



**EBR Systems, Inc.**  
**Bioshares 18<sup>th</sup> Biotech**  
**Summit**

12 JULY 2024

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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



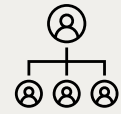
### Positive results

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



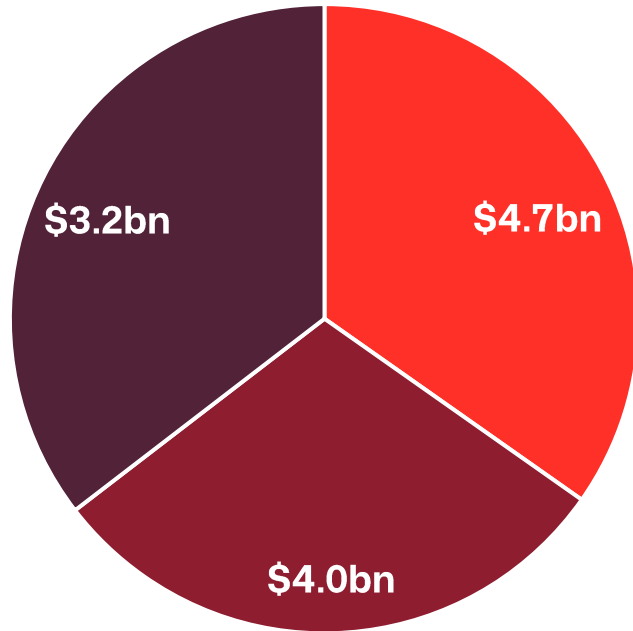
### Strong team

Experienced management team with significant clinical development and commercial expertise

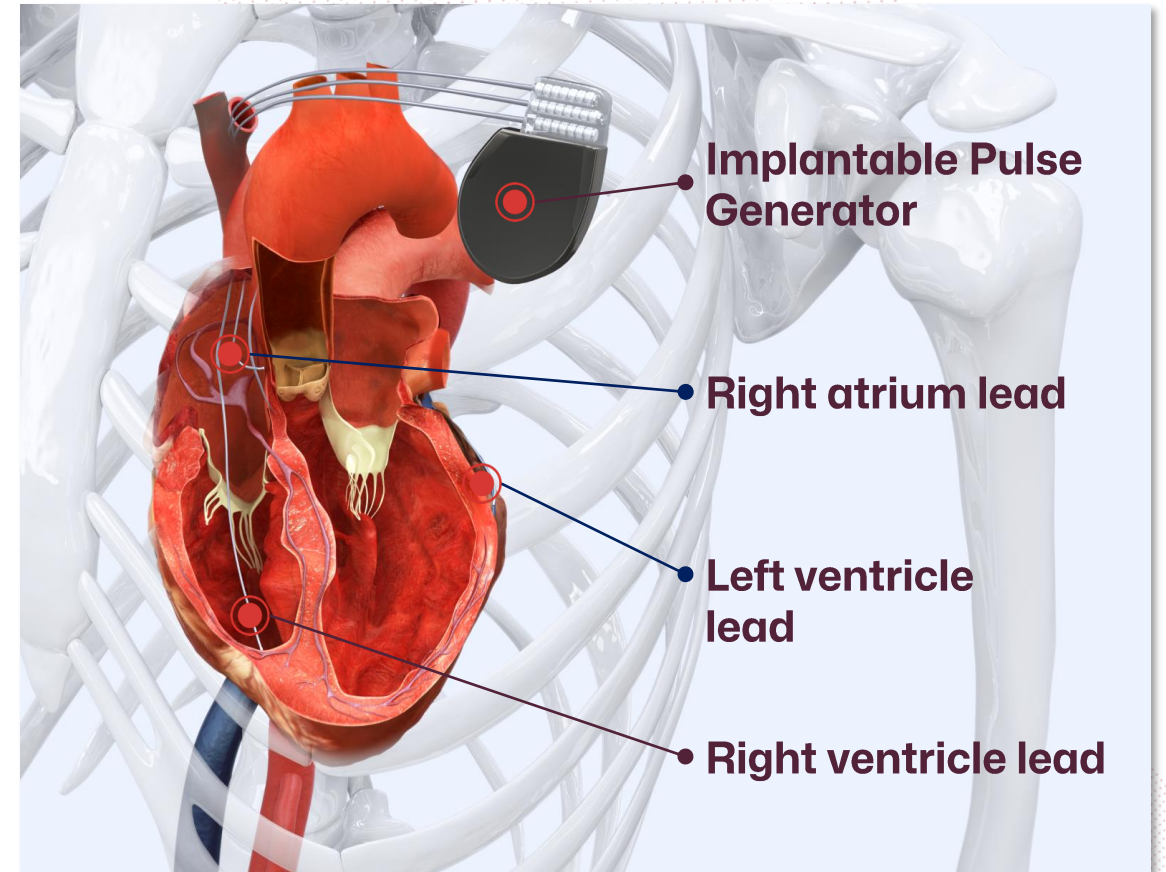
# Cardiac Rhythm Management Market

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

**Worldwide CRM Market  
(~US\$12bn)<sup>1</sup>**

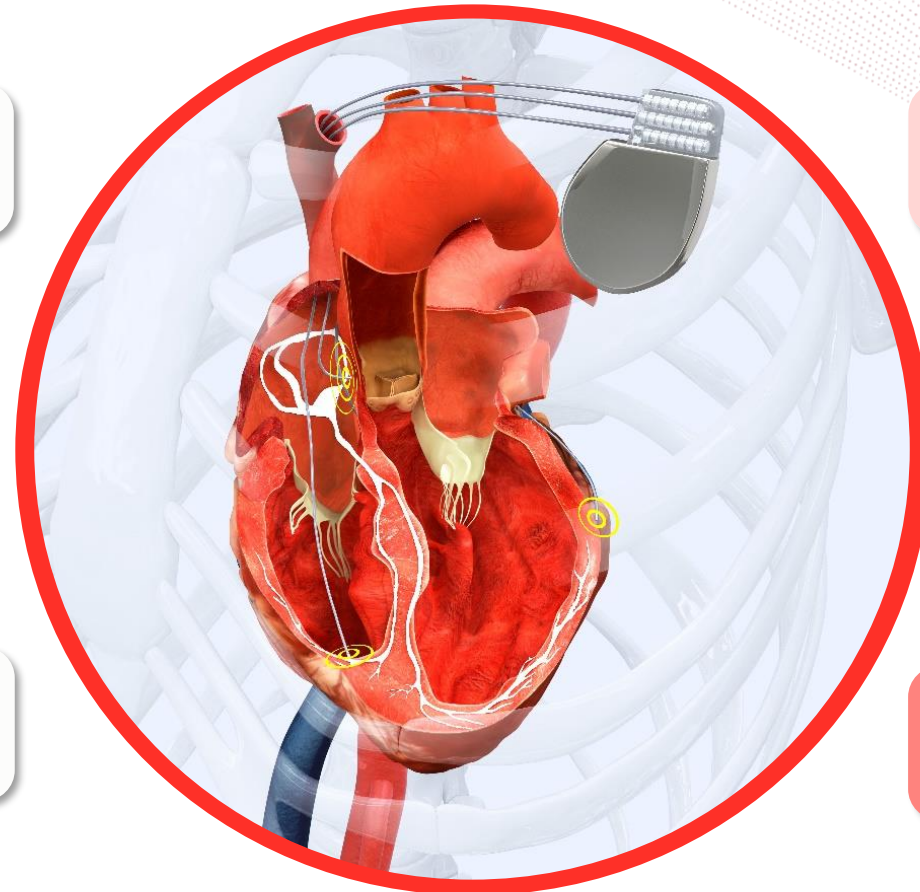


- Cardiac Resynchronisation Therapy (CRT)
- Implantable Cardioverter Defibrillation (ICD)



# 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<sup>1</sup>



EBR Systems  
WiSE CRT System

### Right ventricle / atrium<sup>1</sup>



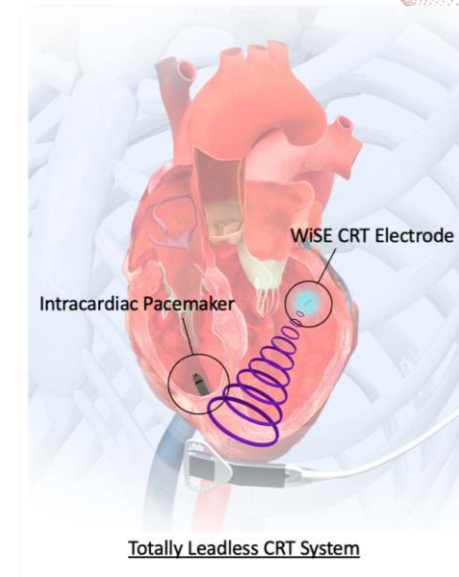
Medtronic  
Micra<sup>®</sup>



Boston  
Scientific  
Empower<sup>®</sup>



Abbott  
Aveir<sup>®</sup>



# Pivotal SOLVE-CRT Study meets primary endpoints

Positive results confirm WiSE CRT System as a highly effective treatment option for patients with heart failure<sup>1</sup>

## 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<sup>2</sup>

Studies using SoC treatment for CRT upgrades have shown 81.3% freedom from device & procedure related complications<sup>3</sup>



### Other key data

Observed complication rates decreased over time with experience

# Randomised sub-study supports primary results

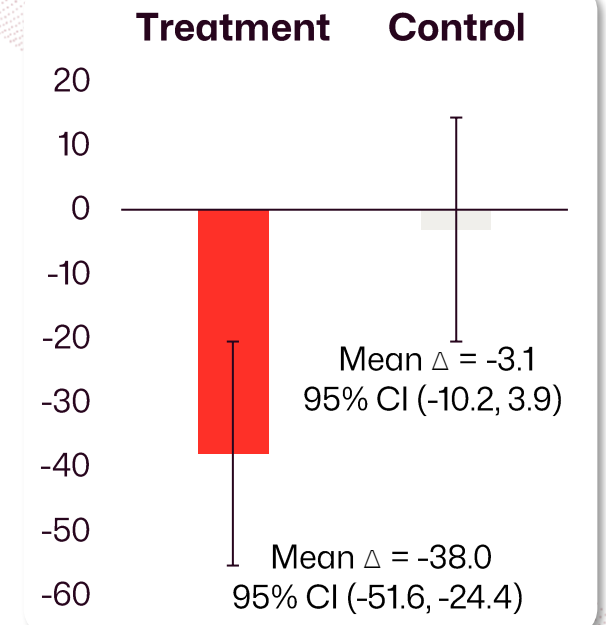
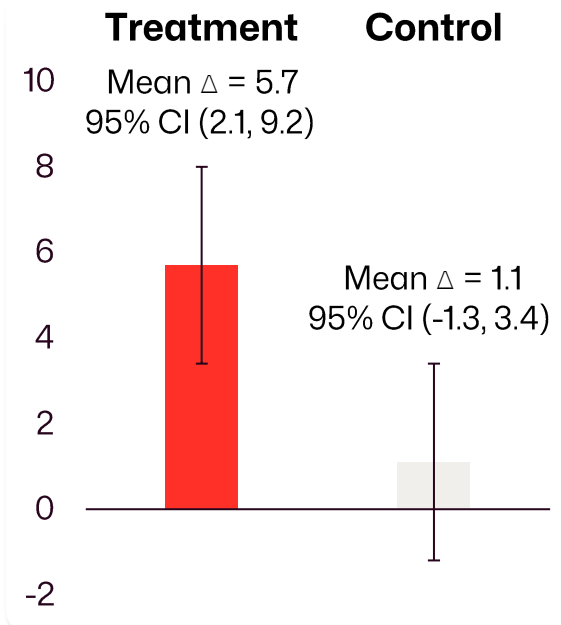
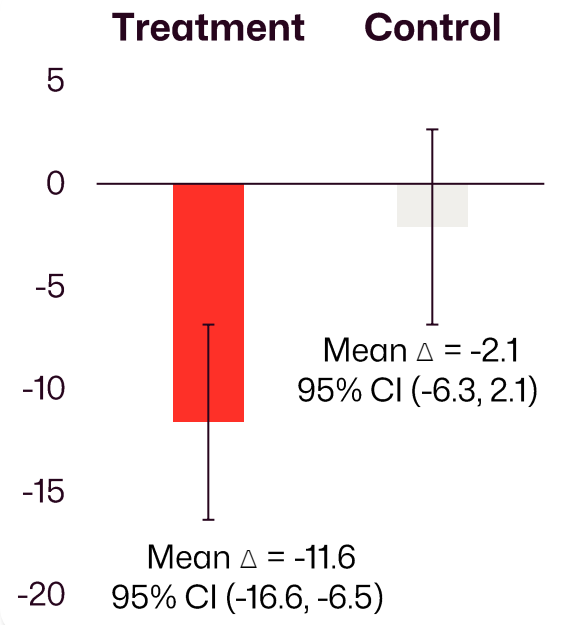
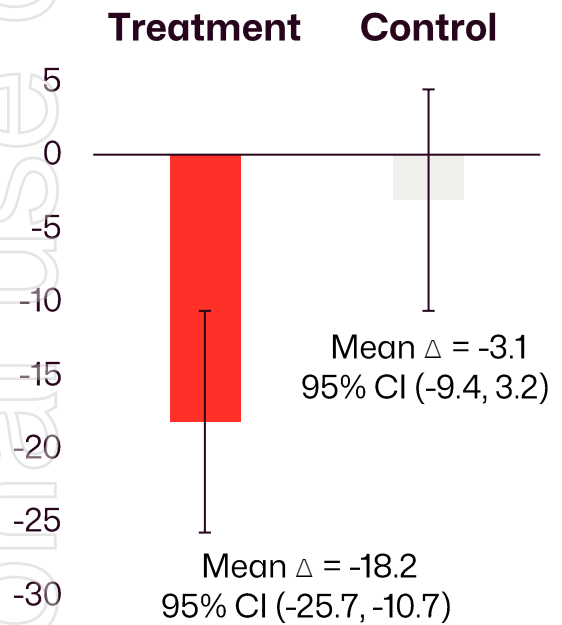
The WiSE CRT System demonstrates clinically and statistically significant evidence of reverse remodelling and electrical response within previously untreatable and high-risk patients

**LVESV (%)**  
 $p = 0.002^\dagger$

**LVEDV (%)**  
 $p = 0.004^\ddagger$

**LVEF (%)**  
 $p = 0.025^\dagger$

**QRS (ms)**  
 $p < 0.001^\ddagger$



Control n = 29, Treatment n = 22



# Commercialisation pathway

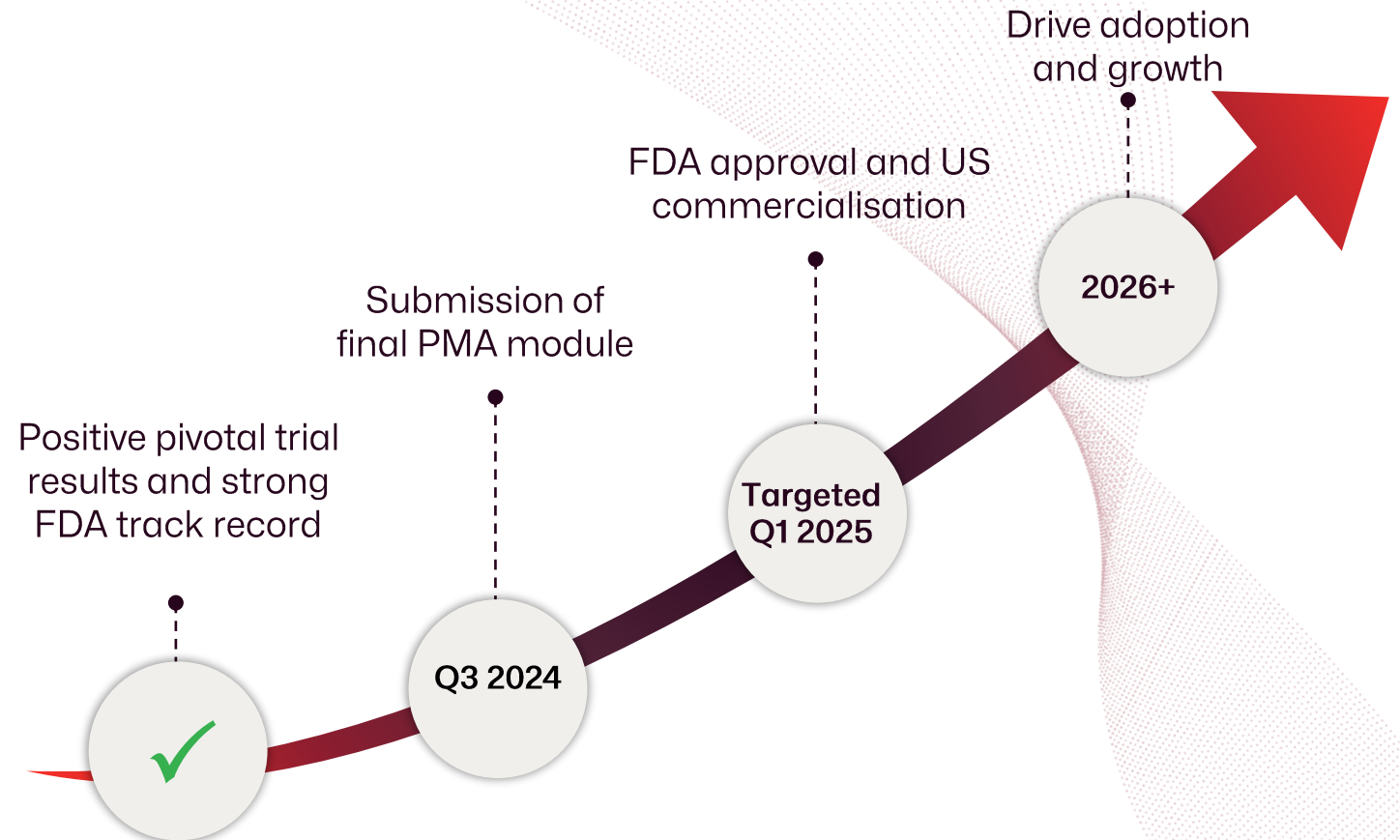
Positive pivotal trial results and strong track record with the FDA provide a clear pathway to approval and commercialisation

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<sup>1</sup>

- CMS<sup>1</sup> recently updated WiSE specific CPT<sup>1</sup> codes (e.g. 0515T, 0522T)
- CPT<sup>1</sup> codes already assigned to interim APC<sup>1</sup> codes (e.g. 5231, 5741)
- Clear pathway to NTAP<sup>1</sup> and TPT<sup>1</sup> 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<sup>2</sup>

# 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 capability 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<sup>(1)</sup>

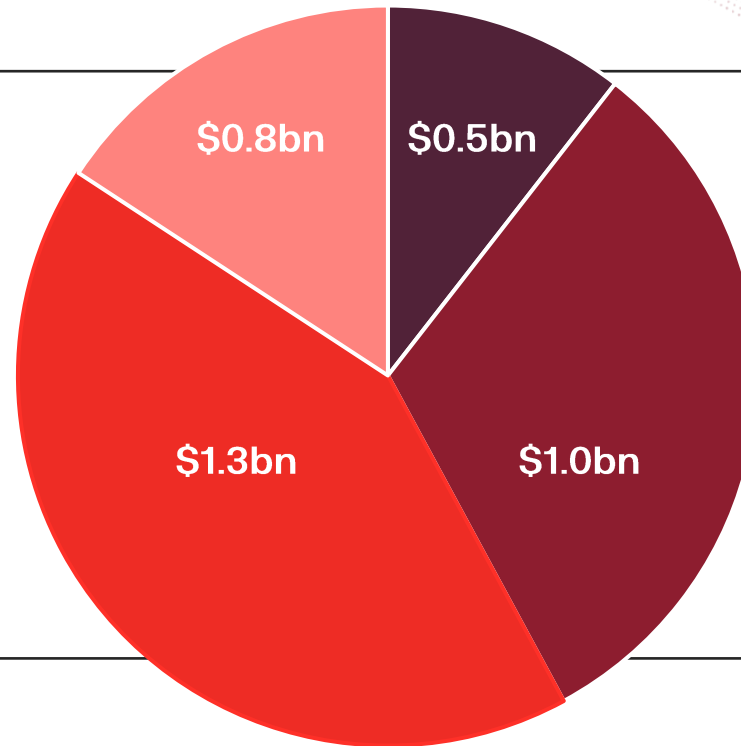
## Leadless Upgrades

- 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

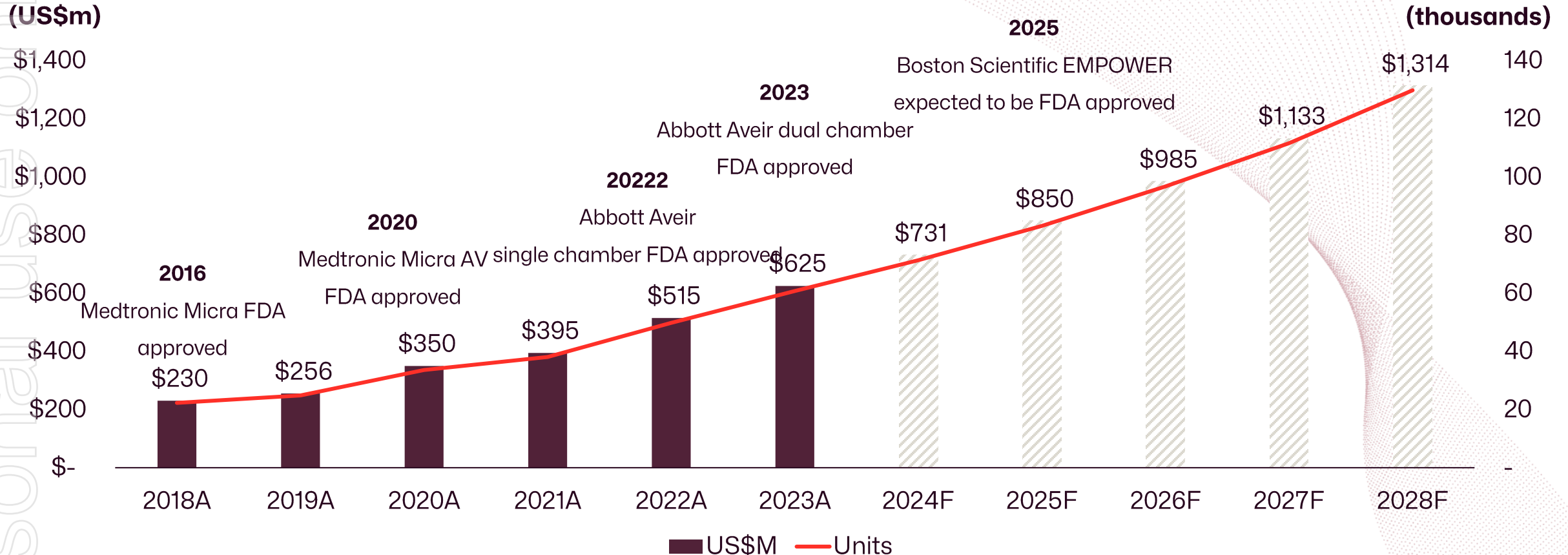
## High Risk Upgrades

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

# Leadless pacemaker growth feeds EBR's addressable market

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

## Global Leadless RV Pacemaker Market Revenue and Unit Growth



# 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

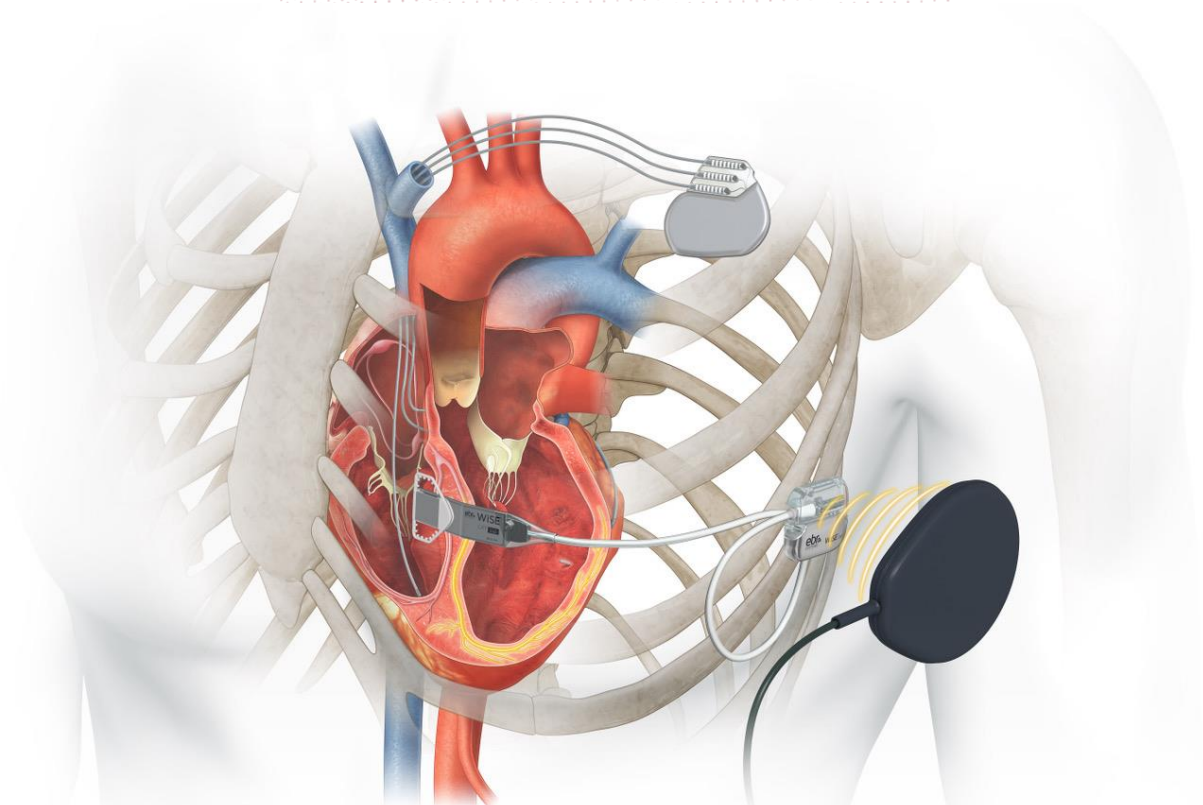
- Drives higher uptake by removing barriers to adoption
- Potential to become a first-line therapy option
- Diversifies applicability of the WiSE CRT System and grows the addressable market

## Patient benefits

- Reduces need for future battery replacement surgery
- Recharge interval once per week<sup>1</sup>
- 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*

# 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<sup>1</sup> markets as regulatory and reimbursement coverage is secured using US market entry as a template for success

# 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<sup>®</sup> 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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