# CVRX

JP Morgan Healthcare Conference January 11, 2023



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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 forwardlooking 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 ability to establish and maintain sales and marketing capabilities; 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, including the outbreak of the novel strain of coronavirus, COVID-19; any failure of clinical studies for future indications to produce results necessary to support regulatory clearance or approval in the U.S. or elsewhere; 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; 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, 2021. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

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

This presentation includes market and industry data and forecasts that the Company has developed from independent research reports, publicly available information, various industry publications, other published industry sources or the Company's internal data and estimates. Independent research reports, industry publications and other published industry sources generally indicate that the information contained therein was obtained from sources believed to be reliable, but do not guarantee the accuracy and completeness of such information. Although the Company believes that the publications and reports are reliable, the Company has not independently verified the data and makes no representation or warranty with respect to the accuracy of such information.



## **CVRx** management team



Nadim Yared
President & Chief
Executive Officer



Chief Financial Officer



**Paul Verrastro**Chief Marketing & Strategy
Officer



Craig Palmer
Senior Vice-President of US Sales



**Liz Galle**Vice-President of Clinical
Research



Thomas Hengsteler
VP, European Sales &
Marketing



**Paul Pignato**VP, Operations



Jonelle Burnham VP, General Counsel



**Al Crouse**VP, Quality Assurance and Regulatory Affairs



**Ivana Stojanovic**VP, Market Access and DTC Marketing



**Jim Georgakopoulos**Distinguished Scientist





With significant advancements in drug therapy for Heart Failure with reduced Ejection Fraction, do we need a new device therapy in NYHA Class II and III patients?



## **GDMT** improves heart failure morbidity and mortality

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

#### **ARNI**

20% decrease in sudden death, 21% decrease in VA, ICD shock or resuscitated cardiac arrest in PARADIGM-HF

#### **B-Blockers**

31% decreased in sudden death based on meta-analysis of trials

#### MRA

23% decrease in sudden death in RALES, EPHESUS, EMPHASIS-HF

#### SGLT2i

21% decrease in VA, resuscitated cardiac arrest or sudden death in DAPA-HF

# 1.4-6.3 years

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

1. Heidenreich PA, et al. 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure. Circulation 2022;

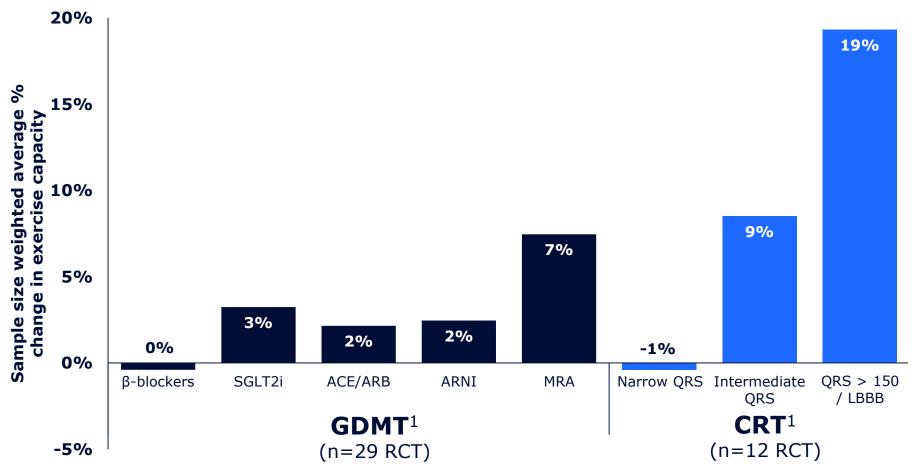
3. Rahamim E, et al. Contemporary Pillars of Heart Failure with Reduced Ejection Fraction Medical Therapy. J. Clin. Med. 2021, 10, 4409



<sup>2.</sup> Vaduganathan M, et al. Estimating lifetime benefits of comprehensive disease-modifying pharmacological therapies in patients with heart failure with reduced ejection fraction: a comparative analysis of three randomised controlled trials. Lancet Vol 396, Issue 10244, P121-128, July 11, 2020;

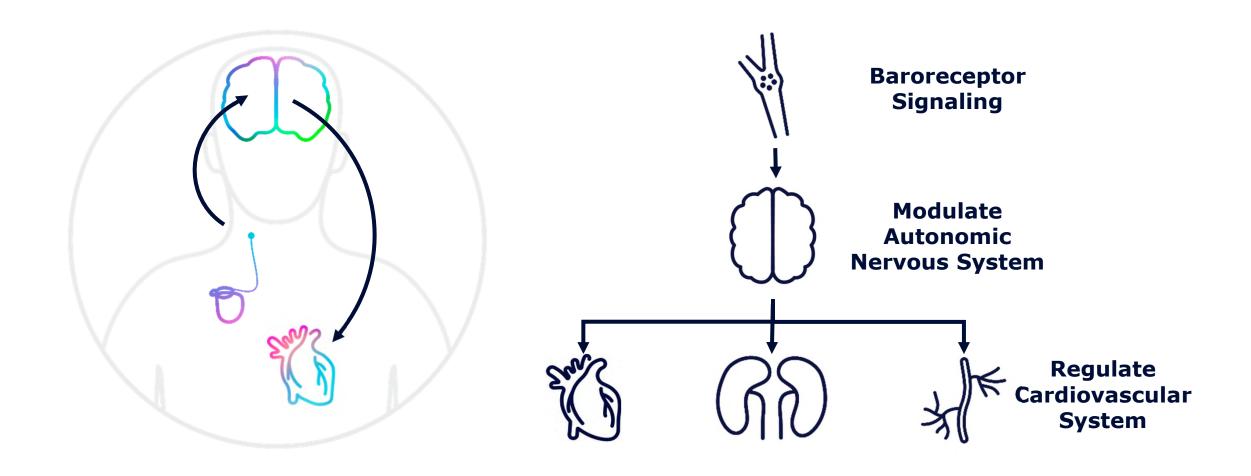
# **GDMT** produces modest improvements in exercise capacity

#### % Improvement in exercise capacity versus control arm





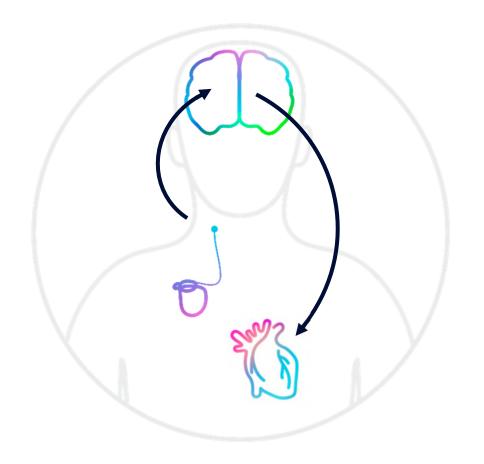
# Baroreflex is integral to maintaining cardiovascular homeostasis





## **Effects of Barostim**

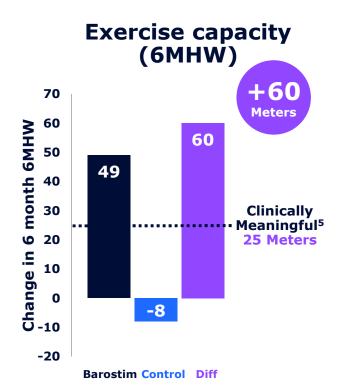
	Heart Failure	Barostim
Baroreflex Sensitivity	1	3
Sympathetic Outflow  Parasympathetic Outflow	2 W	4
Heart Failure Symptoms		?



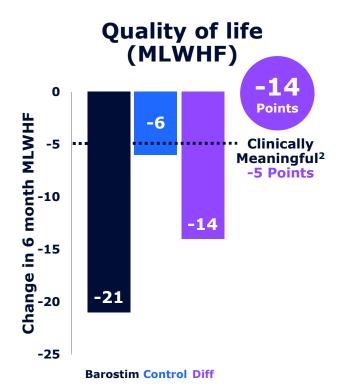
- Creager MA, Creager SJ. J Am Coll Cardiol. 1994;23(2):401-5;
   Mortara A. Circulation. 1997;96:3450-3458;
   Gronda, E, et al. European Journal of Heart Failure 16.9 (2014): 977-983;
   Wustmann et al, Hypertension 2009 Sep;54(3):530-6



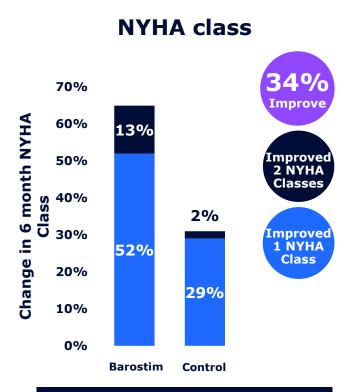
## BeAT-HF pivotal trial: symptom improvement<sup>1</sup>



CRT trial results			
CONTAK CD <sup>3</sup>	NYHA III or IV LVEF ≤ 35% QRS > 120ms	39	
MIRACLE <sup>4</sup>	NYHA III or IV LVEF ≤ 35% QRS > 130ms	29	



CRT trial results		
CONTAK CD <sup>3</sup>	NYHA III or IV LVEF ≤ 35% QRS > 120ms	-11
MIRACLE <sup>4</sup>	NYHA III or IV LVEF ≤ 35% QRS > 130ms	-9



CRT trial results			
CONTAK CD <sup>3</sup>	NYHA III or IV LVEF ≤ 35% QRS > 120ms	20%	
MIRACLE <sup>4</sup>	NYHA III LVEF ≤ 35% QRS > 130ms	30%	



<sup>\*</sup>Data from different studies and different patient populations may not be directly comparable

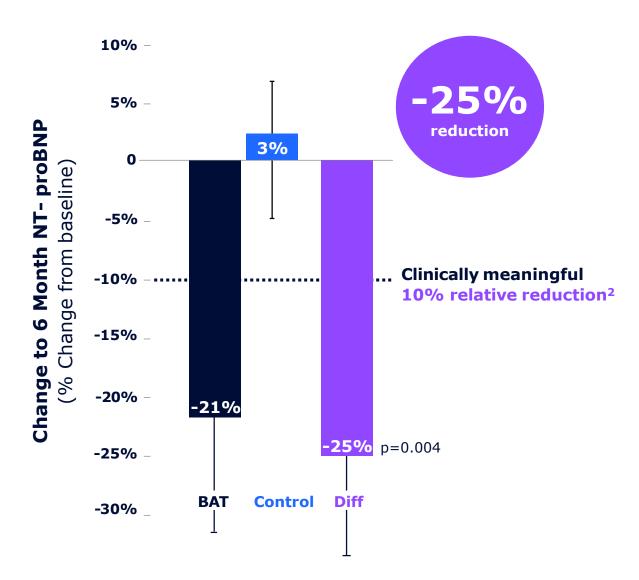
<sup>1.</sup> Zile MR, et al. J Am Coll Cardiol 2020; 76:1-13.

<sup>2.</sup> Rector TS, et al. J Card Fail. 1995;1(3):201-216.

<sup>3.</sup> Higgins SL, et al. J Am Coll Cardiol 2003;42:1454 –1459.

Abraham WT, et al. N Engl J Med 2002;346:1845-1853. 5. Gremeaux V, et al. Arch Phys Med Rehabil. 2011;92(4):611-619.

# BeAT-HF pivotal trial: NT-proBNP reduction<sup>1</sup>

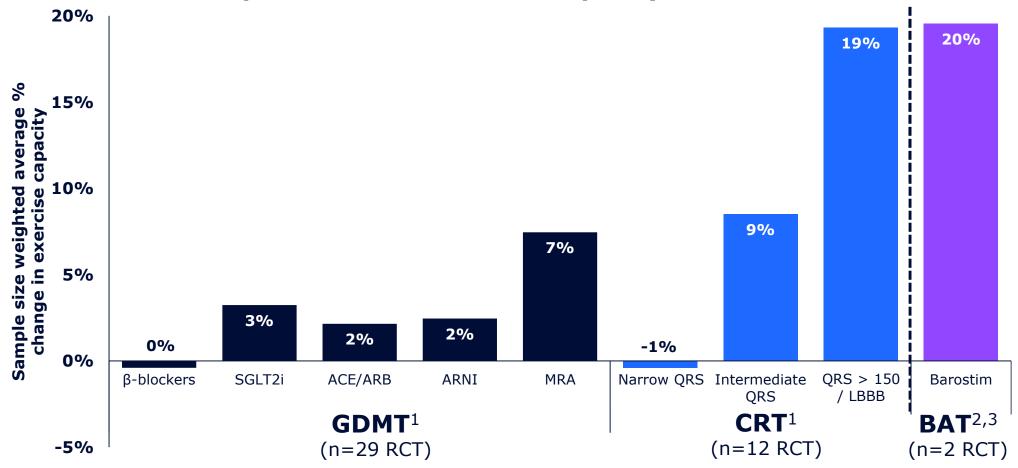


PARADIGM-HF (ARNI)
 authors noted morbidity and
 mortality were reduced when
 NT-proBNP fell by as little as
 10%, regardless of
 treatment group<sup>2</sup>



## Barostim's improvements in exercise capacity in HFrEF

### % Improvement in exercise capacity versus control arm



<sup>1.</sup> Adapted from Lewis G et al, Developments in Exercise Capacity Assessment in Heart Failure Clinical Trials and the Rationale for the Design of METEORIC-HF. Circ Heart Fail. 2022 May;



<sup>2.</sup> Abraham WT, Zile MR et al. JACC: Heart Failure 2015 June; 3(6):487-496;

<sup>3.</sup> Zile MR, et al. J Am Coll Cardiol 2020; 76:1-13

## 1. Large market opportunity

U.S.

**5 EU Countries** 

Prevalence (patients)
6.2 million
8.6 million

**Incidence (patients / year)** 

1.3 million

1.4 million

Initial Addressable Patient Incidence Rate (patients/year)\*

55,000

61,000

**Initial Annual Market Opportunity (\$/year)** 

\$1.4 billion

\$1.5 billion

Initial Annual Market Opportunity from U.S. and largest 5 countries in Europe with initial addressable HFrEF patient population



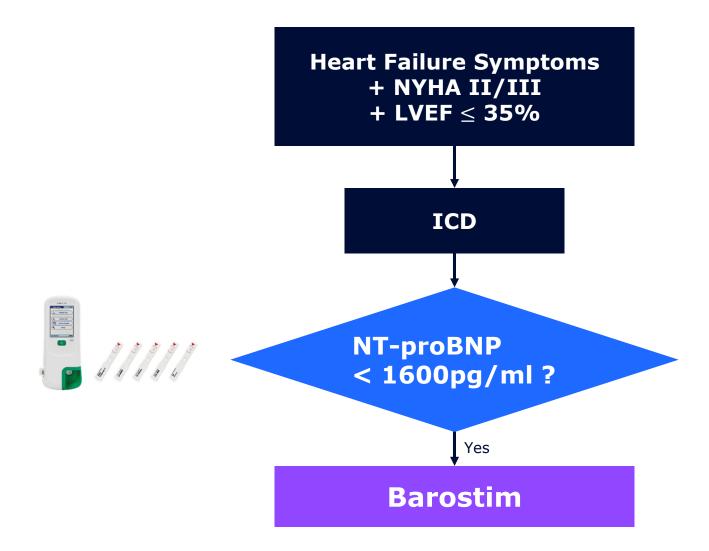
#### Assumptions:

- (1) Average selling price of \$25,000
- (2) Excludes replacement market of approx. 30-40% of de novo market in the future (+\$0.9B-\$1.2B)
- (3) Market data reflects our estimates involving a number of assumptions and limitations



<sup>\*</sup> NYHA III & II (with a recent history of III); LVEF  $\leq$  35%; NT-proBNP < 1600pg/ml; mentally and clinically fit; not indicated for CRT

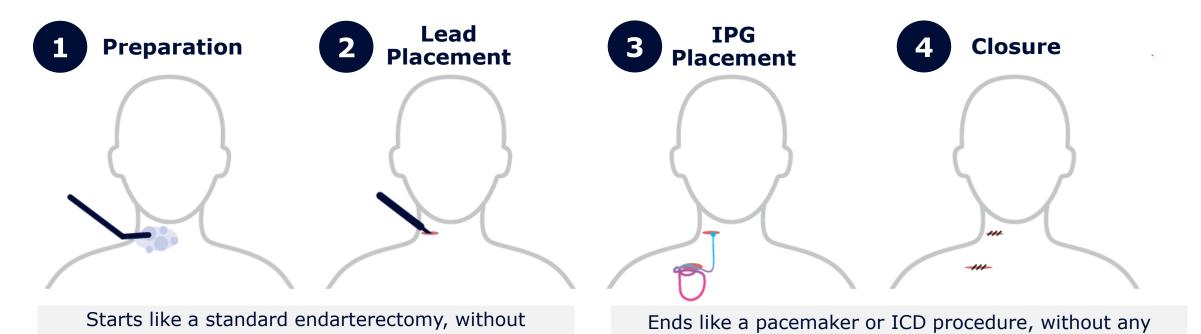
## 2. Straightforward Patient Identification





## 3. One-hour Outpatient Procedure

opening any artery







hardware in the heart



## 4. Favorable Hospital Economics

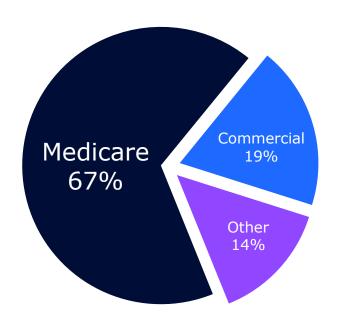
### **Payment**

- CMS granted Barostim add-on payments for outpatient procedures (Transitional Pass-Through or TPT)
- TPT is hospital-specific:

CPT Code	CPT Code Description	2023 Medicare National Average Payment*
0266T	Implantation or replacement of carotid sinus baroreflex activation device; total system	\$29,358** + TPT
0272T 0273T	Interrogation device evaluation (in person), with interpretation and report	\$145

### Coverage

- Claim-by-claim adjudication allowed by CMS in all 7 MACs since July 2020
- Transitional Pass-Through (TPT) carries a presumption of coverage

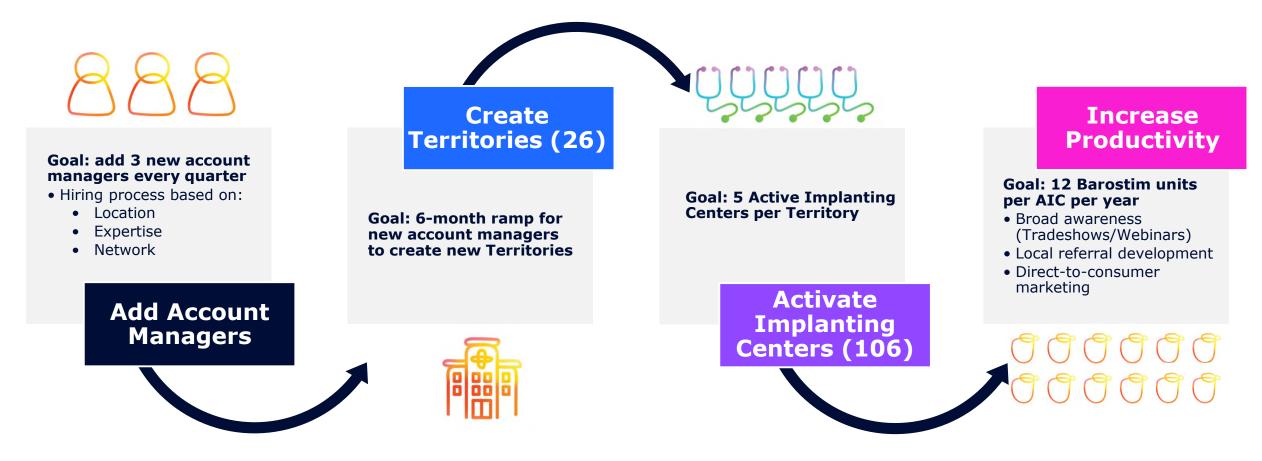




<sup>\*</sup> Payment codes such as APC 5465 are indexed to adjust for cost of living and thus vary by location. These payments generally cover the hospital's costs for the device and the implantation procedure.

<sup>\*\*</sup> APC 5465 was \$29,445 for CY2021 and \$30,063 for CY2022.

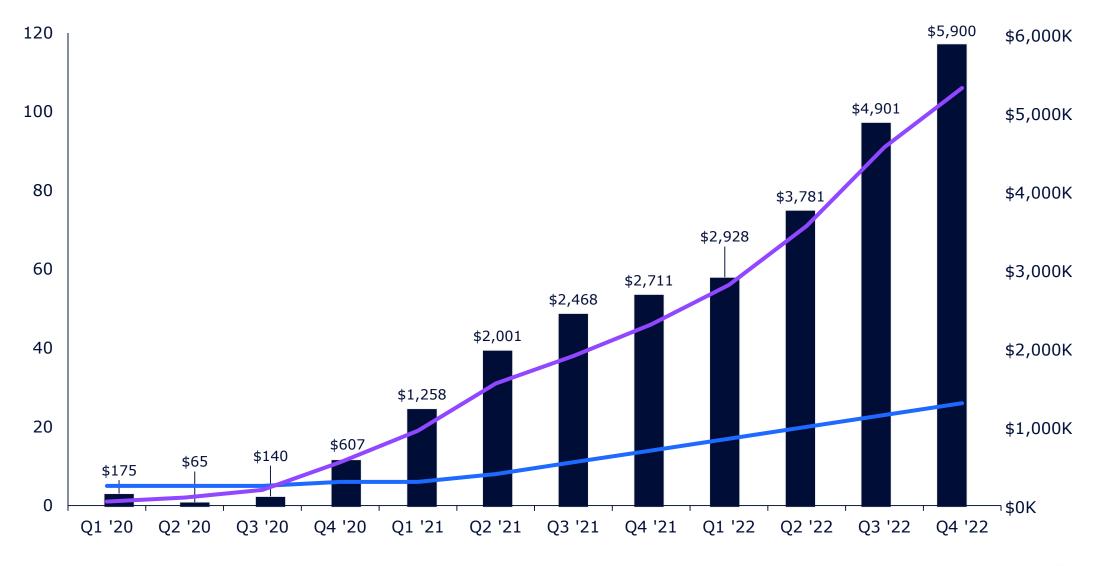
## 5. Proven Go-to-market Strategy



GOAL: Account Manager target  $5 \times 12 = 60$  units per year  $\times $25K = $1.5$  million annual revenue

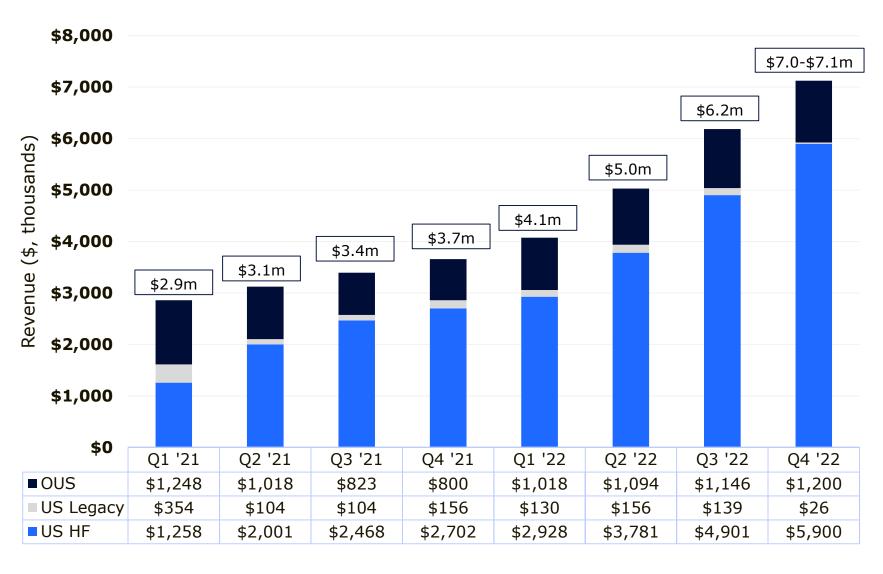


## Focus: Building Scalable US Distribution





## **Financial Results**



## **Highlights**

#### Q4 2022

- Revenue:\$7.0M \$7.1M
- US HF Revenue: \$5.9M (+118%)
- US HF ASP: \$30.9K
- US Territories: 26
- Active Implanting Centers: 106
- 12/31 Cash: \$106M

#### Full Year 2022

- Revenue: \$22.3M \$22.4M
- US HF Revenue: \$17.5M (+108%)
- US HF ASP: \$29.9K



## 2023 Guidance

- For the full year of 2023, we expect:
  - Total revenue between \$35.0 million and \$38.0 million;
  - Gross margin between 78.0% and 79.0%;
  - Operating expenses between \$76.0 million and \$80.0 million
- For the first quarter of 2023, we expect total revenue between \$7.1 million and \$7.5 million



## **R&D Update**

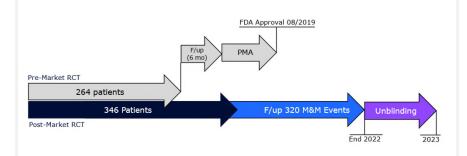
### New Device (2022)

- Improve battery longevity by ~20% (average of 6 years)
- Smaller size, more ergonomic for patients
- New programmer
- 3 PMA supplements approved by FDA: MRI Compatibility, new IPG, new programmer



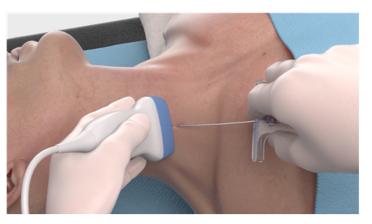
## **New Data (2023)**

- Post-market randomized controlled study for Mortality & Morbidity data enrolled
- 320 M&M events accrued in 2022, unblinding in 2023



### **New Procedure (2025)**

- Ultrasound guided implant toolkit to provide access to interventionalists
- Eliminates need for cut-down and suture on the carotid
- Enables use of local anesthetics





## **BeAT-HF study design**

Initial Enrollment April 2016

FDA PMA approval

Potential Label Expansion

### **BeAT-HF Primary Endpoint**

(n=408)

Additional (n=59)

**Intended Use Population** 

(n=264)

Intended Use Pop.

(n=59)



# **Primary Endpoint at 6 months** (n=264)

Exercise capacity improvement (6MHW) @ 6 month
Quality-of-life improvement (MLWHQ) @ 6 months
NYHA class improvement @ 6 months
Reduction in NT-proBNP @ 6 months

# Additional Follow-up at >3.5 years (n=323)

- CV Mortality or Morbidity @ >3.5 years
- Symptom improvement @ >3.5 years
- Additional clinical and economic endpoints



## **BeAT-HF – M&M outcomes**

### **Primary endpoint**



**CV Mortality** 



LVAD / Transplant



HF Hospitalizations & ER visits

**Composite endpoint** 

# Pre-specified additional analyses include:

- Hierarchical win ratio analysis
- COVID sensitivity analyses
- Days alive out of the hospital
- Severity of hospitalization

- Barostim has already proven that it is safe and effective, and that the benefits outweigh the risks.
- We believe that the outcome of this post-market trial will not impact the current reimbursement level.
- We plan to submit the totality of evidence to FDA, which may provide multiple opportunities for FDA to allow for additional claims.



## **Summary**

- Targeting an underserved morbid disease with a proprietary solution
- Large \$1.4B\* U.S. market
- Straightforward identification of patients
- One-hour outpatient procedure
- Favorable reimbursement
- Successful early commercial launch
- Proven in-house manufacturing capability
- Attractive financial profile and strong balance sheet
- Experienced leadership team







# Thank you

