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FDA PMA Approval Webinar

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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

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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

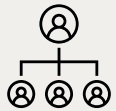
Safety and efficacy endpoints met for SOLVE-CRT trial and Breakthrough Device Designation granted



FDA approved

PMA approval received on 11 Apr 2025, US PDT / 12 Apr 2025 AEST

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)

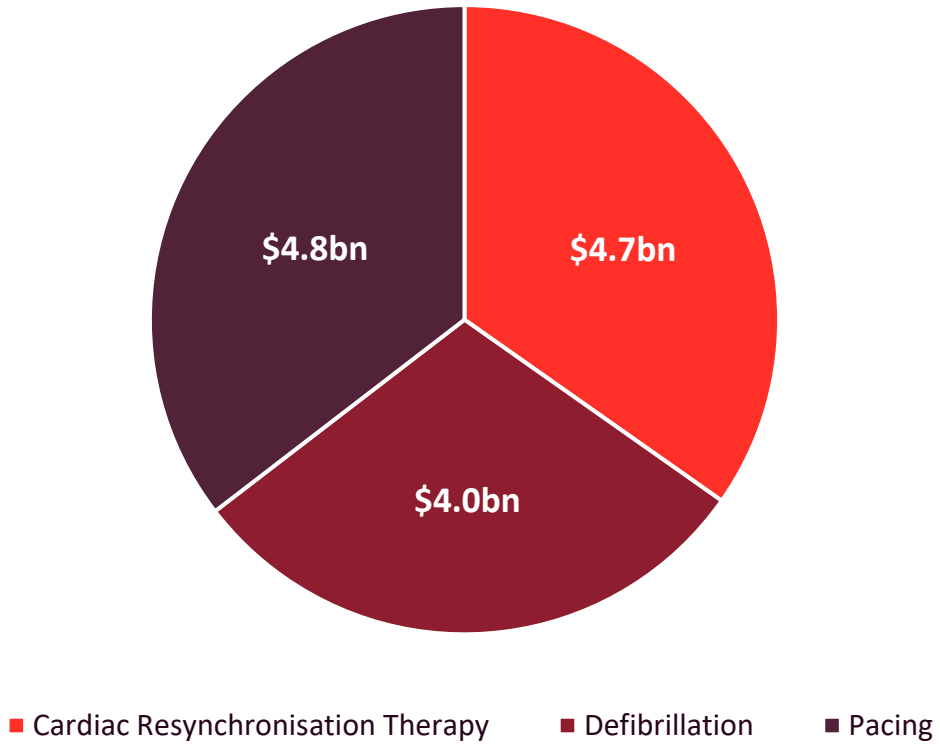
(1) As of 31 December 2024. Assumes A$:US$ 0.6214 exchange rate.

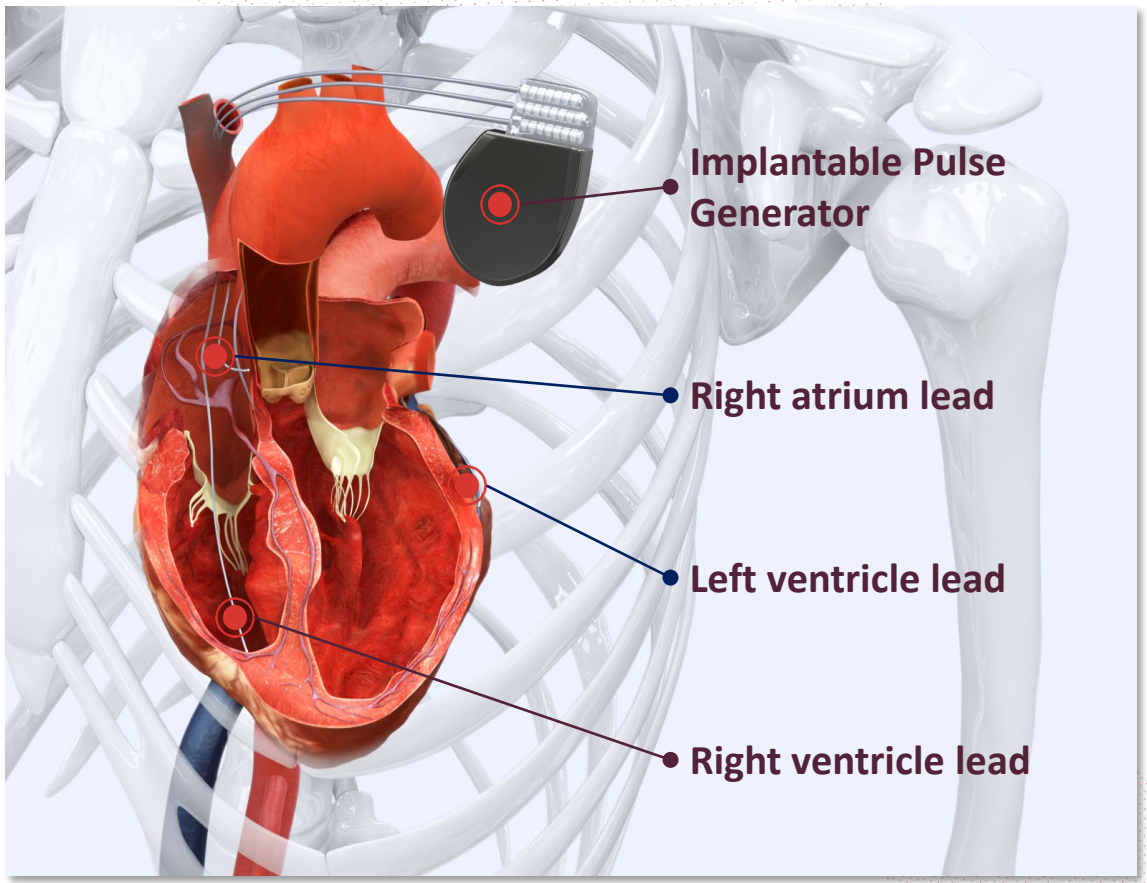
Cardiac Rhythm Management Market

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

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





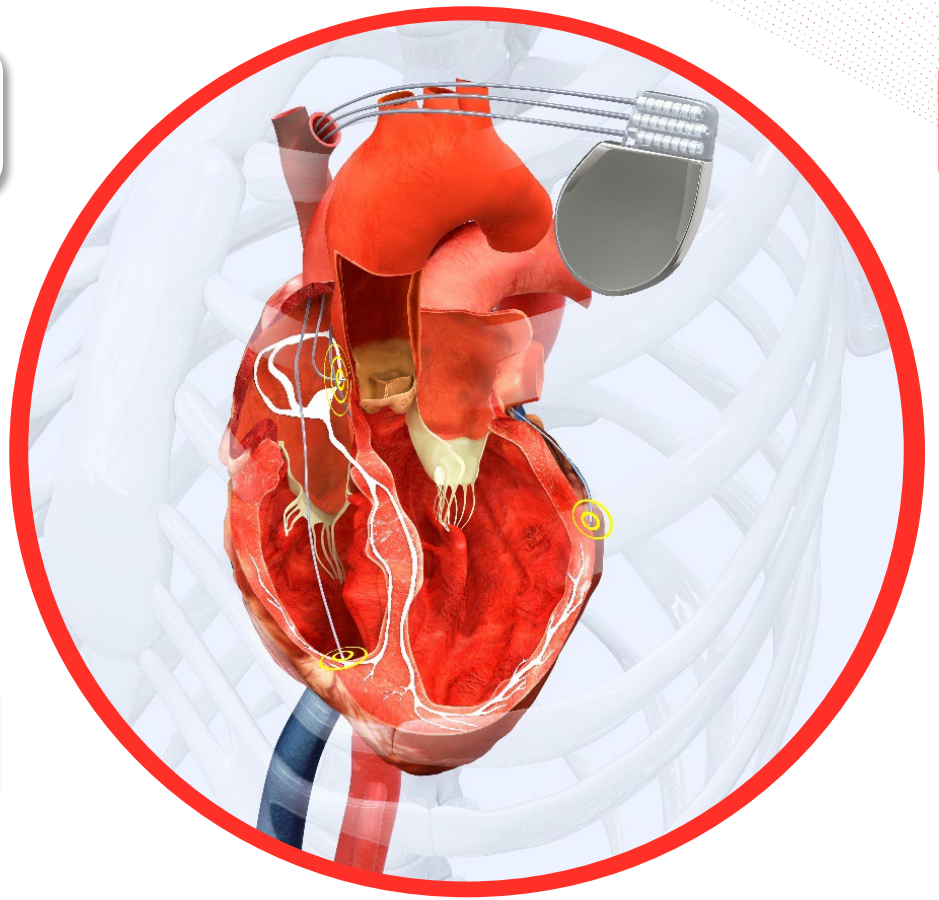
(1) Cardiac Rhythm Market - Grand View Research

Traditional CRT systems are suboptimal

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

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- 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

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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)



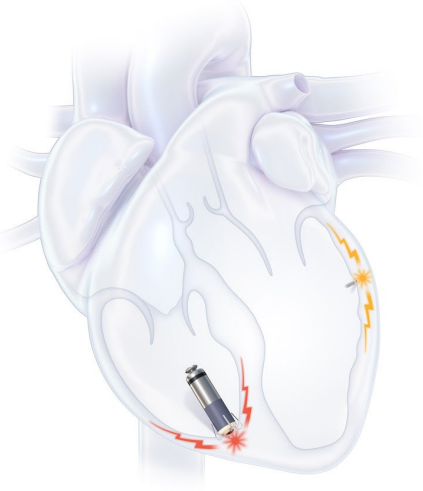
Medtronic Micra®



Boston Scientific Empower®



Abbott Aveir®



Extravascular / Subcutaneous ICD



Boston Scientific Emblem®

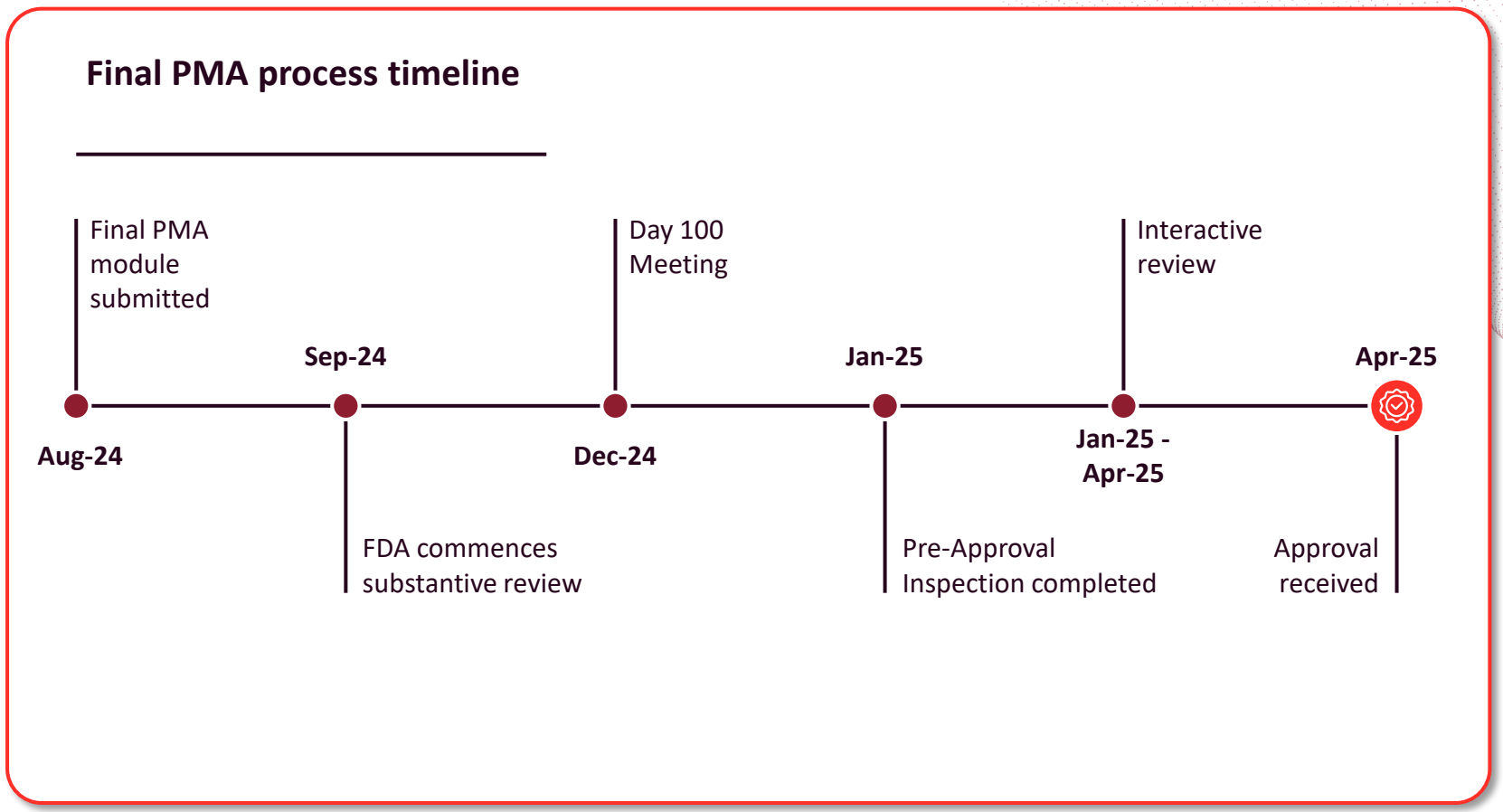


Medtronic Aurora®

(1) Illustrative sizing (not to scale)

FDA Approval of WiSE CRT System

EBR has successfully advanced the WiSE CRT System to FDA approval, having received an approval letter authorising commercial marketing



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Approved Indications Support US$3.6bn TAM

The FDA has approved the WiSE CRT System with the expected indications

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The WiSE CRT System is indicated for adult patients who are at least 22 years of age, are indicated for cardiac resynchronization therapy (CRT), have an existing implanted right ventricular pacing system, and are in one of the following two categories:

- Patients in whom previous coronary sinus lead implantation was unsuccessful, or where an implanted lead has been turned off – referred to as “previously untreatable”
- Patients with previously implanted pacemakers* or ICD’s in whom standard CRT upgrade is not advisable due to known relative contraindications for CS lead or CRT device implantation, referred to as “high-risk upgrades”

* Includes leadless pacemakers. Medtronic's Micra leadless pacemaker has been qualified for use with WiSE CRT.
Abbott’s Aveir leadless pacemaker has not yet been qualified for use with WiSE CRT, but testing conducted by EBR is in progress.

Contraindications:

1. Patients on triple anticoagulant who cannot tolerate peri-procedural stopping of anticoagulation therapy
2. Patients who cannot tolerate, or are allergic or hypersensitive to, procedural anticoagulation or contrast agents, or to the post-procedural antiplatelet regimen

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

Post-approval Study

EBR will undertake a post-approval study to help assure continued safety and effectiveness

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Post-approval study summary

- Prospective, real-world, observational
- 320 subjects
- Follow-up period of 5 years

Primary end point and additional data

Primary endpoint: Rate of serious adverse events (SAEs) occurring within ≤ 30 days after the implantation related to the WiSE CRT System and/or the implantation procedure.

Additional data collected to include typical endpoints for CRT – success rates, HF symptoms, mortality, device performance, other physiological metrics and other complications

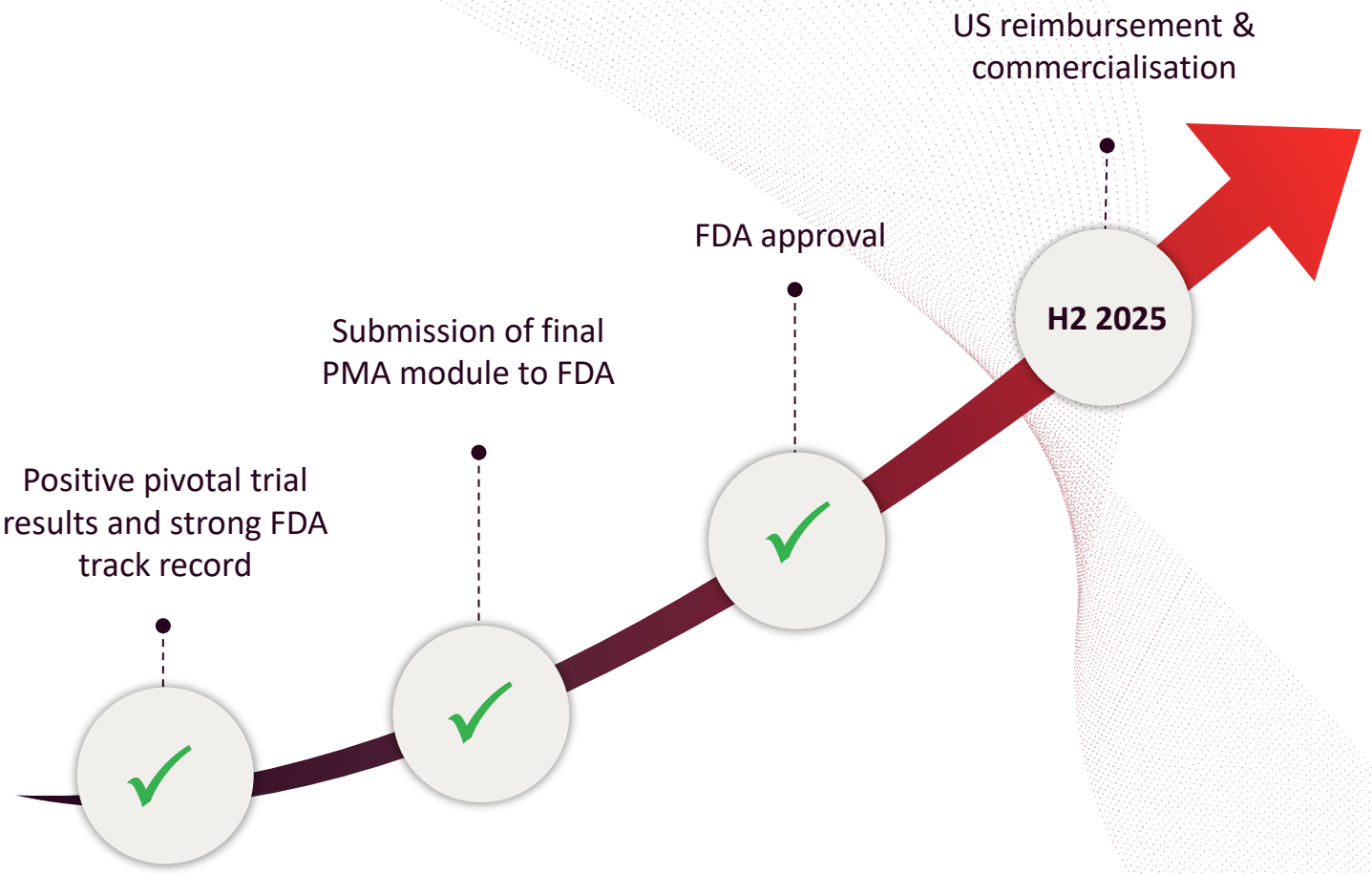
Commercialisation pathway

Successful FDA approval follows positive pivotal trial results and strong track record with the FDA with focus now shifting to commercialisation activities

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EBR is now focused on ramping up commercial activity, focused on:

- Optimising commercial capabilities
- Limited market release in H2 2025
- Direct, specialist sales force to execute plan



Initial commercialisation strategy

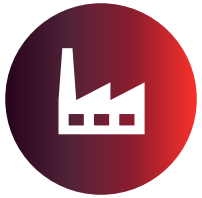
EBR will leverage its established partnerships and presence in the US to drive initial sales growth

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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 calibre 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

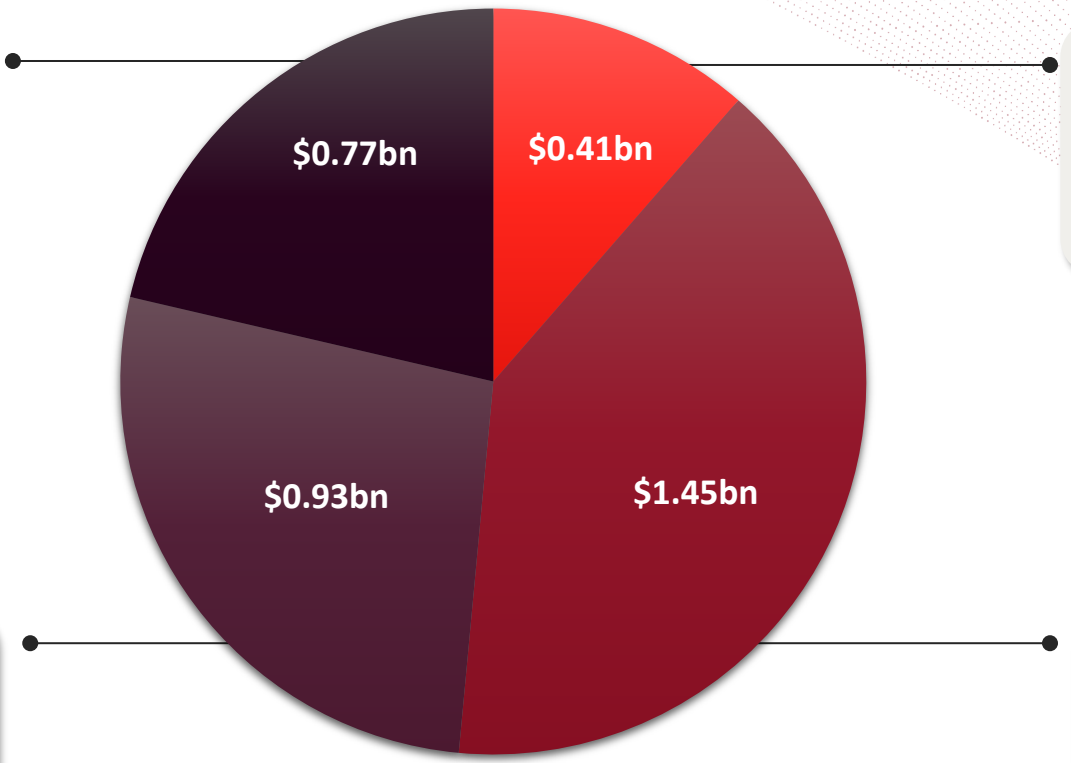
US$3.6bn initial addressable market

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

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High Risk Upgrades - Leadless

- 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 (Abbott Aveir pending)*



Acute Lead Failure

Unable to implant CRT wire in a new CRT patient.

High Risk Upgrades - Conventional

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

Chronic Lead Failure

Traditional CRT system implanted but has ceased to provide effective CRT

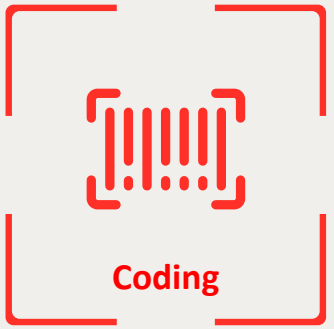
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Reimbursement System

The reimbursement system in the US is a function of coding and coverage to determine the amount paid for a procedure

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Coding

Coding allows uniformity in claims submission for a specific service – "The language of insurers"

- CPT
- ICD-10-PCS
- ICD-10-CM
- HCPCS

Procedure and Diagnosis Codes

- APC
- MS-DRG

Payment Codes



Coverage

Will they pay for it?

Payor criteria for coverage whether implicit (no NCD) or explicit (with NCD) to ensure appropriate utilisation.



Payment

How much will they pay for it?

The amount paid for the procedure or bundle of services provided.

To offset the costs of new technologies CMS established NTAP and TPT.

WiSE Reimbursement

EBR has multiple pathways for WiSE Reimbursement

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Medicare Coverage

Transitional Coverage of Emerging Technologies (TCET)

- Active discussions with CMS. Timing TBD

Benefits of TCET:

- Early CMS engagement for an efficient review process
- Expedited Medicare coverage
- Transitional Medicare coverage for up to 5 years
- Expanded optionality for reimbursement programs available to EBR

Medicare In-patient Payment

New Technology Add-On Payment (NTAP)

- Effective 1 Oct 2025

Benefits of NTAP:

- Increased hospital adoption
- Reduced financial barriers for patients and improves access
- Validates the technology's innovation and clinical benefit
- Ensures near-term reimbursement support

Medicare Out-patient Payment

Transitional Pass-Through (TPT)

- Effective 1 Oct 2025

Benefits TPT:

- Increased hospital adoption
- Allows sales teams to present a clear reimbursement pathway to hospitals
- External validation that the technology represents a meaningful clinical advancement

Favourable US market dynamics

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

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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(1)

- Clear pathway to NTAP(1) and TPT(1) reimbursement schemes post FDA approval, which will provide payment to cover EBR's selling price
- WiSE one of first 5 technologies accepted onto CMS TCET(1) reimbursement pathway

(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, TCET: Transitional Coverage for Emerging Technologies

Summary

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

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- 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 achieved in April 2025 authorising the US commercial marketing of EBR's WiSE CRT System
- 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

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Expanding manufacturing capabilities

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

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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

