

# **Investor Presentation**

January 2024



## EBR Systems at a glance

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\$2.6bn and potential for further growth



Funded through initial commercialisation with US\$73.4/A\$107.8m cash in bank as of 31 Dec 2023



## Traditional pacemakers are suboptimal

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



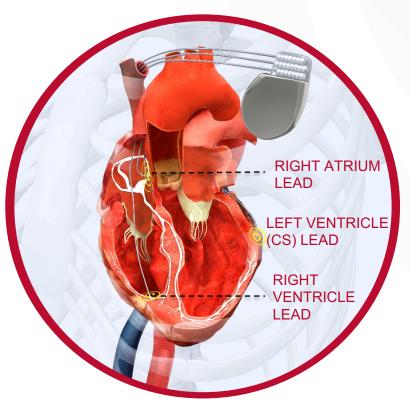
Coronary Sinus limits Left Ventricle (LV) lead placement locations



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 patients

EBR's WiSE CRT System is the only wireless device that can deliver cardiac resynchronisation therapy

## WiSE CRT System fills the gap

Currently the only leadless solution globally for LV pacing including CRT.

## Other wireless pacemakers are too big for LV pacing

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

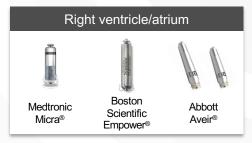
#### **Complementary solution**

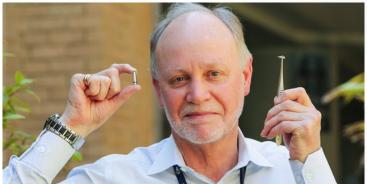
WiSE CRT System can be used in conjunction with wireless RV/RA pacemakers to deliver CRT.

## Strong competitive protection

WiSE CRT System is protected by over 97 issued patents globally.







Dr. Jeffrey Alison, Monash Hospital, Melbourne.

Micra on the left, WiSE CRT device held by tweezers on the right.



Note: Illustrative sizing (not to scale)

# Pivotal SOLVE-CRT Study meets all endpoints

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

## **Primary efficacy endpoint met**

**-16.4%** p = 0.003

Decrease in 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

Other studies using standard of care (SoC) treatment for CRT upgrades have shown 81.3% freedom from device & procedure related complications<sup>1</sup>



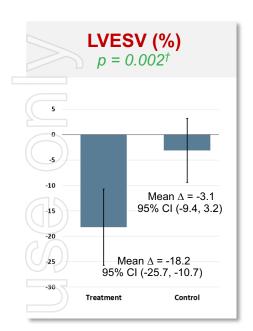
#### Other key data

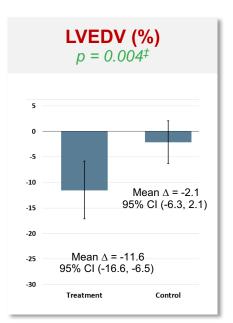
Observed complication rates were higher in early phases and decreased with experience

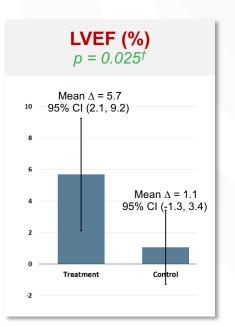


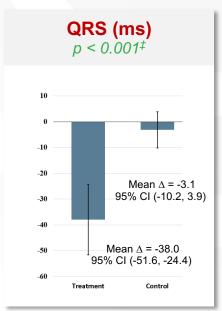
# Randomised sub-analysis supports primary results

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









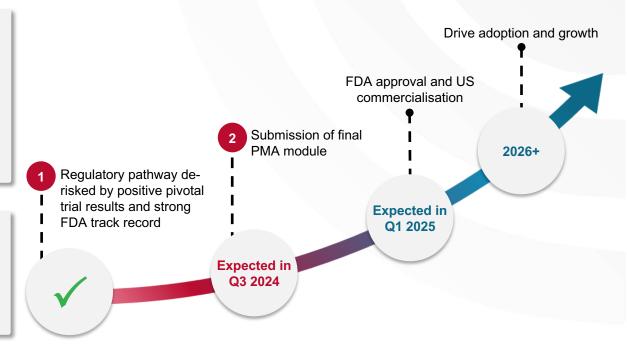


Control n = 29, Treatment n = 22

## Commercialisation pathway

Positive pivotal trial results and strong track record with the FDA de-risk EBR's regulatory approval process and underpin a clear pathway to commercialisation

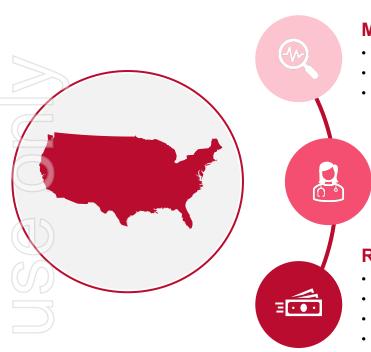
- Confidence in FDA approval process underpinned by positive pivotal trial results and a track record of successful engagement with the FDA resulting in:
- Award of Breakthrough Device Designation
- Approval of pivotal study re-design
- Approval of leadless pacemakers as a coimplant in pivotal study
- 2
- EBR has submitted four out of five required modules for the PMA submission
- The final module is related to biocompatibility & device verification testing which is currently underway





# 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
- Low barrier to transition to become first-line therapy (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**

- CMS recently updated WiSE specific CTP codes (eg 0515T, 0522T)
- CPT codes already assigned to interim APC codes (eg 5231, 5741)
- Clear pathway to NTAP and TPT reimbursement schemes post FDA approval
- · Automatic process to reassign APC codes based on actual claims data
- WiSE CRT System ASP: US\$35,000 US\$45,000<sup>1</sup>



## Initial commercialisation strategy

EBR will leverage its established partnerships and presence in the US to drive initial sales growth, targeting first sales during H1 2025



## 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)
- 2026-2027: Target top 200 to 250 clinical sites, representing >50% US CRT market



## Specialist sales force established

- Execution of commercial launch supported by specialised direct sales force to target high volume sites
- SOLVE-CRT team in place with clinical and technical expertise of WiSE CRT System
- Grow initial sales and expand into new areas, targeting 35 sales territories by the end of 2027



## Scale manufacturing capability

- Existing manufacturers already in place with cabability to scale
- Expand in-house manufacturing facility to meet future demand
- As demand increases, seek to optimise operations to reduce global supply chain risk



## Long term growth strategy

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



#### **Pursue new indications**

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



#### **Product development**

Grow addressable market through product development initiatives including development of a rechargeable battery



## **Expand internationally**

Launch in select OUS¹ markets as regulatory and reimbursement coverage is secured using US market entry as a template for success



## US\$2.6bn initial addressable market

At commercial launch, EBR estimates to have an initial addressable market of ~US\$2.6bn

#### Leadless Upgrades **Acute Lead Failure** Patients with a leadless right ventricle Unable to implant CRT wire in a new CRT pacemaker can only upgrade with WiSE CRT System to receive effective CRT \$0.3bn \$0.5bn patient WiSE CRT System used in conjunction with the Medtronic Micra (single chamber) or Abbott Aveir (single chamber) device \$0.8bn Near term upside potential – see slide 12 \$1.0bn **Chronic Lead Failure High Risk Upgrades** Traditional CRT system implanted but has Patient requiring CRT, but is deemed too high ceased to provide effective CRT risk for a conventional CS lead placement



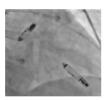
# Totally Leadless CRT is a growth market

The Totally Leadless CRT (TLC) market has the potential to grow by an additional US\$4.2bn

## **Dual Chamber Leadless Upgrades**

WiSE CRT System used in conjunction with the Abbott Aveir dual chamber device, estimated to launch late 2023





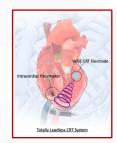
\$2.2bn segment TAM

Near term expansion opportunity (3-4 years)

#### First-line treatment with TLC

WiSE CRT System used in conjunction with any leadless device





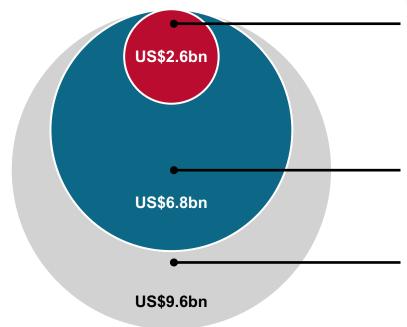
**\$2.0bn** segment TAM

Near term expansion opportunity (~4 years)



# Market expansion opportunity

The WiSE CRT System can be expanded for use in other patient groups, indications and geographies, increasing EBR's market opportunity and underpinning future growth



#### Initial addressable market

- Acute Lead Failure
- · Chronic Lead Failure
- High Risk Upgrades
- Single Chamber Leadless Upgrades

#### Addressable market in ~4 years

- Dual Chamber Leadless Upgrades
- First-line CRT treatment with Totally Leadless CRT

#### Long term addressable market with next-gen systems

- International expansion
- · Conduction system pacing
- De novo implants for bradycardia



Note: Expanding into any additional clinical indications and/or patient groups may require supporting data from clinical studies, additional regulatory approvals, and establishing payment coverage or reimbursement.

# 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

Charging unit

#### 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



## 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 randomized sub study and released positive dataset
- Randomised data presented at industry conferences including APHRS<sup>1</sup>

#### **Near term**

- ☐ Publication of manuscript in a peer reviewed medical journal
- ☐ Submit Final PMA Module including transmitter upgrades
- Additional sub-studies published using SOLVE-CRT dataset
- Expand manufacturing facility
- Production of prototype rechargeable batteries

## **Next steps**

- □ FDA approval in the US
- Commercial launch in the US
- Expand use of WiSE CRT System into new patient groups
- Initiate ACCESS and TLC studies
- □ Drive adoption in US
- □ Launch of rechargeable battery



<sup>&</sup>lt;sup>1</sup> Asia Pacific Hearth Rhythm Society

<sup>2</sup> OUS: Outside the US

## Investment highlights

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

**High value market opportunity** 

**De-risked pathways to market** 

**Expert leadership** 



#### **Unique solution**

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



#### Large markets

Targeting initial addressable market of US\$2.6bn with expansion opportunity up to US\$9.6bn



#### 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 achieve first sales



## Strong team

Experienced
management team
with significant
clinical development
and commercial
expertise



# Appendix







## Patient success story - Richard

EBR has allowed the patient to once again partake in all the activities he enjoyed before his heart failure

#### Pre heart failure

US Marine and Vietnam war veteran who enjoyed a very active and outgoing lifestyle

"Sport was a very big part of my life. I was an active person."











#### Onset of heart failure

## Heart failure materially impact the patient's quality of life

- 2014: Pacemaker implanted due collapsing from a low heart rate.
- **2016:** Developed pacing induced heart failure. Conventional lead-based CRT implanted. Multiple lead failures.
- 2017: Rapid deterioration: "I couldn't walk up a flight of stairs. I couldn't work, I couldn't do anything. I was just existing."

#### **Post WiSE CRT Implant**

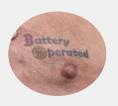
# Post WiSE CRT implant, the patient has been able to enjoy everything he used to do

"I was energised immediately. I could now take out the bins and walk up a flight of stairs."

"I was able to resume daily walks and open water swimming. Got stronger and lost 20kg."

"I'm happy, extremely happy. It's given me my life back!"







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