EBR

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



Funded through initial commercialisation with pro form cash balance of ~US\$74.22m / ~AU\$107.2m¹

Cardiac Rhythm Management Market

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

\$4.8bn \$4.7bn \$4.0bn Cardiac Resynchronisation Therapy Defibrillation Pacing



Worldwide CRM Market (~US\$13.6bn)¹

Traditional CRT systems are suboptimal

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



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



Pivotal SOLVE-CRT Study met all endpoints

Positive results confirm WiSE CRT System as a highly effective treatment option for patients with heart failure¹



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 ASP¹

- Clear pathway to NTAP¹ and TPT¹ reimbursement schemes post FDA approval
- WiSE one of first 5 technologies accepted onto CMS TCET reimbursement pathway
- WiSE CRT System target US ASP: US\$45,000²



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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

- **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 cabability 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



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

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 in early 2025

ESC European Society of Cardiology Europace (2020) 00, 1–8 doi:10.1093/europace/euaa342

CLINICAL RESEARCH

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

Adrien Carabelli © ¹, Mariem Jabeur¹, Peggy Jacon¹, Christopher Aldo Rinaldi², Christophe Leclercq³, Giovanni Rovaris © ⁴, Martin Arnold⁵, Sandrine Venier¹, Petr Neuzil⁶, and Pascal Defaye¹*



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 week¹
- 66% reduction in size from current battery

Development status

- Specifications and initial design completed
- Regulatory and commercial timing to be announced as project progresses





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
- □ Clinical study of rechargeable battery

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 funded with a pro forma cash balance of ~US\$74.2m / ~AUD\$107.2m¹

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Thank you