# CVRX

JP Morgan Healthcare Conference
January 2025

**NASDAQ: CVRX** 



#### **Disclaimer**

#### **Cautionary Note Regarding Forward-Looking Statements**

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The forward-looking statements in this presentation are only predictions and are based largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition, and results of operations. These forward-looking statements speak only as of the date of this presentation and are subject to a number of known and unknown risks, uncertainties and assumptions, including, but not limited to, our history of significant losses, which we expect to continue; our limited history operating as a commercial company and our dependence on a single product, Barostim; our limited commercial sales experience marketing and selling Barostim; our ability to demonstrate to physicians and patients the merits of our Barostim; any failure by third-party payors to provide adequate coverage and reimbursement for the use of Barostim; our competitors' success in developing and marketing products that are safer, more effective, less costly, easier to use or otherwise more attractive than Barostim; any failure to receive access to hospitals; our dependence upon third-party manufacturers and suppliers, and in some cases a limited number of suppliers; a pandemic, epidemic or outbreak of an infectious disease in the U.S. or worldwide; product liability claims; future lawsuits to protect or enforce our intellectual property, which could be expensive, time consuming and ultimately unsuccessful; any failure to retain our key executives or recruit and hire new employees; impacts on adoption and regulatory approvals resulting from additional long-term clinical data about our product; and other important factors that could cause actual results, performance or achievements to differ materially from those that are found in "Part I, Item 1A. Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2023 and in "Part 2, Item 1A. Risk Factors" in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2024, as such factors may be updated from t

#### **Market & Industry Data**

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### **Company overview**



World's first neuromodulation therapy to improve heart failure symptoms

\$2.2B annual market opportunity

Well-defined patient population with limited treatment options

Highly differentiated therapy with a compelling safety profile and high response rate

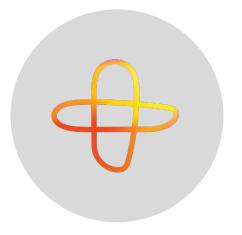
Focused plan to drive Barostim therapy to standard of care



## Heart failure (HF) is a burdensome, life-limiting disease affecting over 6M people living in the U.S.<sup>1</sup>









>1.1M hospital discharges<sup>1</sup>

>1.3M emergency room visits<sup>1</sup>

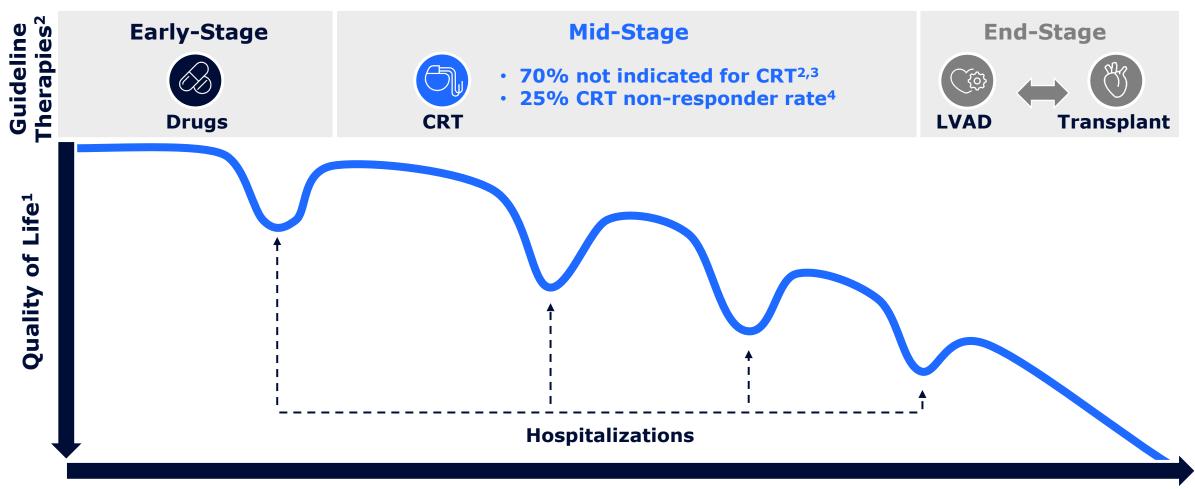
>8M physician office visits<sup>1</sup>

Annual costs expected to reach \$70B by 2030<sup>1</sup>

All figures are annual estimates for the U.S.



## Heart failure is a progressive disease characterized by steady decline in quality of life (QoL), with limited treatment options



#### **Disease Progression**



### Heart failure drug therapies have been shown to improve survival

#### 2022 AHA/ACC/HFSA HF Guidelines<sup>1-3</sup>

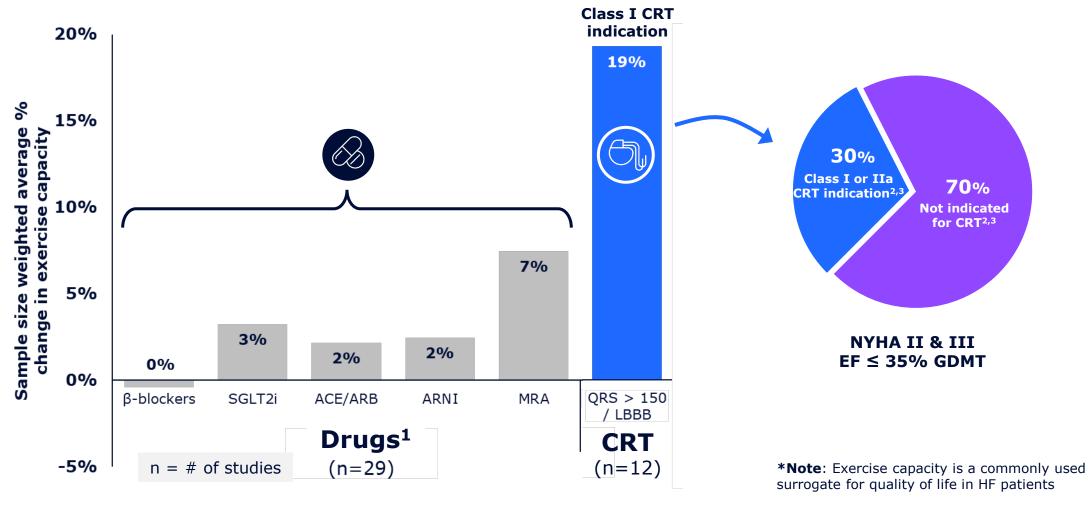


1.4-6.3 years

Estimated aggregate mortality benefit of comprehensive quadruple therapy in HFrEF<sup>1</sup>



## ...but these drugs have minimal impact on QoL\*; CRT has shown meaningful improvements in QoL, but few patients are eligible







## ...leaving the majority of HF patients to suffer from significantly diminished quality of life

HF negatively impacts quality of life particularly among those with reduced ejection fraction (HFrEF)



66%

have mobility problems<sup>1</sup>



76%

find usual activities difficult<sup>1</sup>



68%

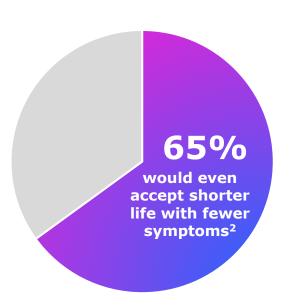
report pain or discomfort<sup>1</sup>



**50%** 

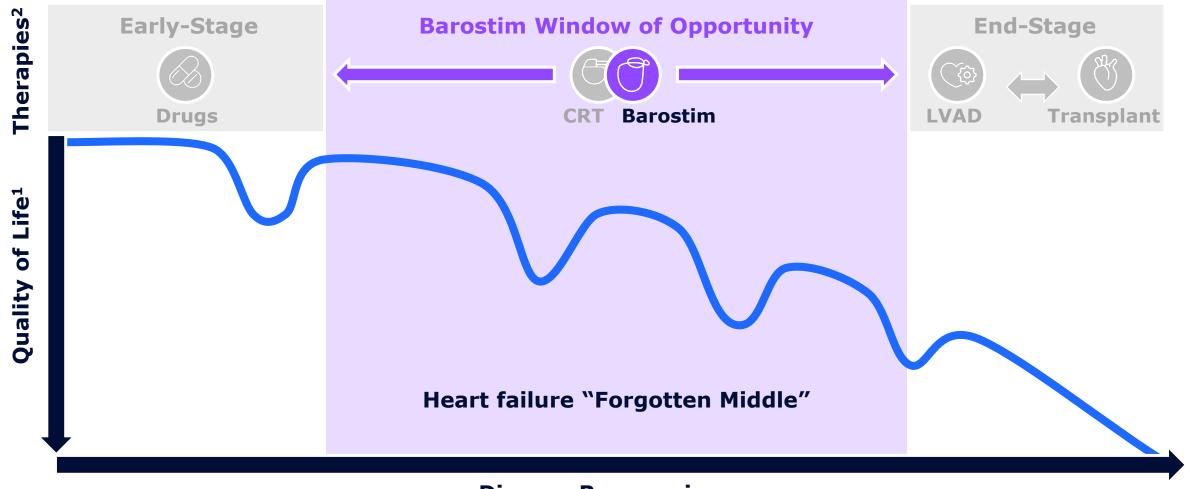
have anxiety or depression<sup>1</sup>

Majority of patients value symptom improvement over longevity



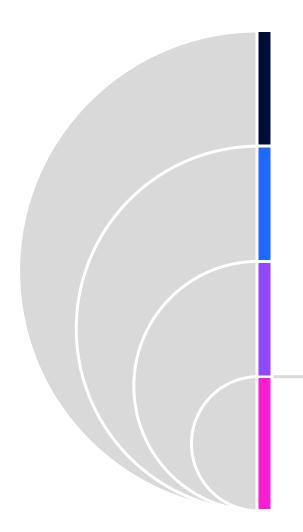


### Barostim addresses this significant and long-standing unmet need in the heart failure treatment continuum





### \$2.2B U.S. annual net addressable market for Barostim



**6.2M**HF Prevalence

1.3M
HF Incidence

**290K**NYHA II/III with EF ≤ 35%

**76K**Annual net addressable patients\*

\*Calculated using NYHA III & II (with a recent history of III); LVEF ≤ 35%; NT-proBNP < 1600pg/ml; mentally and clinically fit; on quideline-recommended therapies





### Barostim Therapy





### **Barostim system components**



**Barostim Generator**(Average battery life of 6 years)



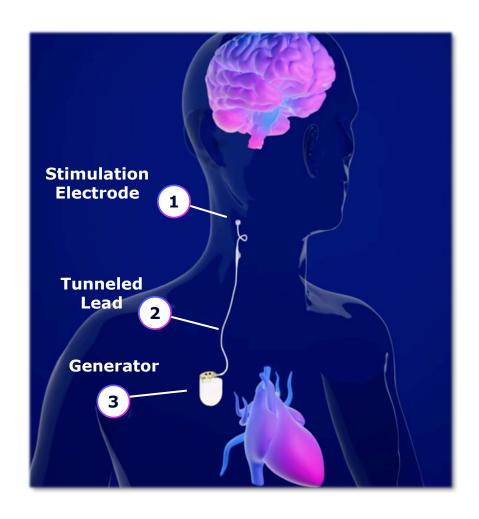
**Carotid Sinus Lead** 



**Barostim Programmer** 



## Barostim is implanted in a 60-min procedure<sup>1</sup>, with 97% freedom from major complications<sup>2</sup>

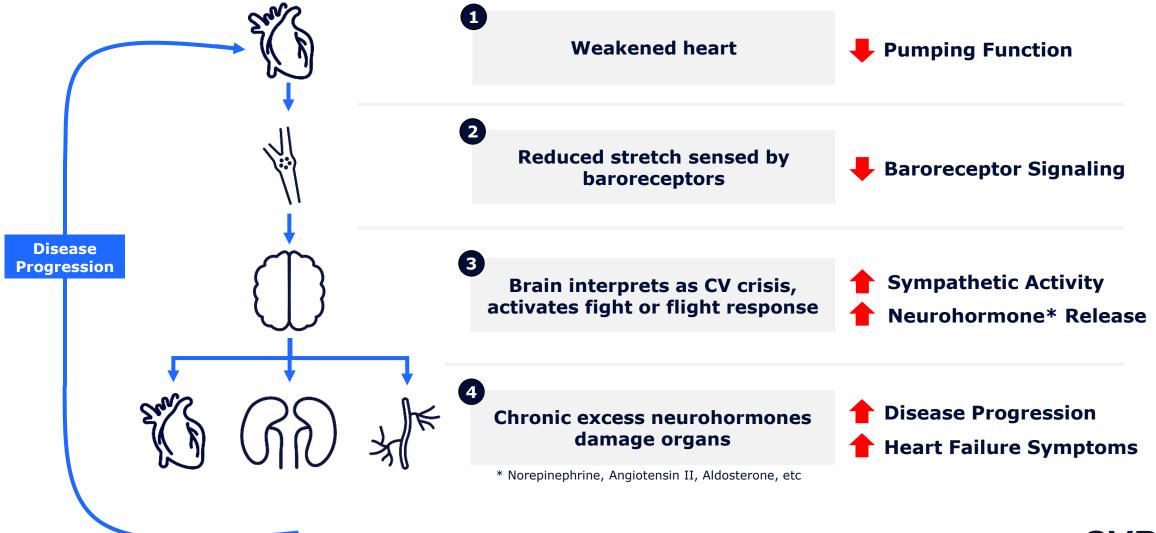


- Implanted on either an inpatient or outpatient basis
- Requires a small incision in both the neck and chest
- Entirely extravascular, with no leads in the heart or vasculature
- Procedure is proven safe; achieved a 97% MANCE-free rate<sup>2</sup>

MANCE - Major Adverse Neurological and Cardiovascular Events includes all events that occur within 6 months of implant

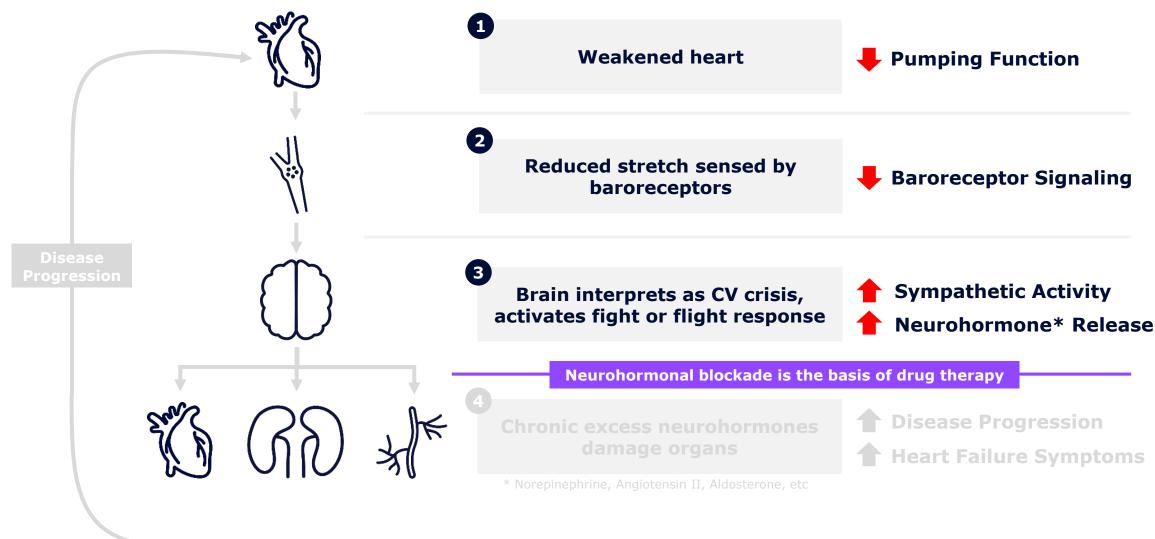


## Heart failure symptoms and disease progression are driven by the body's "fight or flight" response



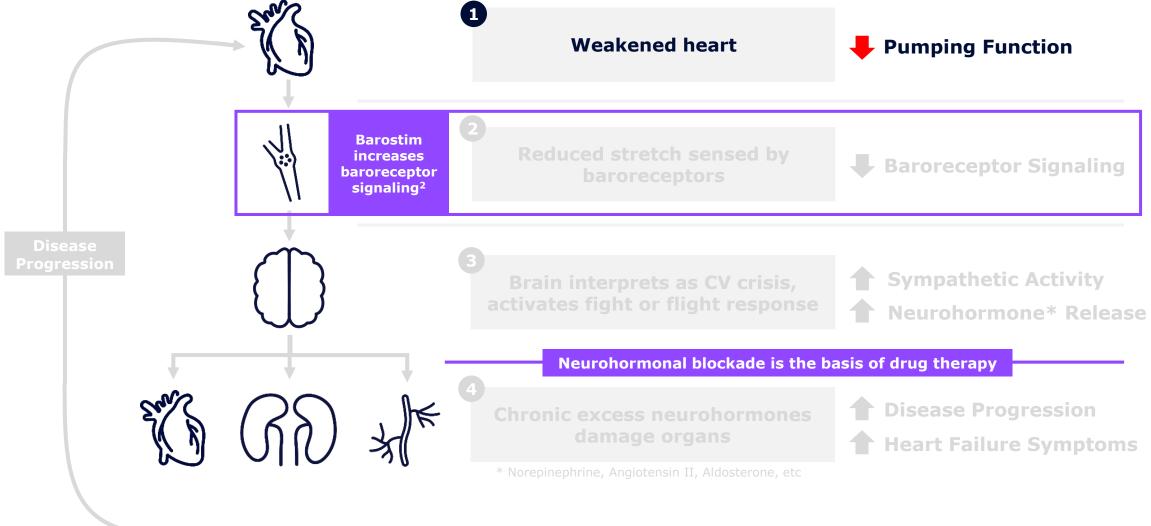


### Drug therapies work by blocking specific excess neurohormones





## Barostim complements drug therapy by acting upstream to restore signaling and reduce neurohormonal activation





## Barostim is an effective, predictable, and durable therapy to improve quality of life for HF patients



**Capacity** 









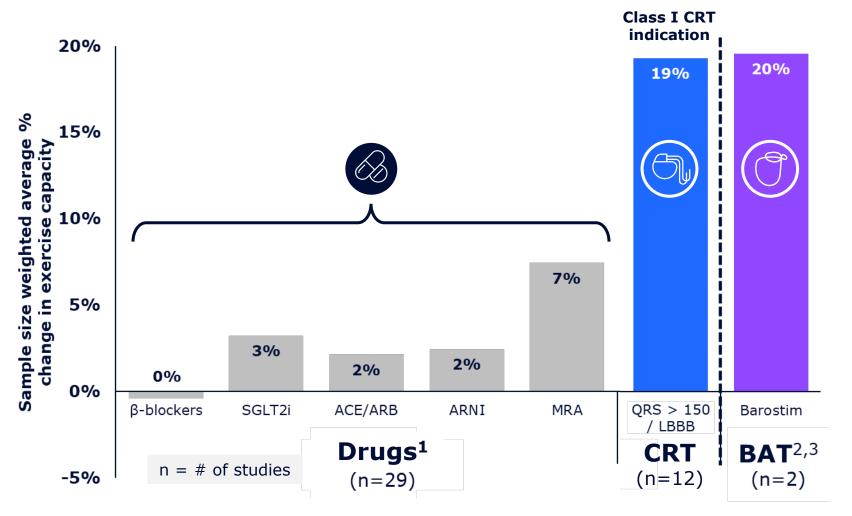








## Barostim offers a QoL\* improvement comparable to CRT for the 70% of patients who are not indicated for CRT



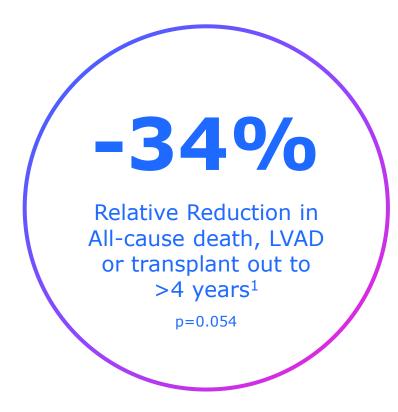


NYHA II & III EF ≤ 35% GDMT

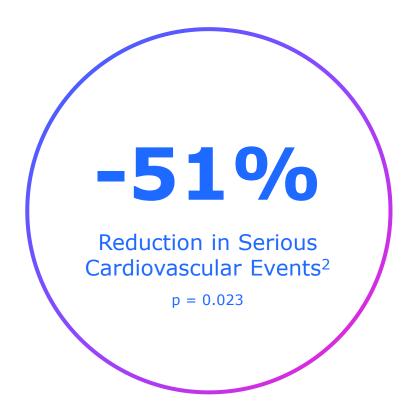
\*Note: Exercise capacity is a commonly used surrogate for Quality of Life in HF patients



### The BeAT-HF trial showed a positive signal to reduce all-cause mortality and a significant reduction in serious cardiovascular events



Note: Not a powered endpoint

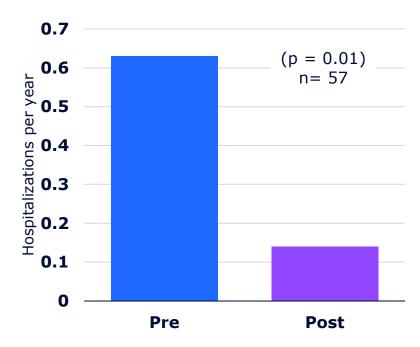


Note: Not a powered endpoint



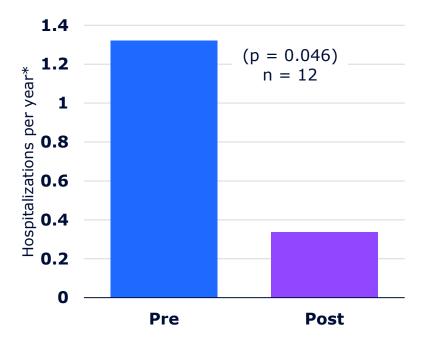
### A growing body of evidence, free of the confounding impact of COVID-19, suggests a significant and consistent effect on HF hospitalizations

### HOPE4HF publication<sup>1</sup> (Pre-COVID-19)



Fewer hospitalizations in the 6 months post- vs. 6 months pre-Barostim implant

### USC Keck ACC abstract<sup>2</sup> (Post-COVID-19)



Fewer hospitalizations in the 12 months post- vs. 12 months pre-Barostim implant\*



<sup>1.</sup> Abraham WT, et al. JACC Heart Fail 2015 3(6):487-496. 2. Pham, Vu, et al. Effects of BAT with Maximally-Tolerated GDMT on Hospitalization Rates in Patients with HFrEF, ACC 2024 abstract 1244-123

### Our revised go-to-market strategy is focused on driving Barostim to become Standard of Care for HFrEF

### **Three Key Strategies**

1

Build a world-class sales organization

2

Focus on developing sustainable Barostim Programs

3

Address the barriers to adoption



1

## We are building a world-class sales organization focused on developing sustainable programs with deep therapy adoption

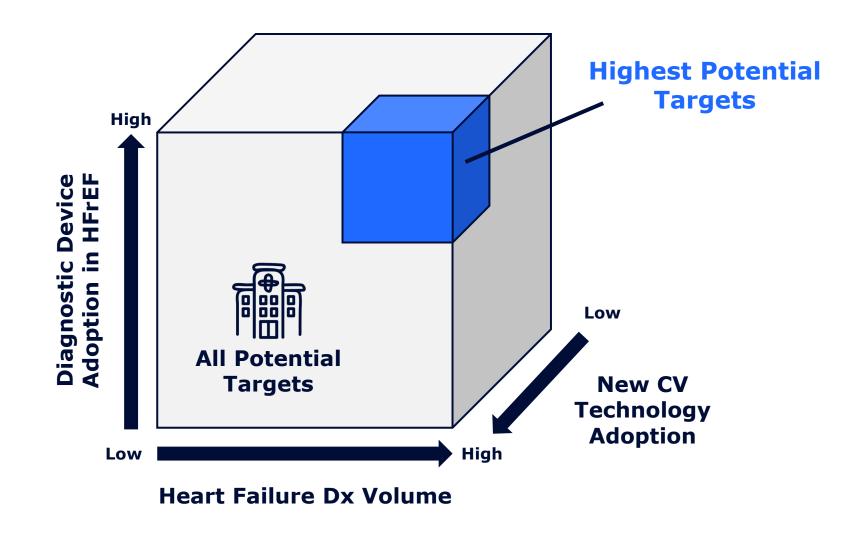
Recruit sales reps with strong therapy development backgrounds

**Strengthen training & development programs** 

Align incentives to a program-oriented sales process



## We will focus on developing sustainable Barostim programs by targeting centers with the highest potential for success







## ...and will replicate the elements present in Barostim centers that have achieved the deepest adoption

### **Sustainable Barostim Program**







### **Referrers** (Identify potential patients)



**HFS** 



**APP** 



EP



GC/IC

**Prescribers** 

(Prescribe the therapy and send for implant)





**HFS\*** 

**Implanters** (Technicians)





VS / CTS

\*May also be an EP, GC, or IC depending on account





## We have implemented a market development strategy focused on addressing the key barriers to adoption

- 1) <u>Therapy Awareness</u>: Increase therapy awareness among referrers and patients
- 2) <u>Clinical Evidence</u>: Develop more robust clinical evidence
- 3) <u>Patient Access</u>: Improve patient access to Barostim



### 1) Therapy Awareness: We are engaging more deeply with the referral network that surrounds targeted centers

#### **Expanded Regional Medical Education Programs**







**HFS** 

GC/IC



Sustainable **Barostim Program** 



**Launch of New APP-Focused Programs** 







#### Launch of **ASCEND Fellows Program**







## 2) <u>Clinical Evidence</u>: We are developing a steady cadence of clinical evidence to support Barostim therapy in two key areas

#### **Evidence Supporting Mechanism of Action**

### Areas of . Interest:

- Reduced sympathetic nerve activity
- Restored cardiac parasympathetic control
- Anti-inflammatory effect
- Reversed remodeling
- Favorable hemodynamic effect

#### **Evidence of Improved Outcomes**

- Improved QoL & exercise capacity
- Reduced HF and all-cause hospitalizations
- Reduced arrythmias
- Improved ejection fraction
- Decreased diuretic needs

**Evidence Generation Channels:** 



Barostim
Investigator
Initiated
Research (BIIR)

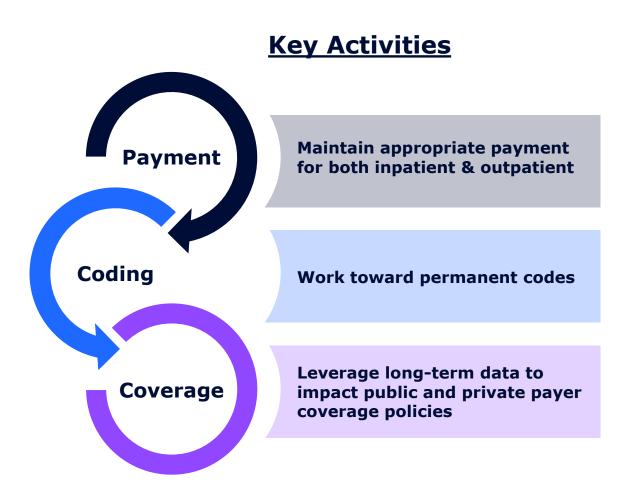




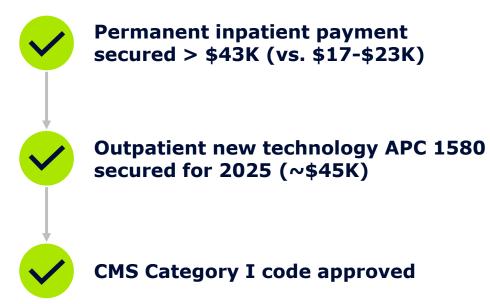
Real-World Evidence



## 3) Patient Access: We made significant progress in 2024 to improve patient access and support therapy adoption



#### **Recent Milestones**





### **Preliminary 2024 financial summary**

#### **2024 Highlights**

- •2024 WW Revenue: \$51.1-\$51.2M (~30%)
- •Q4 WW Revenue: \$15.2-\$15.3M (~35%)
- •Q4 US HF Revenue: \$14.2-\$14.3M (~40%)
- •US Territories: 48 (+3)
- Active Implanting Centers: 223 (+15)
- •Cash Balance at End of Q4: \$105.9M





#### 2025 Guidance

- For the full year of 2025, we expect:
  - Total revenue between \$63.0 million and \$65.0 million;
  - Gross margin between 83% and 84%;
  - Operating expenses between \$100.0 million and \$104.0 million
- For the first quarter of 2025, we expect total revenue between \$14.5 million and \$15.0 million



## We have spent 2024 building a strong foundation for continued future growth

Significantly strengthened executive and commercial teams

Implemented a market development and commercial strategy focused on reaching standard of care

Expanded the body of clinical evidence, including publication of impressive 24-month quality of life improvements

Secured fundamental improvements across key aspects of patient access





