# EBR Systems, Inc.
# Bioshares 18th Biotech Summit

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President and CEO

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# Investment highlights

EBR is focused on executing its clear and targeted commercialisation strategy to deliver shareholder value

## High value market opportunity

### Unique solution

No competition as the WiSE CRT system is complementary to other leadless devices

### Large markets

Targeting an initial addressable market of US$3.6bn

## Pathways to market

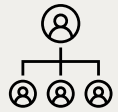
### Positive results

Safety and efficacy endpoints met for SOLVE-CRT trial and Breakthrough Device Designation granted

### Focused strategy

Clear pathway to achieve FDA approval and progress commercialisation activities to initial revenue

## Expert leadership

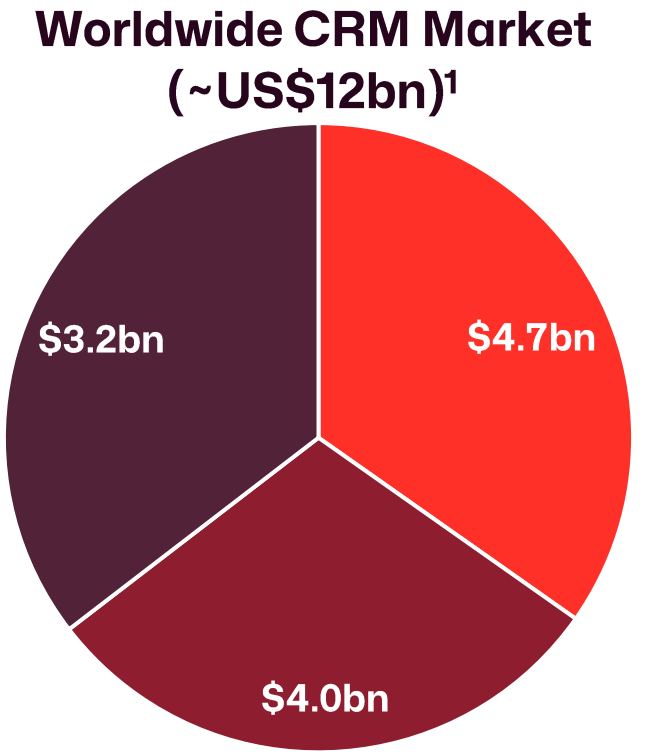


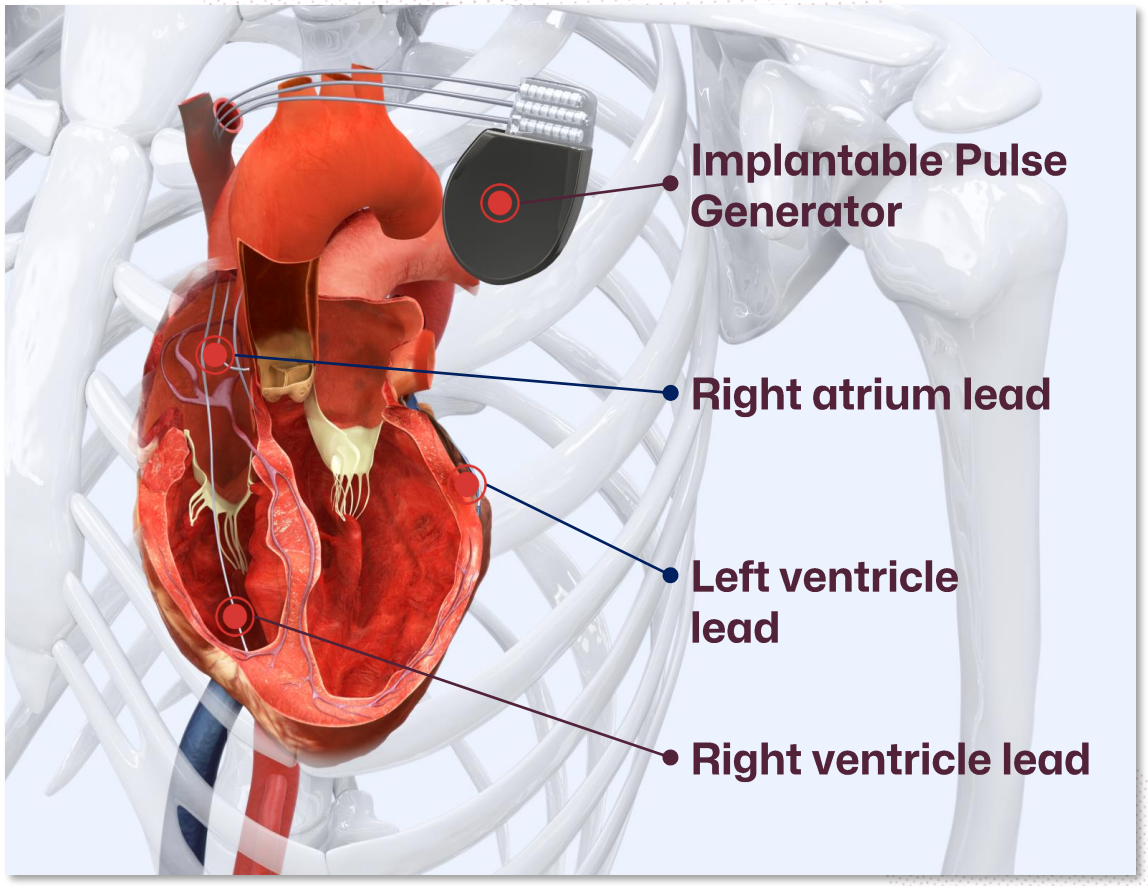
### Strong team

Experienced management team with significant clinical development and commercial expertise

# Cardiac Rhythm Management Market

Three key segments driving growth in the global cardiac rhythm management market



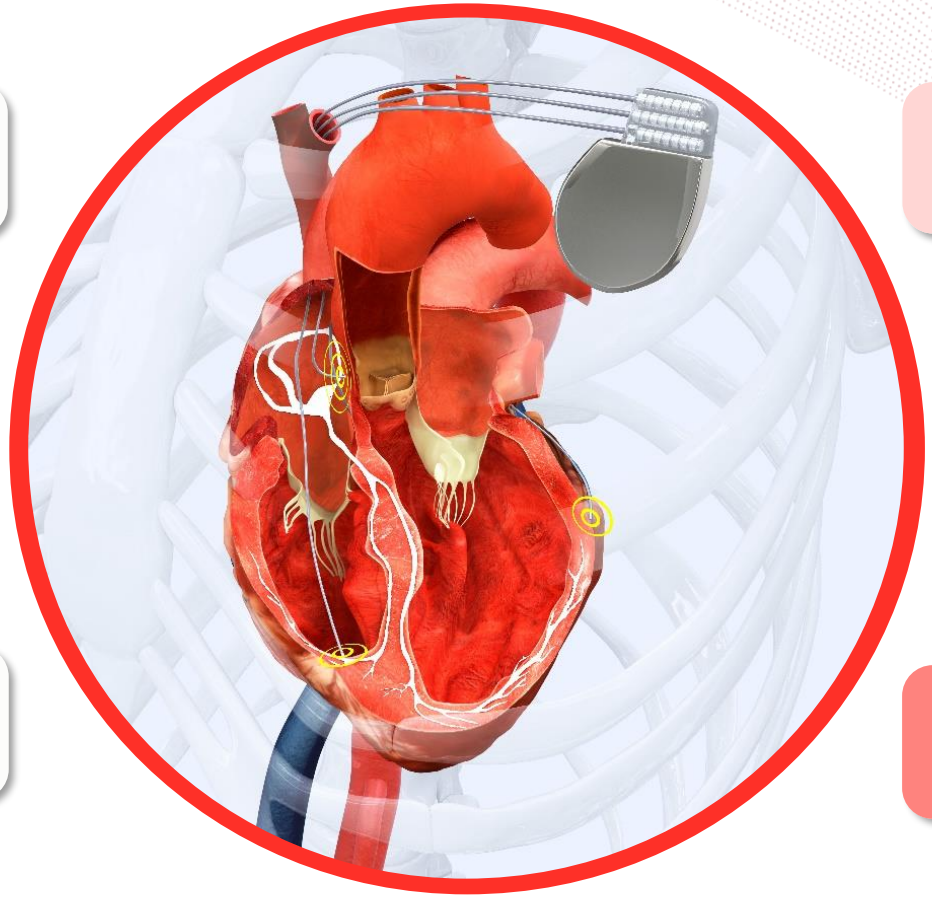




(1) Cardiac Rhythm Market - Grand View Research

# Traditional CRT systems are suboptimal

Traditional CRT systems use wires or leads to deliver energy to the heart, which can lead to many problems

- Coronary Sinus limits Left Ventricle (LV) lead placement locations
- Leads can become a way for pathogens to reach the myocardium
- Leads can be associated with phrenic nerve stimulation



- Leads can migrate and sometimes fracture
- Difficult to place
- LV lead must be placed outside the heart to avoid blood clots

# EBR has a wireless solution for heart failure

EBR's WiSE CRT System is the only wireless device that can synchronously pace the left ventricle

## WiSE CRT System fills the gap

The only leadless solution for left ventricle (LV) pacing

## Other wireless pacemakers are too big for LV pacing

Their size increases the risk of blood clots, restricting their use to right ventricle (RV) and right atrium (RA) pacing only

## Complementary solution

WiSE CRT System can be used in conjunction with wireless RV / RA pacemakers to deliver CRT

## Strong competitive protection

WiSE CRT System is protected by over 97 issued patents globally

**Left ventricle[1]**

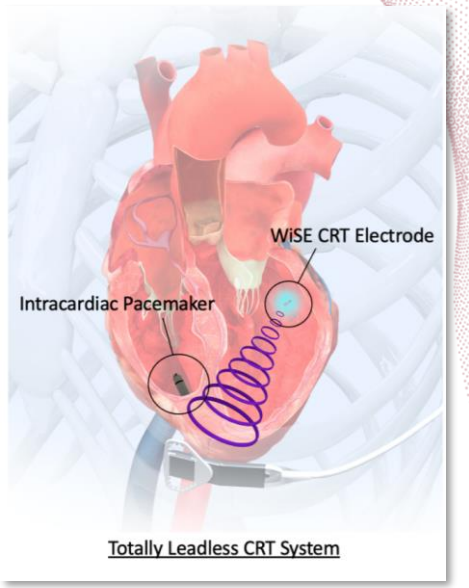
**EBR Systems WiSE CRT System**

**Right ventricle / atrium[1]**

**Medtronic Micra®**

**Boston Scientific Empower®**

**Abbott Aveir®**




Totally Leadless CRT System

(1) Illustrative sizing (not to scale)

# Pivotal SOLVE-CRT Study meets primary endpoints

Positive results confirm WiSE CRT System as a highly effective treatment option for patients with heart failure[1]

## Primary efficacy endpoint met

**-16.4%**
*p = 0.003*

Decrease in left ventricular end systolic volume (vs. -9.3% target), showing improved heart function

**Success in high-risk patients**

SOLVE-CRT patient pool consists of patients who have failed conventional CRT

**Other key data**

All data analysed to date shows consistent, positive results in reversing heart failure symptoms and physiology

## Primary safety endpoint met

**80.9%**
*p < 0.001*

Patients free from type I complications (vs. 70% target)

**Safety profile comparable to SoC[2]**

Studies using SoC treatment for CRT upgrades have shown 81.3% freedom from device & procedure related complications[3]

**Other key data**

Observed complication rates decreased over time with experience

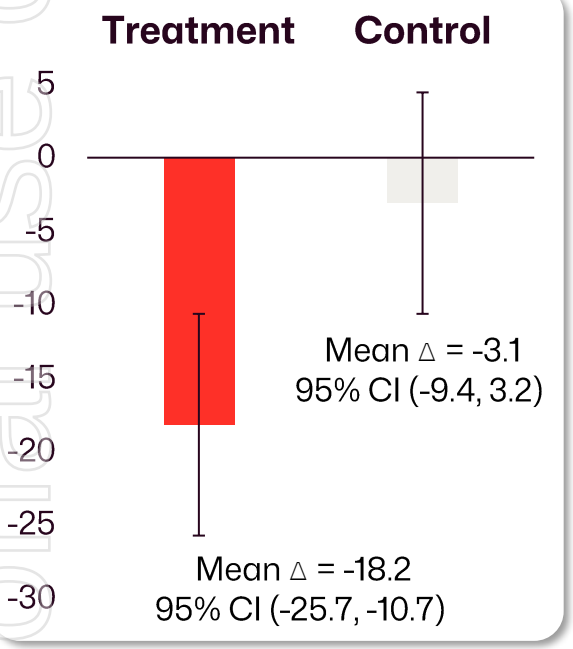


(1) "CEO Presentation on SOLVE-CRT Pivotal Trial Top-line Data" ASX release on 22 May 2023; (2) Standard of Care; (3) Poole, J. E., et al. (2010). Circulation 122(16): 1553-1561

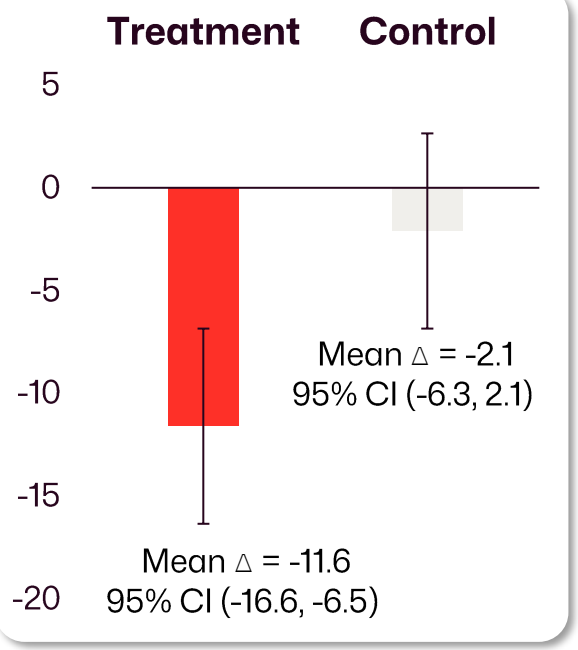
# Randomised sub-study supports primary results

The WiSE CRT System demonstrates clinically and statistically significant evidence of reverse remodelling and electrical response within previously untreatable and high-risk patients

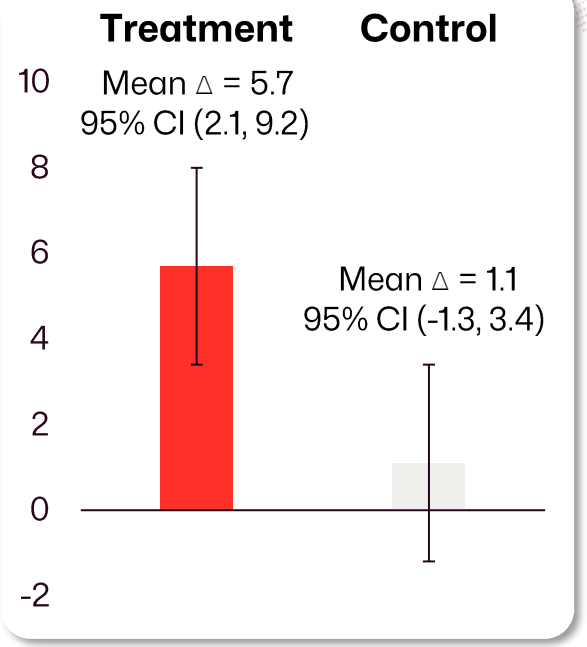
**LVESV (%)**
*p = 0.002†*



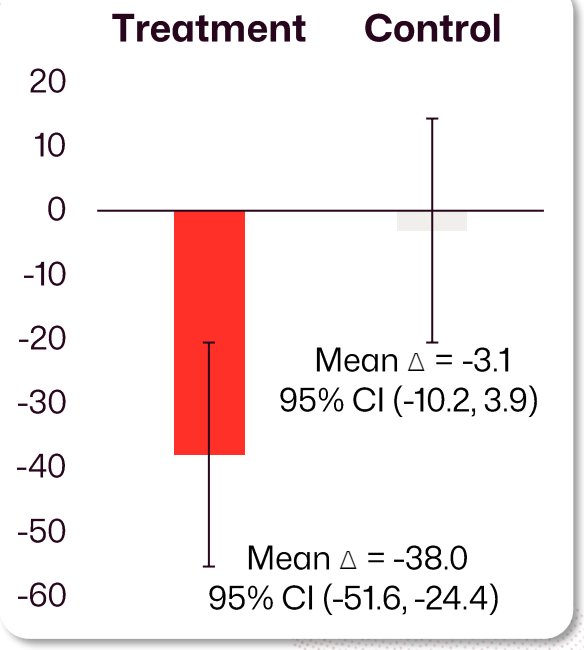

**LVEDV (%)**
*p = 0.004‡*




**LVEF (%)**
*p = 0.025†*




**QRS (ms)**
*p < 0.001‡*




**Control n = 29, Treatment n = 22**

†T-test; ‡Wilcoxon rank-sum test

# Commercialisation pathway

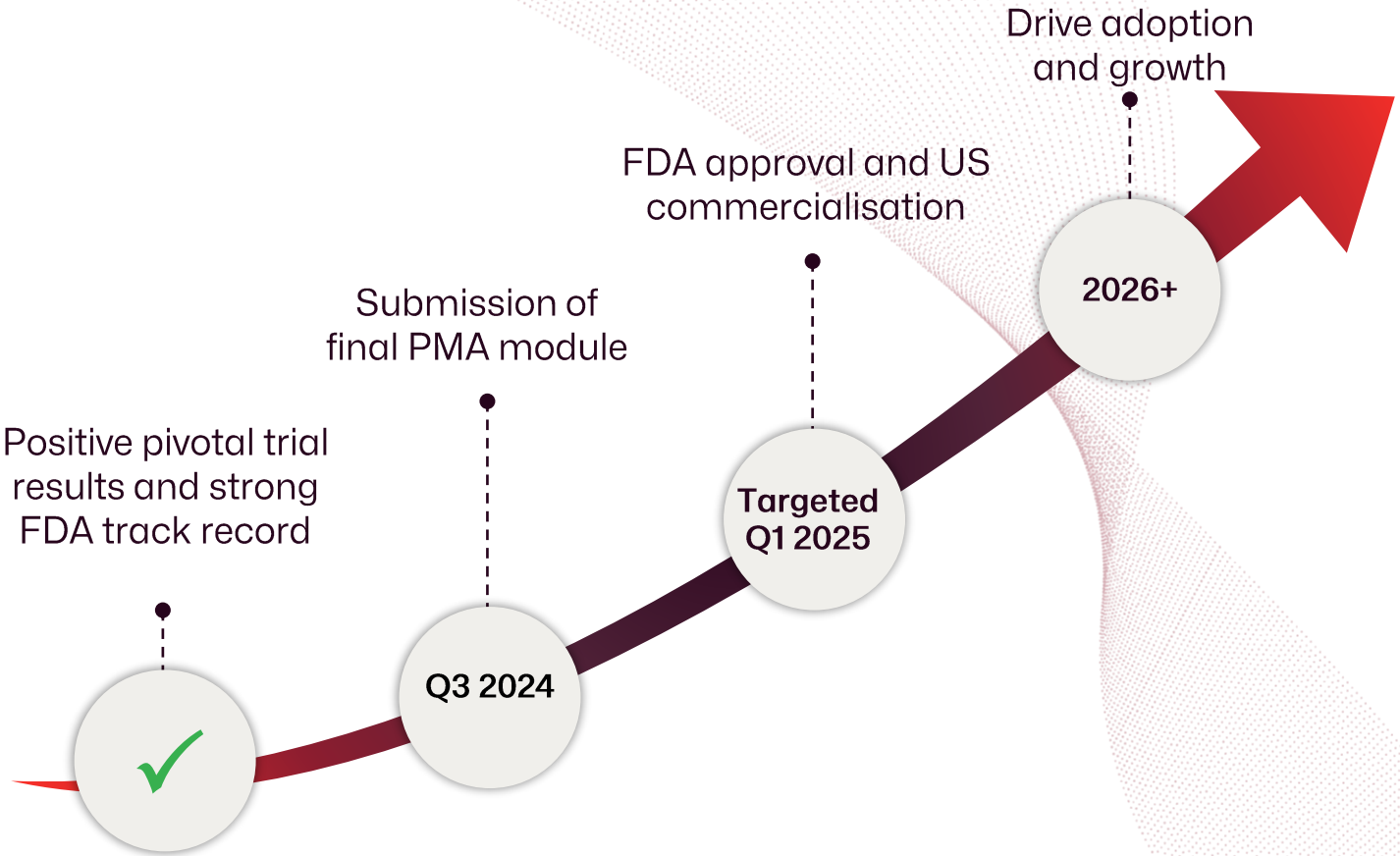
Positive pivotal trial results and strong track record with the FDA provide a clear pathway to approval and commercialisation

FDA approval process underpinned by positive pivotal trial results and a track record of successful engagement with the FDA resulting in:

- Award of Breakthrough Device Designation
- Approval of pivotal study re-design
- Approval of leadless pacemakers as a co-implant in pivotal study

EBR has submitted four out of five required modules for the PMA submission

- The final module includes biocompatibility & device verification testing
- Submission in Q3 2024



# Favourable US market dynamics

Market dynamics in the US support initial adoption of the WiSE CRT System

## Market validation

- Support of Key Opinion Leaders (KOLs)
- Unmet need underscored by FDA Breakthrough Device designation
- No direct competitors

## Low hospital adoption barriers

- Low barrier for opening new accounts
- No capital equipment required and reimbursement available post-approval
- Proven and refined implanter training program

## Reimbursement & High ASP[1]

- CMS[1] recently updated WiSE specific CPT[1] codes (e.g. 0515T, 0522T)
- CPT[1] codes already assigned to interim APC[1] codes (e.g. 5231, 5741)
- Clear pathway to NTAP[1] and TPT[1] reimbursement schemes post FDA approval
- Automatic process to reassign APC codes based on actual claims data
- WiSE CRT System target US ASP: US$45,000[2]



(1) APC: Ambulatory Payment Classification, ASP: Average Selling Price, CMS: Centers for Medicare & Medicaid Services, CPT: Current Procedural Terminology, NTAP: New Technology Add-on Payment, TPT: Transitional Passthrough Payment; 2 U.S. pricing with New Technology Add-on Payment (NTAP) post-approval

# Initial commercialisation strategy

EBR will leverage its established partnerships and presence in the US to drive initial sales growth

### Clinical trial sites to drive initial sales

- CRT market is concentrated - targeting high-volume CRT procedure sites
- **2025:** Targeting US sites that have participated in the SOLVE-CRT trial and other high-volume sites with Key Opinion Leaders (KOLs)
- **2026+:** Target top 200 to 250 clinical sites, representing >50% US CRT market

### Direct, specialist sales force

- Execution of commercial launch supported by specialised direct sales force to target high volume sites
- SOLVE-CRT core team in place with clinical and technical expertise of WiSE CRT System
- Grow initial sales and expand into new areas with sales force expansion over time

### Manufacturing capabilities

- Manufacturing capabilities in place with cabability to meet early demand
- Expand in-house manufacturing facility to meet future demand

# US$3.6bn initial addressable market

At commercial launch, EBR estimates an initial addressable market of ~US$3.6bn[1]

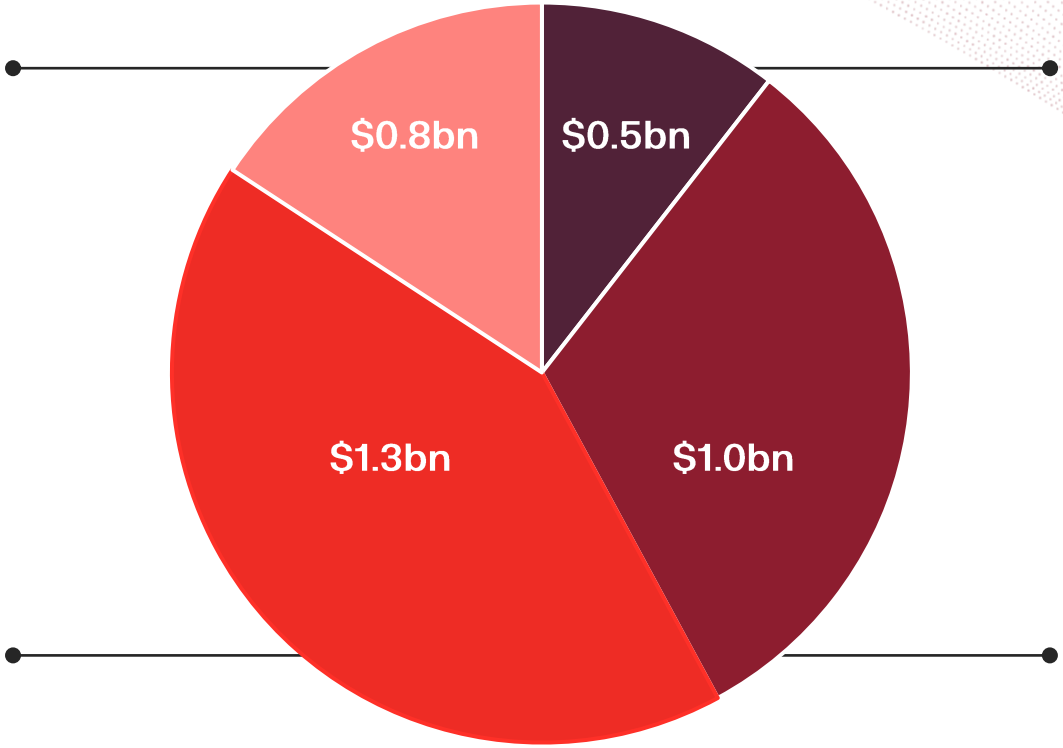
## Leadless Upgrades

- Patients with a leadless right ventricle pacemaker can only upgrade with WiSE CRT System to receive effective CRT
- WiSE CRT System used in conjunction with the Medtronic Micra (single chamber) or Abbott Aveir (single chamber) device

*Further growth potential – see next slide*

## Chronic Lead Failure

Traditional CRT system implanted but has ceased to provide effective CRT




## Acute Lead Failure

Unable to implant CRT wire in a new CRT patient

## High Risk Upgrades

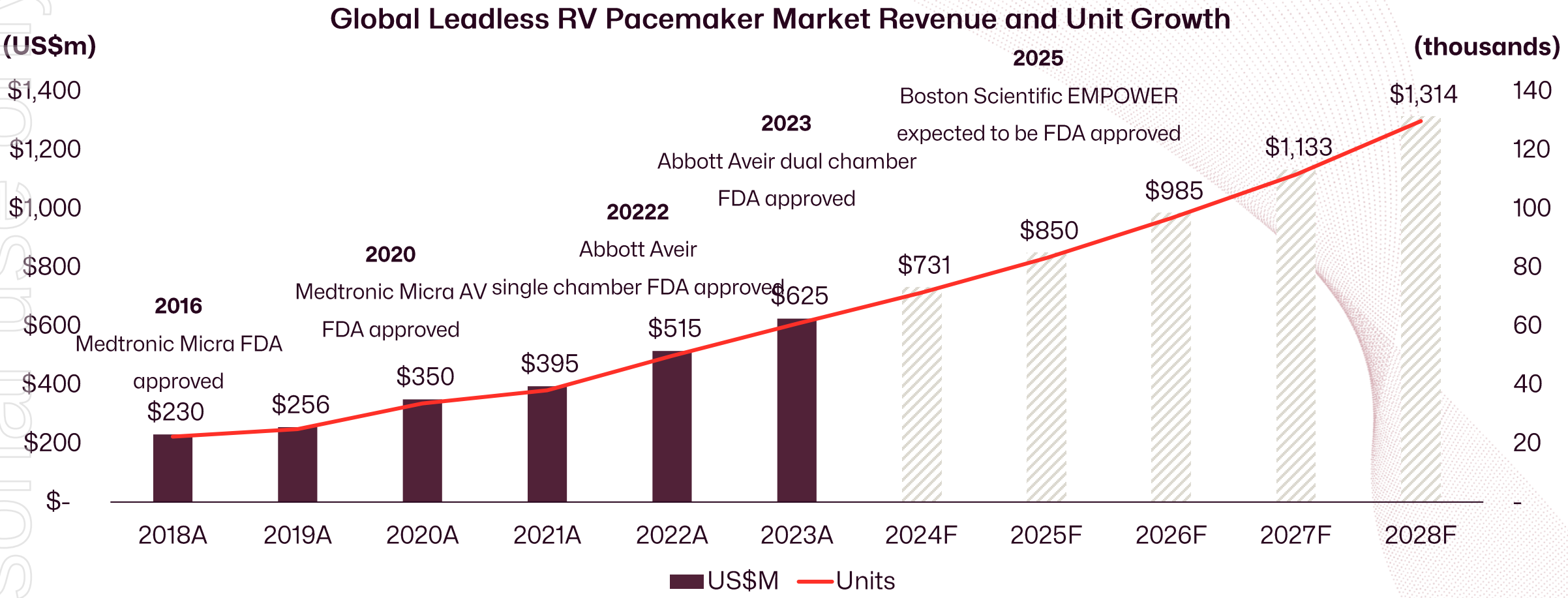
Patient requiring CRT, but is deemed too high risk for a conventional CS lead placement



(1) Grand View Research – Leadless Pacemakers Market, Cardiac Rhythm Market, Cardiac Resynchronization Therapy Market, WiSE current indications, - TAM increased from our prior figure of US$2.6bn as updated 2Q 2024

# Leadless pacemaker growth feeds EBR's addressable market

Continued global growth and adoption of leadless RV pacemakers significantly expands EBR's market opportunity




Sources: WHO, U.S. Centre for Disease Control and Prevention, US Food and Drug Administration, Investor Presentations, Primary Interviews, Grand View Research – Leadless Pacemakers Market

# Product development: Rechargeable battery

EBR is developing a new rechargeable battery that will support the WiSE CRT System in becoming a first-line therapy option and treat a broader suite of patients

**Commercial benefits**

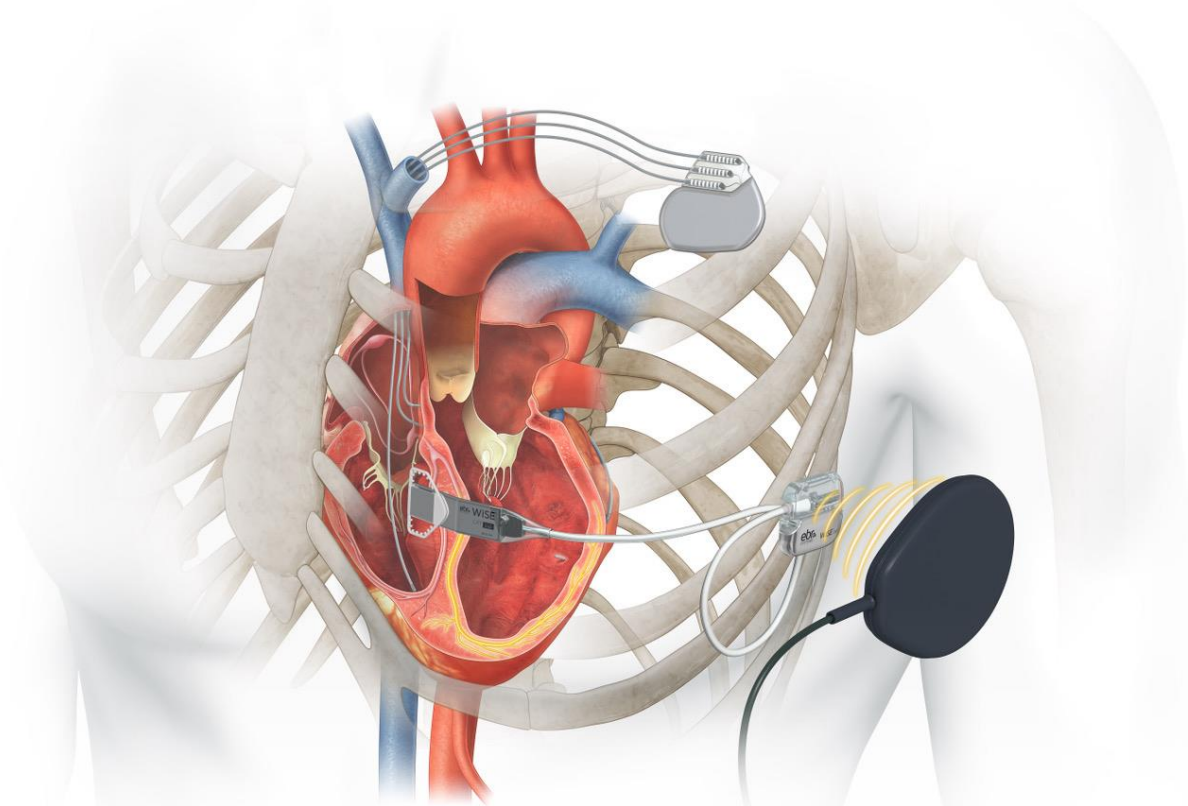
- Drives higher uptake by removing barriers to adoption
- Potential to become a first-line therapy option
- Diversifies applicability of the WiSE CRT System and grows the addressable market

**Patient benefits**

- Reduces need for future battery replacement surgery
- Recharge interval once per week[1]
- 66% reduction in size from current battery

**Development status**

- Specifications and initial design completed
- Regulatory and commercial timing to be announced as project progresses



*EBR's rechargeable battery will charge using a patch and external device to provide non-invasive, wireless charging*

(1) 95% of patients will only need to recharge once per week

# Long term growth strategy

Long term growth opportunity targeting new patient groups, indications and geographies

**Product development**

Grow addressable market through product development initiatives including a rechargeable battery

**Pursue new indications**

Progress clinical studies to expand indications and diversify product applications, opportunity to build a new market as first-line-therapy

**Expand internationally**

Launch in select OUS[1] markets as regulatory and reimbursement coverage is secured using US market entry as a template for success





(1) OUS: Outside the US

# Upcoming milestones

EBR continues to achieve significant value catalysts and pave the way to future value creation

## Delivered

- ✓ SOLVE-CRT 6 month follow up completed for final patient in February 2023
- ✓ Headline data released at Heart Rhythm Society conference
- ✓ Positive trial data unlocks second tranche of growth capital facility
- ✓ Clinical module for PMA application submitted to the FDA
- ✓ Completed randomised sub study and released positive dataset
- ✓ Randomised data presented at industry conferences including Asia-Pacific Heart Rhythm Society

## Upcoming

- ❑ Publication of manuscript in a peer reviewed medical journal
- ❑ Submit final PMA module including transmitter upgrades
- ❑ Additional sub-studies published using SOLVE-CRT dataset
- ❑ FDA approval in the US
- ❑ Commercial launch in the US

## Next steps

- ❑ Expand manufacturing capacity
- ❑ Initiate ACCESS and TLC studies
- ❑ Drive adoption in US
- ❑ Clinical study of rechargeable battery
- ❑ Enter international markets
- ❑ Expand use of WiSE CRT System into new patient groups

# Summary

EBR remains driven to deliver superior treatment for patients suffering from cardiac rhythm diseases

- Developer of the world's first and only leadless pacemaker for heart failure
- EBR's WiSE® CRT System has no direct competitors and is complementary to other pacemaker technologies
- Positive pivotal trial results de-risk the regulatory pathway and validate the device as safe and highly effective
- Clear commercial strategy in place focusing on high-volume procedure sites in the US, minimising execution risk
- Significant market opportunity with an initial addressable market of US$3.6bn and potential for further expansion
- Funded through initial commercialisation with US$64.1/A$98.4m cash in bank as of 31 Mar 2024

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