

# Bell Potter Healthcare Conference Presentation

**November 2023**

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# Traditional pacemakers are suboptimal


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




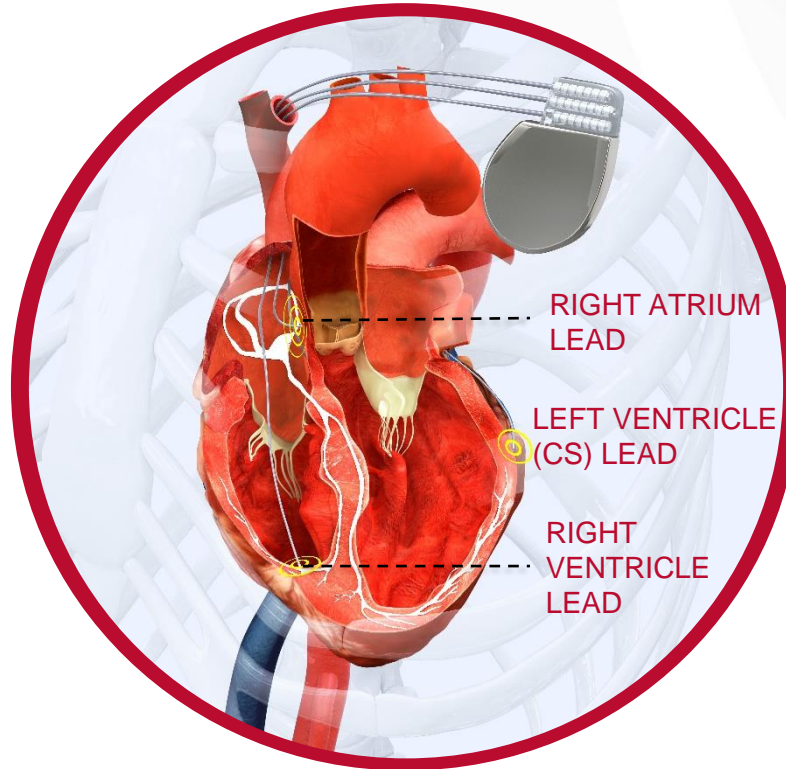
Coronary Sinus limits  
Left Ventricle (LV) lead  
placement locations




Pathway for  
pathogens to  
myocardium




Associated with  
phrenic nerve  
stimulation



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

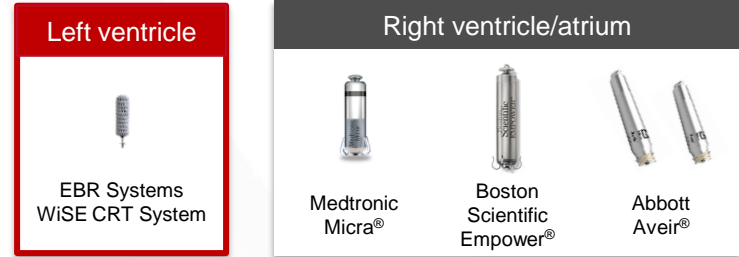
This increases the risk of blood clots, restricting their use to right ventricle (RV) and right atrium (RA) pacing only.

## 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.*

# 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>

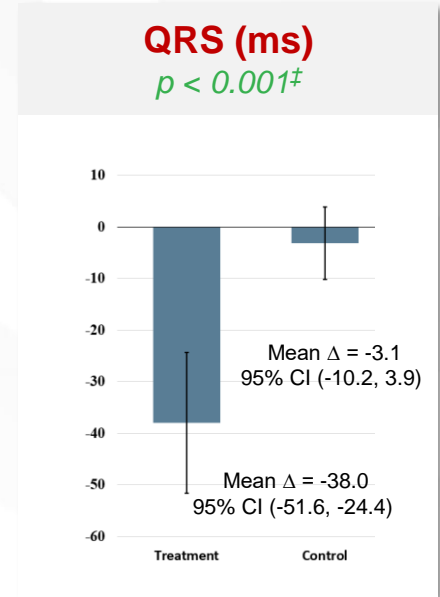
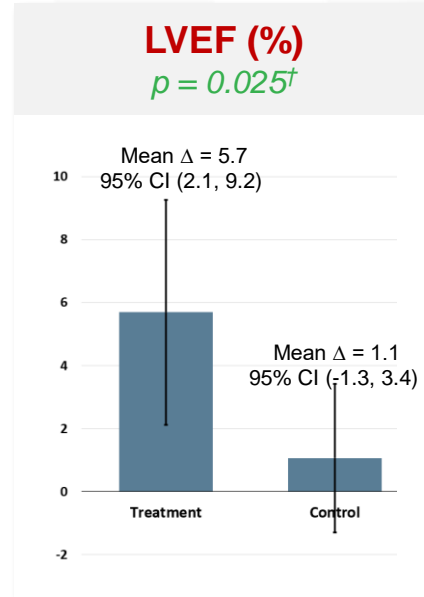
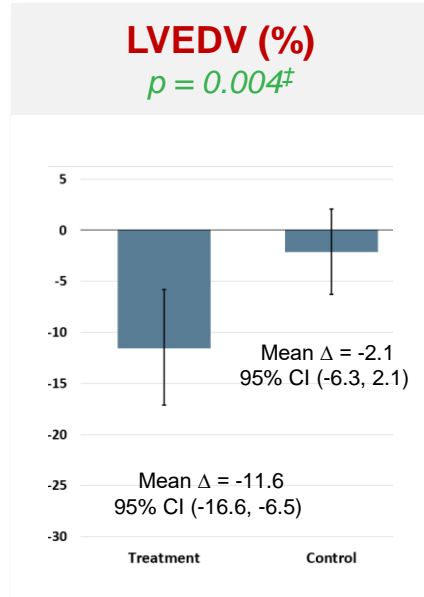
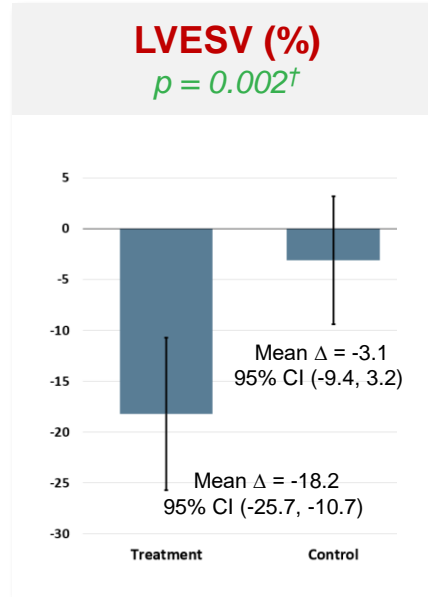


### Other key data

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

# Clear regulatory pathway

EBR's track record of successful engagement underpins confidence for FDA approval process

## ● 2019

### **FDA granted Breakthrough Device Designation to WiSE CRT System**

Provides EBR with interactive and timely access to and input from the FDA during premarket development phase, and a prioritised review of regulatory submissions filed with the FDA.

## ● 2020

### **FDA approved trial re-design of pivotal study**

Pivotal study was redesigned with the FDA to be completed with a single-arm, treatment only phase. This was underpinned by extensive clinical experience with >450<sup>1</sup> patients treated with WiSE CRT System to date.

## ● 2022

### **FDA approved leadless pacemakers as a co-implant in pivotal study**

FDA approval to include leadless pacemakers as a co-implant in the pivotal SOLVE-CRT trial. If approved during the PMA submission, this would potentially expand EBR's addressable market by ~US\$550m.

## ● 2023+

### **Clear pathway to approval with modular submission approach**

EBR has already submitted four out of five modules to the FDA and targets submission of the final module in early 2024. EBR expects to receive FDA approval by the end of Q4 2024.

**PMA submission to the FDA remains on track with approval expected by H2 2024**

# Focused commercialisation strategy

EBR will leverage its established partnerships and presence in the US to drive initial sales growth, targeting initial sales in 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 device
- Grow from an initial 7 sales territories to 35 sales territories by the end of 2027

## Enhanced by supporting market factors:



### Unmet need and strong data

- Unmet need underscored by FDA Breakthrough Device designation
- Support of Key Opinion Leaders (KOLs)
- Low barrier to transition to become first-line therapy



### 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



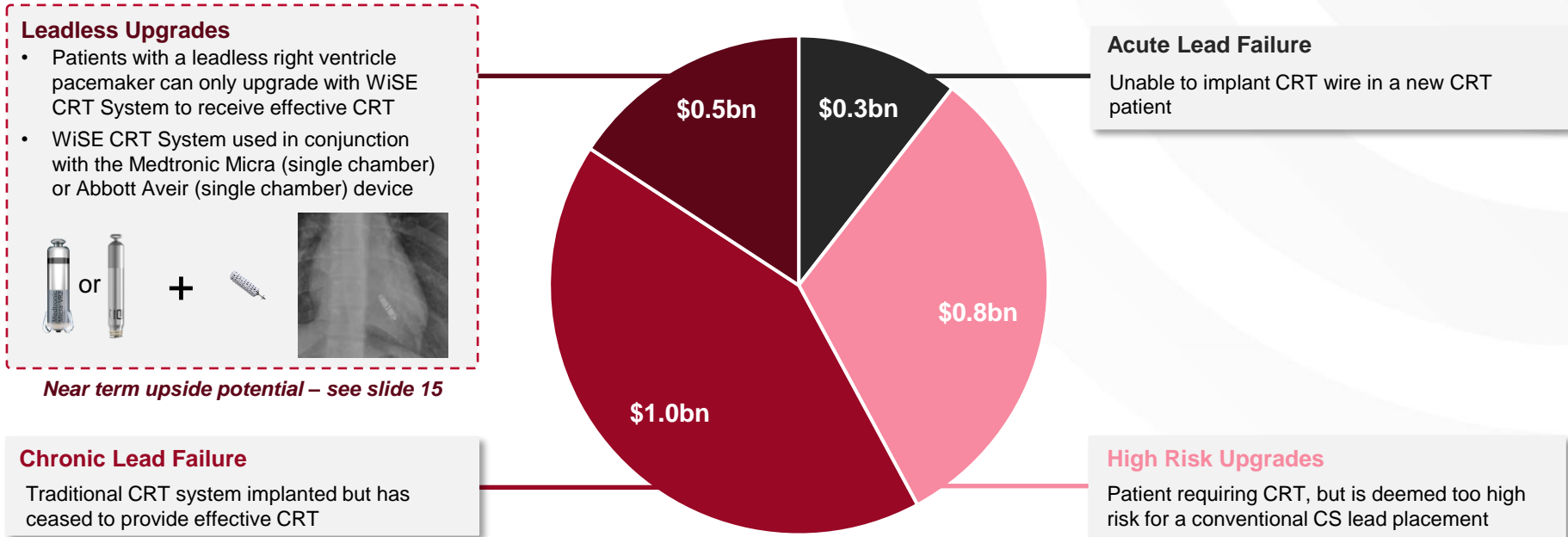
### Reimbursement & High ASP

- New Technology Add-on Payment (NTAP) and Transitional Passthrough Payment (TPT) expected post FDA approval
- WiSE CRT System ASP - US: US\$35,000<sup>1</sup> and OUS: US\$20,000<sup>2</sup>



# US\$2.6bn initial addressable market

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



# Totally Leadless CRT is a growth market

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

## Upgrading dual chamber leadless

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)*

## TLC as first-line therapy

WiSE CRT System used in conjunction with any leadless device

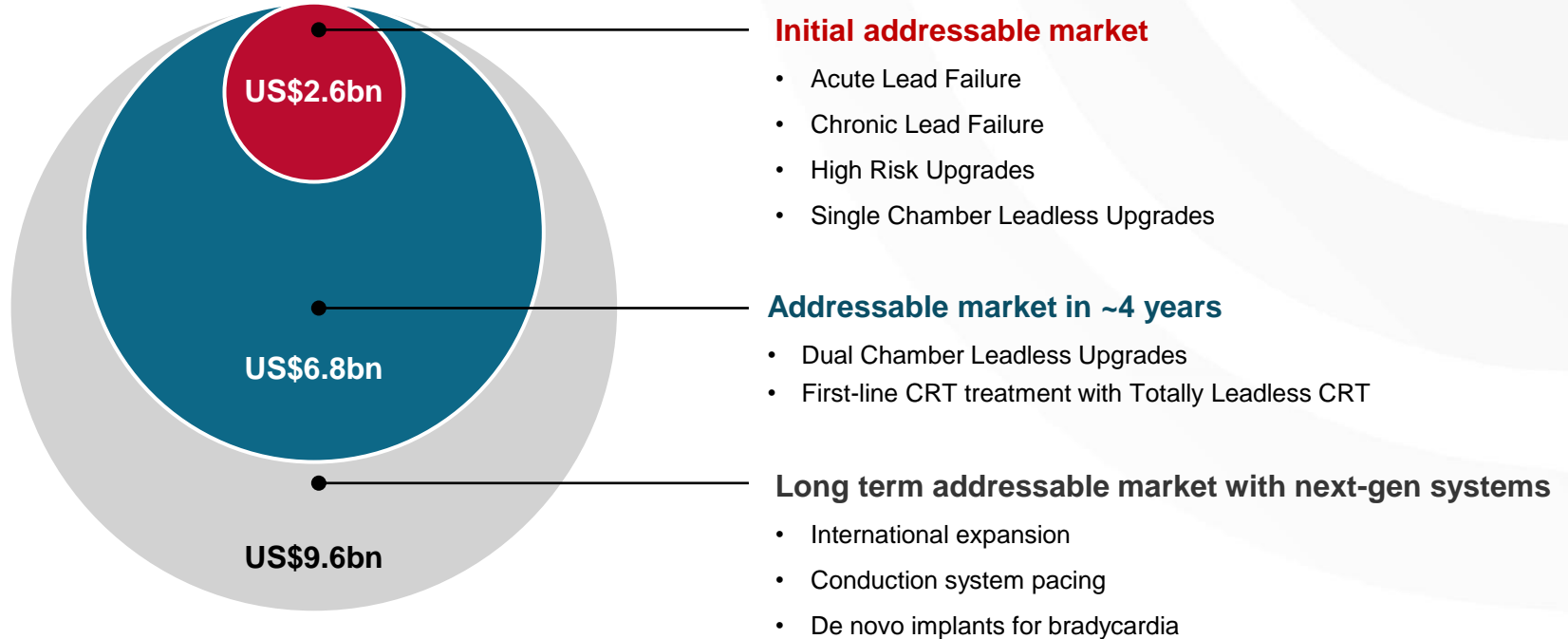


**\$2.0bn** segment TAM

*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



# Product development

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

## Background

EBR is developing a rechargeable battery and wireless charging system based on feedback from implanters and patients

## Benefits

- Reduces the 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
- First working product for testing expected in H1 2024
- Regulatory and commercial timing to be announced as project progresses



**EBR's new rechargeable battery charges uses a patch and external device to provide non-invasive, wireless charging**

# Clinical development: totally leadless CRT

EBR is currently progressing planning activities for studies to expand indications

## Totally leadless CRT

- WiSE CRT System can pair with a leadless RV pacemaker to achieve totally leadless CRT
- Increased adoption of leadless pacemakers expands the need for WiSE CRT System
  - Approximately 30% of these patients will need CRT within 4 years
  - WiSE CRT System provides the only means to upgrade leadless pacemakers to CRT
- Opportunity to build a new market as first-line-therapy with de novo totally leadless CRT
  - Avoid issues associated with implant of transvenous pacing leads
- Initiating TLC Study in H2 2024, the study is physician-initiated and includes long-term follow-up on existing patients

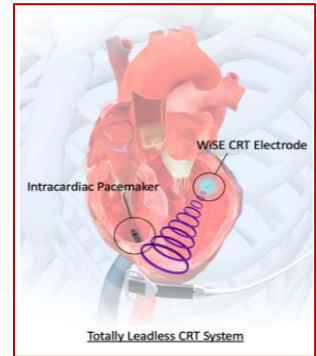
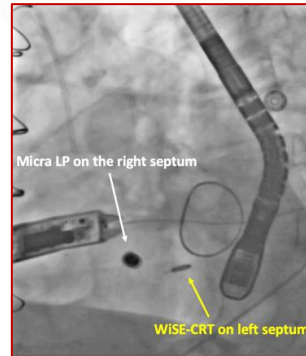
ESC  
European Society  
of Cardiology

Europace (2023) 00, 1–8  
doi:10.1093/europace/eaad342

CLINICAL RESEARCH

### European experience with a first totally leadless cardiac resynchronization therapy pacemaker system

Adrien Carabelli<sup>1</sup>, Mariem Jabeur<sup>1</sup>, Peggy Jacon<sup>1</sup>, Christopher Aldo Rinaldi<sup>2</sup>, Christophe Leclercq<sup>3</sup>, Giovanni Rovaris<sup>4</sup>, Martin Arnold<sup>5</sup>, Sandrine Venier<sup>1</sup>, Petr Neuzil<sup>6</sup>, and Pascal Defaye<sup>1\*</sup>



# Upcoming milestones

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

2023

- ✓ 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**
- ✓ Submit Clinical Module for PMA application to the FDA
- ✓ Present at industry conferences including APHRS<sup>1</sup>
- ❑ Publication of manuscript in a peer reviewed medical journal

2024

- ❑ Submit Final PMA Module including transmitter upgrades
- ❑ Production of working rechargeable batteries for design verification testing
- ❑ Additional sub-studies published using SOLVE-CRT dataset
- ❑ Initiate ACCESS and TLC studies
- ❑ Expand manufacturing facilities
- ❑ FDA approval in the US

2025+

- ❑ Commercial launch in the US
- ❑ Launch in select markets OUS<sup>2</sup> as reimbursement and regulatory coverage is secured
- ❑ Expand use of WiSE CRT System into new patient groups and geographies
- ❑ Launch of rechargeable battery

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



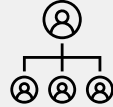
### Positive results

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



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