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): November 18, 2021

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 7.01 Regulation FD Disclosure.

On November 18, 2021, Better Therapeutics, Inc. (the "Company") issued a press release entitled "Better Therapeutics Completes Enrollment of Pivotal Trial for BT-001, a Prescription Digital Therapeutic for Type 2 Diabetes." A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K and incorporated herein by reference.

On November 18, 2021, the Company expects to present an updated Company presentation to certain parties. A copy of the presentation is attached as Exhibit 99.2 to this Current Report on Form 8-K and incorporated herein by reference.

The information contained in Item 7.01 of this Current Report on Form 8-K and the Exhibits 99.1 and 99.2 attached hereto is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of 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 or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits. The exhibits shall be deemed to be filed or furnished, depending on the relevant item requiring such exhibit, in accordance with the provisions of Item 601 of Regulation S-K (17 CFR 229.601) and Instruction B.2 to this form.

Exhibit Number	Description
99.1	Press release issued November 18, 2021
99.2	Company Presentation dated November 2021
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: November 18, 2021

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

Exhibit 99.1

Better Therapeutics Completes Enrollment of Pivotal Trial for BT-001,
a Prescription Digital Therapeutic for Type 2 Diabetes

Primary endpoint data expected in Q1 2022

SAN FRANCISCO, November 18, 2021 – Better Therapeutics, Inc. ("Better Therapeutics"; NASDAQ: BTTX), a prescription digital therapeutics company developing cognitive behavioral therapy to address the root causes of cardiometabolic diseases, today announced the completion of patient enrollment in its potentially pivotal study to evaluate the safety and efficacy of BT-001 for the treatment of type 2 diabetes.

BT-001 is being developed as an FDA-regulated, prescription digital therapeutic that delivers a novel form of cognitive behavioral therapy to patients with uncontrolled type 2 diabetes. The study exceeded its target, enrolling 662 patients from California, Illinois, Florida, Georgia, New York, and Texas.

"We are deeply thankful to our study participants, investigators and partners for their dedication to this study. With their help, we now can demonstrate that use of BT-001 can meaningfully improve upon the Standard of Care," said Mark Berman, M.D., chief medical officer of Better Therapeutics. "With roughly half of all patients living with type 2 diabetes not reaching treatment goals despite use of medications, the need for a novel treatment approach is urgent. We see tremendous potential for the development of prescription digital therapeutics, such as BT-001, to improve treatment outcomes without adding to the burden of drug-related side-effects."

If positive, study results may support a regulatory submission for marketing authorization from the U.S. Food & Drug Administration (FDA). Exploratory endpoint data captured during this study, including change in insulin resistance, blood lipids, inflammation, blood pressure and weight, could accelerate the development of Better Therapeutics' product candidates to treat other cardiometabolic conditions.

Better Therapeutics is also conducting a real-world evidence study with Mass General Brigham, Colorado Prevention Center and Catalyst Health Network to evaluate the long-term effectiveness and healthcare utilization changes associated with the use of BT-001. It is expected that primary care providers will prescribe, and insurers will reimburse the company's therapeutics much like they would a traditional medication.

The Better Therapeutics platform blends clinical, behavioral, and psychological inputs into a series of therapy lessons and skill-building modules. These are designed to isolate and shift the underlying thoughts and beliefs which guide diet and lifestyle behaviors that cause a wide range of cardiometabolic diseases, including type 2 diabetes

Clinical data on the efficacy and safety of Better Therapeutics developmental product candidates has been published in multiple peer-review journals including Journal of the Endocrine Society, JMIR Cardio, JMIR Diabetes and more.

About Better Therapeutics

Better Therapeutics is a prescription digital therapeutics (PDT) company developing a novel form of cognitive behavioral therapy to address the root causes of cardiometabolic diseases. The company has developed a proprietary platform for the development of FDA-regulated, software-based solutions for type 2 diabetes, heart disease and other conditions. The cognitive behavioral therapy delivered by Better Therapeutics' PDT is designed to enable changes in neural pathways of the brain so lasting changes in behavior become possible. Addressing the underlying causes of these diseases has the potential to dramatically improve patient health while lowering healthcare costs. Better Therapeutics clinically validated mobile applications are intended to be prescribed by physicians and reimbursed like traditional medicines. For more information visit: bettertx.com

Forward-Looking Statements

Certain statements made in this press release are "forward-looking statements" within the meaning of the safe harbor provisions under the United States Private Securities Litigation Reform Act of 1995. Forward-looking statements are typically identified by words such as "plan," "believe," "expect," "anticipate," "intend," "outlook," "estimate," "forecast," "project," "continue," "could," "may," "might," "possible," "potential," "predict," "should," "would" and other similar words and expressions, but the absence of these words does not mean that a statement is not forward-looking. The forward-looking statements 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 approve PDTs and insurance companies to reimburse their use; and other risks and uncertainties included under the header "Risk Factors" in the definitive proxy statement/prospectus filed by us on October 12, 2021.

Media Contact
Heidi Chokeir
heidi.chokeir@canalecomm.com
+1 619 203 5391

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Exhibit 99.2

COMPANY PRESENTATION | NOVEMBER 2021

Pioneering a prescription digital therapeutics platform for cardiometabolic diseases

Better
THERAPEUTICS

Disclaimer

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

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

Forward-Looking Statements.

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

Recent Progress

- Pivotal trial of BT-001 (type 2 diabetes) is fully enrolled; primary endpoint Q1 2022
- BT-002 (hypertension) pivotal trial expected to begin in 2022
- Early clinical discovery in non-alcoholic fatty liver disease (NAFLD) to enroll 1st patient in Q1 2022
- Real-world evidence study enrolled 1st patient in Q4 2021; Mass General Brigham joins study
- New patent family filed covering inventions in nutritional CBT and use of AI to guide treatment
- Completed deSPAC and PIPE transactions; funded through Q1 2023

Executive Team

David Perry
Co-Founder, Chairman

Kevin Appelbaum
Co-Founder, Chief Executive Officer

Mark Berman, MD
Chief Medical Officer

Justin Zamirowski
Chief Commercial Officer

Mark Heinen
Interim Chief Financial Officer

Kristin Wynholds
Chief Product Officer

Thiago Oliveira
Chief People Officer

Deepti Jaggi, PharmD
Chief Strategy Officer

indigo · P&G · one medical · HARVARD MEDICAL SCHOOL · EDGE Therapeutics, Inc. · astellas

SEPHORA · Yale University School of Medicine · Otsuka · UCSF · Johnson & Johnson

Next Generation Therapeutics:
Using Software Instead of Drugs

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

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

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

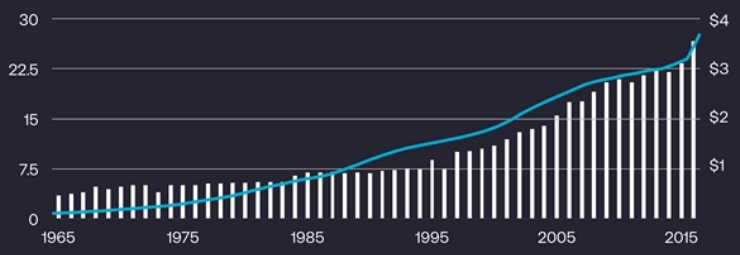
Platform Leverage – because we treat common root causes, we believe we can rapidly iterate our software and efficiently advance our pipeline with minimal product changes

1. Milken Institute. 2017.

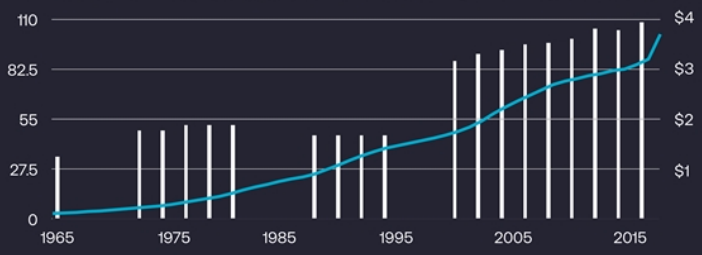
Better

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

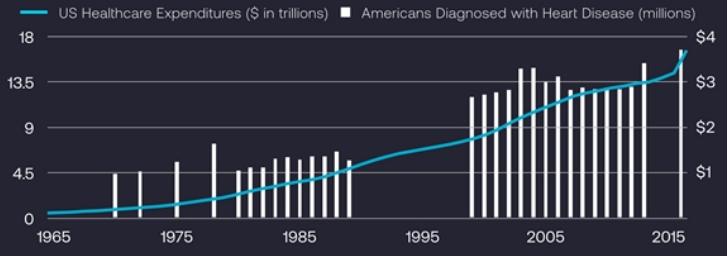
DIABETES



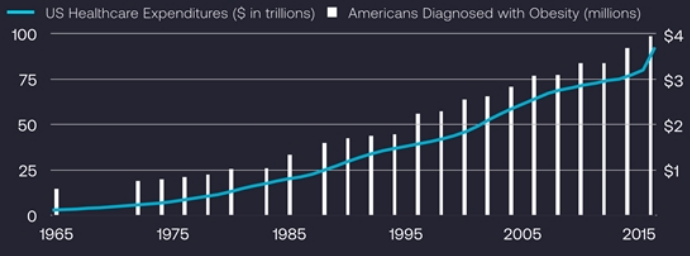
HYPERTENSION



CORONARY ARTERY DISEASE

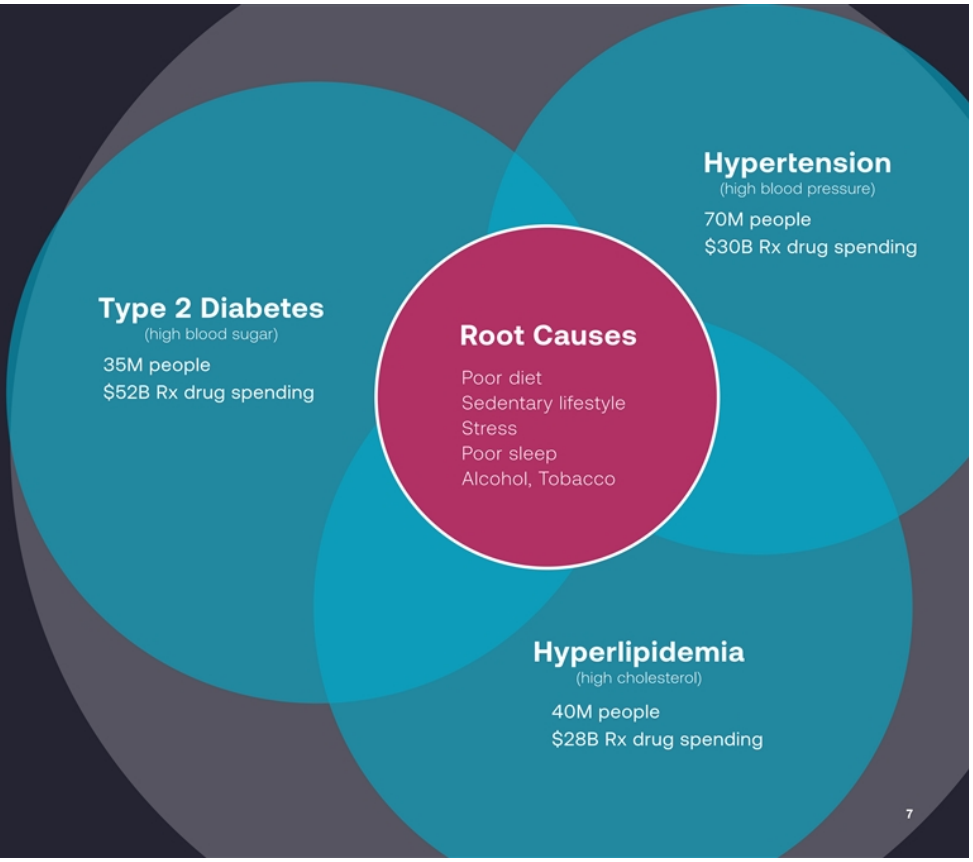


OBESITY



Better+

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



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

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

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

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

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

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

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

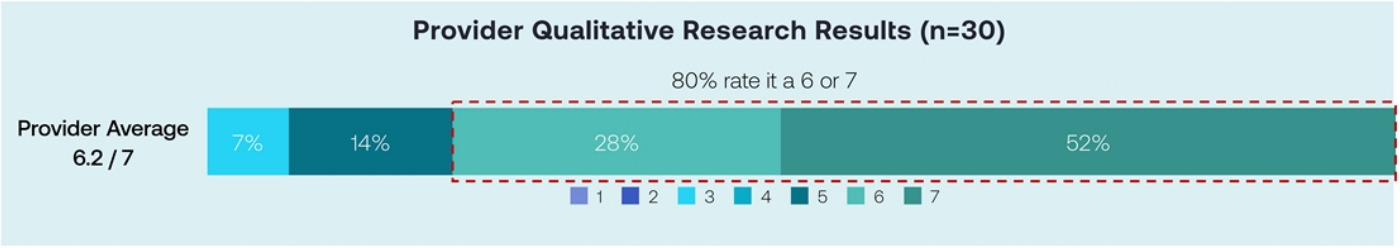
Better Therapeutics was founded on the hypothesis that we could create software that would change patient behavior and **treat underlying causes of cardiometabolic diseases**; and deliver it in a **scalable and affordable** mobile application

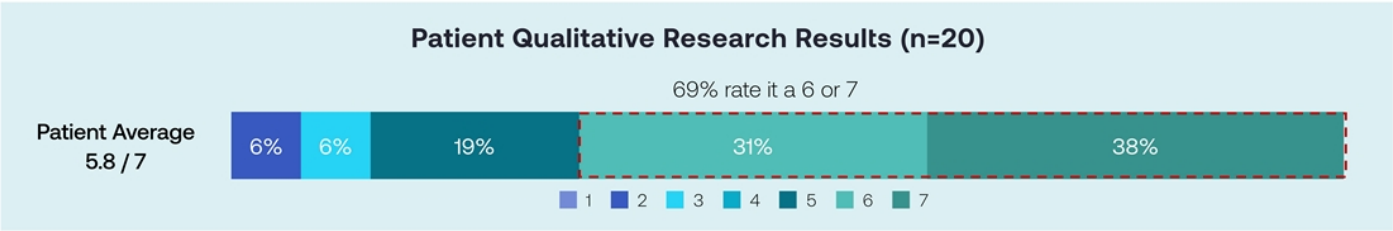
In 2017, the FDA established a pathway for the approval of software as a treatment

- Our first submission will be a de novo classification request
- Subsequent submissions may be 510(k)s
- Pear Therapeutics, Akili Interactive, Mahana Therapeutics have received authorization or clearance via this approach

Better

Both patients and healthcare providers are highly interested in treatment alternatives that address the underlying causes of disease

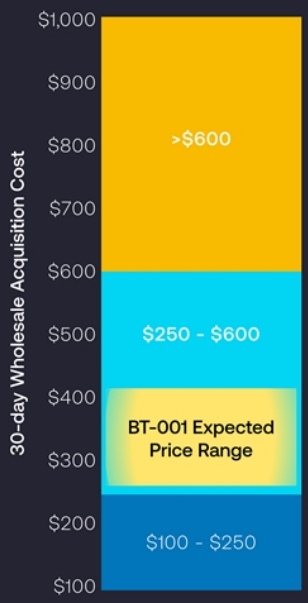




Source: Better Therapeutics Market Research, Oct 2020. The 1 to 7 scale represents the intent of the patient to ask their provider to prescribe BT-001, and the intent of the provider to prescribe BT-001, where 1 was "not at all likely" and 7 was "extremely likely."

Payer research supports our coverage and reimbursement assumptions

- Blinded interviews conducted with 17 key decision-makers in Commercial and Medicare Advantage payers
- Payers viewed evidence from our pivotal and real world evidence studies as comprehensive and compelling to support favorable coverage
- Payers responded favorably to BT-001 target product profile with a willingness to pay within the range of other branded T2D treatments



High Risk

- At this price range, payers will likely attempt to strictly manage BT-001 beyond label
- Not covered, Medical Exception only

Moderate Risk

- Payers will likely start implementing stricter management on par with branded, non-preferred T2D treatments
- Patient population may be restricted to inclusion/exclusion criteria from clinical trial

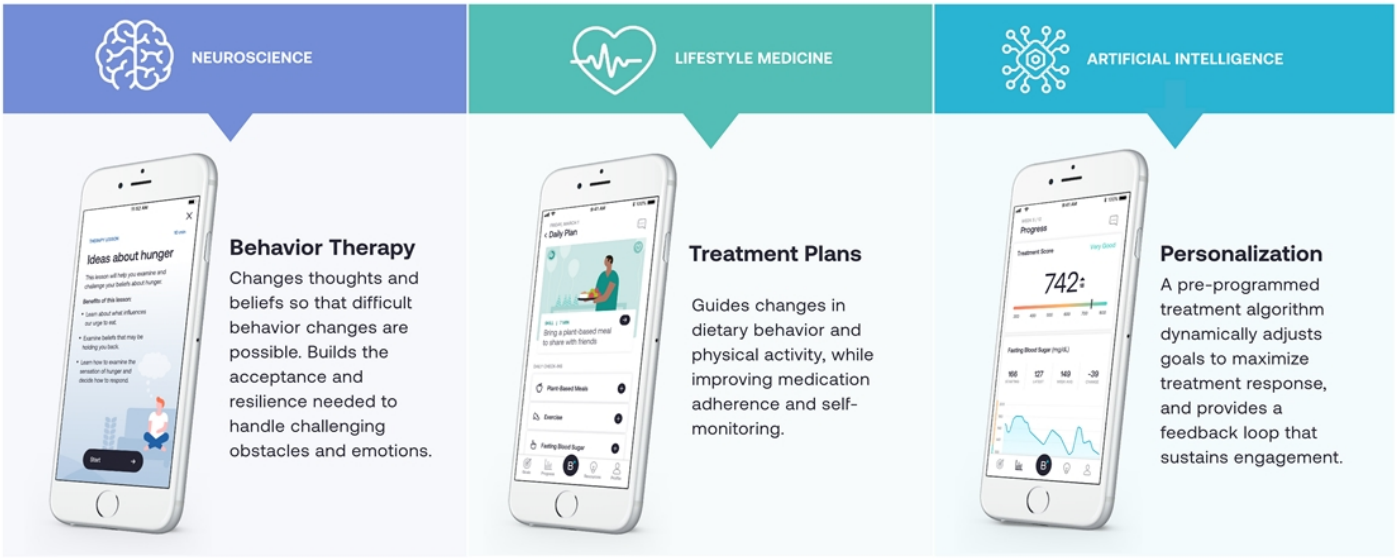
Low Risk

- Payers will likely cover with non-limiting criteria similar to branded, preferred T2D treatments

Now is a unique time to build a very valuable prescription digital therapeutics company

- We can't continue to **pay more** money for **worse outcomes**
- **CBT** is well established to **treat the underlying causes** of these diseases
- Our **software platform** has demonstrated **clinically meaningful results in multiple trials**
- The **FDA has established a pathway for regulation** and multiple companies have used it successfully
- **Payers** are increasingly **interested** in these solutions
- The field of digital health has **significant momentum**

We have created a software platform that delivers nutritional CBT and it has demonstrated clinically meaningful results in multiple trials



In our most recent pilot study in patients with type 2 diabetes, we observed that use of our software generated results similar to prescription drugs with few side effects

Clinical Observations

Greater than expected changes in fasting blood glucose

Data quality is high in frequency, prevalence and consistency of self-reporting

Greater engagement with behavioral therapy content results in greater improvement in blood glucose; even a low level of use resulted in meaningful improvement

Change in Fasting Blood Glucose

(n = 80, enrolled with baseline A1c 7.0 to 11.0%) [1]

Study Week	Mean (mg/dL)	Est. A1c Change
2	-8.9	-0.4%
4	-17.9	-0.8%
6	-23.9	-1.0%
8	-24.4	-1.1%
10	-21.6	-0.9%
12	-22.6	-1.0%

[1] This data is based on a single-arm, uncontrolled, unblinded pilot study conducted by BTX. Type 2 diabetes is defined as an A1c of 6.5% or higher.

A pivotal trial of our product for treating type 2 diabetes is underway; we expect primary data in Q1 2022 and an FDA submission in mid 2022

Sample Size: 648 participants with type 2 diabetes located in 5 geographically distinct US regions

Power: 90% power to detect 0.4% A1c difference with 0.05 alpha

Inclusion: 18-75 years old; baseline A1c 7% or above but less than 11%; stable drug regimen for 4 months prior to randomization

Exclusion: Use of prandial insulin; any unstable life-threatening medical condition; COVID-19

Randomization: 1:1 randomization to Standard of Care arm (control) or Standard of Care + BT-001 arm (intervention)

Primary Efficacy Endpoint: Day 90 A1c (difference in the mean change from baseline in A1c between groups)

Secondary Efficacy Endpoint: Day 180 A1c (difference in the mean change from baseline in A1c between groups)

Primary Safety Endpoint: Occurrence, relatedness & severity of adverse events at Day 90

Secondary Safety Endpoint: Occurrence, relatedness & severity of adverse events at Day 180

Exploratory Endpoints: Changes in insulin resistance, blood lipids, inflammation, blood pressure, cardiovascular risk score, weight, medications, quality of life; NPS (BT-001 only)

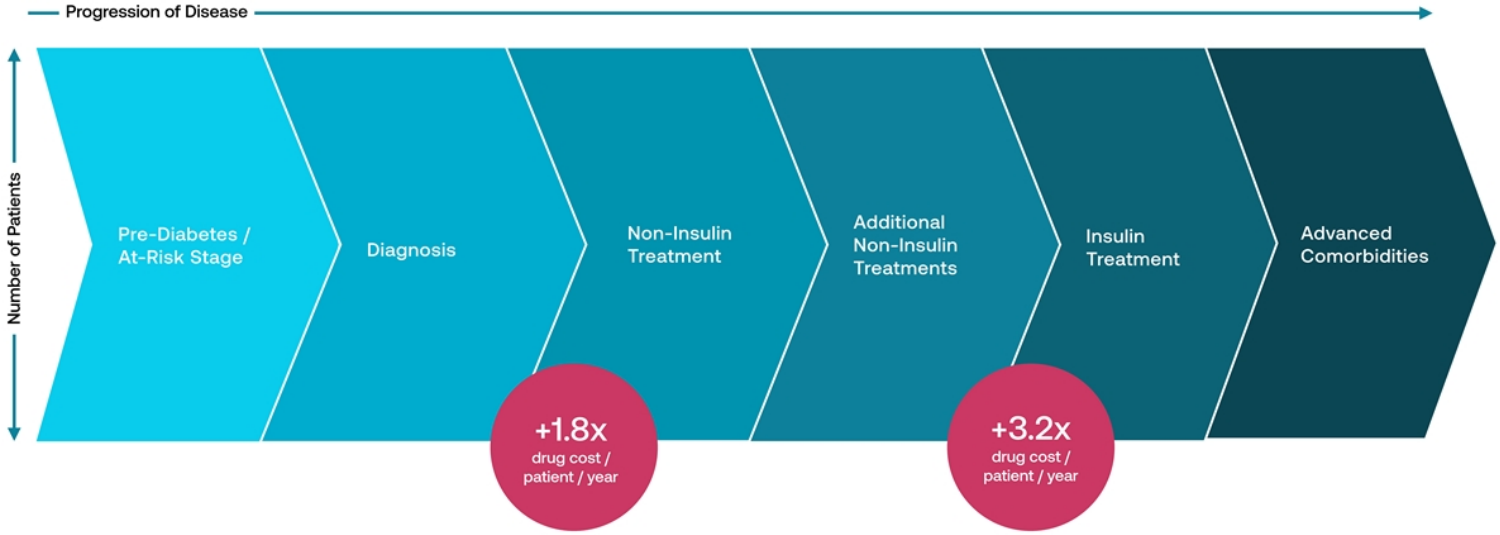
We believe **we can develop this pipeline faster and at less cost** than traditional therapeutics, allowing us to scale much more quickly

Additional Scientific Areas of Interest

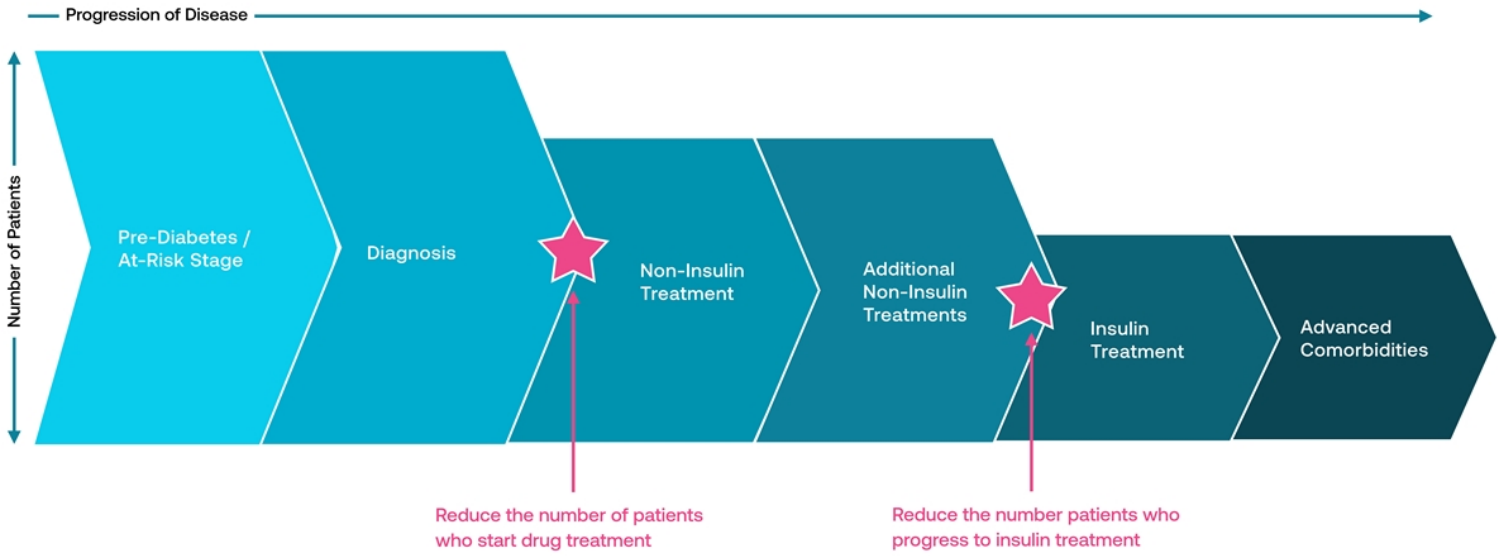
Increasingly, it is appreciated that there are shared pathways of pathophysiology, such as inflammation and immune activation that underlie the development of cardiometabolic conditions as well as conditions in other disease classes, such as Alzheimer's disease, multiple sclerosis and certain cancers.

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

In the current treatment paradigm, disease symptoms worsen and healthcare costs increase for the remainder of life



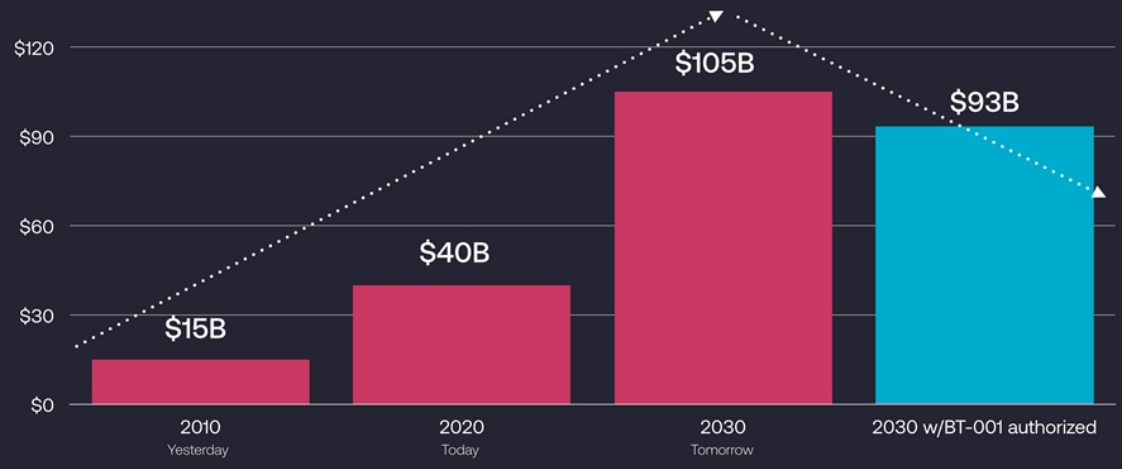
By treating the underlying causes of disease, we make a new paradigm possible; one in which disease progression stops and in many patients is reversed



In diabetes alone, there is over $40B of addressable drug spending on insured patients with uncontrolled diabetes

12M	×	73%	×	$4,500	=	$40B
Patients with uncontrolled diabetes and A1c 7-11%		Covered by Commercial Payers or Medicare Part D		Annual diabetes drug costs per patient		Immediate Addressable Market

Diabetes drug spending is expected to grow by 2.5x over the next 10 years, but our approach could begin to reduce the cost of treating diabetes and almost every other metabolic disease



Better+

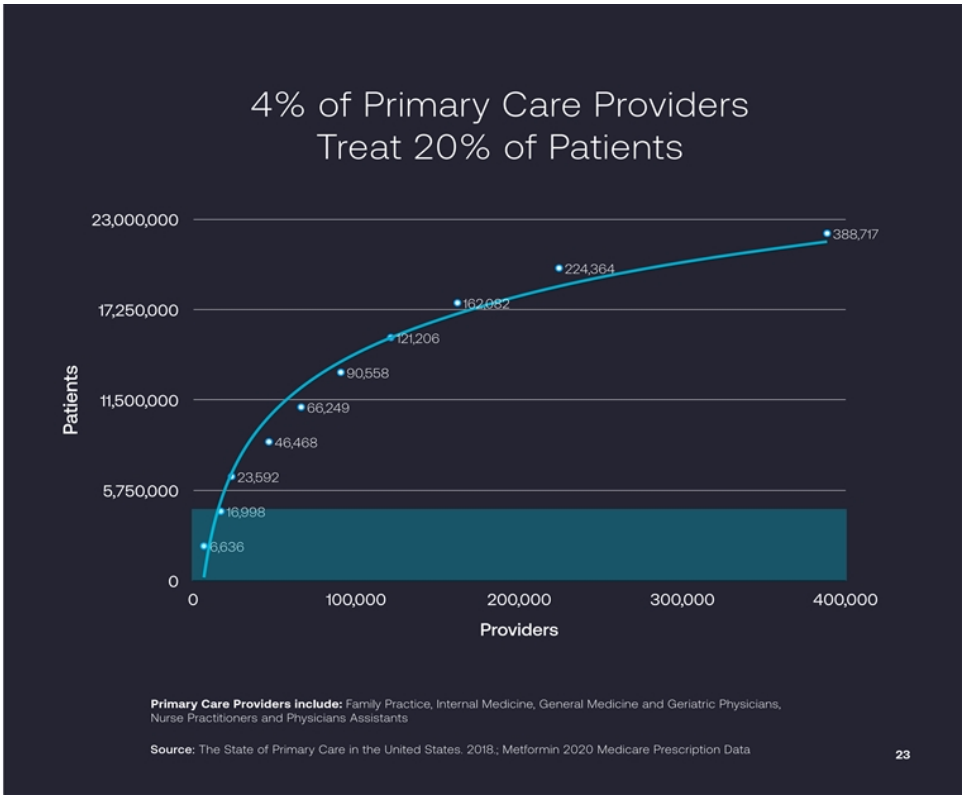
By choosing to seek FDA approval for our products, we seek to fit seamlessly within the existing healthcare system to enable adoption and scale, while only changing the form of therapy

Aligned with Existing Clinical Guidelines

- Physician examines patient
- Physician diagnoses patient
- Physician prescribes therapy
- Payer reimburses like a drug
- Patient remains in care of physician
- NEW — New Product Form requiring Patient + Provider Education

86% of type 2 diabetes patient care (pre insulin) is delivered by primary care providers.

A small portion of providers care for a disproportionate number of patients.



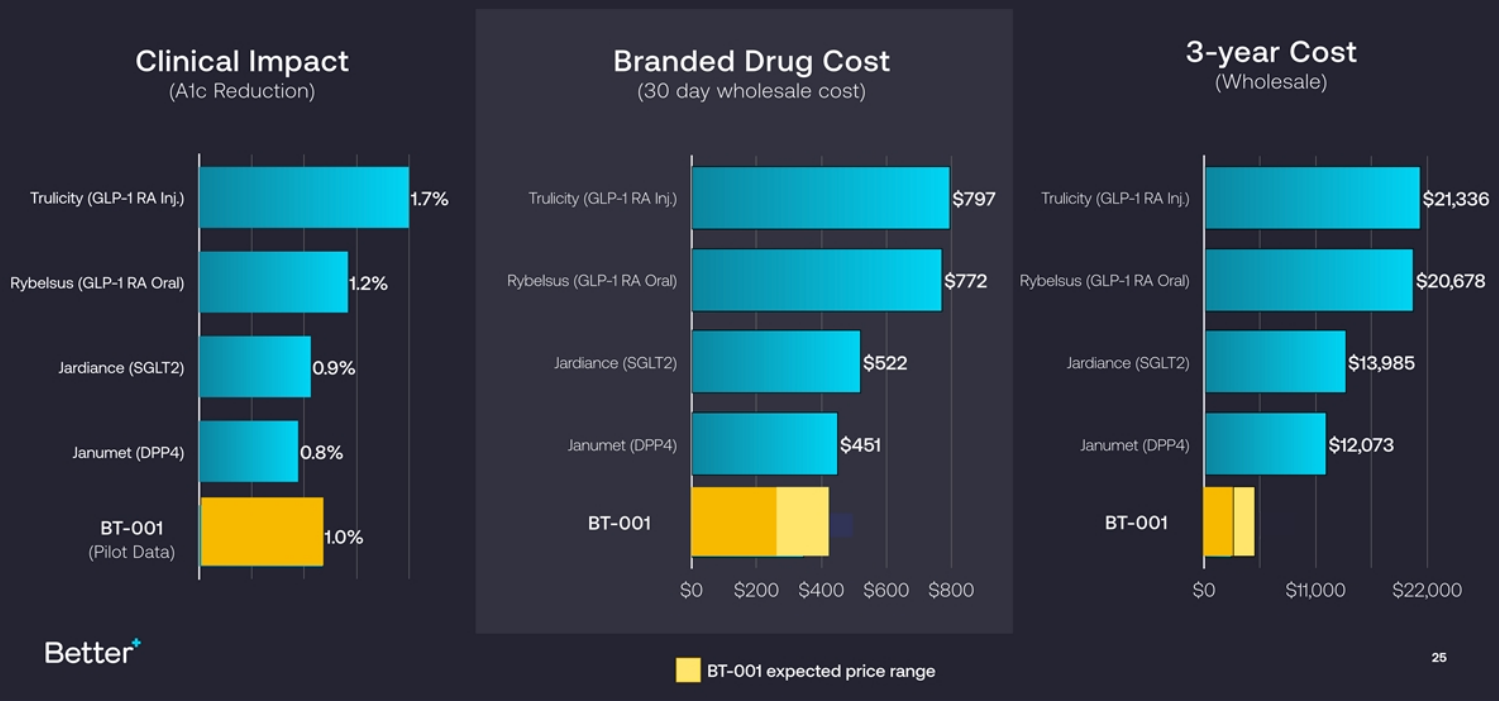
Better+

We plan to build a commercial capability to launch BT-001 and scale an emerging portfolio of digital therapeutics in primary care.

Commercial Team Composition

Role	Focus	Sizing at FDA Authorization	Annualized Cost
Engagement and Education	Health System formulary acceptance and digital first engagement and education for providers and patients	~20	$8M
Medical Liaisons	KOL engagement, real world study support, advocacy organization engagement	~3	$1M
Payer Executives	National and regional payer coverage, contracting and reimbursement support	~4	$3M
Technical Implementation Specialists	EHR integration support for e-prescribing and health system data exchange	~2	$1M
Patient Services Specialists	Patient focused, coordinated virtual support for information and reimbursement support	~7	$2M
	Total	**~40**	**~$15M**

BT-001 is expected to both improve patient outcomes and save payers money



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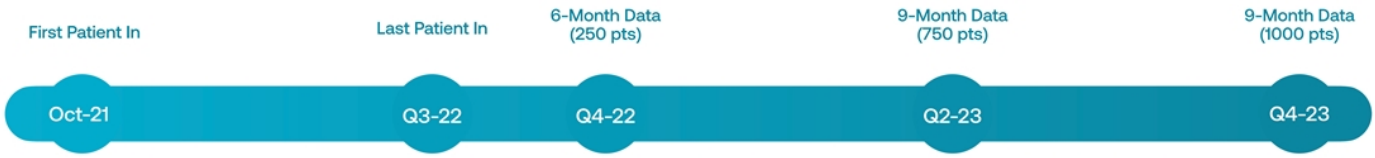
We have begun enrolling a 1,000 participant real-world evidence (RWE) study to understand BT-001 durability of effect and impact on total cost of care



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

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

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

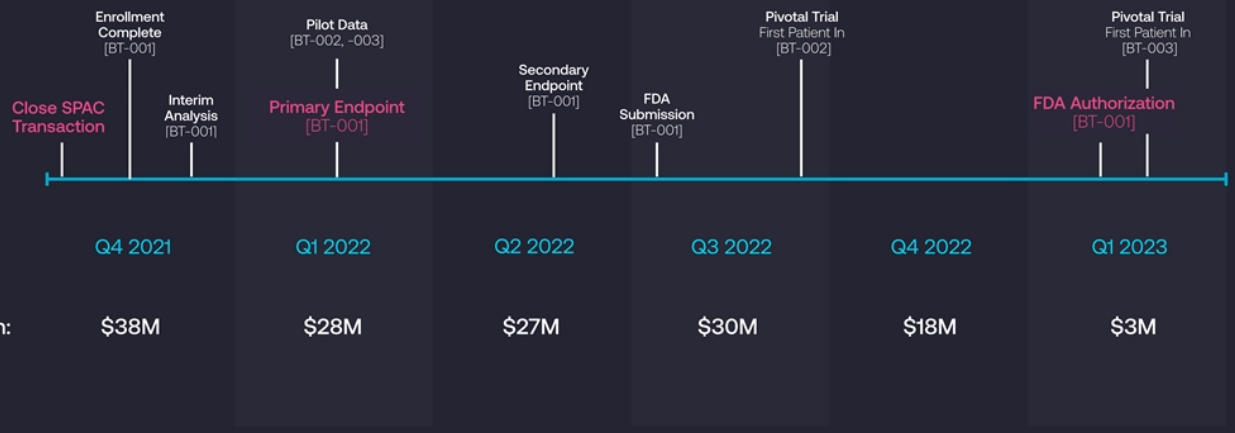
Primary Measures: Mean change in A1c after 6 and 12-months (mean change within participant or compared to control)

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

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

We have the opportunity to create a valuable company based on diabetes revenues alone

We expect multiple value creation milestones over the next 18 months



	Q4 2021	Q1 2022	Q2 2022	Q3 2022	Q4 2022	Q1 2023
Ending Cash:	$38M	$28M	$27M	$30M	$18M	$3M

Cash forecast assumes: Minimum/latest borrowings on the Hercules debt agreement ($5M in Q2 2022 and $10M)

Better