# Investor Presentation

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ASX:EBR

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# Investment highlights

Developer of the world's first and only leadless pacemaker for heart failure

## High value market opportunity

### Unique solution

No competition as the WiSE CRT system is complementary to other leadless devices. It is the only leadless device to deliver CRT

### Large markets

Targeting an initial addressable market of US$3.6bn

## Pathways to market

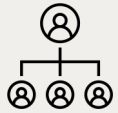
### Positive results

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

### Clear pathway to FDA approval

FDA completed Day-100 Meeting and PAI. Approval expected on or before 13 April 2025.

## Defined Strategy



### Clear commercial strategy in place

Progressing commercialisation activities to initial revenue in H2 2025 by targeting high-volume sites in the US

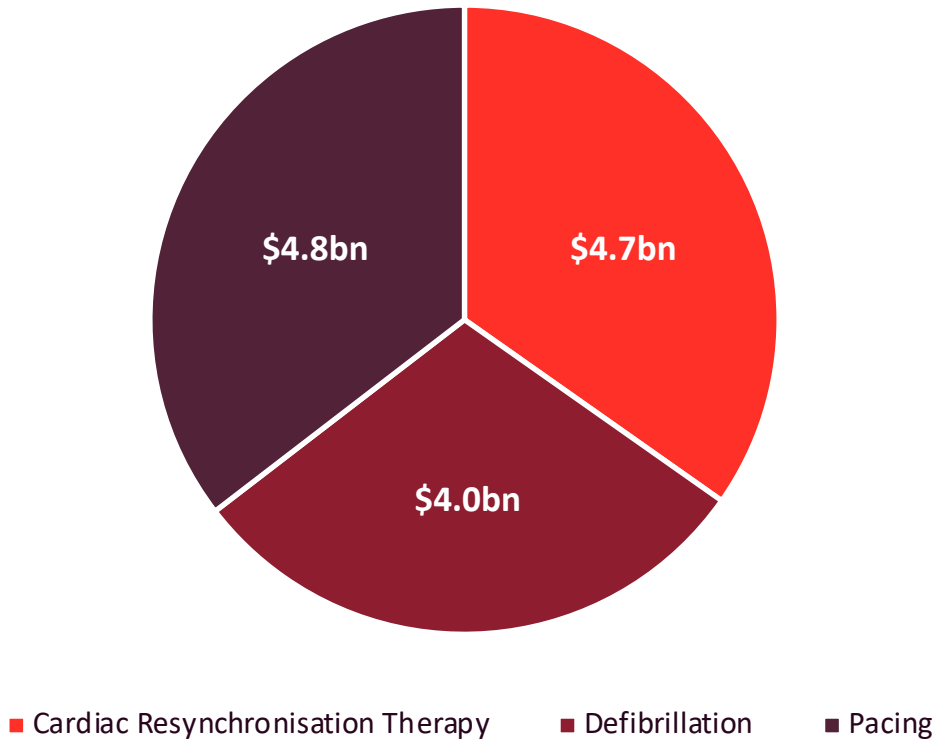
**Well-capitalised through to initial commercialisation with cash and short-term investments of US$66.0m / A$106.1m[1]**

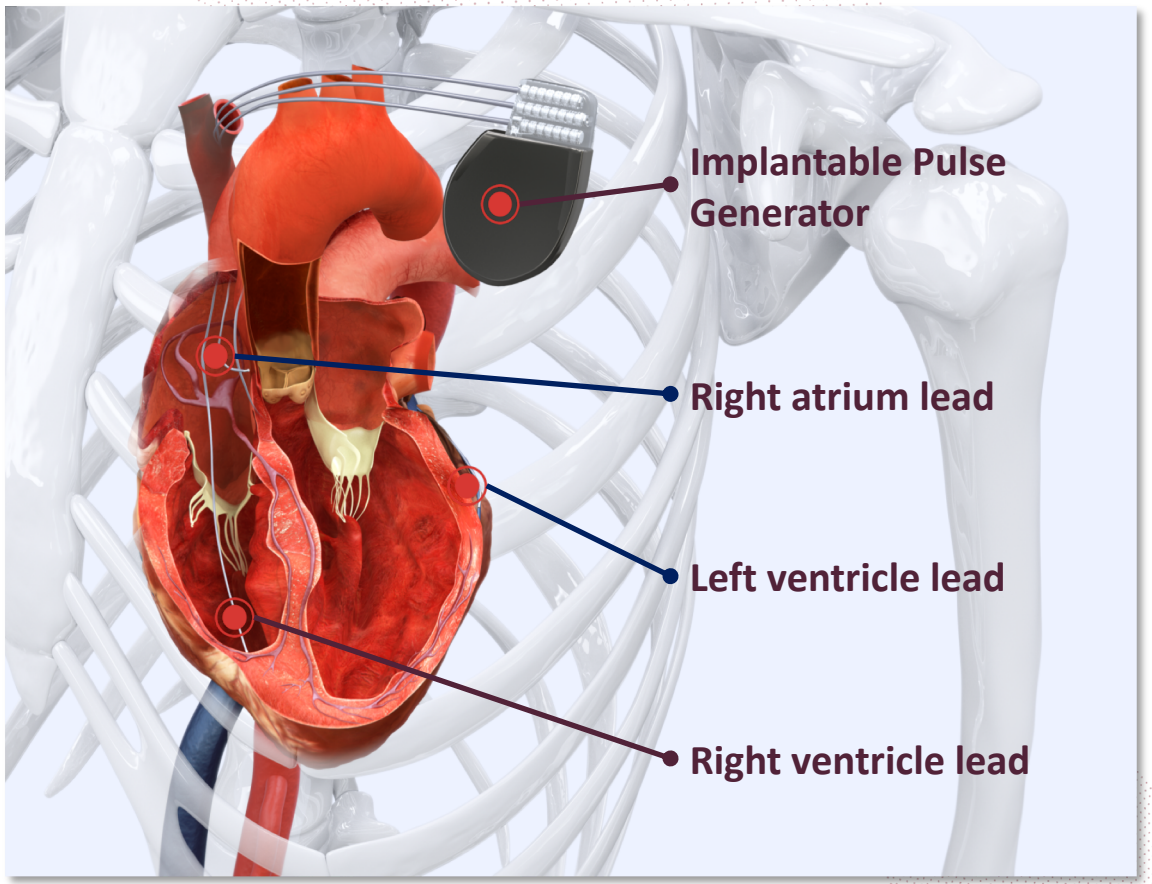
(1) As of 31 December 2024. Assumes A$:US$ 0.6214 exchange rate.

# Cardiac Rhythm Management Market

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

**Worldwide CRM Market (~US$13.6bn)[1]**



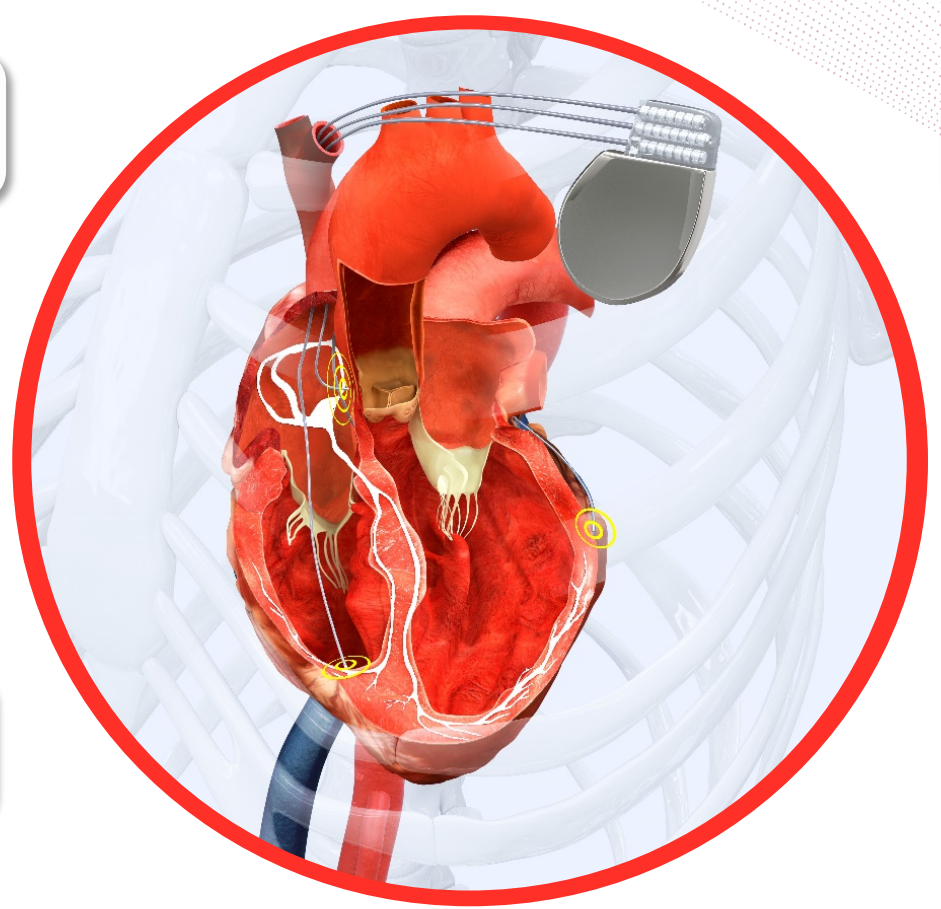




(1) Cardiac Rhythm Market - Grand View Research

# Traditional CRT systems are suboptimal

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

- Leads can migrate and sometimes fracture
- Leads can become a way for pathogens to reach the myocardium
- Difficult to place



- LV lead must be placed outside the heart to avoid blood clots
- Coronary Sinus limits Left Ventricle (LV) lead placement locations
- Leads can be associated with phrenic nerve stimulation

# EBR has a wireless solution for the heart

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

## 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]**

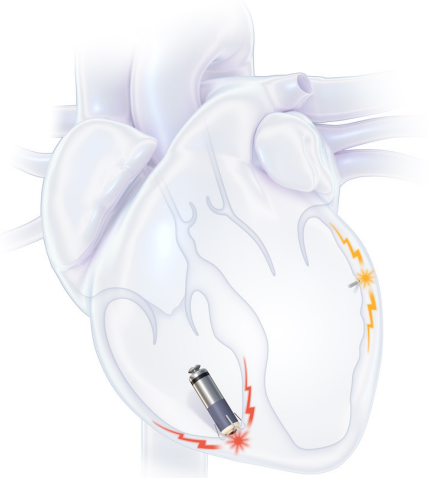
EBR Systems WiSE CRT System

**Right ventricle / atrium[1]**

Medtronic Micra®

Boston Scientific Empower®

Abbott Aveir®



**Extravascular / Subcutaneous ICD**


Boston Scientific Emblem®


Medtronic Aurora®

(1) Illustrative sizing (not to scale)

# Pivotal SOLVE-CRT Study met all 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

# Strong Support from Global Key Opinion Leaders



**Jagmeet P. Singh M.D., Ph.D.**
Cardiologist & Electrophysiologist, *Harvard Medical School,*
*Massachusetts General Hospital,*
*Boston, Mass*

"This study opens the window for the future care of patients who require CRT. By pacing endocardially, this allows us to explore individual treatment strategies to provide more physiologic treatment of patients with heart failure. What I'm also really excited about is the potential to achieve totally leadless CRT by pairing WiSE with leadless pacemakers."

**Prash Sanders, MBBS, PhD, FHRS**
Cardiologist & Electrophysiologist,
*University of Adelaide,*
*Adelaide, Australia*

"EBR Systems' WiSE technology is the future of CRT and pacing. Today it allows us to treat previously failed patients. WiSE also has a unique opportunity to enable Leadless Left Bundle Branch Pacing or Conduction System Pacing, and down the road, act as a standalone system."

**Timothy Betts, MD, MBChB, FRCP**
Cardiologist & Electrophysiologist
*Oxford University Hospitals NHS Foundation Trust, Oxford, UK*

"The WiSE CRT system has enabled me to successfully treat many patients who had previously failed treatment with conventional CRT devices. Without WiSE, these heart failure patients would be relegated to progressive deterioration of their condition and repeated hospitalizations."

# Commercialisation pathway

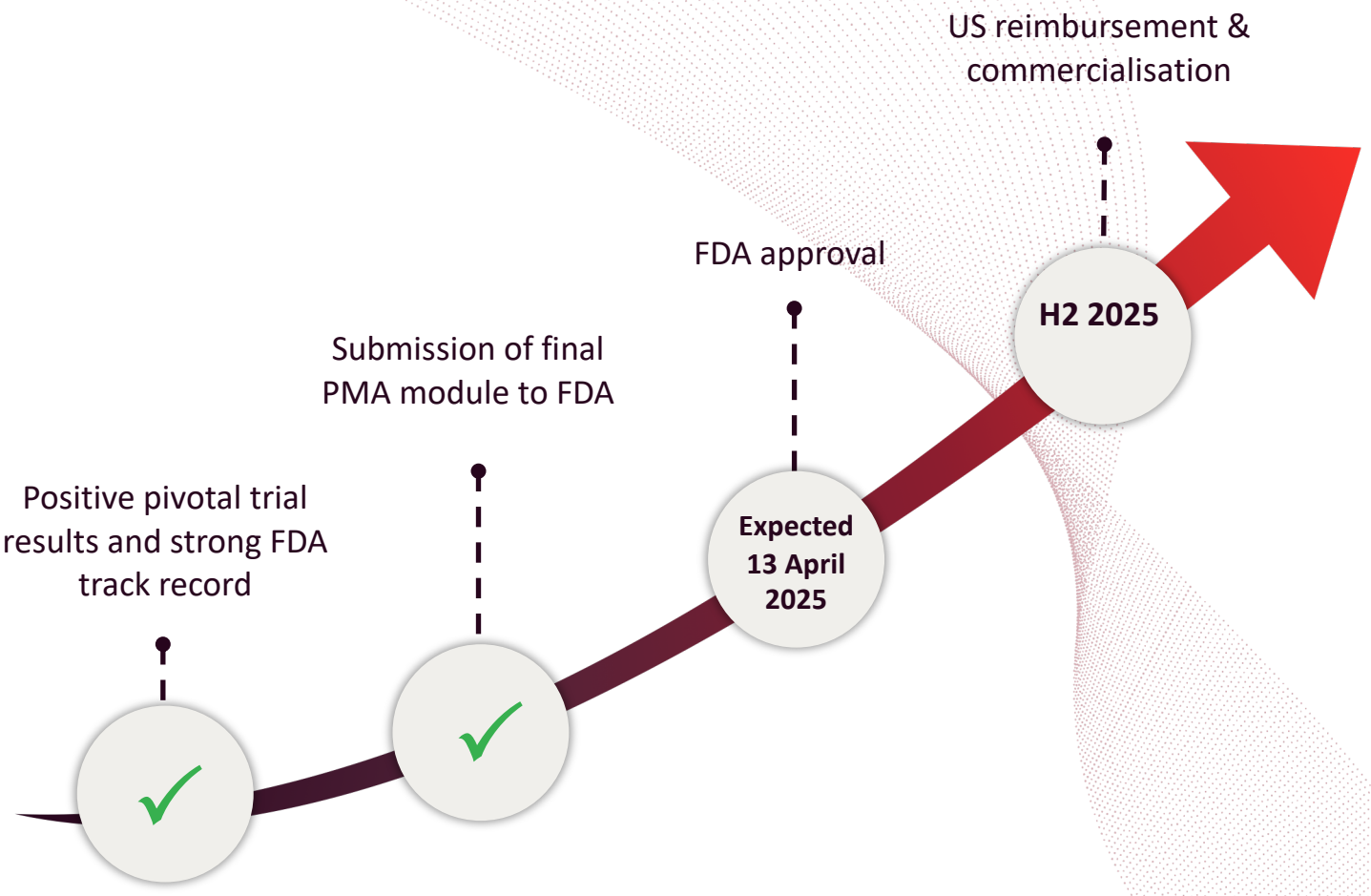
Positive pivotal trial results and strong track record with the FDA provide a clear pathway to approval and commercialisation

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 finalised its PMA submission to the FDA. Breakthrough Device Designation ensures prioritised review process:

- Filing acknowledgement
- 100-day meeting
- Pre-Approval Inspection (PAI)



# 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
- CRT market is highly concentrated - targeting high-volume CRT procedure sites

## 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]

- Clear pathway to NTAP[1] and TPT[1] reimbursement schemes post FDA approval
- WiSE one of first 5 technologies accepted onto CMS TCET reimbursement pathway
- WiSE CRT System target US ASP: US$45,000[2]



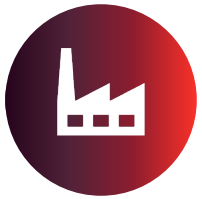
(1) APC: Ambulatory Payment Classification, ASP: Average Selling Price, CMS: Centers for Medicare & Medicaid Services, CPT: Current Procedural Terminology, NTAP: New Technology Add-on Payment, TPT: Transitional Passthrough Payment; 2 U.S. pricing with New Technology Add-on Payment (NTAP) post-approval

# Initial commercialisation strategy

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

### Commercial Leadership

- EBR is expanding and optimizing its commercial capabilities in the US market to ensure the company is well positioned to drive growth and impact
- Commercial Leadership team in place:
  - Chief Commercial Officer
  - 2 x VPs of sales
  - VP Marketing & Market Access
  - Sr Dir Training & Education



### LMR Supports Adoption and Advocacy

- **2025:** Limited Market Release (LMR) targeting combination legacy sites and accounts where we can leverage existing Key Opinion Leader (KOL) relationships
- **2026+:** As the sales team expands, continue to penetrate strategically important, high-volume sites

### Direct, specialist sales force to execute plan

- Execution of commercial launch supported by specialised direct sales force to target high volume sites
- High caliber new hires supplemented by legacy WiSE CRT clinical & technical experts
- Growth driven by combination of increasing utilisation rates in existing sites and penetrating new accounts with sales force expansion

# Expanding manufacturing capabilities

EBR has secured a new state-of-the-art facility at favourable terms to support long-term commercial growth and scale

**Significant Facility Expansion:**

- New 11-year lease secured for 51,000 sq ft (4,751 sqm) facility
- Expansion of manufacturing capability from critical manufacturing processes to manufacture of complete units
- Expands EBR's manufacturing capacity to accommodate future growth and demand for WiSE

**Phased Financial Commitment:**

- Rent payments deferred until January 2026
- Gradual space occupancy and rent scaling up annually to full occupancy by year four
- Landlord to finance approximately US$4M in tenant improvements

**Timing**

- Facility upgrades and qualifications to be completed progressively over the next year, with the full transition expected in H1 2026

# US$3.6bn initial addressable market

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

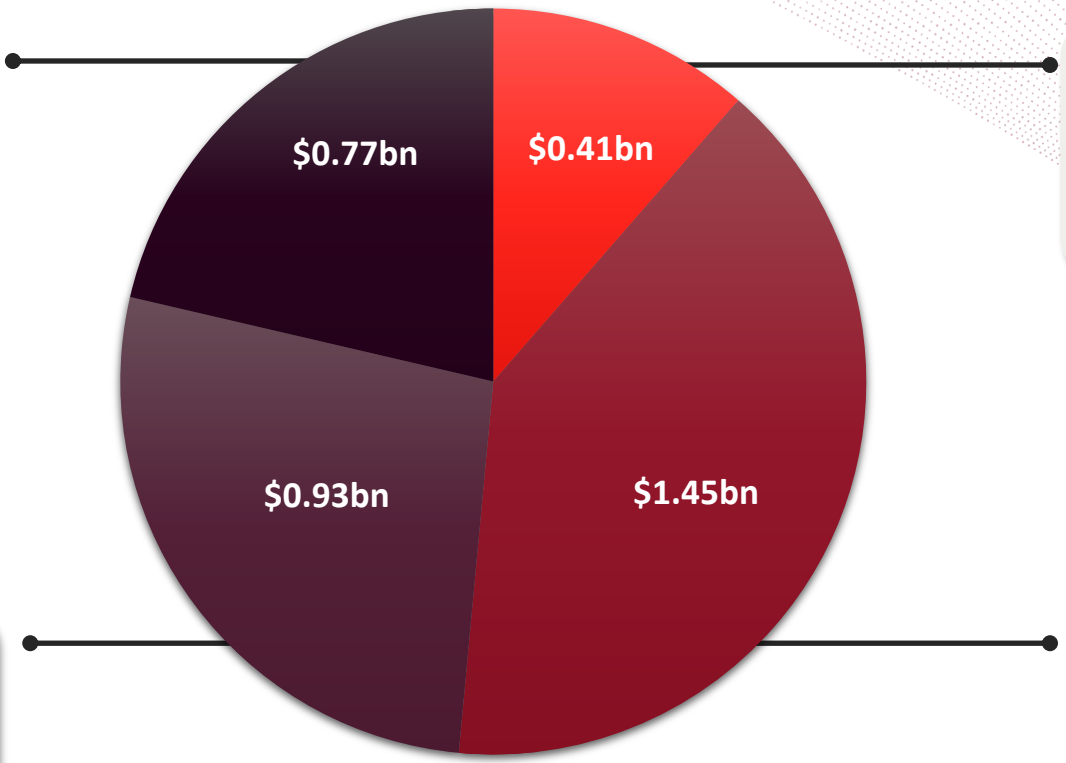
### Leadless Upgrades

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

*Further growth potential – see next slide*

### High Risk Upgrades

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




### Acute Lead Failure

Unable to implant CRT wire in a new CRT patient.

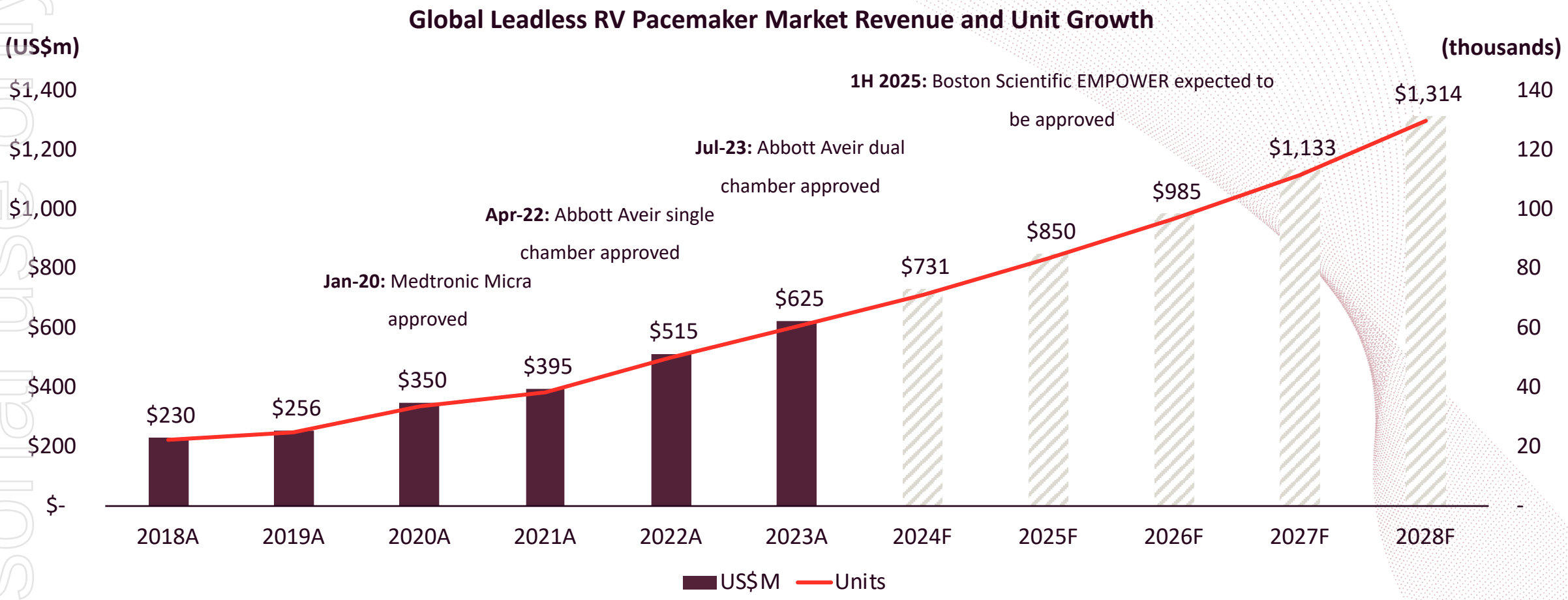
### Chronic Lead Failure

Traditional CRT system implanted but has ceased to provide effective CRT

(1) Grand View Research – Leadless Pacemakers Market, Cardiac Rhythm Market, Cardiac Resynchronization Therapy Market, WiSE current indications

# Totally Leadless CRT grows the 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

# 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 a rechargeable battery

**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

# Clinical development: Totally Leadless CRT

EBR is actively progressing activities to initiate studies to support expanded indication

**Commercial benefits**

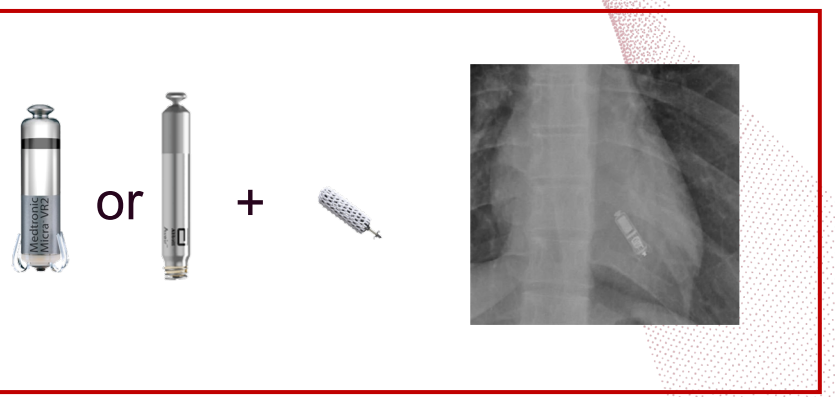
- Increased adoption of leadless pacemakers expands the need for WiSE, including upgrading dual chamber leadless pacemakers
- Opportunity to build a new market as first-line therapy with de novo totally leadless CRT

**Patient benefits**

- Avoid complications associated with lifelong implant of transvenous pacing leads
- More physiological pacing therapy

**Development status**

- Initiate the TLC-AU study in Australia & UK H2 2025

# 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**

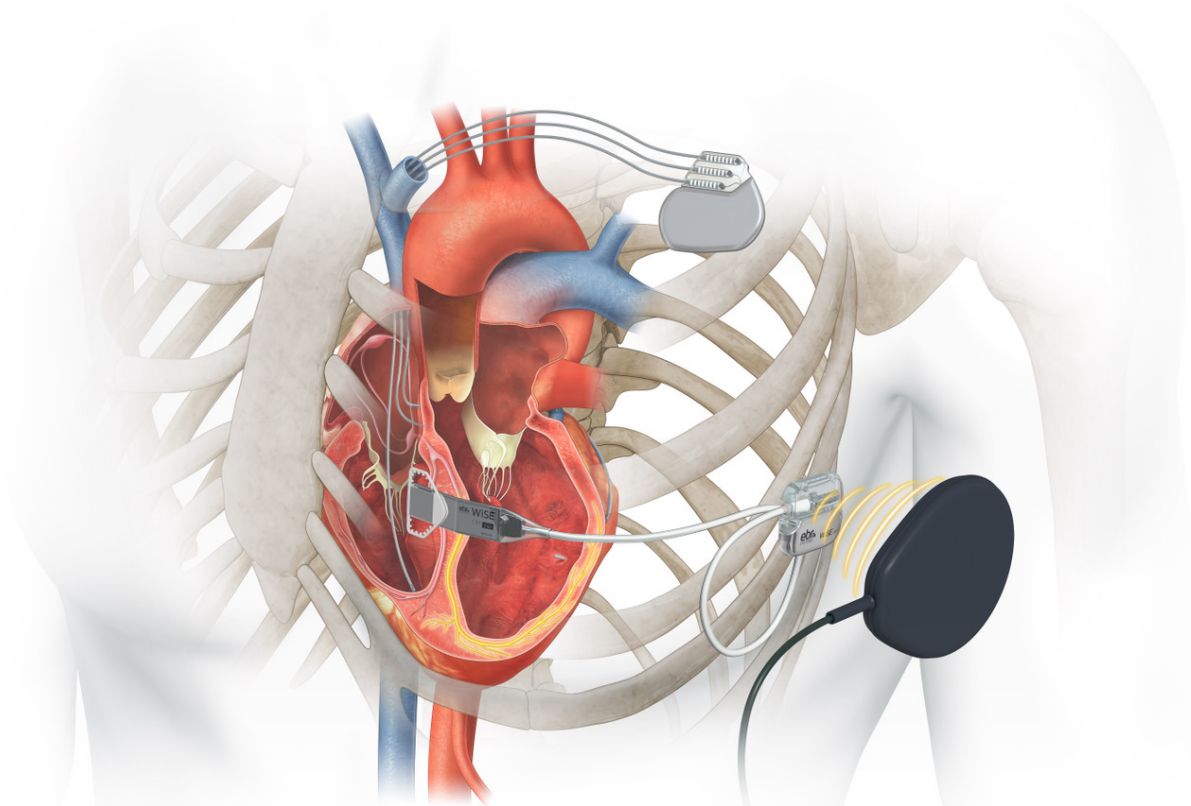
- Drives higher uptake by removing barriers to adoption
- Potential to become a first-line therapy option
- Diversifies applicability of the WiSE CRT System and grows the addressable market

**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

# Upcoming milestones

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

## Delivered

- ✓ Headline data released at Heart Rhythm Society conference
- ✓ Randomised data presented at Asia-Pacific Heart Rhythm Society
- ✓ Publication of manuscript in a peer reviewed medical journal
- ✓ Additional sub-studies published using SOLVE-CRT dataset
- ✓ Final PMA module submitted to the FDA
  - ✓ Substantial review begun
  - ✓ 100-day meeting completed
  - ✓ PAI completed

## Near term

- ❑ FDA approval in the US
  - ❑ Expected on or before 13 APR 2025
- ❑ Reimbursement established
  - ❑ TPT
  - ❑ NTAP
  - ❑ TCET
- ❑ Commercial launch in the US
- ❑ Continued clinical publications
- ❑ Initiate ACCESS and TLC studies

## Next steps

- ❑ Expand manufacturing facility
- ❑ Expand use of WiSE CRT System into new patient groups
- ❑ Drive adoption in US
- ❑ Rechargeable battery project

# 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
- FDA approval expected on or before 13 April 2025
- 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 growth
- Well-capitalised through to initial commercialisation with cash and short-term investments of US$66.0m / A$106.1m[1]





(1) As of 31 December 2024. Assumes A$:US$ 0.6214 exchange rate.

# Thank you