

Bell Potter Healthcare Conference

Andrew Shute (Sr Vice President, Business Development) 20 November 2024

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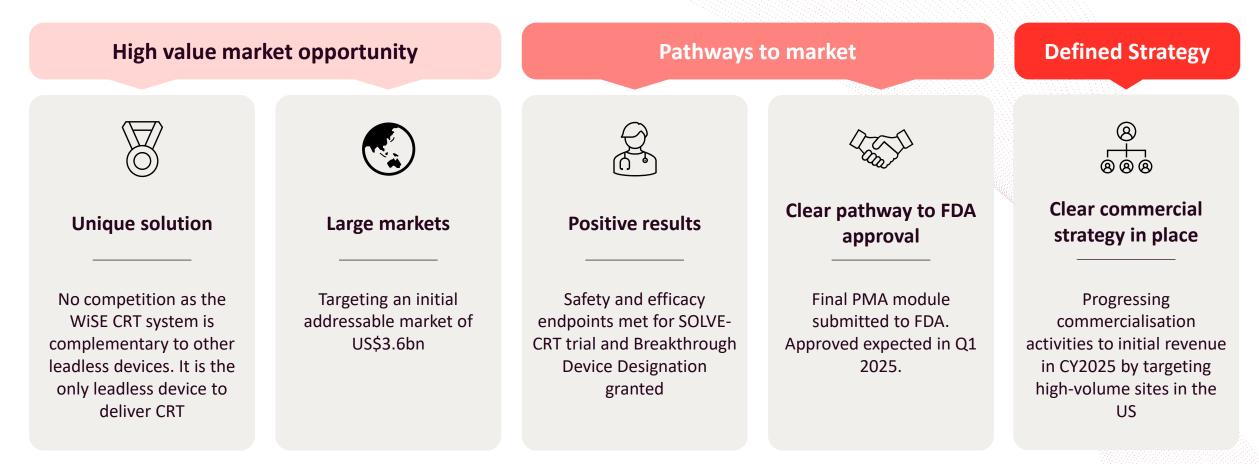
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Investment highlights

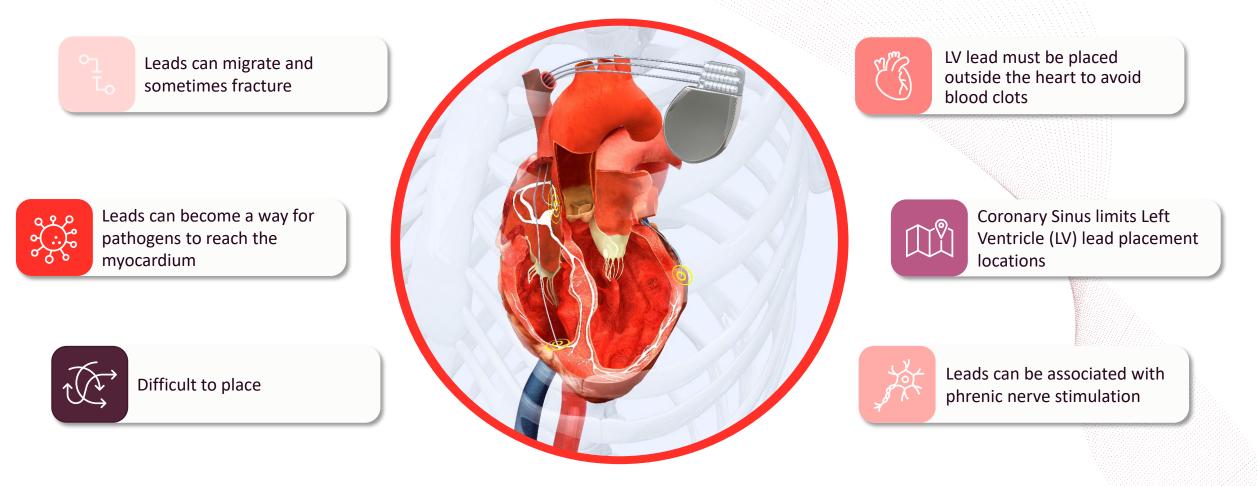
Developer of the world's first and only leadless pacemaker for heart failure





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

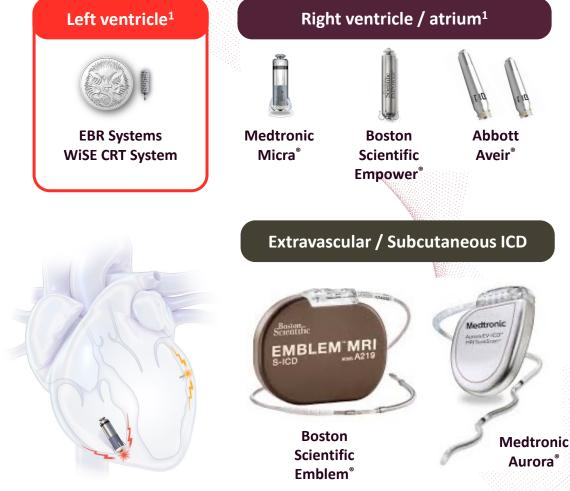
Their size increases the risk of blood clots, restricting their use to right ventricle (RV) and right atrium (RA) pacing only

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



Commercialisation Pathway

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



Efficacy: -16.4% decrease in left ventricular systolic volume (vs -9.3% target), showing improved heart function¹

Safety: 80.9% freedom from type I complications (vs 70% target)^{1,} increasing to 85.7% post mitigations⁴

PMA Submission

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

- Filing acknowledgement
- 100-day meeting
- Biomedical Monitoring audit (BIMO)
- Pre-Approval Inspection (PAI)

Reimbursement

- Clear pathway to NTAP² and TPT² reimbursement schemes post FDA approval
- CMS issued WiSE specific CPT² codes
- CPT codes already assigned to interim APC² codes
- Defined process to reassign APC codes based on actual claims data
- WiSE CRT System target US ASP: US\$45,000³



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

²APC: 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; ³ U.S. pricing with New Technology Add-on Payment (NTAP) post-approval; ⁴James S, et al. (2024). APHRS 2024 Abstract.

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



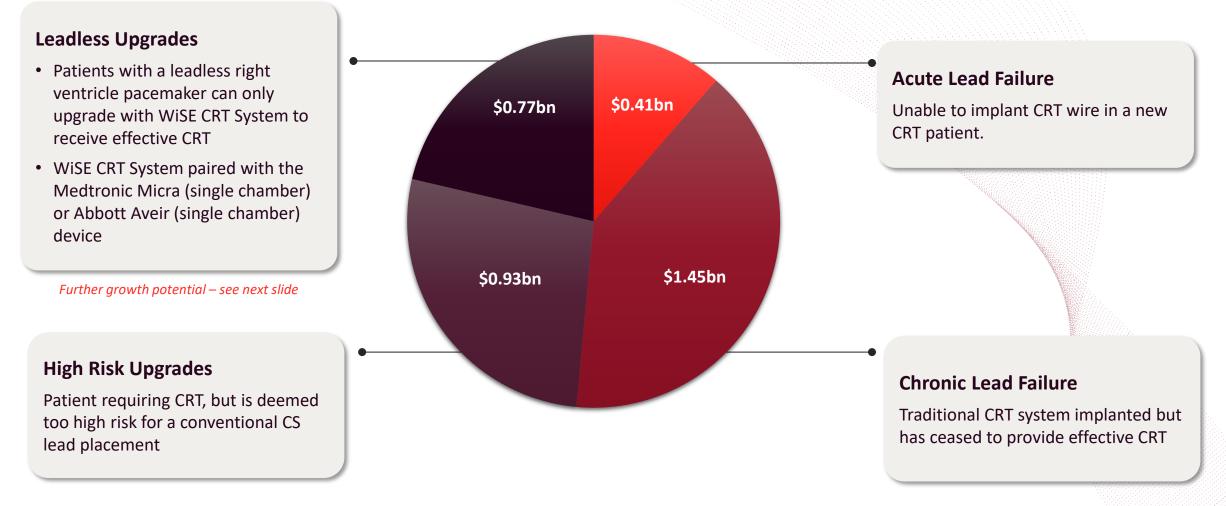
Manufacturing capabilities

- 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

Global Leadless RV Pacemaker Market Revenue and Unit Growth (US\$m) (thousands) 1H 2025: Boston Scientific EMPOWER expected to \$1,400 140 \$1,314 be approved \$1,133 \$1,200 Jul-23: Abbott Aveir dual 120 chamber approved \$985 \$1,000 100 **Apr-22:** Abbott Aveir single \$850 chamber approved \$731 \$800 80 Jan-20: Medtronic Micra \$625 approved \$600 60 \$515 \$395 \$350 \$400 40 \$256 \$230 \$200 20 \$-2018A 2022A 2023A 2028F 2019A 2020A 2021A 2024F 2025F 2026F 2027F US\$M — Units

:::::EBR

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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

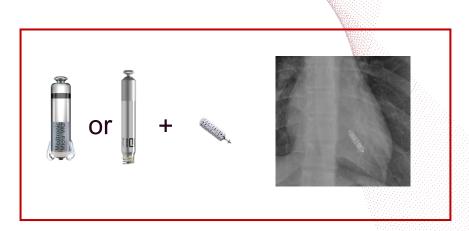
• Initiate the TLC-AU study in Australia in early 2025

European Society 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*





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 industry conferences including 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

Near term

- □ FDA approval in the US
 - 100-day meeting
 - BIMO audit
 - D PAI
- Reimbursement established
- 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

