**FEBRUARY 2023** 

Pioneering Prescription Digital Therapeutics for Cardiometabolic Diseases





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# Contents



### **The Problem**

- Better Therapeutics Approach
- How our Product Works
- BT-001 Pivotal Trial
- Fatty Liver Pilot Study
- Go-to-Market Plan
- Investment Summary

**US National Health** Expenditure in 2020<sup>1</sup>

S Z I

of healthcare dollars are spent on chronic disease maintenance<sup>2</sup>



Sources: 1. Centers for Medicare and Medicaid Services; 2. Holman HR. The Relation of the Chronic Disease Epidemic to the Health Care Crisis. ACR Open Rheumatol. 2020 Mar;2(3):167-173. doi: 10.1002/acr2.11114. Epub 2020 Feb 19. PMID: 32073759; PMCID: PMC7077778.

of adults in the US have a chronic disease<sup>2</sup>

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 money to get worse outcomes This is not sustainable

US Healthcare Expenditures (\$ in trillions)





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

Diagnosis

Non-Insulin Treatment

### **Pre-Diabetes**

Incremental cost per patient per year

······\$2,000 ··

LIFESTYLE CHANGES

Changes to exercise and diet

### FIRST LINE TREATMENT

Metformin

DUAL THERAPY

Metformin

+ Sulfonylurea





····· \$10,000 ····· \$19,000 ···· \$35,000 + ··≻

| 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

Fatty Liver Pilot Study

Go-to-Market Plan

Investment Summary







Our mission is to advance human health through the power of behavior change.

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

Better Therapeutics combines medical, behavioral and data sciences to develop clinically proven software based therapeutics targeting behavior change at scale.

We make societies healthier and meaningfully reduce healthcare costs around the world.



# **Next Generation Therapeutics:** The Better Therapeutics Approach

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Prescription Digital Therapeutics (PDTs) authorized by the FDA, prescribed by physicians and reimbursed via health insurance

Focus on cardiometabolic diseases that share lifestyle behaviors as a common root cause

Novel Cognitive Behavioral Therapy (CBT) delivered digitally via an app to improve access and scalability

Rigorous development incorporating Randomized Controlled Studies, backed by Real World Evidence





# 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.





people suffering

Rx drug spending





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



# **Type 2 Diabetes**

# **35 million**

# \$52 billion

### **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



toc l WWW.DIABETES.DRG/DIABETESCAR

AMERICAN DIABETES ASSOCIATION STANDARDS OF MEDICAL CARE IN DIABETES-2022



**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

# **Using Software:** Unique Benefits of Digital Therapeutics



**Opportunity to address healthcare inequities and access** Connect patients to the best care despite barriers

**Insights into use and efficacy drives continuous improvement** Potential for better efficacy without increased risk

Novel insights through broad data generation Enables b**etter care and novel pricing models** 

**Development requires substantially less time and investment** Potential for rapid expansion into other indications



13

## Potential to Disrupt and Create Substantial Value Favorable Risk-Return Profile

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

Better

14

# Contents



Investment Summary



### The Problem

Better Therapeutics Approach

### How our Product Works

BT-001 Pivotal Trial

Fatty Liver Pilot Study

Go-to-Market Plan





# 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** 

16

We created a novel CBT protocol 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 Al into a single therapeutic experience



**Think:** CBT stimulates conscious thought about what drives unconscious motives behind our behaviors.

**Do:** We introduce new ideas and encourage patients to put them into action.

Learn: Patients learn through experience and practice...

**Reinforce:** ...making them receptive on how to make further behavioral changes.





### Think

### Therapy Lesson

Guidance

Skill Building

Our proprietary CBT is delivered in a weekly stepby-step process to enable and reinforce cognitive restructuring

Progress Reporting

Goal Setting

Do

Tracking Biometrics + Behaviors

18



**COGNITIVE BEHAVIORAL THERAPY** 

To initiate, advance and maintain behavioral change, our proprietary CBT targets cognitive patterns that drive dietary, exercise and other lifestyle behaviors.



Start







### LIFESTYLE MEDICINE

CBT creates the desire to change. Lifestyle medicine provides the "how."







### 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.







### **Therapy Lessons**

Lessons are interactive. CBT techniques are used to identify and shift false beliefs and ideas around nutrition, exercise, sleep and stress.

### LESSON

# Ideas about our ability to change

This lesson will help you examine and challenge limiting beliefs about your ability to make lasting changes.

### Benefits of this lesson:

Learn about how your brain

 can change at the cellular level

Examine beliefs about your

- ability to change that may be holding you back
- Reflect on ways you can replace those beliefs

Start





- Lessons help patients identify emotions and beliefs that are barriers to behavior change
- Gradually advance from simpler concepts to more advanced ones
- Create emotional resilience and acceptance needed to make enduring changes

## **Skill Building**

Skill-building modules reinforce ideas introduced in Lessons and put them into practice, initiating new behaviors.

### SKILL

# Define what motivates you

Research shows that identifying our deepest reasons for wanting to improve our health helps us stay motivated when we face obstacles.







• Patients look for real-world opportunities to practice what they've learned in therapy



## **Goal Setting**

Algorithmically prescribed weekly goals **personalize therapy** and encourage biometric selfmonitoring.

### GOAL SETTING

### Set goals for the week

Research shows that taking the time to set goals can help you:

- 1 Do important things you want to do
- 2 Increase your motivation
- 3 Build a realistic path toward your ideal future self

Why setting goals helps

Start





- Patients reflect on the previous week and their achievements
- And review, adjust and commit to recommended goals for the week ahead



## Progress Reporting

A Treatment Score and Progress Reports connect changes in behavior to measurable health improvements week over week.



Profile





- relation to each of the biometrics and behaviors they are tracking
- They can easily see where they are On Track or Off Track in their treatment

| • | • |   |   |
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| _ | _ | _ |   |

# Reinforcement & Support

Core treatment elements are reinforced through reminders, nudges and rewards to enhance engagement and efficacy.

In-app product support is there for patients when they are stuck.

Safety is enhanced by biometric notifications.



Rewards

Product Support





Therapy Lesson

### Guidance

Skill Building

Nutritional Cognitive Behavioral Therapy (nCBT)

Progress Reporting

> Tracking Biometrics • Behaviors

Goal Setting

### Reminders

Biometric Notifications





### Our modular application

design allows us to create new products targeting new indications rapidly, with only minor changes to content and functionality. Treatment algorithms, logic, and user interfaces remain unchanged.









# 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
- Al Algorithms predict patient success from engagement patterns





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|                | 28                         |                 |

# Contents



### The Problem

Better Therapeutics Approach

How our Product Works

### **BT-001 Pivotal Trial**

Fatty Liver Pilot Study

Go-to-Market Plan

Investment Summary



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



Patients had longstanding type 2 diabetes, were on multiple diabetes medications, and had multiple comorbidities



Mean change in A1c reduction between BT-001 & Control Group

Mean change in A1c reduction between BT-001 & Control Group

Multiple additional exploratory endpoints



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



- Control arm is Standard of Care (i.e. gold standard care), • not just treatment as usual
- Medication use and adjustment by investigators was not ulletlimited; 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

- Investigators mirror real-world prescribers
- Robust study design employed to minimize bias and set high comparison bar:



# **Pivotal Trial Results**

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



- Both primary (p<0.0001) and secondary endpoint (p=0.01)</li> were met
- Significant improvements observed in BT-001 group despite use of fewer diabetes medications

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 demonstrated clinically meaningful and sustained reduction in A1c over 180 days



## 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



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.









## 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







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



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







# 180 Day safety data reveals significantly fewer Adverse Events

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

|  | Standard of Care<br>(n=343) |             |                   | BT-001<br>(n=325) |           |
|--|-----------------------------|-------------|-------------------|-------------------|-----------|
| Number of subjects who experienced:                      | Subjects<br>n (%)           | Events<br>n | Subjects<br>n (%) | Events<br>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<br>Intervention | 0 (0.0%)                    | Ο           | 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%) |
|---------|----------|----------|
|         |          |          |

| Adverse Reaction (>/= 5%)         | GLP1 | SGLT2 | <b>BT-001 Pivotal</b> |
|-----------------------------------|------|-------|-----------------------|
| 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                    |
| Device 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

- Mood Scores
- Quality of Life Scores (Physical Health-Related)



Statistically significant findings in:

- Systolic Blood Pressure
- Weight Reduction

Adverse Event and Serious Adverse Event Rates

Data to be submitted for peer-review publications.

41

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









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



- 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



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

43

# Contents





### The Problem

Better Therapeutics Approach

How our Product Works

BT-001 Pivotal Trial

Fatty Liver Pilot Study

Go-to-Market Plan

Investment Summary

44

# LivVita Study was designed to assess potential for both efficacy and safety in NAFLD and/or NASH

Partnered with leading specialty liver health clinic - Arizona Liver Heath - to design study and recruit diverse set of participants in 2 sites

BT's cardiometabolic Cognitive Behavioral Therapy (CBT) research platform was evaluated over a 3-month treatment period Basic liver health education provided in 1 phone session prior to treatment

MRI-PDFF and robust set of biomarkers evaluated, to potentially enable planning of pivotal study

App-engagement and qualitative data collected, to inform customizations needed for liver-specific product



45

### LivVita Study Topline Key Endpoints

that provides the most validated and reproducible non-invasive quantitative measure of liver fat

damaged or injured

with the Aspartate Transaminase (AST) blood test to predict degree of NASH risk

provides point of care screening and assessment of liver fat and stiffness

would recommend a product to a friend or family member. Scores range from -100 to +100



- Magnetic Resonance Imaging-Proton Density Fat Fraction (MRI-PDFF): A specialized type of MRI
- Alanine Transaminase (ALT): An enzyme produced by liver cells. ALT blood levels rise when the liver is
- FAST Score: A composite score the uses FibroScan's measures of liver stiffness and fat combined
- FibroScan CAP Score: A quantitative measure of liver fat using a specialized type of ultrasound that
- **Net Promoter Score (NPS):** A survey that measures user satisfaction and likelihood that the individual

46

## LivVita Study demonstrated clear potential for response, with no safety related concerns observed, supporting our hypothesis and research platform



CBT's broad mechanism of action



great potential for patient-centric NAFLD/NASH treatment



Potential exists to establish NAFLD/NASH PDT as part of standard of care treatment either alone or alongside future pharmacotherapy treatments



Study also serves as proof-of-concept of BT's indication discovery platform - which could afford for rapid ability to expand indication pipeline



Consistent improvements in MRI-PDFF and broad range of liver biomarkers found, with notable changes in ALT and FAST scores; improvements are consistent with our

Generally well-tolerated profile and excellent patient-satisfaction scores suggests



## The primary endpoint, MRI-PDFF, showed positive signal with statistically significant reductions in liver fat (p = 0.01)









# ALT results showed statistically significant reductions in marker of liver damage (p = 0.002)





 $\begin{array}{ll} \mbox{Mean Change} in ALT \\ \mbox{-17} & \mbox{JUJJL} \\ \mbox{n=17} & \mbox{p=0.002} \end{array}$ 

Mean Change in those with Elevated Baseline ALT

-23 JU/L n=13 p = 0.001





## FAST Score results showed statistically significant reductions in NASH Risk (p = 0.006)







# CAP and Weight Change showed statistically significant reductions in markers of liver damage









# Trending average change in patient-reported weight showed gradual and steady improvements, with no clear peak







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## Dose response demonstrated positive relationship between CBT engagement and improvements in liver health biomarkers







## Safety data revealed no device related adverse events (AEs) were experienced

BT's CBT was generally well-tolerated with few overall AEs reported over 3-month period

|  | Salety Population (n=22) |             |      |          |        |  |
|--|--------------------------|-------------|------|----------|--------|--|
| Number of subjects who experienced:                      | Subjects<br>n (%)        | Events<br>n | Mild | Moderate | Severe |  |
| An Adverse Event (AE)                                    | 6 (27%)                  | 10          | 5    | 5        | Ο      |  |
| An AE Possibly/Probably<br>Related to Study Intervention | 0 (0%)                   | Ο           | _    | _        | _      |  |
| An AE that is Related to<br>Medical Device               | 0 (0%)                   | Ο           | _    | _        | _      |  |
| Serious Adverse Event (SAE)                              | 0 (0%)                   | Ο           |      |          |        |  |

### Sofaty Dopulation (n-99)



During 90 days of use, patient engagement and satisfaction significantly of Life improvements also reported<sup>10</sup>





# exceeded benchmarks for consumer health & wellness apps<sup>8,9</sup>. Notable Quality



+75

### NPS Score after 90 days

Scored on a scale from -100 to +100





# Contents





### The Problem

Better Therapeutics Approach

How our Product Works

BT-001 Pivotal Trial

Fatty Liver Pilot Study

**Go-to-Market Plan** 

Investment Summary



## We plan to focus initially 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**



# Targeted Approach to Commercial Launch

### Payer / Health System Analysis



Note: Further characterization of Payers and Health systems will refine targeting and field sizing



### **Claims Analysis**





Payers perceive diabetes as the highestpriority area for managing PDT products





Sources: "Prescription Digital Therapeutic (PDT) Formulary Design and Access Trends" - Academy of Managed Care Pharmacy N=50.

### Payer DTx priorities by disease state



# Non-Rx DTx vs PDT: Which is preferred?

When payers were surveyed, the majority (64%) agreed that being a PDT would improve coverage



### N=50

Q3a: If a DTx is a prescription-only product, how would that impact coverage decisions? The remaining 2% of respondents answered "Not enough experience with DTx to answer"







Those definitely/more likely to cover PDTx (N=32) Q3b: Why is your organization more likely to cover a product if it is prescription only? Multiple selections allowed



60

"When forced to make tradeoffs, objective clinical effectiveness is the most useful health outcome for review of DTx, followed by **cost** offset and adherence data."





The usefulness of health outcomes to review DTx today (Point scale of 0-100)



# 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)

# 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







# 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, Feb/Mar 2022. The 1 to 7 scale represents the likelihood of the payer to reimburse BT-001 to at least some of their patients, where 1 was "not at all likely" and 7 was "extremely likely."

### Likelihood to Cover BT-001

(n=14)





# Provider Survey

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





Source: Better Therapeutics Quantitative Market Research, Feb/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."

### Likelihood to Prescribe BT-001

(n=25)



# Contents



### The Problem

Better Therapeutics Approach

How our Product Works

BT-001 Pivotal Trial

Go-to-Market Plan

Fatty Liver Pilot Study

**Investment Summary** 

65

# We expect multiple value creation milestones through 2023





66

## Potential to Disrupt and Create Substantial Value Favorable Risk-Return Profile

### Focus on cardiometabolic conditions targets diseases with blockbuster potential

Platform approach offers multiple expansion opportunities & diversifies risk Addressing significant unmet medical needs and massive expense burdens

## Strong pivotal data - Impact on several health outcome measures Statistically significant & clinically meaningful results in diverse patient population with advanced T2D Potential to not just impact symptoms but change/reverse the course of disease

### Compelling use case for patients, providers and payers

Unique combination of efficacy, safety & accessibility Alignment with current treatment guidelines and beneficial from a health economics perspective

### Higher profitability business model at lower risk than traditional pharma

Ability to expand pipeline faster & with significantly less investment than traditional pharma Lower tox/safety, manufacturing or supply chain risk



