

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 10, 2023

Better Therapeutics, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

548 Market Street
#49404
San Francisco, California
(Address of Principal Executive Offices)

001-39864
(Commission File Number)

85-3472546
(IRS Employer
Identification No.)

94104
(Zip Code)

Registrant's Telephone Number, Including Area Code: 415 887-2311

(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	The Nasdaq Stock Market LLC

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 Events.

On July 10, 2023, Better Therapeutics, Inc. (the "Company") announced that the Food and Drug Administration authorized AspyreRx (formerly BT-001), a prescription-only digital therapeutic treatment indicated to provide cognitive behavioral therapy to patients 18 years or older with type 2 diabetes (T2D). A copy of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein.

On July 11, 2023, the Company used a corporate presentation 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) Exhibit.

Exhibit	Description
99.1	Press Release issued by Better Therapeutics, Inc., date June 10, 2023.
99.2	Corporate Presentation of Better Therapeutics, Inc., dated June 11, 2023.
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 hereunto duly authorized.

Better Therapeutics, Inc.

Date: 07/12/2023

By: /s/ Mark Heinen

Mark Heinen
Chief Financial Officer

Better Therapeutics Receives FDA Authorization for AspyreRx™ to Treat Adults with Type 2 Diabetes

First prescription digital behavioral therapeutic device delivering novel form of cognitive behavioral therapy via smartphone

In a randomized controlled trial AspyreRx demonstrated clinically meaningful and statistically significant durable reductions in A1c

Company to host conference call and webcast on July 11 at 8:30 a.m. ET

SAN FRANCISCO--(BUSINESS WIRE)--July 10, 2023-- Better Therapeutics, Inc. (NASDAQ: BTTX), a pioneer in developing software to treat cardiometabolic diseases, today announced that the Food and Drug Administration (FDA) authorized AspyreRx™ (formerly BT-001), a prescription-only digital therapeutic (PDT) treatment indicated to provide cognitive behavioral therapy to patients 18 years or older with type 2 diabetes (T2D). AspyreRx was reviewed through the FDA's De Novo pathway and its authorization creates a new class of diabetes digital behavioral therapeutic devices. AspyreRx is expected to launch commercially in Q4 2023.

"AspyreRx is a game-changer as we now have an evidence-based intervention to help clinicians and people living with type 2 diabetes address the underlying factors that contribute to disease progression and achieve treatment outcomes beyond glucose management alone," said David Kerr MBChB, DM, FRCP, FRCPE, Director of Digital Health at the Diabetes Technology Society. "The cornerstone of modern diabetes care is helping to improve self-efficacy and AspyreRx now provides a prescription tool for physicians that seamlessly integrates with existing disease management programs to help patients make and sustain meaningful changes to improve their overall health."

"This regulatory milestone signals a promising future where technology, psychology, and medicine converge to address for the first time the behavioral causes of disease for the 37 million patients living with T2D in the U.S.," said Frank Karbe, Chief Executive Officer at Better Therapeutics. "This De Novo authorization also provides a foundation for potential future growth opportunities. Given cardiometabolic diseases share common underlying factors that contribute to their development and progression, we intend to expand our PDT platform to multiple related conditions in the future."

AspyreRx was granted marketing authorization based on efficacy and safety data from a randomized controlled trial involving 668 participants, demonstrating clinically meaningful results, which were published in Diabetes Care.

Summary of Clinical Trial Results

- The trial met its primary ($p < 0.0001$) and secondary ($p = 0.01$) endpoints showing statistically significant decreases in HbA1c levels when compared to a control group receiving standard of care and a control app. The results were sustained and improved between day 90 and day 180 of the trial, demonstrating that BT-001 has the potential to deliver meaningful, durable reductions in blood sugar for a complex range of patients with T2D.
- 1 in 2 people achieved a mean A1c reduction of 1.3% after 180 days of use.
- On average, subjects who used BT-001 also experienced a host of cardiometabolic improvements including improved fasting blood glucose, reduced systolic blood pressure, reduced weight, improved mood, improved quality of life scores, lower medication utilization and fewer diabetes related risks compared to subjects who did not use BT-001.
- A clear dose-response between greater engagement in CBT and greater reductions in HbA1c was found, supporting CBT as a mechanism of action to generate positive clinical outcomes.
- Patient engagement and adherence was excellent with 94% of the participants using the intervention at day 90 and 81% still engaged at day 180.

The majority of patients with T2D progress in their disease, despite advances in pharmacotherapy. Treatment guidelines emphasize lifestyle behavior change as the cornerstone in the prevention and treatment of disease; however, given the constraints of delivering in-person therapy there has been limited advancement in helping patients make and sustain behavior change in a way that is standardized, convenient and scalable. AspyreRx is designed to address these barriers, leveraging technology to deliver an evidence-based therapeutic intervention to patients. The involvement of healthcare providers adds an important layer of expertise and oversight, ensuring seamless coordination between AspyreRx and other aspects of treatment.

“Our team has dedicated eight years to developing this treatment and we are grateful for the thousands of patients who have used our platform and for the many clinicians who have guided us to this point,” said Mark Berman, MD, Chief Medical Officer at Better Therapeutics. “We are immensely proud of this milestone and believe AspyreRx holds the promise to enhance access to care for the diversity of the patient population, empowering individuals to live healthier lives.”

Better Therapeutics Conference Call and Webcast

Better Therapeutics will hold a conference call on July 11 at 8:30 a.m. Eastern Time / 5:30 a.m. Pacific Time to discuss the FDA authorization of AspyreRx. Investors and the general public may access a live webcast of the call by visiting <https://edge.media-server.com/mmc/p/adggoags>

About Type 2 Diabetes

Type 2 diabetes (T2D) is a widespread chronic disease in the U.S. According to the Centers for Disease Control and Prevention (CDC), around 35 million people in the U.S. have T2D. About half of the T2D patients have uncontrolled blood sugars despite being on multiple medications. The prevalence of T2D has been steadily increasing over the years, primarily due to factors such as sedentary lifestyles, poor dietary habits, and an aging population. T2D disproportionately affects certain populations, particularly racial and ethnic minority groups, and those from lower socioeconomic backgrounds. Factors like limited access to healthcare, health disparities, cultural differences, and social determinants of health contribute to these disparities. Addressing health inequities, slowing down disease progression and preventing costly complications, without overuse of high-cost therapies, is a major unmet need in T2D.

About AspyreRx

AspyreRx (formerly BT-001) is Better Therapeutics' clinically validated prescription digital therapy for the treatment of T2D. Using proven techniques that target the underlying psychological, behavioral and cognitive factors that sustain or worsen T2D, AspyreRx is a self-paced, engaging experience that patients can access anytime/anywhere. It is prescribed by a healthcare provider in 90-day increments, with proprietary CBT delivered digitally in a weekly step-by-step process. Through interactive therapy lessons, skill-building modules, weekly goal setting and tracking, patients connect changes in behavior to improvements in blood sugar and other biometrics. Each step in the experience builds on the prior to enable and reinforce cognitive restructuring, building the emotional resilience and acceptance needed to make enduring changes. AspyreRx is backed by robust data demonstrating clinically meaningful and sustained reduction in HbA1c when used up to 180 days.

Indications for Use

BT-001 is a prescription-only digital therapeutic device intended to provide cognitive behavioral therapy to patients 18 years or older with type 2 diabetes. The device targets behavior to aid in the management of type 2 diabetes in patients who are under the care of a healthcare provider. BT-001 provides cognitive behavioral therapy as a treatment that should be used adjunctively with standard of care.

About Better Therapeutics

Better Therapeutics is a prescription digital therapeutics company developing a novel form of cognitive behavioral therapy to address underlying factors that sustain or worsen cardiometabolic diseases. The Company has developed a proprietary platform for the development of FDA-regulated, software-based solutions for T2D, 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 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 Better Therapeutics' plans and expectations regarding FDA submissions, plans related to the potential commercial launch of AspyreRx (formerly BT-001) for the treatment of T2D, expectations related to the efficacy and potential benefits of BT-001 and CBT and their potential treatment applications, the potential of AspyreRx to address barriers and enhance access to care, Better Therapeutics' plans regarding the research and advancement of its product candidates for additional treatments, expectations related to pricing research and results and the interest of healthcare providers and payers in PDTs, Better Therapeutics' plans regarding publications, and statements related to its long-term plans and expectations, among others. These forward-looking statements are based on the current expectations of the management of Better Therapeutics and are inherently subject to uncertainties and changes in circumstances and their potential effects and speak only as of the date of such statement. There can be no assurance that future developments will be those that have been anticipated. These forward-looking statements involve a number of risks, uncertainties or other assumptions that may cause actual results or performance to be materially different from those expressed or implied by these forward-looking statements including: risks related to Better Therapeutics' business, such as the willingness of the FDA to authorize PDTs, for commercial distribution and insurance companies to reimburse their use, market acceptance of PDTs, including AspyreRx, the risk that the results of previously conducted studies will not be interpreted favorably by the FDA or repeated or observed in ongoing or future studies involving Better Therapeutics' product candidates and other risks and uncertainties included under the header "Risk Factors" in Better Therapeutics' quarterly report on Form 10-Q for the quarter ended March 31, 2023 filed with the Securities and Exchange Commission (SEC) on May 11, 2023, and those that are included in any of Better Therapeutics' subsequent filings with the SEC.

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FDA Grants Authorization for AspyreRx™ *(Formerly BT-001)*

JULY 11, 2023

Better⁺
THERAPEUTICS



Introduction



Mark Heinen
Chief Financial Officer



Better Therapeutics Team



Frank Karbe
President &
Chief Executive Officer



Mark Heinen
Chief Financial Officer



Mark Berman, MD
Chief Medical Officer



Diane Gomez-Thinnes
Chief Commercial Officer



Kristin Wynholds
Chief Product Officer

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, 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, the Company's expectations about potential business development and royalty deals, expectations and assumptions regarding the addressable market, covered lives, market penetration, prescription numbers and fill rates for AspyreRx, expectations regarding peak revenue, the Company's expectations about the gap in its current enterprise value and its commercial opportunity and the prospects for any near-term return, 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 March 31, 2023 filed with the Securities and Exchange Commission ("SEC") on May 11, 2023, and those that are included in any of the Company's subsequent filings with the SEC.



Opening Remarks



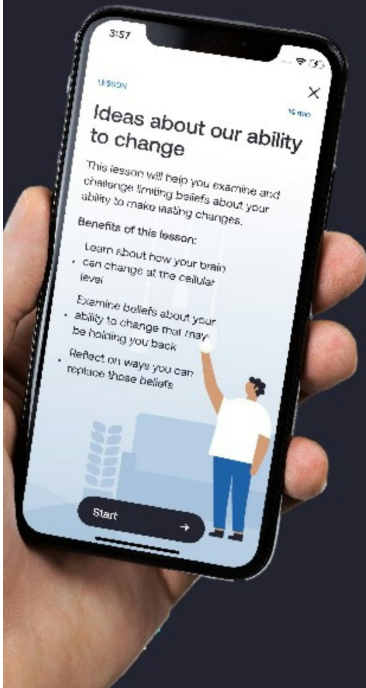
Frank Karbe
President & Chief Executive Officer



AspyreRx™ Now FDA Authorized in the U.S. for the Treatment of Type 2 Diabetes (T2D)

**AspyreRx (formerly BT-001) is the first behavioral therapy
Class 2 device for treatment of a cardiometabolic disease**

- A prescription-only digital therapeutic treatment to provide cognitive behavioral therapy (CBT) to adult patients with T2D
- Intended to be used alongside standard of care diabetes treatments



AspyreRx is differentiated from health and wellness apps in meaningful ways

	AspyreRx	Health & Wellness Applications
Clinically Validated via a Randomized Controlled Trial		
FDA Authorized as a Class 2 Medical Device		
Treatment Claim		
Prescribed by a Healthcare Provider		
Adheres to Strict Security and Data Privacy Regulations		

Type 2 Diabetes is a health crisis in the United States

~37 million

Adults in the US have Type 2 Diabetes^{1,2}

4 million

Adults in the US have uncontrolled T2D¹ despite being on standard of care medications^{1,2}

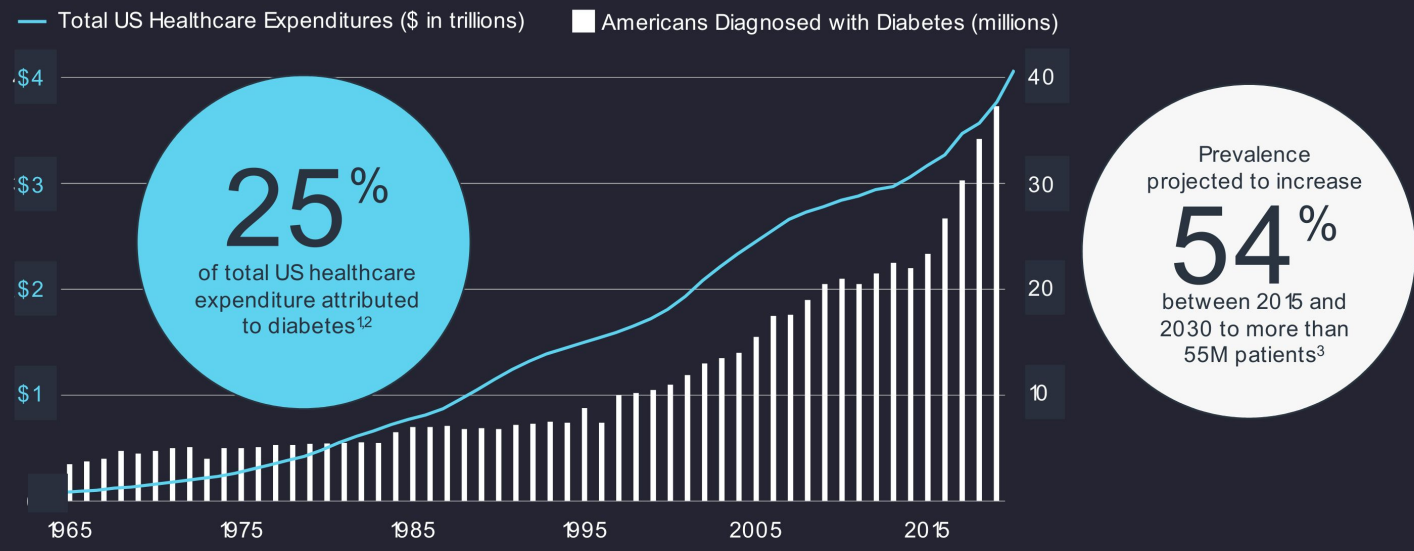
38%

of adults in the US have prediabetes¹

\$52 billion

in annual Rx drug spending alone¹

Diabetes is the most expensive chronic condition in the US and prevalence continues to rapidly increase^{1,2,3}



Better Sources: ¹ American Diabetes Association. Economic costs of diabetes in the US in 2017. Diabetes Care. 2018;41(5):917–928. ² Dieleman JL, Baral R, Birger M, et al. US spending on personal health care and public health, 1996–2013. JAMA. 2016;316(24):2627–2646. ³ Centers for Disease Control and Prevention ³ Rowley WR, Bezold C, Arkan Y, Byrne E, Krohe S. Diabetes 2030: Insights from Yesterday, Today, and Future Trends. Popul Health Manag. 2017 Feb;20(1):6–12. doi: 10.1089/pop.2016.0181 Epub 2016 Apr 28. PMID: 27124621 PMCID: PMC5278808.

FDA Authorization is a Significant Milestone



AspyreRx empowers patients to make & sustain behavior changes that are the cornerstone of diabetes management



Facilitates implementation of T2D treatment guidelines, lowers patient access hurdles



Newly established device classification provides foundation for future growth opportunities



Catalyst for royalty financing transaction and business development discussions



Review of Clinical Data



Mark Berman, MD
Chief Medical Officer

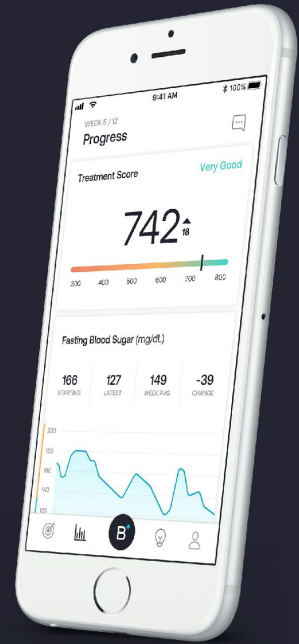


Overview of US Prescribing Information for AspyreRx

Indication for Use Statement

BT-001 is a prescription-only digital therapeutic device intended to provide cognitive behavioral therapy to patients 18 years or older with type 2 diabetes. The device targets behavior to aid in the management of type 2 diabetes in patients who are under the care of a healthcare provider. BT-001 provides cognitive behavioral therapy as a treatment that should be used adjunctively with standard of care.¹

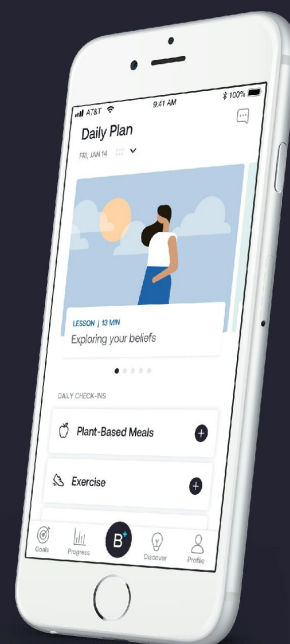
¹Limitations: The device is not intended for use as a stand-alone therapy. The device is not a substitute for a patient's prescribed therapy or medication. The device should not be used by people with unstable psychiatric disorders. The device is not intended for use in the treatment of any psychiatric disorder or symptoms.



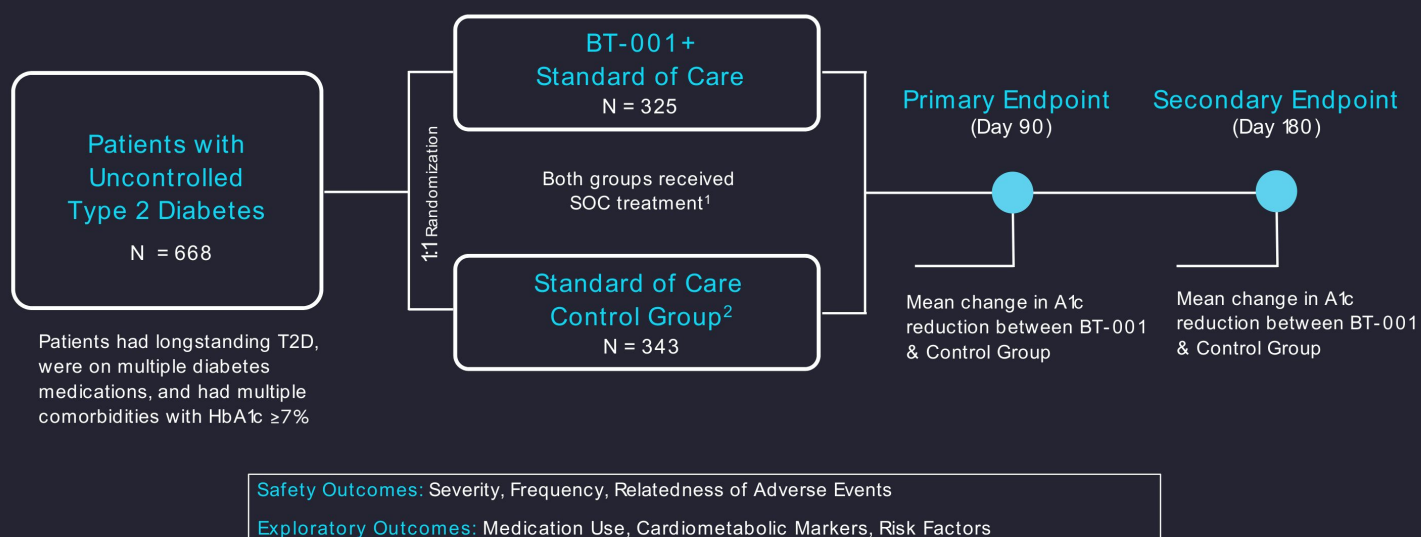
Overview of US Prescribing Information for AspyreRx

Usage Statement

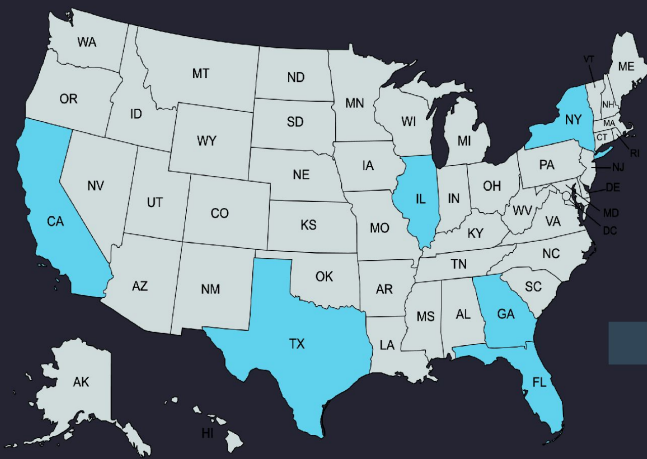
- Compared to standard of care treatment alone, consistent use for 90 days has been shown, on average, to result in more improvements in glycemic control, fewer diabetes-related risks to the patient, and more durable results, with benefits shown to persist up to 6 months with continued use of the device.
- Patients are instructed to complete weekly lessons as directed by the product, and to complete a minimum of 10 lessons during the 90 day treatment period to achieve the best results with BT-001.
- Concurrent to usage, standard of care HbA1c monitoring should be conducted to determine appropriate antihyperglycemic medication type and dosage.



The BT-001 pivotal study was a randomized, controlled, open-label clinical trial designed to evaluate safety and effectiveness after two 90-day treatments for T2D



Broad eligibility criteria and decentralized recruitment were used to ensure a nationally representative, diverse population derived from 6 US states



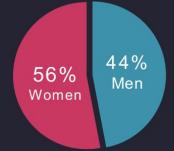
Baseline characteristics included a robust representation of different races and ethnicities, as well diversity in socioeconomic status and levels of education

Zip Codes
Represented

588

~ 40%

Non-White
~30% Black
~17% Latinx



Without College
Degree

~ 40%

98%

Lived in low-income
or medium-income
neighborhoods

Median Household
Income

~ \$68K

The BT-001 Pivotal Study was designed to test BT-001 in a real-world, difficult-to-treat population. The trial set a high bar to demonstrate efficacy by increasing the likelihood the Control group would receive more medications.

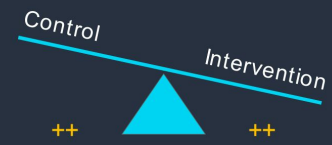
Key attributes allowing for imbalance of medication use:

- Mandated, open-label A1c review at Day 90 and Day 180
- Mandate to adjust medications per standard of care guidelines
- Poorly controlled T2D at baseline

Key attributes favoring real-world conditions:

- Robust background therapy allowed
- Patients with multiple comorbidities and advanced disease included
- No mandate to use BT-001

No Glycemic Equipose



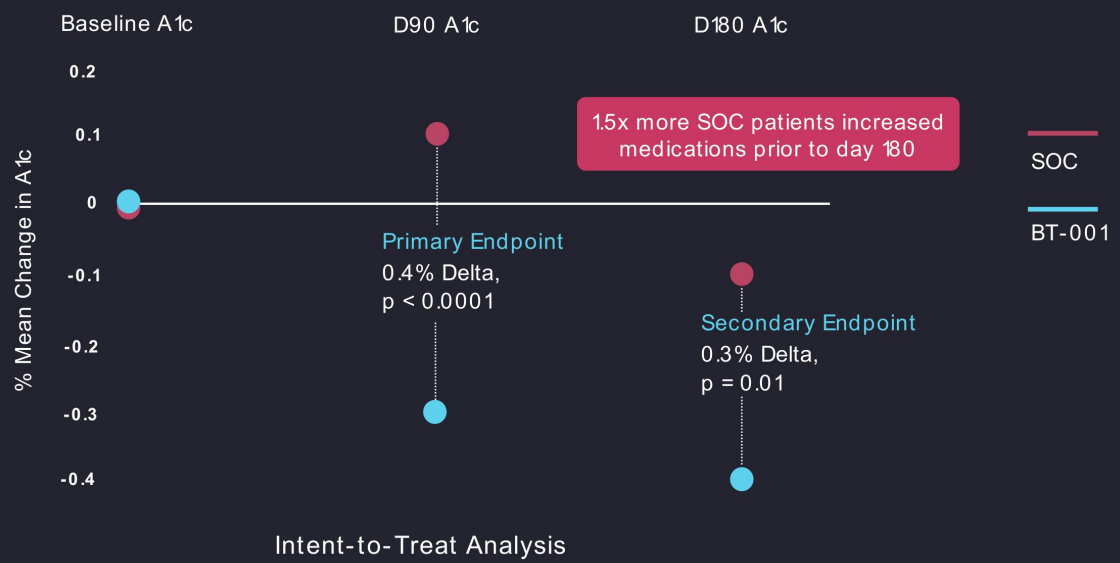
Medications (+): Fixed throughout study

Glycemic Equipose



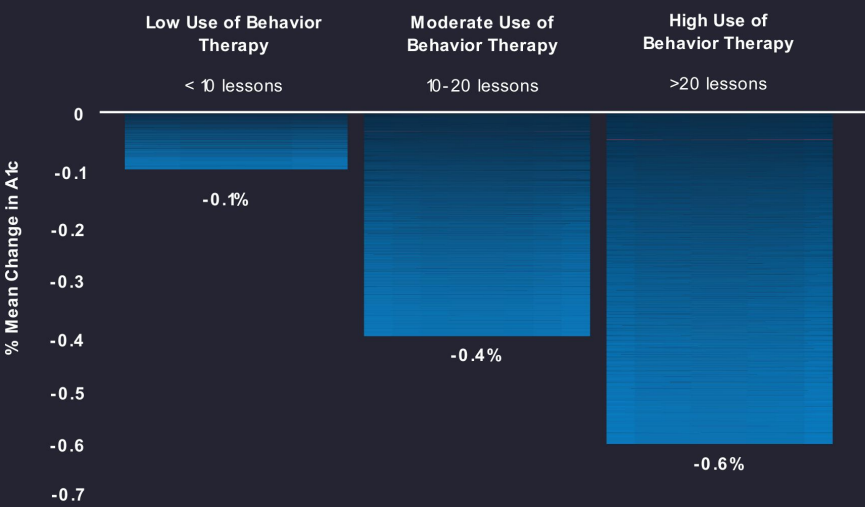
Medications (+): Not fixed, therefore control can respond to higher A1c by increasing meds

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



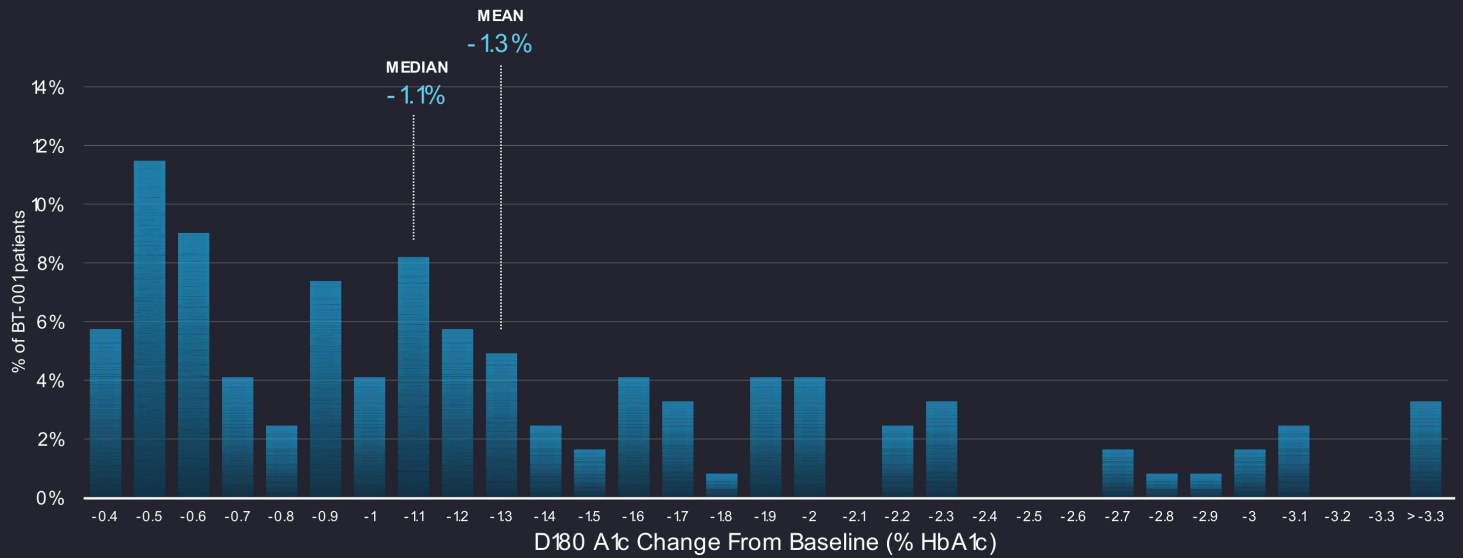
Patients who used BT-001 more had greater reduction in A1c

Higher dose of CBT lessons completed associated with larger A1c improvements at 180 days



BT-001 Meaningful Responders saw a mean decrease of -1.3% HbA1c over 180 days

"Meaningful Responders" defined as 0.4% or more A1c improvement and accounted for 50.4% of the BT-001 group



Statistically significant fewer total adverse events (AEs) and serious AEs occurred in BT-001 patients¹

Summary of AEs at 180 Days	BT-001 (n=325)	Control (n=343)	
Any treatment-emergent AE, n (%)	135 (41.5)	188 (54.8)	P<0.001
Treatment-emergent AE possibly/probably related to study intervention, n (%)	3 (0.9)	0 (0)	
Serious treatment-emergent AE, n (%)	9 (2.8)	24 (7.0)	P=0.01
SAE possibly related to diabetes/cardiometabolic health, n (%)	5 (1.5)	14 (4.1)	
Cardiovascular	2 (0.6)	6 (1.7)	
Respiratory	1 (0.3)	2 (0.6)	
Infectious	2 (0.6)	6 (1.7)	

Note: No adverse device effects were reported by either group.

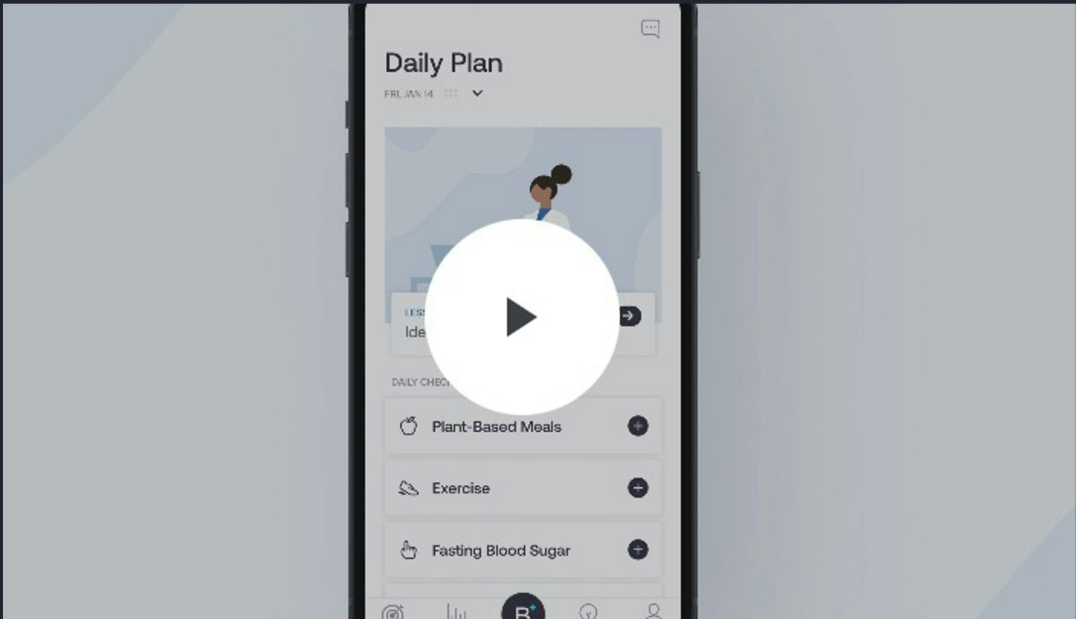


Commercial Update



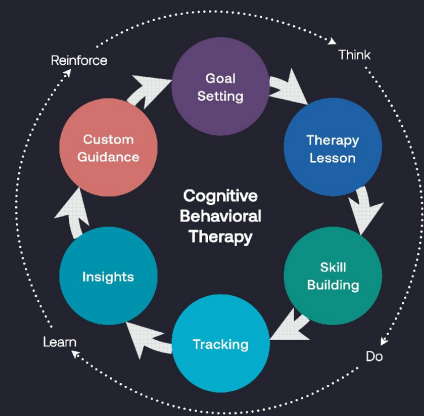
Diane Gomez-Thinnes
Chief Commercial Officer





Only AspyreRx delivers CBT to treat patients with T2D by targeting the underlying behaviors that contribute to disease progression in a proven, convenient, engaging digital app

MECHANISM OF ACTION



CONVENIENT & ENGAGING

81%
Patients using the app at 180 days

61
NPS Score at 180 Days



EVIDENCE BASED

30%
Patients achieve 1% or more A1c reduction

1.3%
Mean A1c reduction for meaningful responders¹

- Fewer diabetes medications
- Reduced systolic blood pressure
- Reduced weight
- Improved mood
- Improved quality of life

Initial target population includes uncontrolled patients across the disease continuum

Type 2 Diabetes Typical Disease Progression



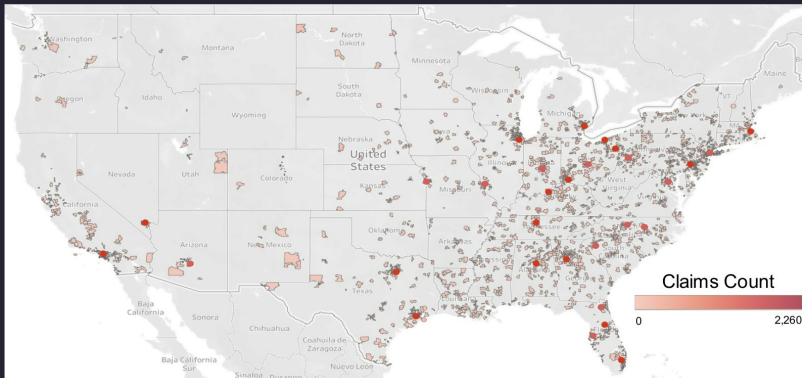
★ Newly Diagnosed or Change / Escalation in Treatment

- Initial focus will be the uncontrolled population
 - Payers and Providers consider this population the most urgent to address
 - Patients with advanced uncontrolled T2D represents the mean patient population studied in the pivotal trial
- Research indicates the most motivated patients are those who are newly diagnosed or about to step up to insulin

Initial Targeted Approach to Commercial Launch

Sequenced Geography by Geography Build

- Custom teams for unique geographical needs
- Virtual resources for flexibility
- Will execute on this strategy with ~50 FTEs



TEAM
Better⁺
THERAPEUTICS

FOCUS ON COVERAGE

Payer Leads,
MSLs



Payers

FOCUS ON PRESCRIBER DEMAND

Key Accounts,
Sales, MSLs

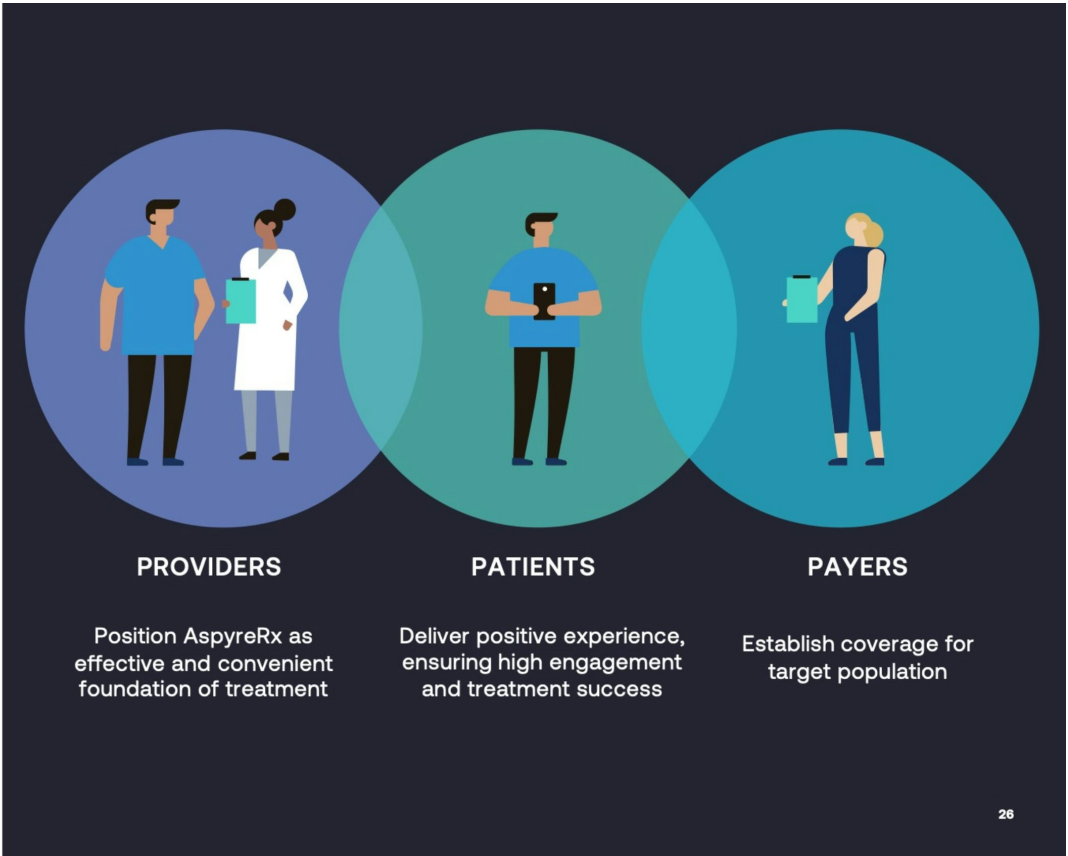


Health Systems



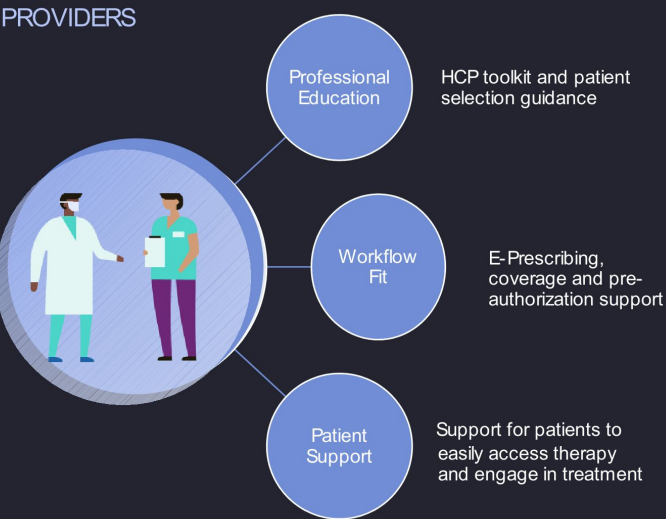
Targeted
Physicians

Successful commercialization requires that we educate all stakeholders on the benefits of this new digital treatment option

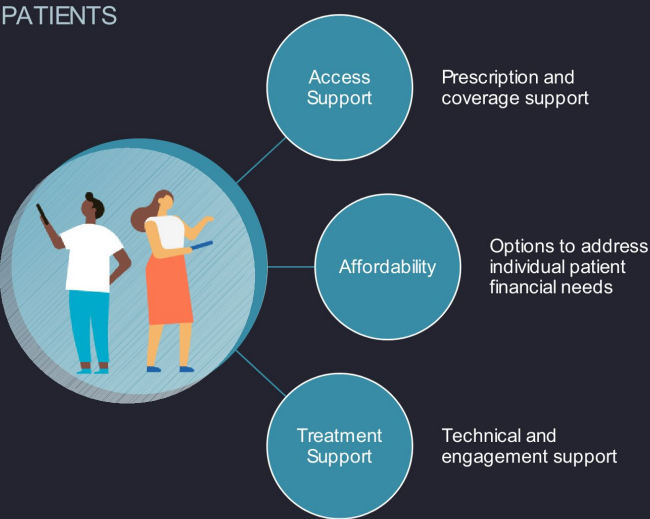


Committed to a positive experience for both health care providers and patients

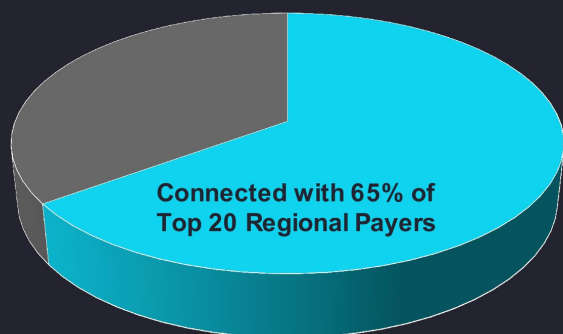
PROVIDERS



PATIENTS



As awareness of PDTs grows, we are making progress with our strategy to target regionally dominant payers



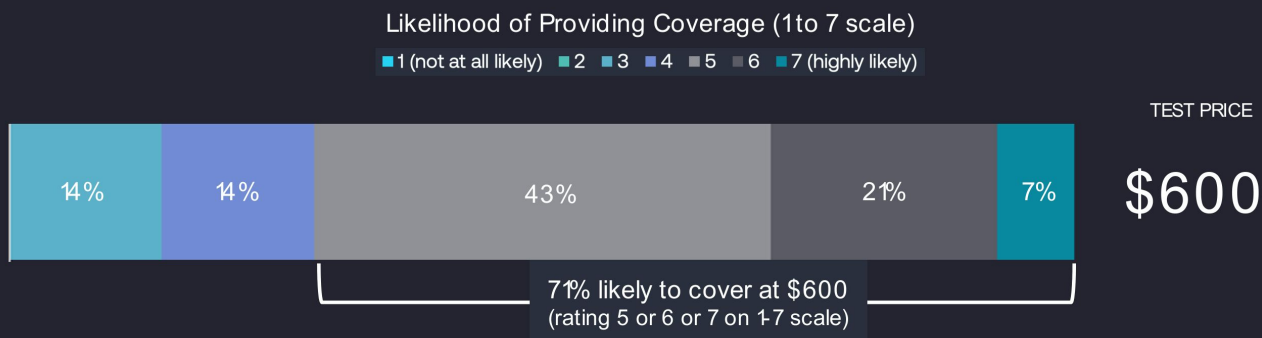
>40 Engagements with Payers, PBMs, Payer / Providers*

Payer Feedback

- Growing awareness of Prescription Digital Therapeutics (PDTs)
- Differentiating PDT vs non-regulated digital therapeutics and wellness apps
- Defining pathways and processes for reviewing PDT
- Reintroduction of the Access to Prescription Digital Therapeutics Act of 2023 signals need for payers to educate their teams and set up processes to review PDTs

Early pricing research suggests price range \$500-\$800 net for one 90-day prescription

Pricing research conducted prior to final pivotal trial results– new pricing study currently underway



Focused Commercial Strategy to Gain Early Traction

- Targeting Top 20 Regionally Dominant Payers
- Phasing launch into 5-6 initial geographies
- Anticipating market release in Q4
- Payer contract negotiations begin immediately
- Launch metrics shared during Q2 Earnings Call



Closing Comments



Frank Karbe
President & Chief Executive Officer



Progress towards resolving our 3 key risks

1

Regulatory



2

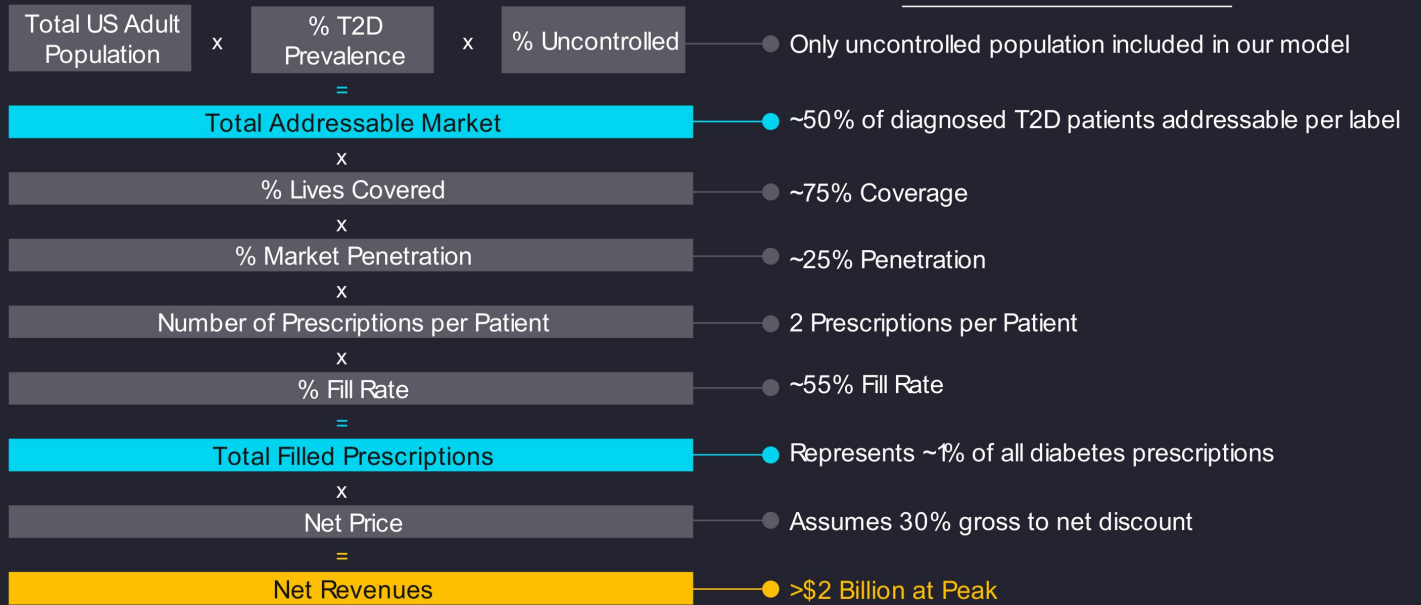
Commercial / Launch Execution

3

Financing

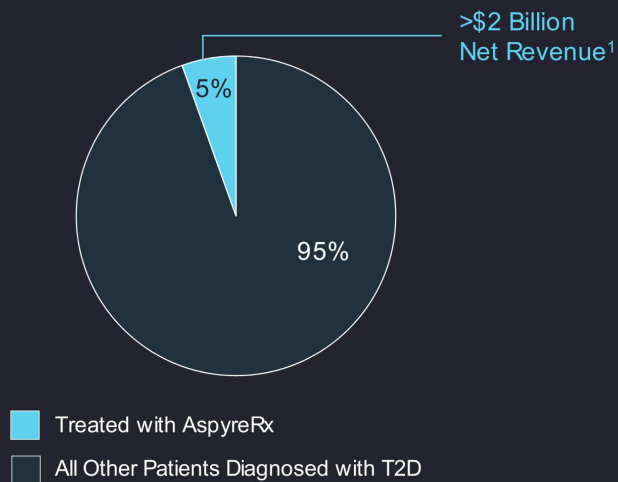
AspyreRx has substantial potential in T2D alone

ASSUMPTIONS AT PEAK



Substantial potential achievable with only 5% utilization

AspyreRx Peak Utilization in US Patients Diagnosed with T2D



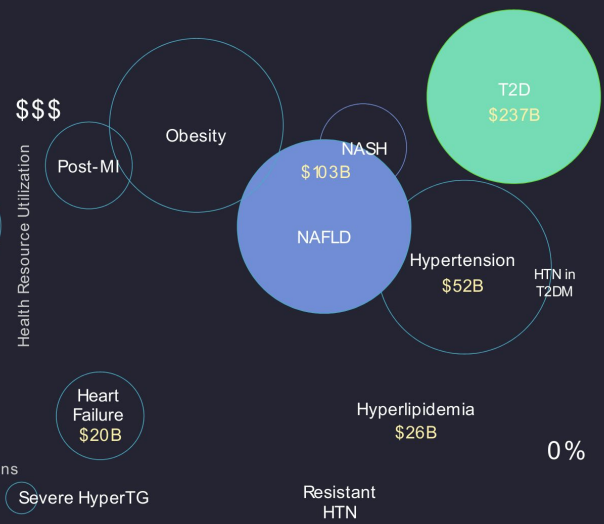
- Projected peak revenue achievable with 5% share of all patients diagnosed with T2D or 11% share of uncontrolled T2D patients
- Additional revenue upside potential:
 - + Larger T2D market share
 - + International expansion
 - + Additional indications

FUTURE INDICATIONS

With moderate platform modifications, we can pursue a broad range of potential indications that may offer significant upside

25%

Degree of Platform Modifications



0%

\$

\$ figures in select bubbles represent annual direct US healthcare expenditures



Prevalence > 20%



Prevalence < 20%



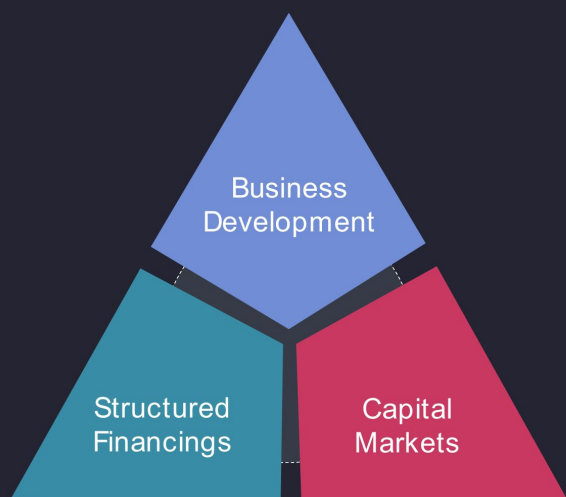
Prevalence < 2%

Proof-of-concept established

Better⁺

Sources: ¹ CDC; ² Younossi, Z.M. (2016) The economic and clinical burden of nonalcoholic fatty liver disease in the United States and Europe. *Hepatology*. 64: 1577-1586. <https://doi.org/10.1002/hep.28785> 2016;64(5):1577-86. ³ Tsao, C.W. (2023) Heart Disease and Stroke Statistics—2023 Update: A Report From the American Heart Association. *Circulation*. 147:e93-e621. <https://doi.org/10.1161/CIR.0000000000001123>

Financing Strategy



- Disciplined management of dilution
- Address majority of financing overhang through non-share dilutive options
- Optimistic in ability to meet critical milestones
- Highly cost-efficient operating model

We envision AspyreRx becoming part of the standard of care for adults with T2D

- Significant & growing unmet medical need
- In-line with existing treatment guidelines
- Valuable at any stage in T2D disease progression
- Broadly accessible to anyone with a smartphone
- Potential cost savings for payers & health systems

Questions & Answers



Frank Karbe

President &
Chief Executive Officer



Mark Heinen

Chief Financial Officer



Mark Berman, MD

Chief Medical Officer



Diane Gomez-Thinnes

Chief Commercial Officer



Kristin Wynholds

Chief Product Officer

Better⁺