

# Introduction



Mark Heinen **Chief Financial Officer** 

# **Better Therapeutics Team**



#### Frank Karbe

President & Chief Executive Officer

#### Mark Heinen

Mark Berman, MD

Chief Financial Officer

Chief Medical Officer





**Diane Gomez-Thinnes** 

Chief Commercial Officer

#### Kristin Wynholds

**Chief Product Officer** 



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# **Opening Remarks**

President & Chief Executive Officer

LESSON X Ideas about our ability 14 min 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 Examine beliefs about your ability to change that may be holding you back Reflect on ways you can replace those beliefs 7 Start

# AspyreRx<sup>TM</sup> Now FDA Authorized in the U.S. for the Treatment of Type 2 Diabetes (T2D)

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





# AspyreRx is differentiated from health and wellness apps in meaningful ways

Clinically Validated via a Randomized Controlled Trial

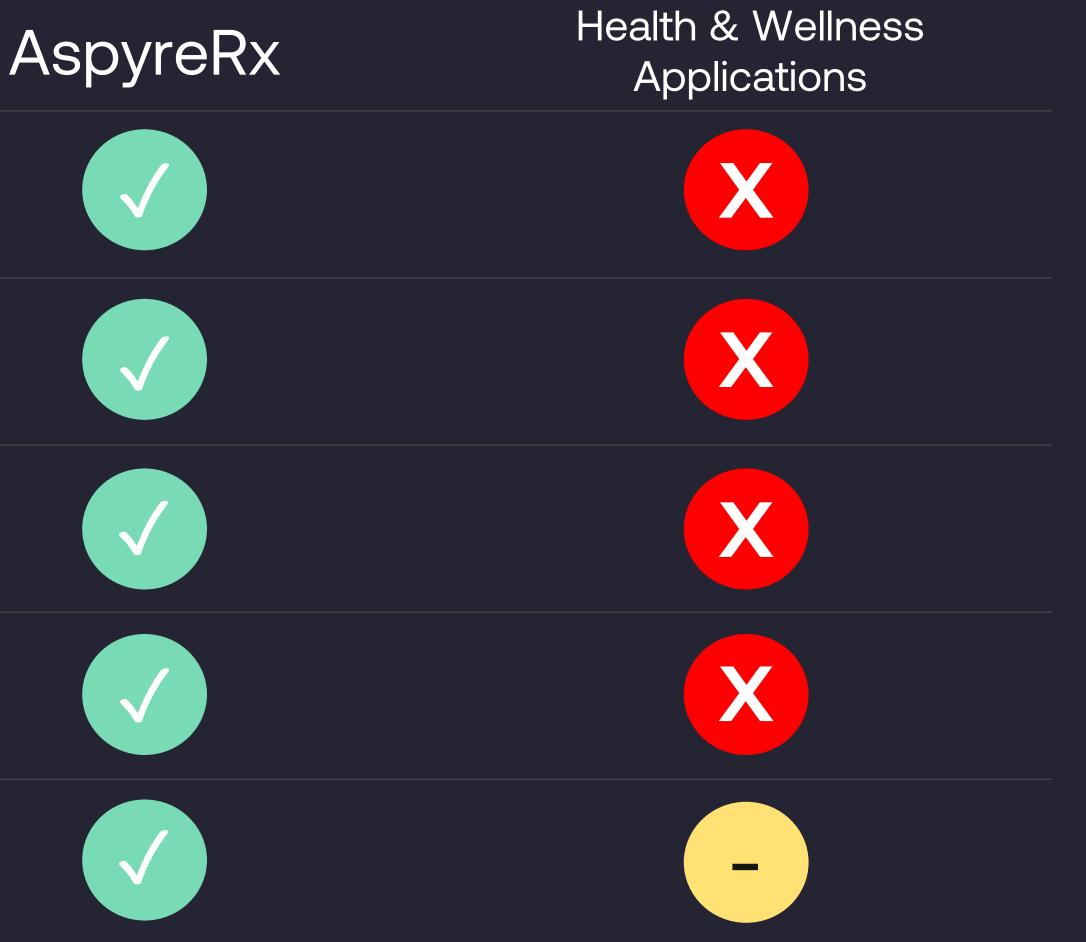
FDA Authorized as a Class 2 Medical Device

**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



million Adults in the US have uncontrolled T2D<sup>1</sup> despite being on standard of care medications<sup>1,2</sup>





Sources: 1. Centers for Disease Control and Prevention National Diabetes Statistics Report 2. US Census Population Projections (2023) Note: The ~37M adults with T2D cited above includes both diagnosed and undiagnosed patients

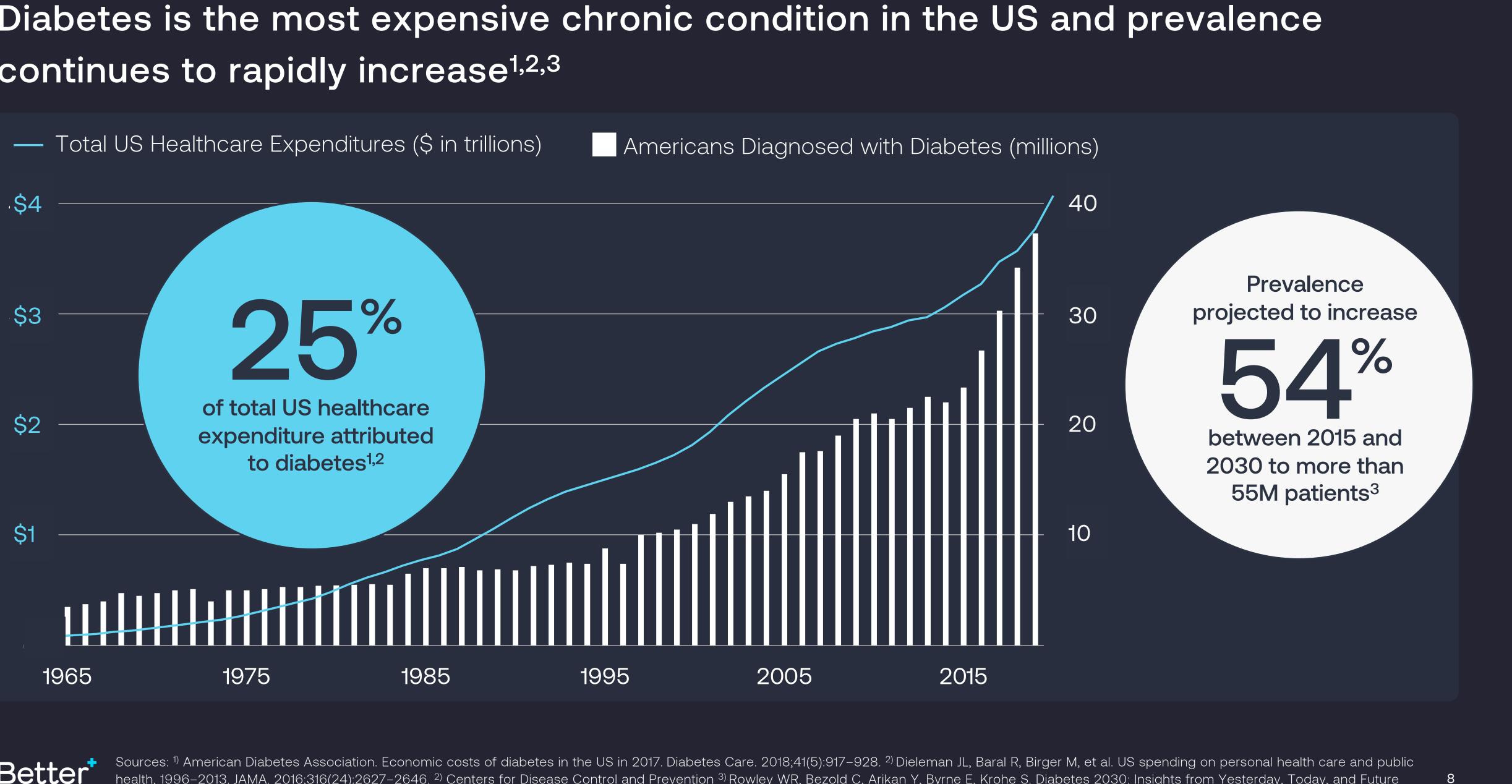


of adults in the US have prediabetes<sup>1</sup>

in annual Rx drug spending alone<sup>1</sup>



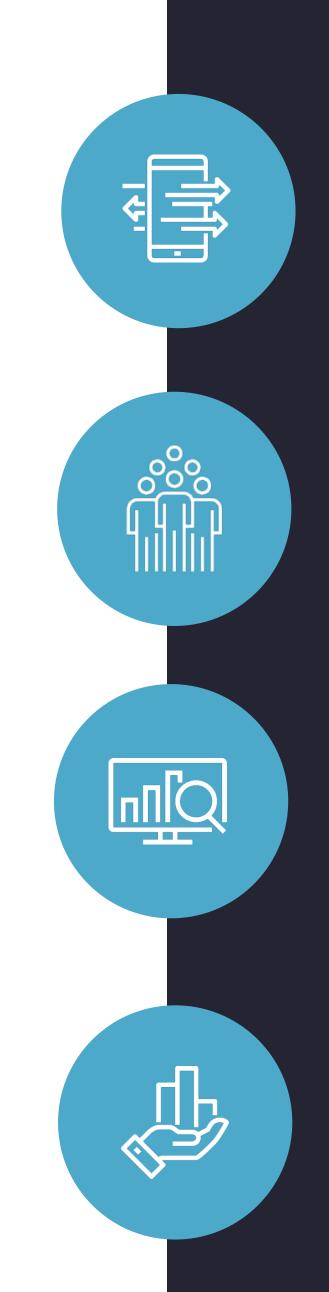
# Diabetes is the most expensive chronic condition in the US and prevalence continues to rapidly increase<sup>1,2,3</sup>





health, 1996–2013. JAMA. 2016;316(24):2627–2646.<sup>2)</sup> Centers for Disease Control and Prevention <sup>3)</sup> Rowley WR, Bezold C, Arikan 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.2015.0181. 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











Mark Berman, MD Chief Medical Officer

# **Review of Clinical Data**

# **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.<sup>1</sup>

<sup>1</sup>Limitations: 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.



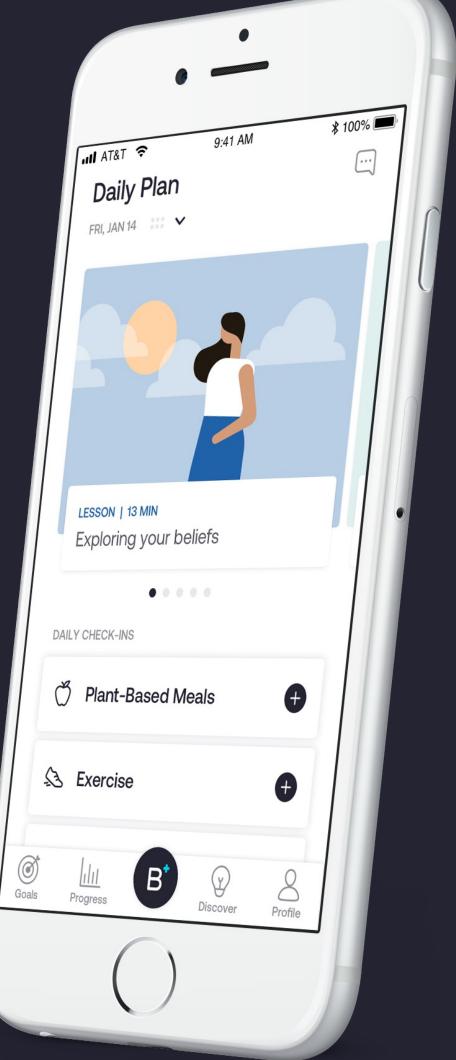
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	42₽	Very Good	U
300 400 500 Fasting Blood Sugar ( 166 127 STARTING LATEST	(mg/dL) <b>149</b>	-39 HANGE	
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# Overview of US Prescribing Information for AspyreRx Usage Statement

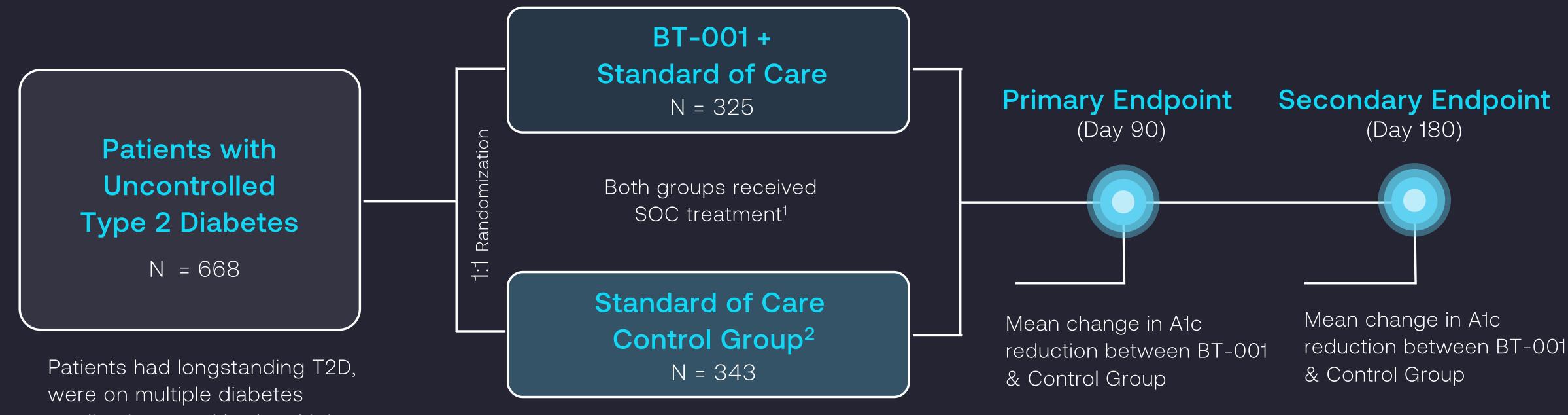
- Compared to standard of care treatment alone, consistent use for 90 days has been shown, on average, to result in more improvements in glycemic control, fewer diabetes-related risks to the patient, and more durable results, with benefits shown to persist up to 6 months with continued use of the device.
- 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.





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# 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



medications, and had multiple comorbidities with HbA1c  $\geq$ 7%

**Safety Outcomes:** Severity, Frequency, Relatedness of Adverse Events

**Exploratory Outcomes:** Medication Use, Cardiometabolic Markers, Risk Factors



Notes: <sup>1</sup>SOC treatment was adjusted as needed at the discretion of the subject's primary care provider or the study investigator. Site investigators were instructed to use their discretion but were given a SOC Guideline Summary to guide medication changes.<sup>2</sup> Control app was downloaded and accessed on the subject's device similar to BT-00-1 but contained no CBT content. Control app prompted subjects to complete the Heath Status Form, SF-12, and PHQ-9 assessments on the same schedule as BT-001. Terms: SOC – Standard of Care



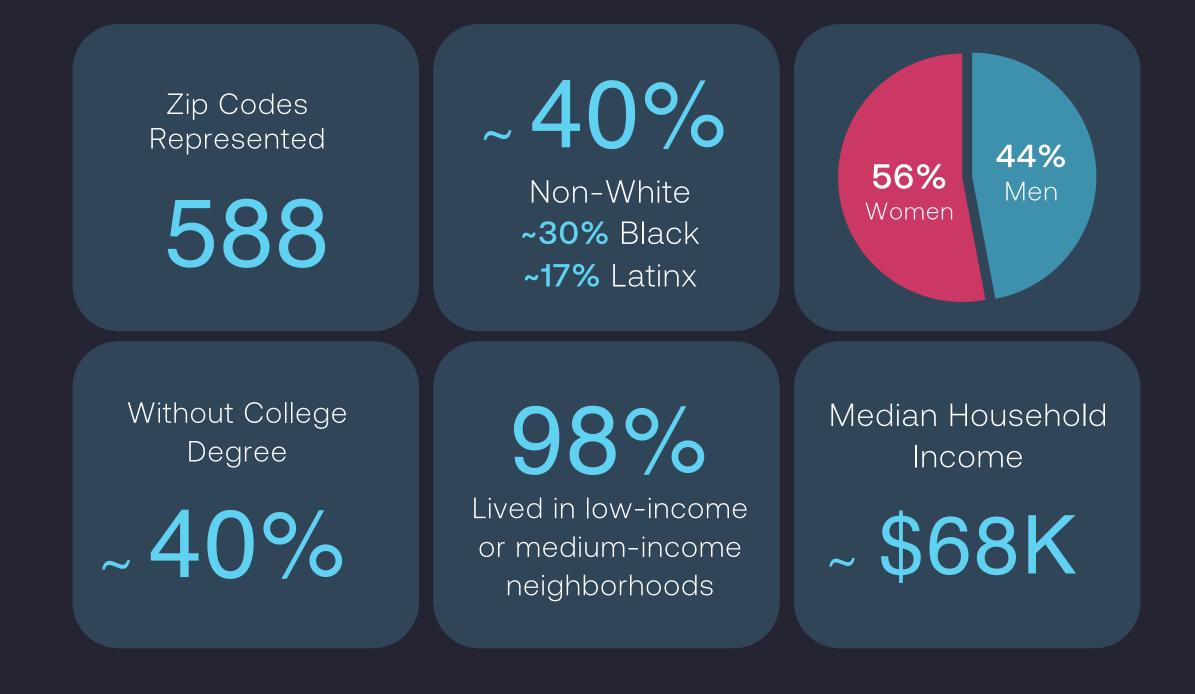
# Broad eligibility criteria and decentralized recruitment were used to ensure a nationally representative, diverse population derived from 6 US states





ME RI NJ E D C

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





### 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

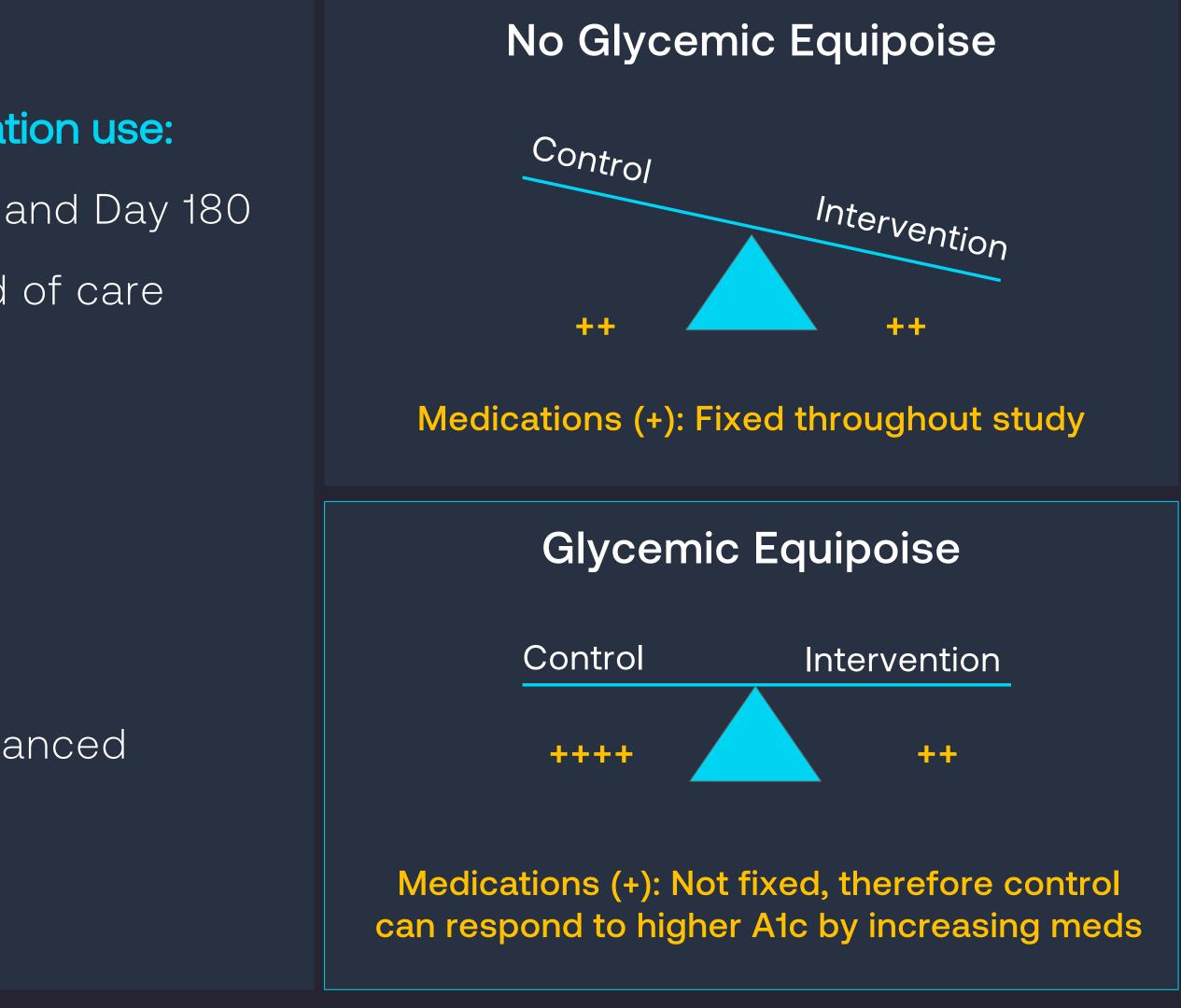
#### Key attributes allowing for imbalance of medication use:

- 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

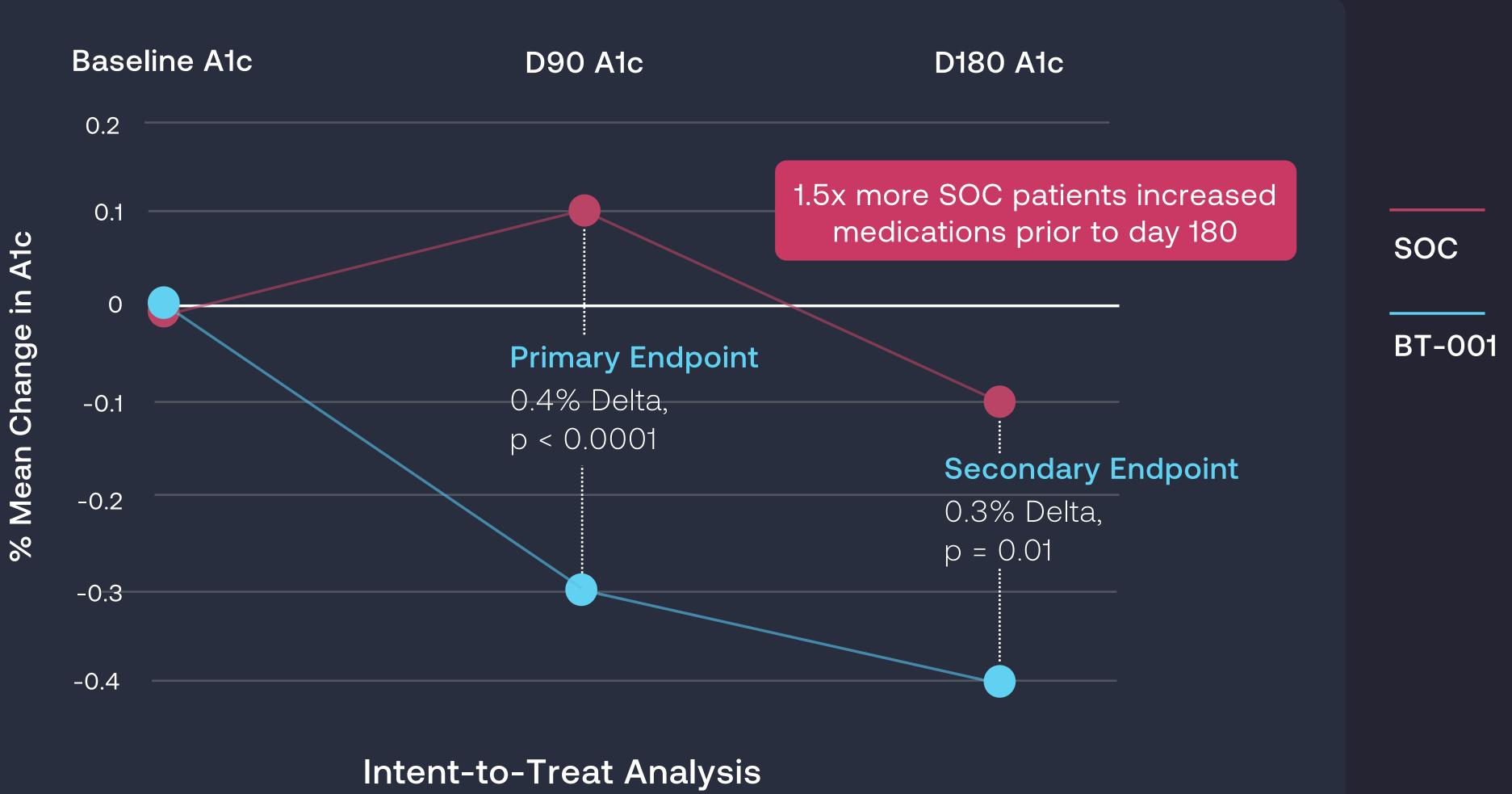








## BT-001 reduced A1c despite on-study addition of more diabetes medication in the Standard of Care control group

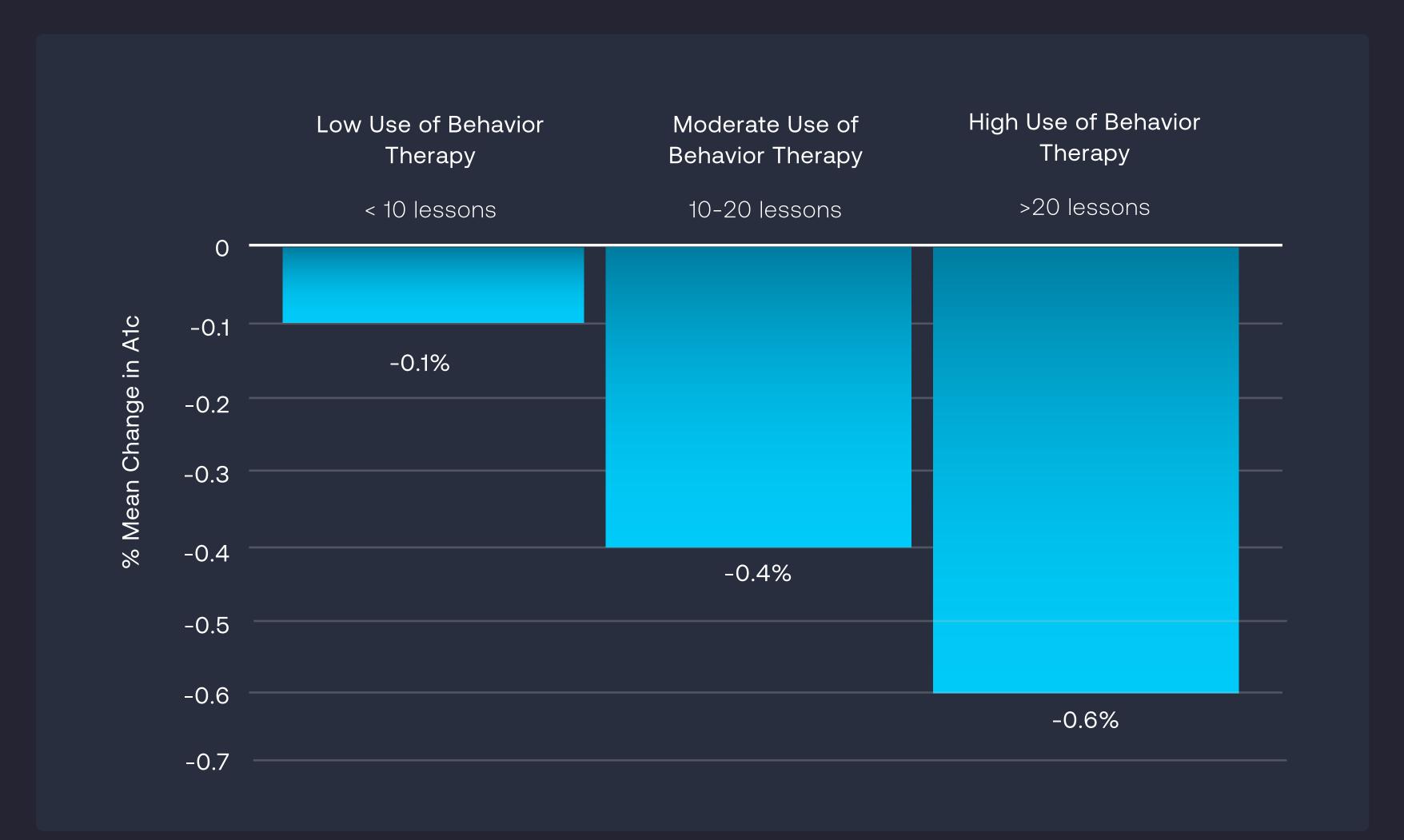






## Patients who used BT-001 more had greater reduction in A1c

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

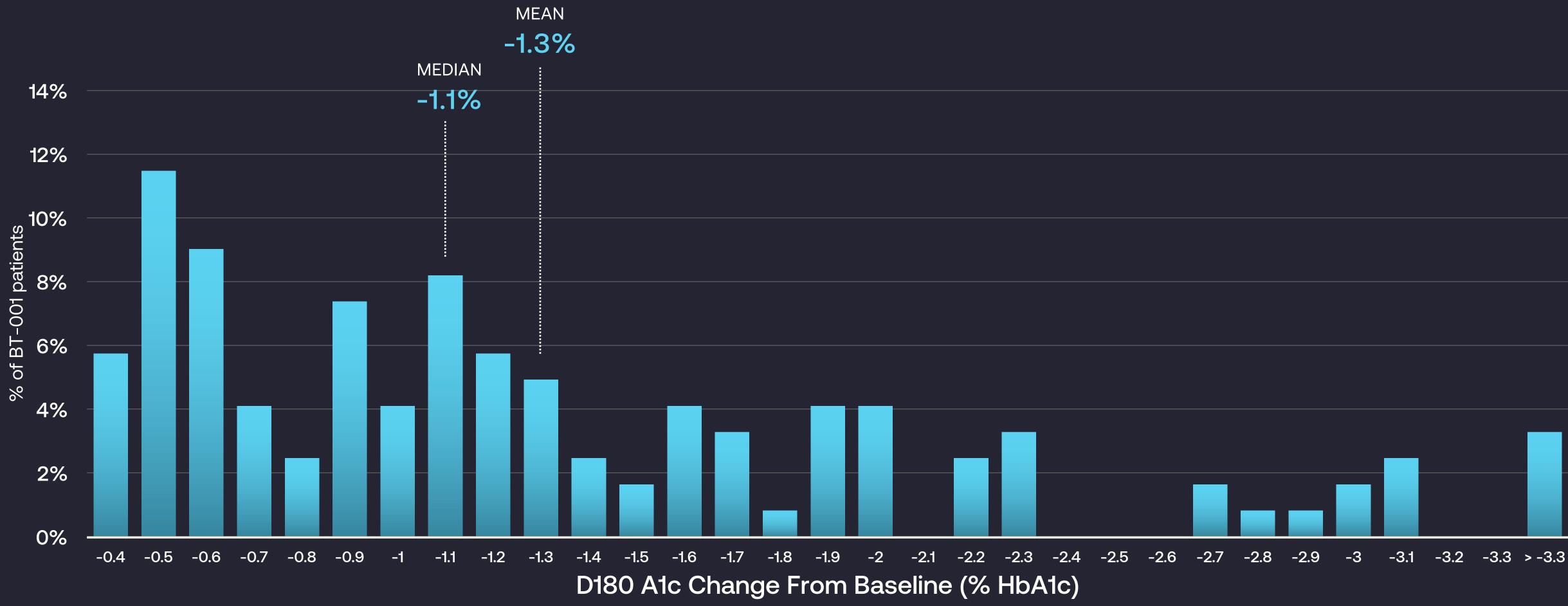






## BT-001 Meaningful Responders saw a mean decrease of -1.3% HbA1C over 180 days

"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 patients<sup>1</sup>

#### Summary of AEs at 180 Days

- Any treatment-emergent AE, n (%)
- Treatment-emergent AE possibly/probably related to study interve
- Serious treatment-emergent AE, n (%)
- SAE possibly related to diabetes/cardiometabolic health, n (%)
  - Cardiovascular
  - Respiratory
  - Infectious

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



	BT-001 (n=325)	Control (n=343)	
	135 (41.5)	188 (54.8)	P<0.001
ention, n (%)	3 (0.9)	0 (0)	
	9 (2.8)	24 (7.0)	P=0.01
	5 (1.5)	14 (4.1)	
	2 (0.6)	6 (1.7)	
	1 (0.3)	2 (0.6)	
	2 (0.6)	6 (1.7)	





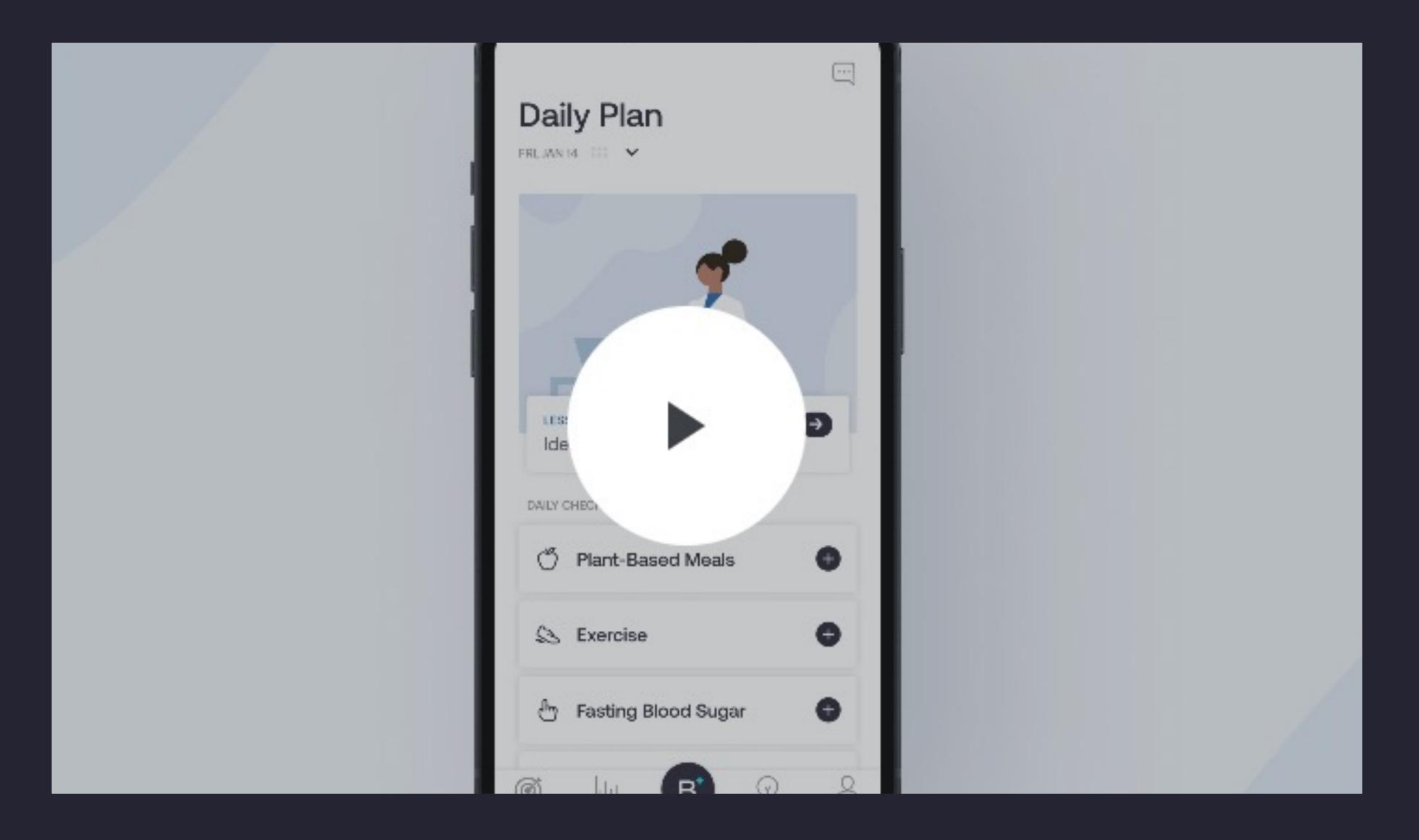


# **Commercial Update**

### **Diane Gomez-Thinnes**

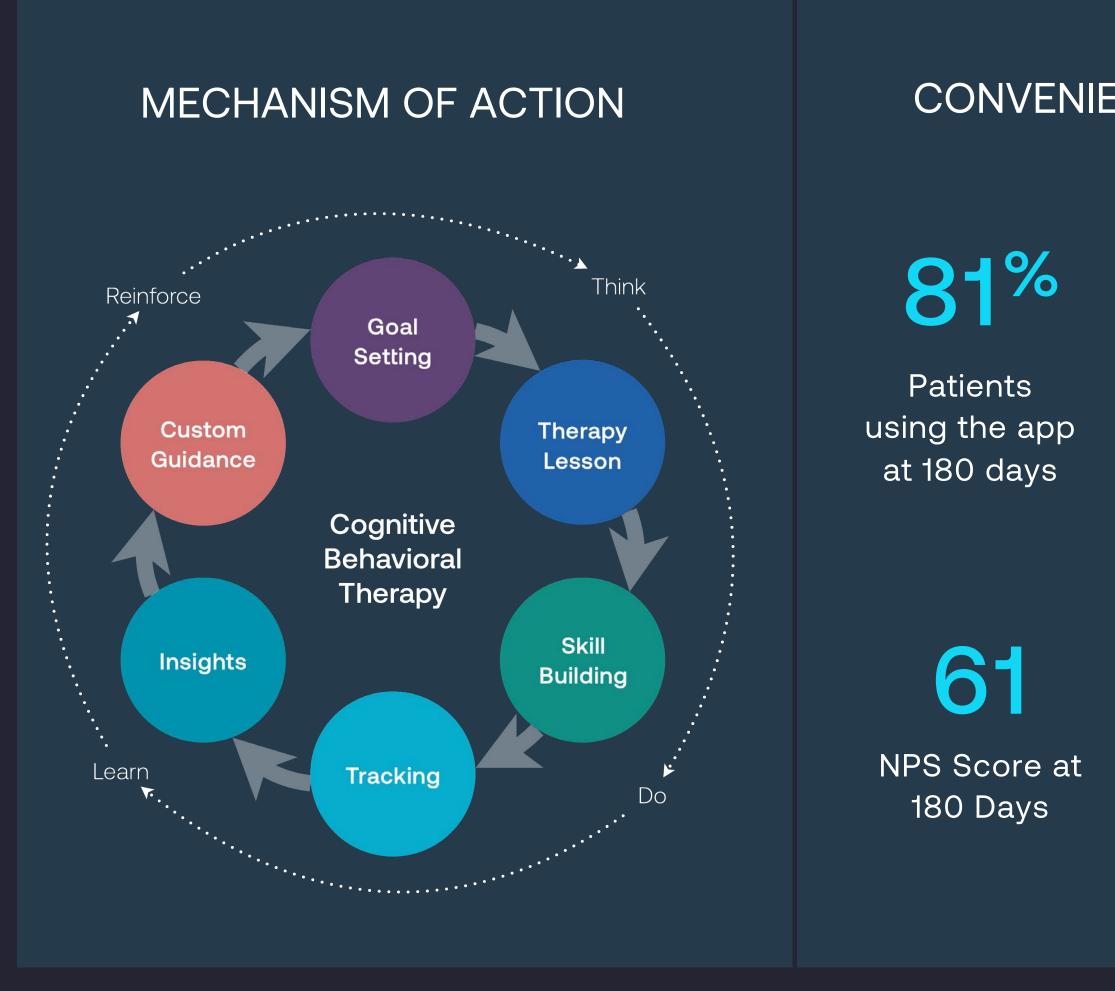
Chief Commercial Officer

## AspyreRx

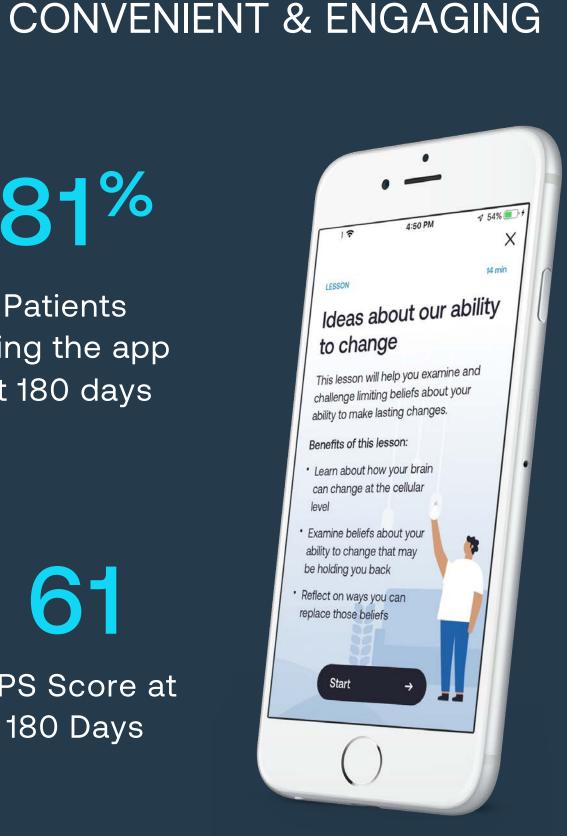




## Only AspyreRx delivers CBT to treat patients with T2D by targeting the underlying behaviors that contribute to disease progression in a proven, convenient, engaging digital app







### **EVIDENCE BASED**

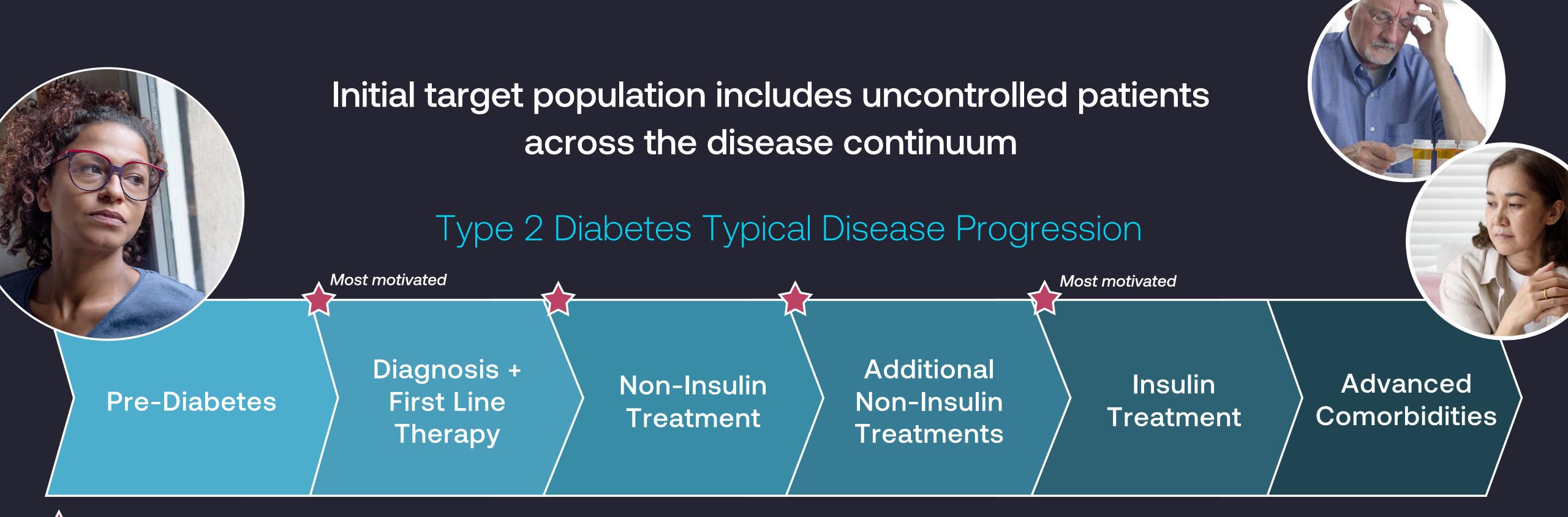
Patients achieve 1% or more A1c reduction

1.3%

Mean A1C reduction for meaningful responders<sup>1</sup>

- Fewer diabetes  $\bullet$ medications
- Reduced • systolic blood pressure
- Reduced • weight
- Improved  $\bullet$ mood
- Improved  $\bullet$ quality of life





Newly Diagnosed or Change / Escalation in Treatment

Initial focus will be the uncontrolled population

Better

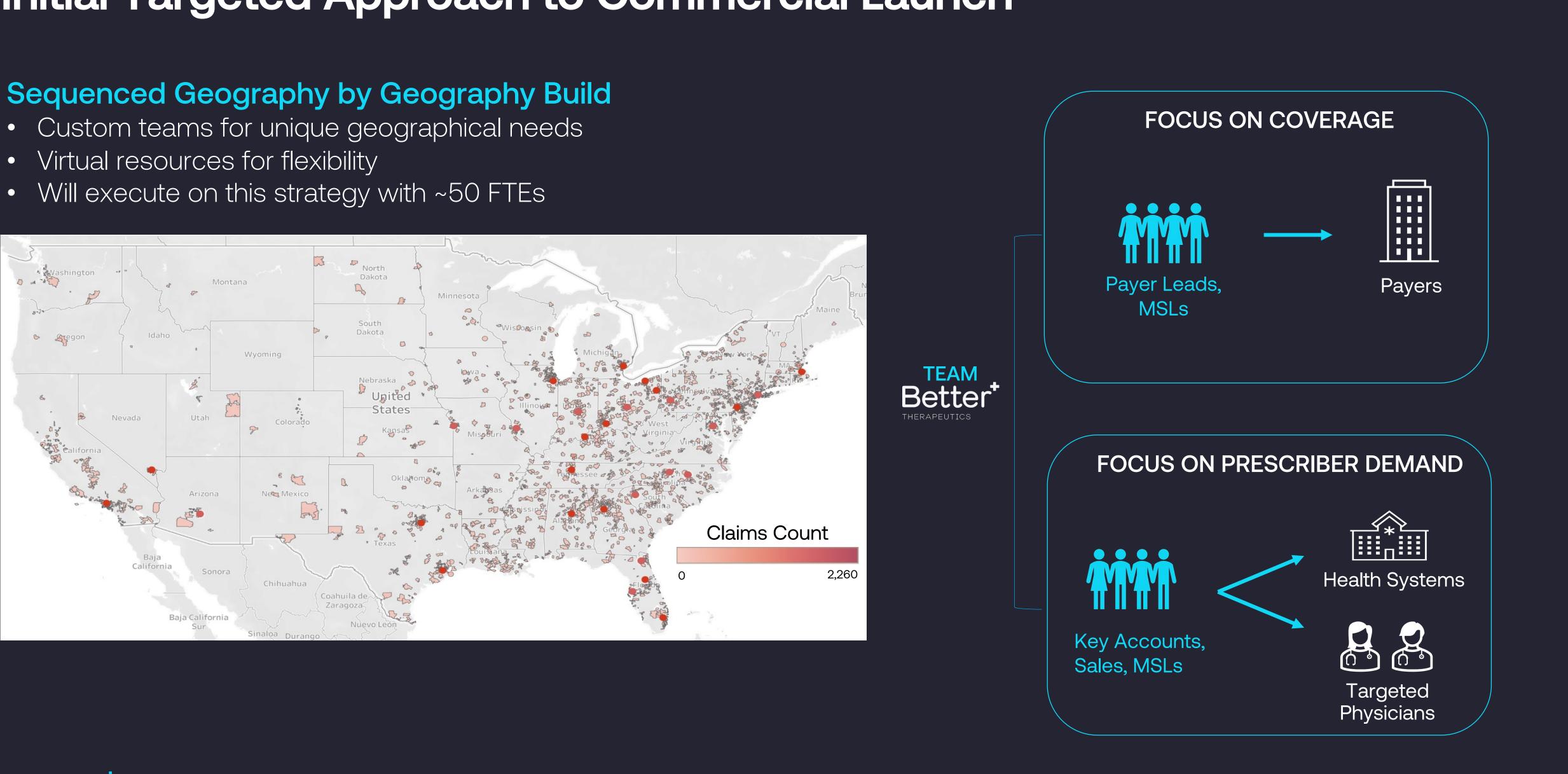
- Payers and Providers consider this population the most urgent to address

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





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



#### PROVIDERS

Position AspyreRx as effective and convenient foundation of treatment

#### PATIENTS

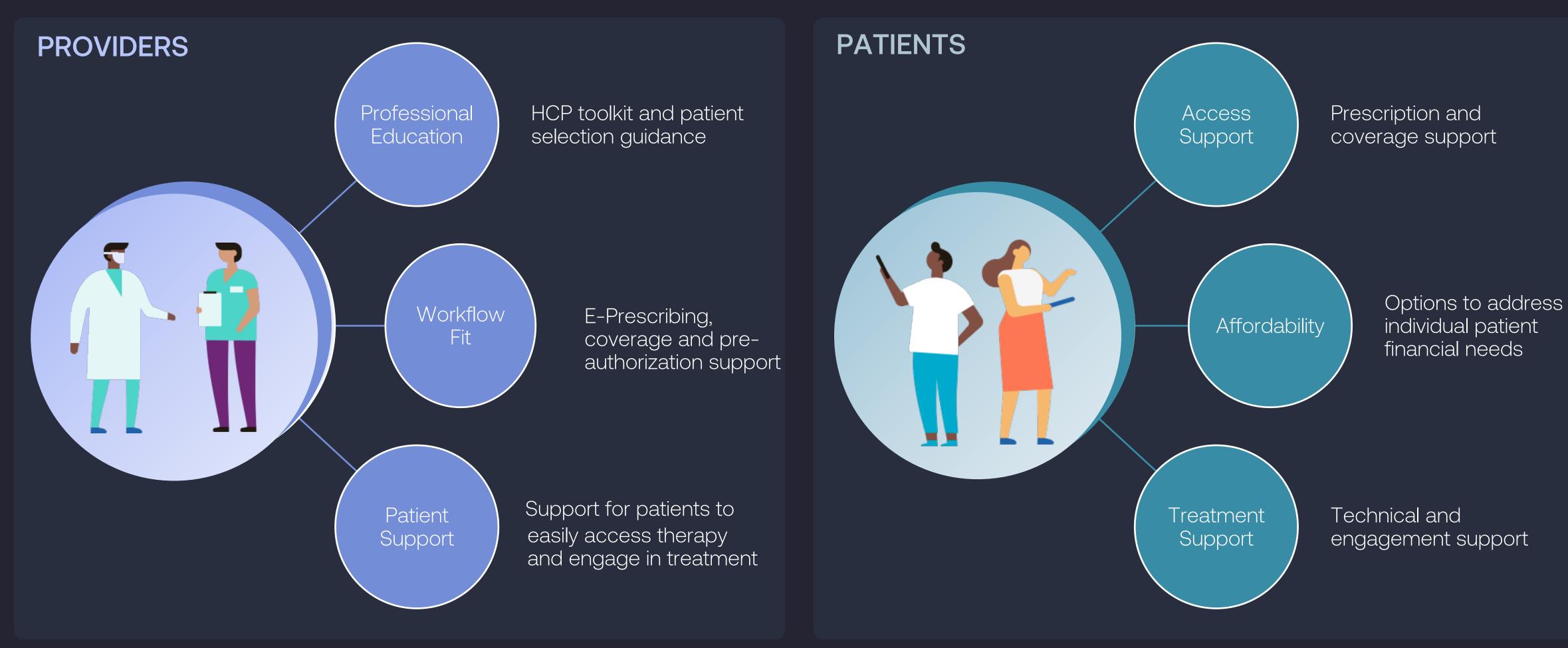
PAYERS

Deliver positive experience, ensuring high engagement and treatment success

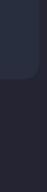
Establish coverage for target population



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







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

Connected with 65% of **Top 20 Regional Payers** 

**Engagements with Payers,** PBMs, Payer / Providers\*



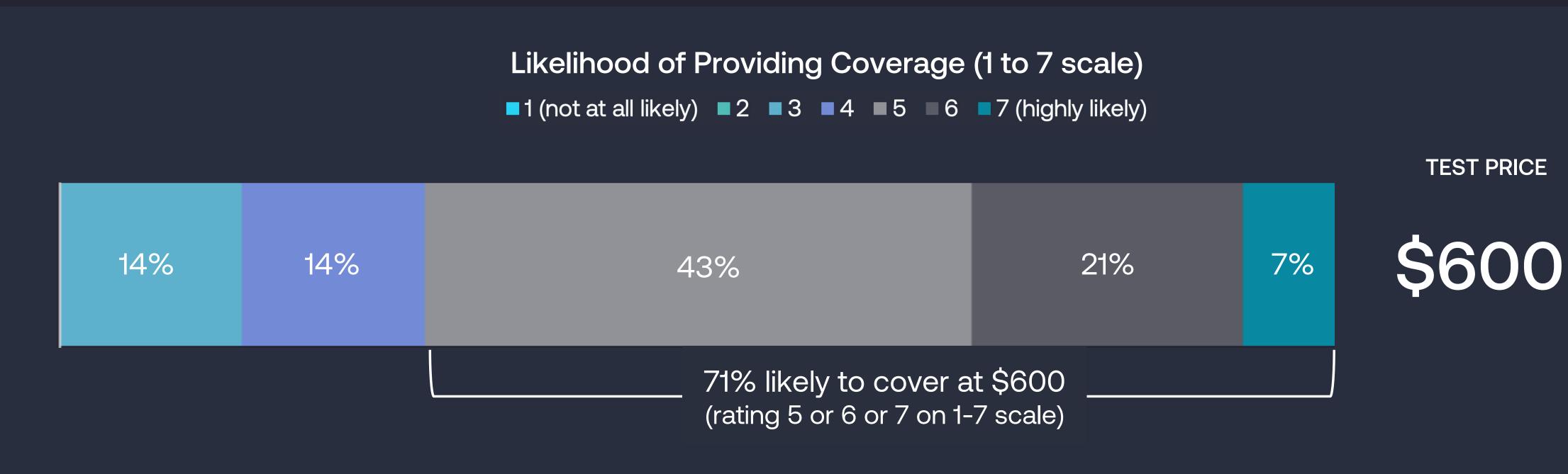
\*Includes market research, consultant engagements, PIE meetings, informal meetings

### Payer Feedback

- Growing awareness of Prescription Digital 0 Therapeutics (PDTs)
- Differentiating PDT vs non-regulated digital 0 therapeutics and wellness apps
- Defining pathways and processes for reviewing 0 PDT
- Reintroduction of the Access to Prescription 0 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





Source: Payer Pricing Research Full Report. Magnolia Innovation June 24,2022 (n = 15) NOTE: Assumes pricing feedback is net pricing

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# **Focused Commercial** Strategy to Gain **Early Traction**



- Phasing launch into 5-6 initial geographies
- Anticipating market release in Q4
- Launch metrics shared during Q2 Earnings Call



## Targeting Top 20 Regionally Dominant Payers

Payer contract negotiations begin immediately





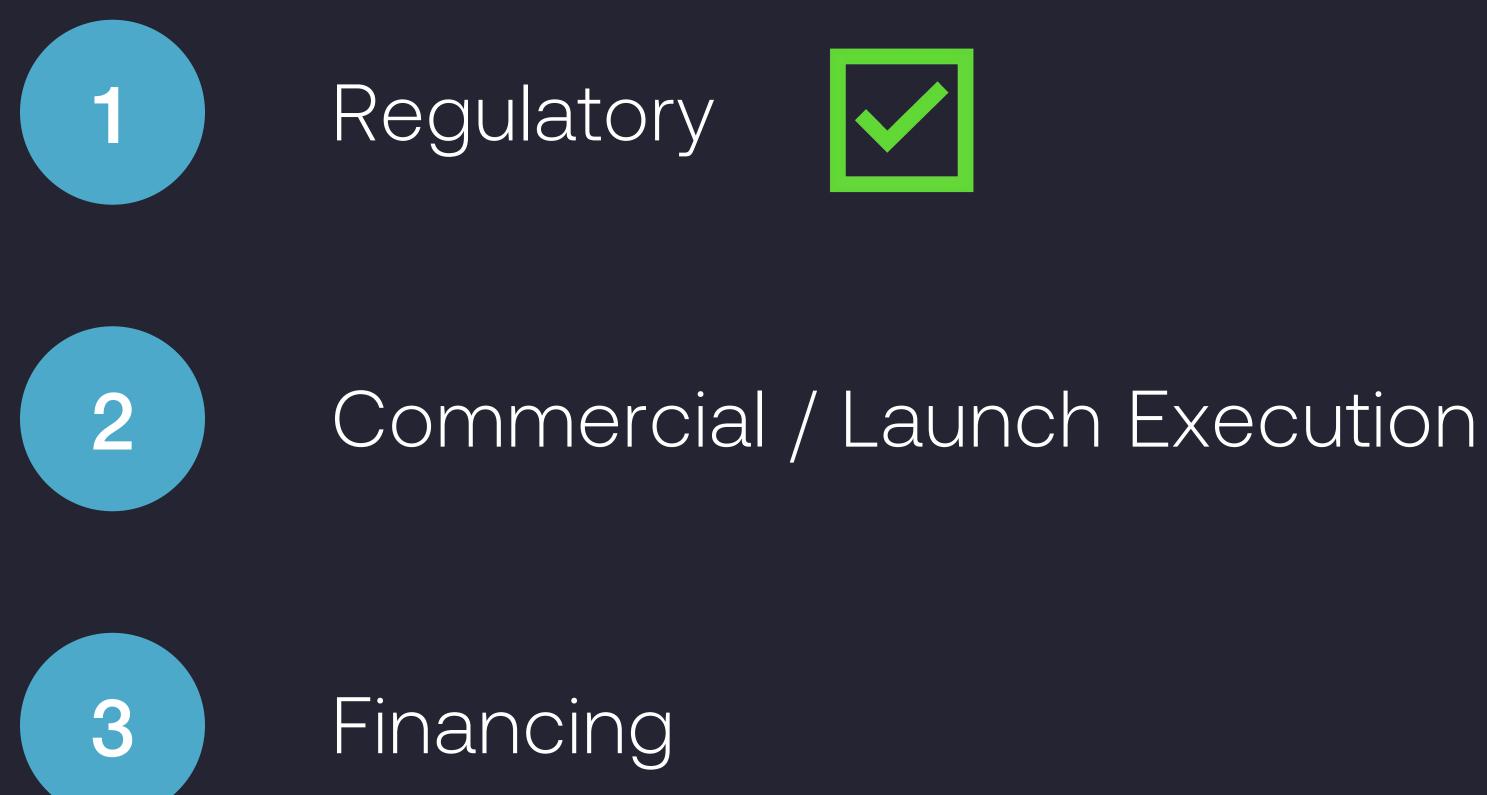




Frank Karbe President & Chief Executive Officer

# **Closing Comments**

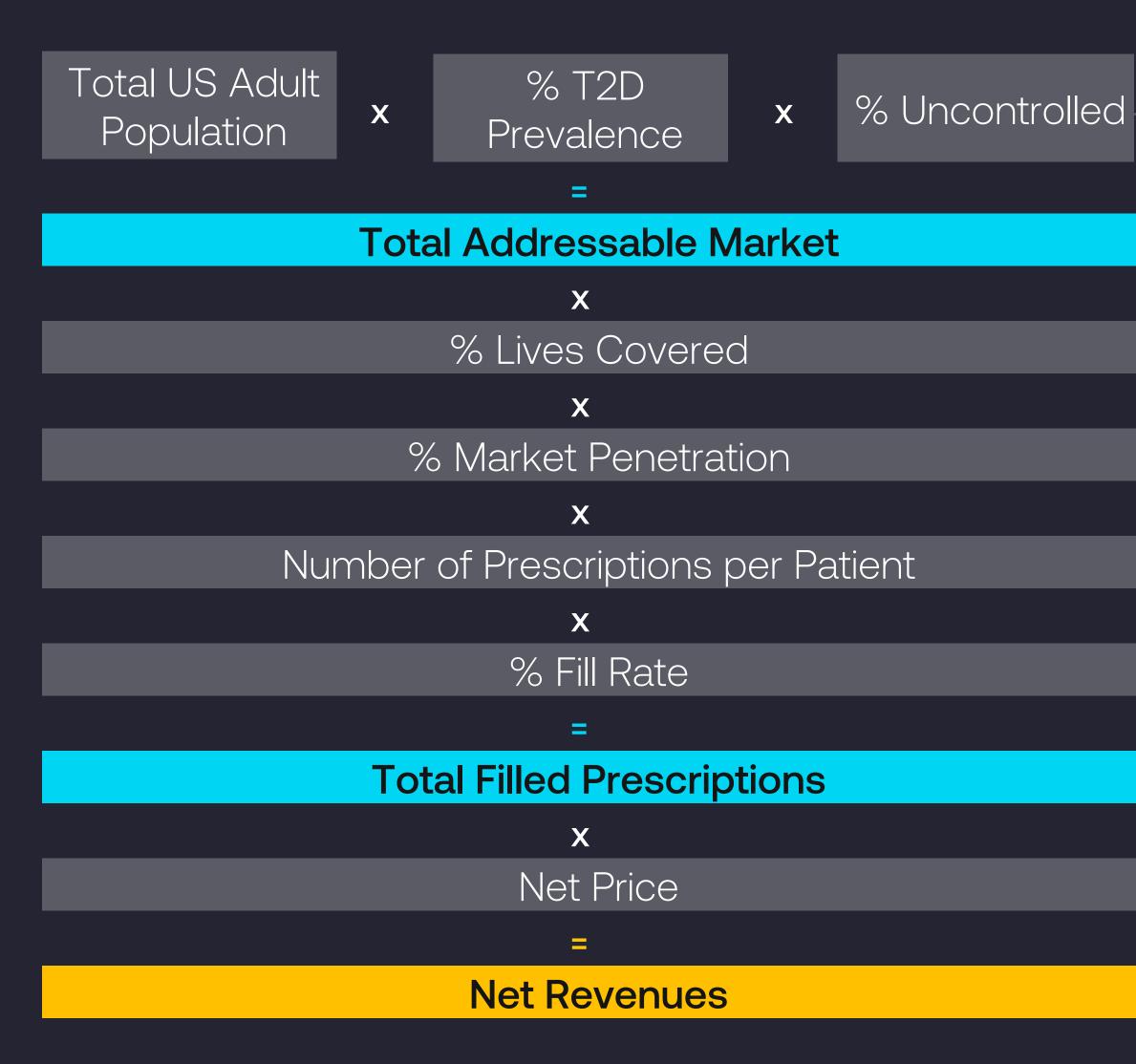
# Progress towards resolving our 3 key risks







# AspyreRx has substantial potential in T2D alone





### ASSUMPTIONS AT PEAK

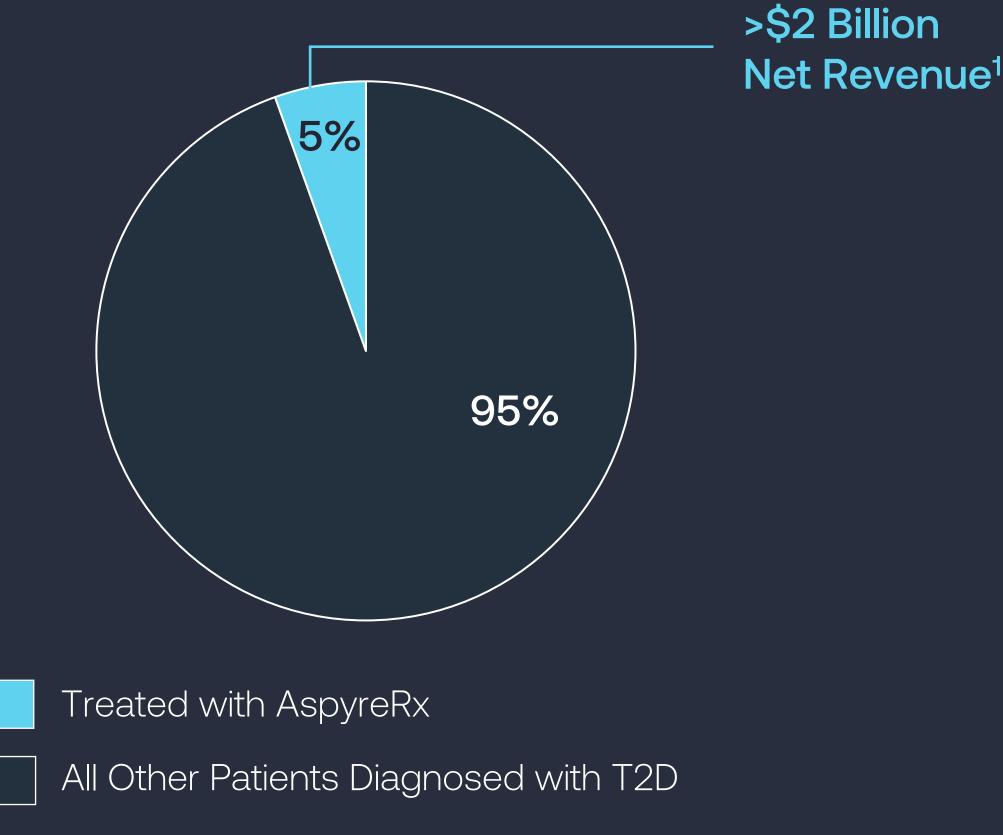
- Only uncontrolled population included in our model
- -> ~50% of diagnosed T2D patients addressable per label
- ~75% Coverage
- ~25% Penetration
- 2 Prescriptions per Patient
- ~55% Fill Rate
- Represents ~1% of all diabetes prescriptions
- Assumes 30% gross to net discount
- >\$2 Billion at Peak





# Substantial potential achievable with only 5% utilization

### AspyreRx Peak Utilization in US Patients Diagnosed with T2D





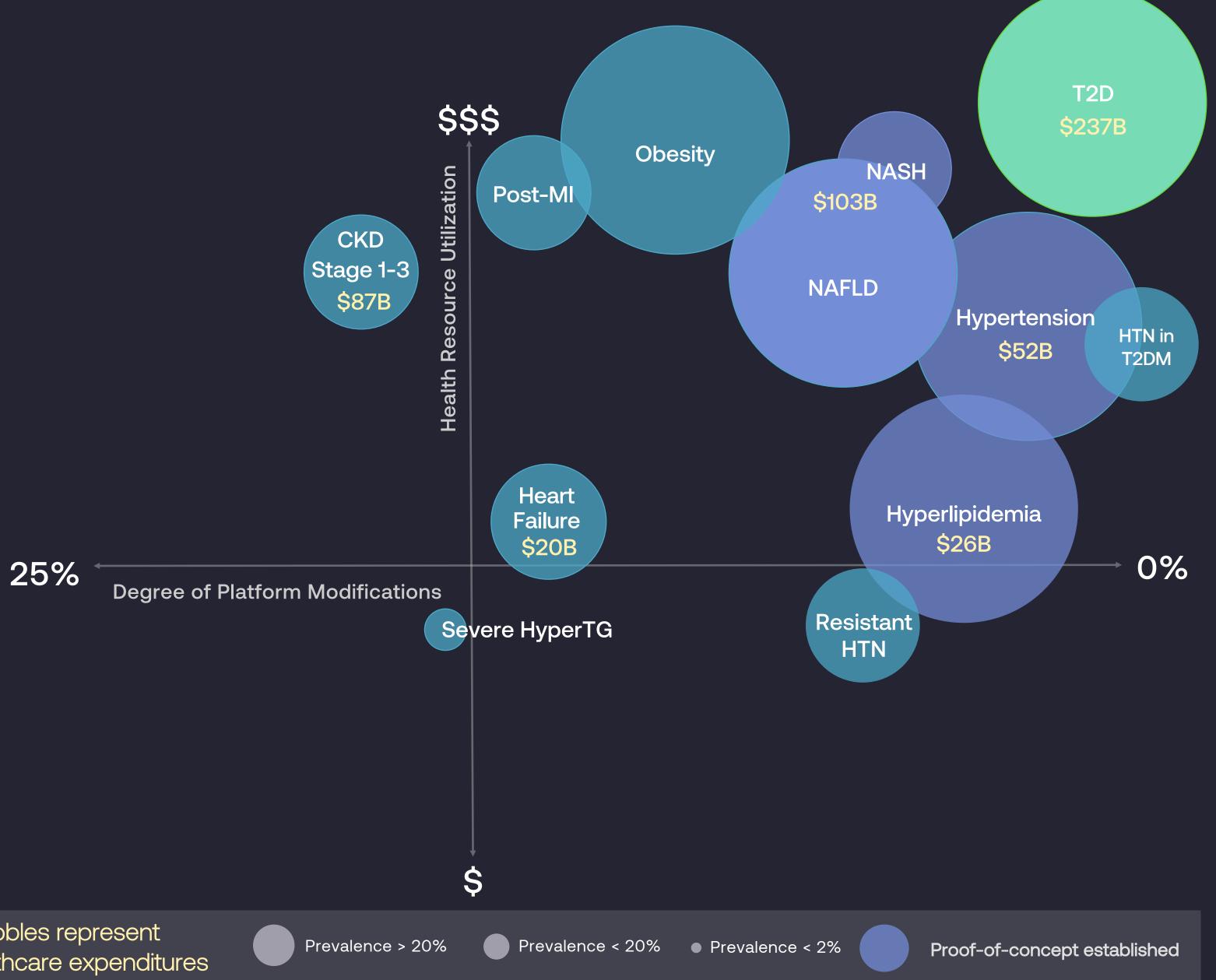
uncontrolled x 75% covered lives x 25% peak penetration x 55% fill rate = 5% of all patients diagnosed with T2D

- 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



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



Sources: <sup>1)</sup> CDC; <sup>2)</sup> 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. <sup>3)</sup> 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.000000000001123



# Financing Strategy

Business Development

Structured Financings Capital Markets



### • 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

Chief Medical Officer



#### Mark Berman, MD

#### **Diane Gomez-Thinnes**

Chief Commercial Officer

#### Kristin Wynholds

Chief Product Officer

