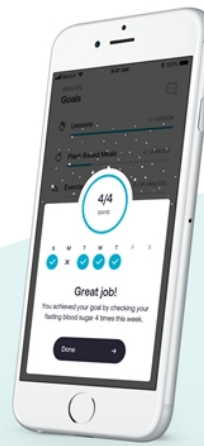
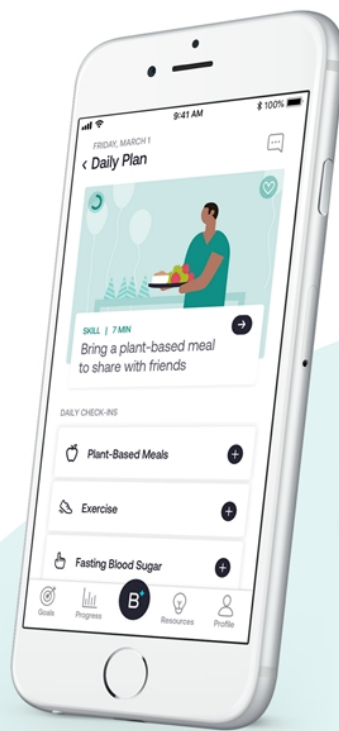
Changes neural pathways in the brain and
builds the acceptance and resilience needed to
handle challenging obstacles and emotions.



LIFESTYLE MEDICINE

CBT creates the desire to change. Lifestyle medicine provides the “how.”

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Treatment Plan

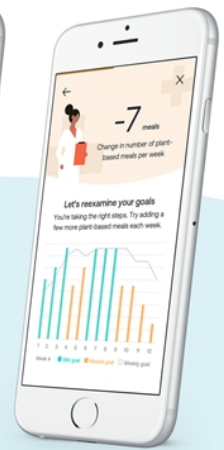
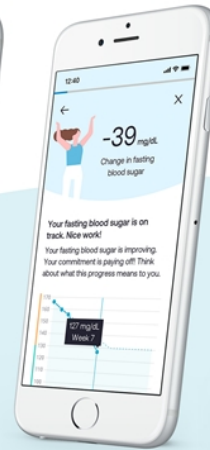
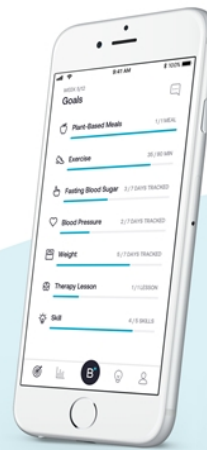
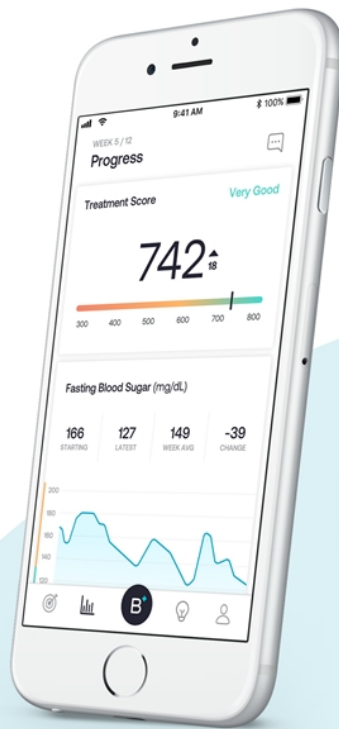
Guides changes in dietary behavior and physical activity, while improving medication adherence and self-monitoring.



ARTIFICIAL INTELLIGENCE

We use AI to reveal the right treatment pace, intensity and support needed to maximize efficacy for each individual.

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Personalization

A treatment algorithm dynamically adjusts goals to maximize treatment response, and provides a feedback loop that is designed to sustain engagement.

The data we collect helps patients get the best possible treatment experience and outcomes

- Visualizations of treatment progress
- Monitoring of engagement and biometrics
- Alerts when patients disengage from treatment to enable early intervention
- Algorithms predict patient success from engagement patterns



Contents

The Problem

Better Therapeutics Approach

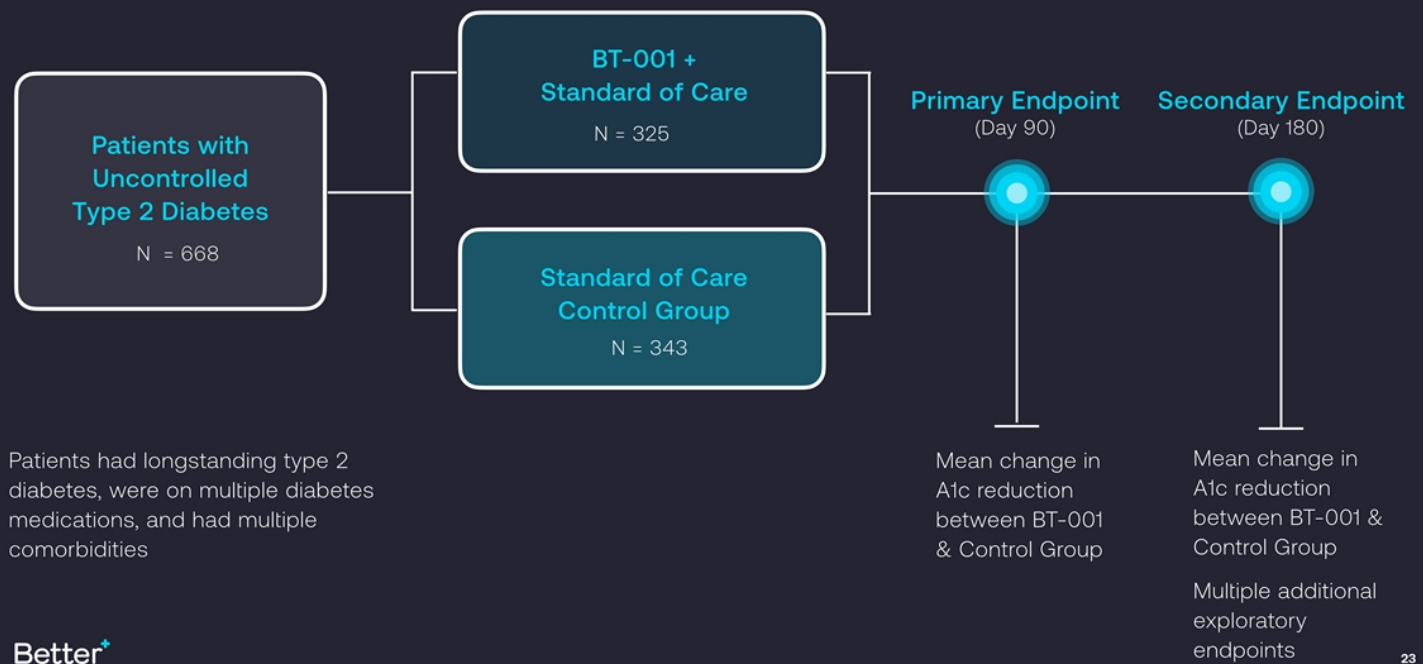
How our Product Works

BT-001 Pivotal Trial

Go-to-Market Plan

Investment Summary

First in class, randomized control pivotal trial in Type 2 Diabetes



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

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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

Pivotal Trial Results

Statistically significant
& clinically meaningful
results in diverse
patient population
with advanced T2D

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BT-001 demonstrated clinically meaningful and sustained reduction in A1c over 180 days

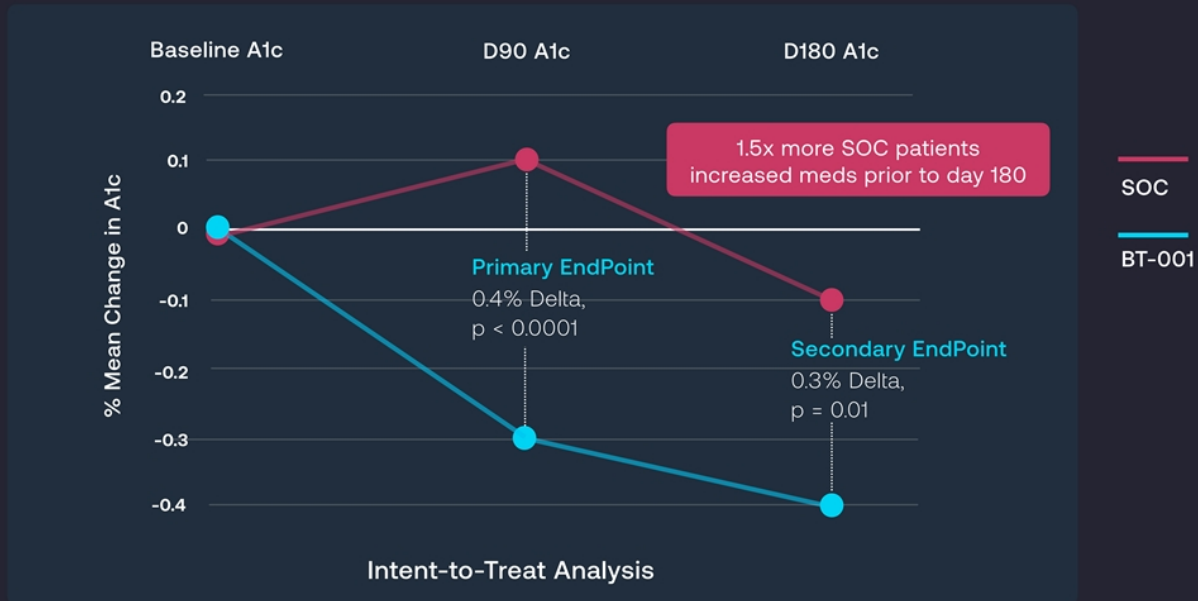
- Both primary (A1c between group delta -0.4% , $p < 0.0001$) and secondary endpoint (A1c delta -0.3% , $p = 0.01$) were met
- Significant improvements observed in BT-001 group despite use of fewer diabetes medications
- Higher dose subgroups showed substantially greater A1c improvements compared to control group
- Half of patients in BT-001 arm achieved absolute mean A1c reduction of 1.3% (SD 0.8%) in this subgroup

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

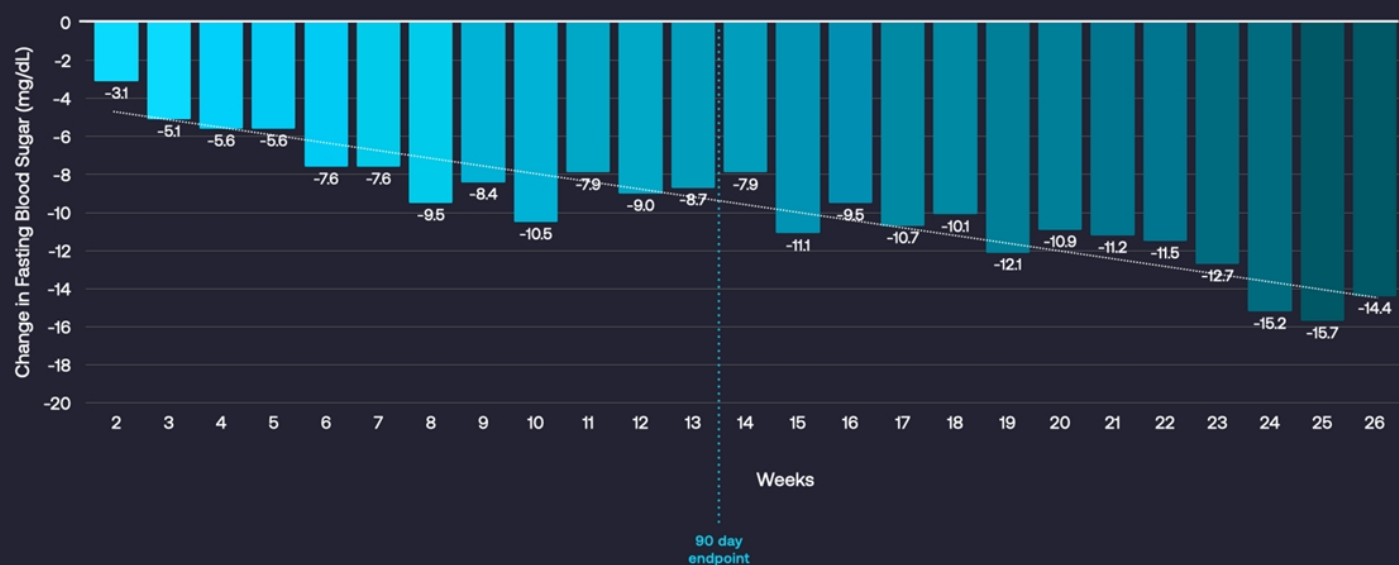
BT-001 use associated with multiple additional cardiometabolic benefits and lower medication and healthcare utilization over time

Patient engagement and persistence exceeded benchmarks for consumer health & wellness apps

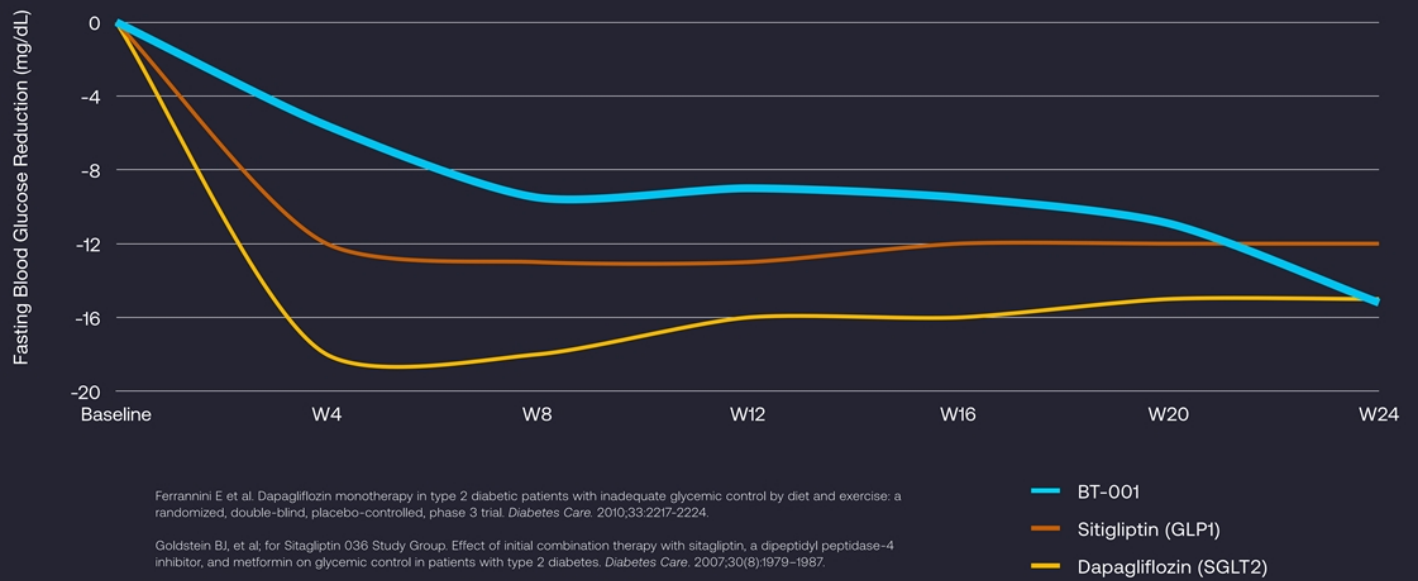
BT-001 reduced A1c despite on-study addition of more diabetes medication in the Standard of Care control group



Trending average change in fasting blood glucose in BT-001 group shows gradual and steady improvements, with no clear peak

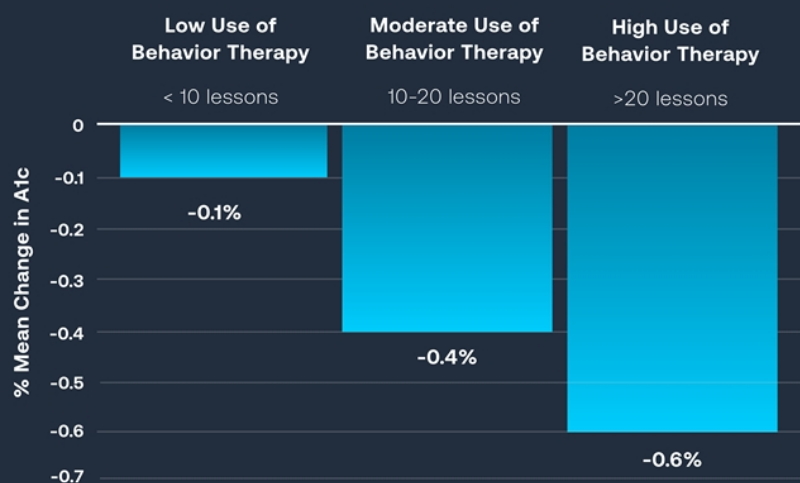


Trends in fasting blood glucose in different therapies



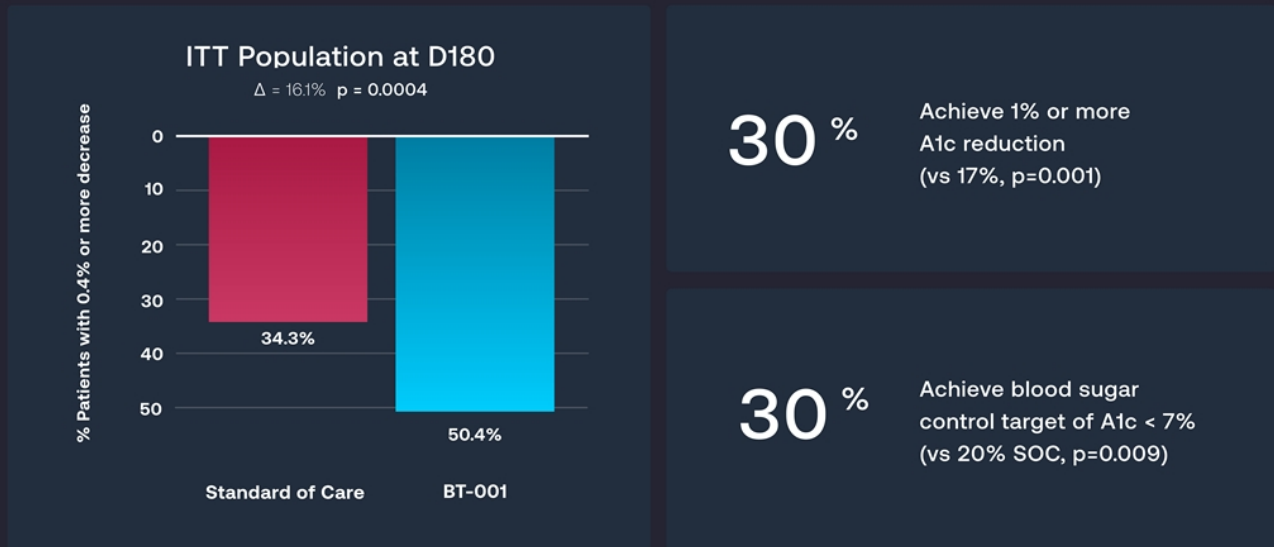
Patients who used BT-001 more had greater reduction in A1c

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



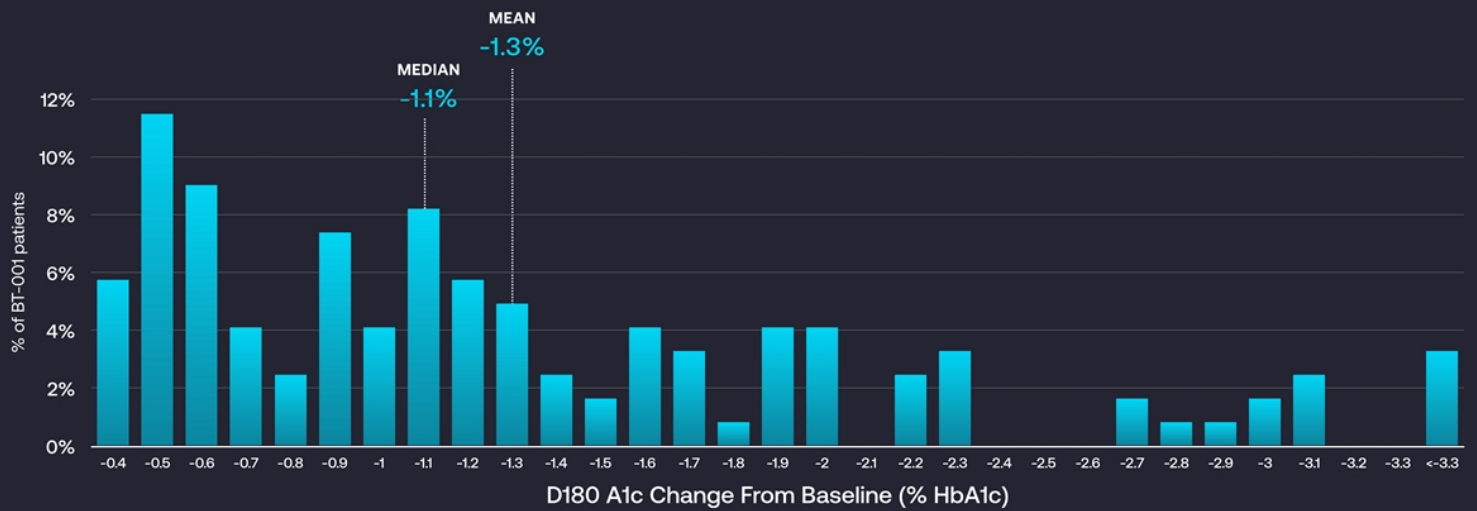
1.5x more BT-001 patients achieved meaningful A1c change

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



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

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



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)		BT-001 (n=325)		
	Subjects n (%)	Events n	Subjects n (%)	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 type 2 diabetes

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.

Exploratory Endpoints

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

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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.

During 180 days of use, patient engagement and persistence exceeded 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



Healthcare
(all)



Medical



Fitness



Health
Insurance

We envision
BT-001 to become
standard of care
for most adult
patients with T2D

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The evidence from our pivotal trial suggests that BT-001 has the potential to be...

- As efficacious as the best available drugs
- Safe - with generally fewer AEs and more use not reflecting any increased risk
- Impactful on several health outcome measures
- Beneficial from a health economics perspective
- Accessible broadly to anyone with a smartphone

Contents

The Problem

Better Therapeutics Approach

How our Product Works

BT-001 Pivotal Trial

Go-to-Market Plan

Investment Summary

Our Digital
Therapeutics platform
targets some of the
most prevalent and
costly conditions in
healthcare

Type 2 Diabetes

(High blood sugar)

35 million

people suffering

\$52 billion

Rx drug spending

Hypertension

(High blood pressure)

70 million

people suffering

\$30 billion

Rx drug spending

Root Causes

- Poor diet
- Sedentary lifestyle
- Stress
- Poor sleep
- Alcohol, Tobacco

NASH / NAFLD

(Non-alcoholic fatty liver disease)

64 million

people suffering

\$100 billion

Direct Healthcare Costs

Hyperlipidemia

(High cholesterol)

40 million

people suffering

\$28 billion

Rx drug spending

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

LEADING
INDICATORS OF
ADOPTION:



PAYERS

- Population health focused
- History of adopting new technologies



HEALTH SYSTEMS

- Centralized decision-making
- Accountable Care Organization (ACO) affiliations

Payer response to pivotal data has been positive

In research conducted with current or recent senior level decision makers from national payers, PBMs, regional payers, and health systems/payers (n=6)

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Payers highlighted the following as meaningful and compelling

- Efficacy, particularly in responders and improvement from 90 days to 180 days
- Study design including patient diversity, robust treatment background, patient self selection of dose
- Patient retention at 180 days; better than drug compliance
- Secondary endpoint results
- Potential for cost offsets

Areas discussed that are going to be addressed with ongoing RWE studies, implementation and innovative contracting/pricing

- Durability of response over time after treatment (1 year)
- Number of lessons needed for meaningful response
- Prediction of patient response based on early engagement patterns



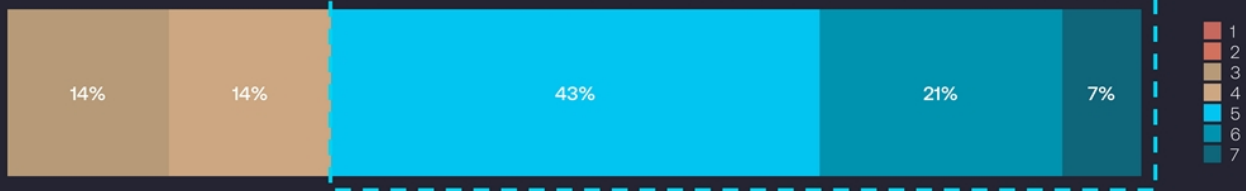
Payer Survey

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

Likelihood to Cover BT-001

(n=14)

71% responded "likely to cover"





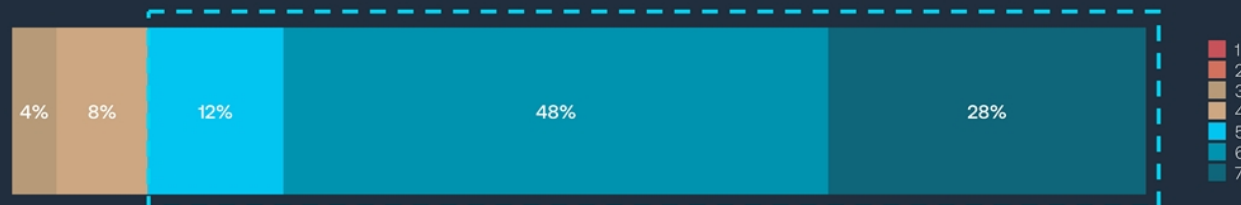
Provider Survey

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

Likelihood to Prescribe BT-001

(n=25)

88% rated "likely to prescribe"



Contents

The Problem

Better Therapeutics Approach

How our Product Works

BT-001 Pivotal Trial

Go-to-Market Plan

Investment Summary

Upcoming
Milestones

Q3 2022	De Novo Submission
Q3 2022	Initiate payer discussions
Q4 2022	Top line data from 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

LivVita Study

Top-Line Data expected in Q4 2022

Single Arm Interventional Cohort Study

Patients with non-alcoholic steatohepatitis (NASH) and non-alcoholic fatty liver disease (NAFLD).

N = 22

Measured at 90 Days

Primary Endpoint

Average change in liver fat after 90 days in participants with baseline proton density fat fraction (PDFF) $\geq 10\%$, as measured by MRI-PDFF

Secondary Endpoints

Average change in liver fat from baseline to end of treatment in all participants and percent who achieve $\geq 30\%$ reduction in PDFF

Exploratory Endpoints

Various clinical markers of liver and cardiometabolic health, along with quantitative feedback from participants to inform future clinical product development in these indications.

Investment in BTTX - Favorable Risk-Return Profile

Potential to disrupt and create substantial value

Targeting some of the largest indications in healthcare

Addressing significant unmet medical needs and massive expense burdens

Strong pivotal data - Impact on several health outcome measures

Potential to not just impact symptoms but change/reverse the course of disease

Good for patients, providers and payers

Efficacy, safety & accessibility plus alignment with current treatment guidelines

Beneficial from a health economics perspective

Ability to expand pipeline faster & with significantly less investment than traditional pharma

Potentially higher profitability business model than traditional pharma



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THERAPEUTICS

Pioneering Prescription
Digital Therapeutics for
Cardiometabolic Diseases