

EBR Systems to Present at 17th Bioshares Biotech Summit

Sunnyvale, California; 21 July 2023: EBR Systems, Inc. (ASX: “EBR”, “EBR Systems”, or the “Company”), developer of the world’s only wireless cardiac pacing system for heart failure, is pleased to announce that Senior VP of Business Development, Andrew Shute, will be presenting at the 17th Bioshares Biotech Summit in Hobart, Tasmania on 24 July 2023.

A copy of the presentation is attached below.

ENDS

This announcement has been authorised for release by the EBR Systems General Disclosure Committee, a committee of the Board of Directors.

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About EBR Systems (ASX: EBR)

Silicon Valley-based EBR Systems (ASX: EBR) is dedicated to superior treatment of cardiac rhythm disease by providing more physiologically effective stimulation through wireless cardiac pacing. The patented proprietary Wireless Stimulation Endocardially (WiSE) technology was developed to eliminate the need for cardiac pacing leads, historically the major source of complications, effectiveness and reliability issues in cardiac rhythm disease management. The initial product is designed to eliminate the need for coronary sinus leads to stimulate the left ventricle in heart failure patients requiring Cardiac Resynchronisation Therapy (CRT). Future products potentially address wireless endocardial stimulation for bradycardia and other non-cardiac indications.

EBR Systems’ WiSE Technology

EBR Systems’ WiSE technology is the world’s only wireless, endocardial (inside the heart) pacing system in clinical use for stimulating the heart’s left ventricle. This has long been a goal of cardiac pacing companies since internal stimulation of the left ventricle is thought to be a potentially superior, more anatomically correct pacing location. WiSE technology enables cardiac pacing of the left ventricle with a novel cardiac implant that is roughly the size of a large grain of rice. The need for a pacing wire on the outside of the heart’s left ventricle – and the attendant problems – are potentially eliminated. WiSE is an investigational device and is not currently available for sale in the US.

Forward-Looking Statements

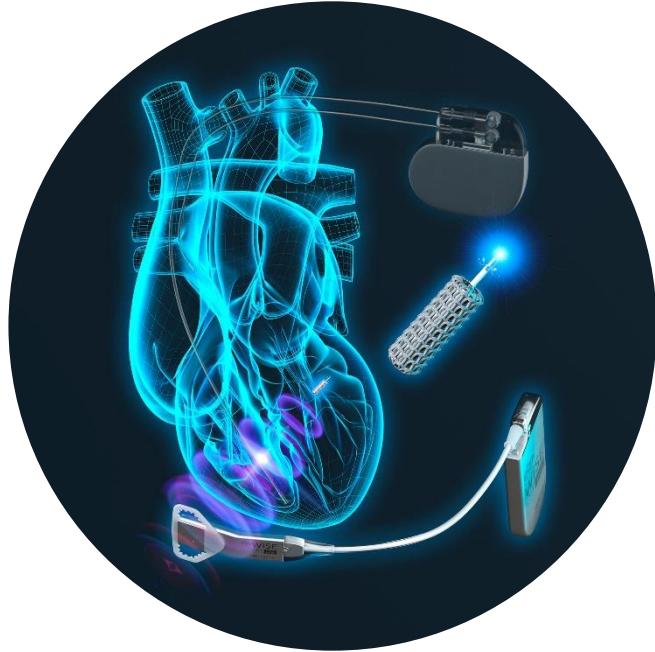
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All statements that address operating performance, events or developments that we expect or anticipate will occur in the future are forward-looking statements, including without limitation our expectations with respect to our ability to commercialize our products including our estimates of potential revenues, costs, profitability and financial performance; our ability to develop and commercialize new products including our ability to obtain reimbursement for our products; our expectations with respect to our clinical trials, including enrolment in or completion of our clinical trials and our associated regulatory submissions and approvals; our expectations with respect to the integrity or capabilities of our intellectual property position.

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Bioshares Conference Presentation


July 2023

Traditional pacemakers are suboptimal


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




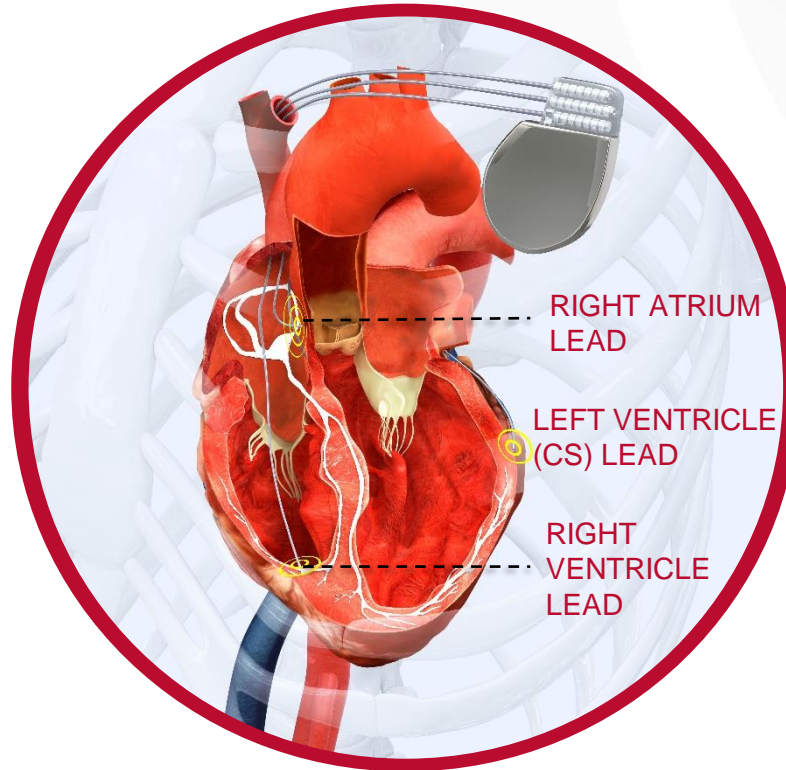
Coronary Sinus limits Left Ventricle (LV) lead placement locations




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 and other leadless pacemakers are complementary

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

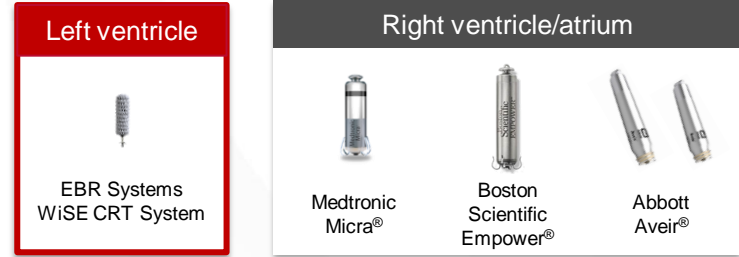
This increases the risk of blood clots, restricting their use to right ventricle (RV) and right atrium (RA) pacing only.

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.

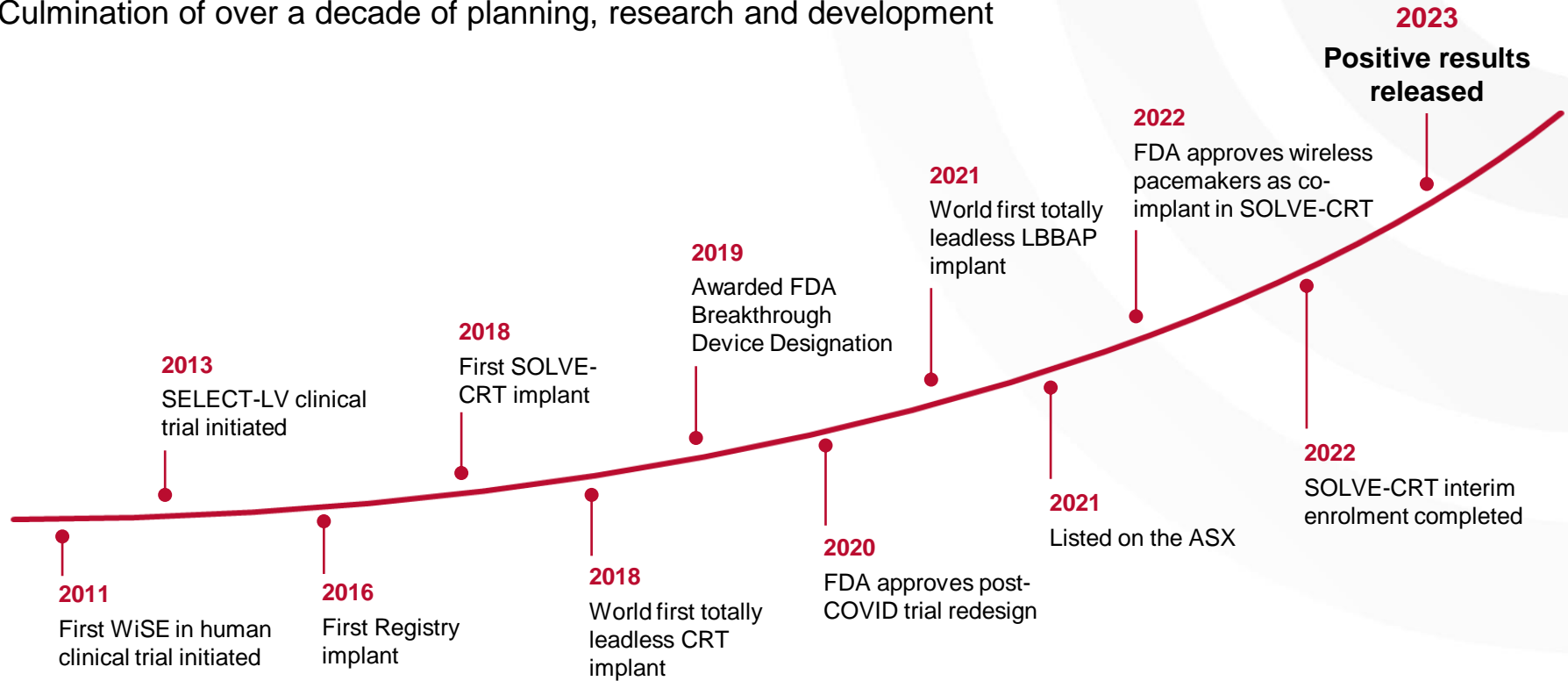


Dr. Jeffrey Alison, Monash Hospital, Melbourne.

Micra on the left, WiSE CRT device held by tweezers on the right.

Journey so far

Culmination of over a decade of planning, research and development



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 complications¹



Other key data

Observed complication rates were higher in early phases and decreased with experience

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 >450¹ 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 three out of five modules to the FDA. The fourth module is scheduled to be submitted by the end of 2023 and the final module by end of Q1 2024. EBR is targeting FDA approval by the end of Q4 2024.

On track to finalise PMA submission to the FDA by end of Q1 2024, with FDA 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

Strategy enhanced by market factors

EBR's commercialisation strategy is underpinned by 3 distinctive features



Unmet need & 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\$35,000¹
 - OUS: US\$20,000²

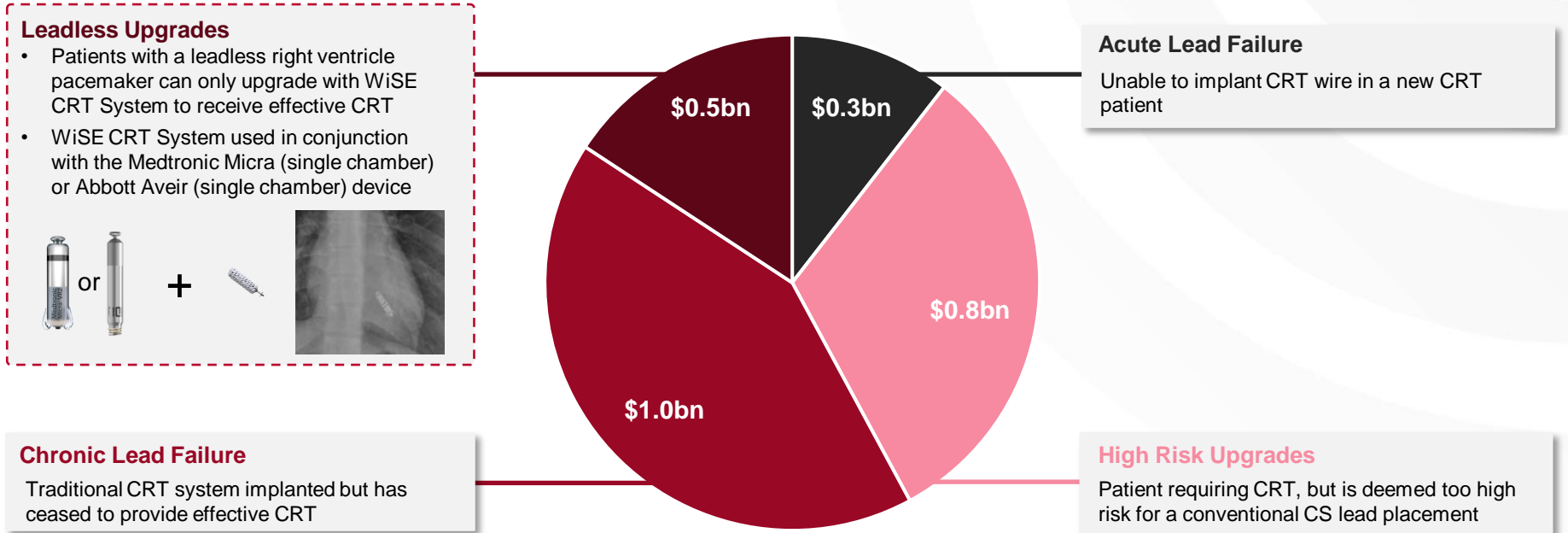
Note: ASP: Average Selling Price

¹ U.S. pricing with New Technology Add-on Payment (NTAP) post-approval

² Initial Phase "OUS Markets" limited to AU, UK, Germany, France, BeNSca

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, received FDA approval July 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

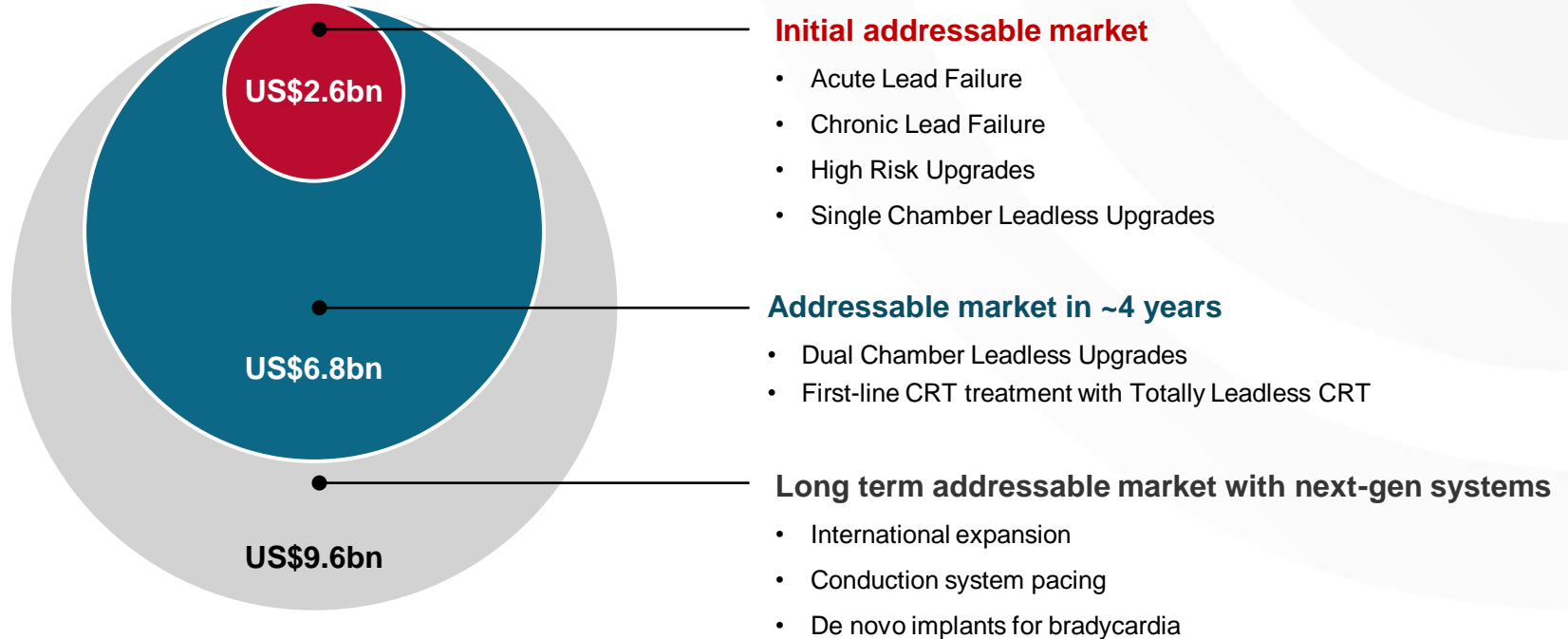


\$2.0bn segment TAM

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



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**
- ❑ Publication of manuscript in a peer reviewed medical journal
- ❑ Submit Clinical Module for PMA application to the FDA
- ❑ Present at industry conferences including APHRS¹

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
- ❑ FDA approval in the US

2025+

- ❑ Commercial launch in the US
- ❑ Launch in select markets OUS² 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



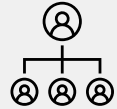
Positive results

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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Appendix



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 week¹
- 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

Patient success story - Richard

EBR has allowed the patient to once again partake in all the activities he enjoyed before his heart failure

Pre heart failure

US Marine and Vietnam war veteran who enjoyed a very active and outgoing lifestyle

“Sport was a very big part of my life. I was an active person.”



Onset of heart failure

Heart failure materially impact the patient's quality of life

- **2014:** Pacemaker implanted due collapsing from a low heart rate.
- **2016:** Developed pacing induced heart failure. Conventional lead-based CRT implanted. Multiple lead failures.
- **2017:** Rapid deterioration: *“I couldn't walk up a flight of stairs. I couldn't work, I couldn't do anything. I was just existing.”*

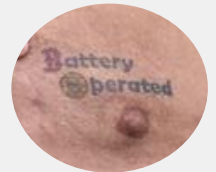
Post WiSE CRT Implant

Post WiSE CRT implant, the patient has been able to enjoy everything he used to do

“I was energised immediately. I could now take out the bins and walk up a flight of stairs.”

“I was able to resume daily walks and open water swimming. Got stronger and lost 20kg.”

“I'm happy, extremely happy. It's given me my life back!”



Patient success story - Brian

The WiSE CRT device has helped the patient regain the ability to participate in his favourite activities

Pre heart failure

Scout leader and avid football fan who enjoyed outdoor activities

Brian enjoyed being outdoors, taking part in activities such as mowing the lawn or walking his dog. He is also an active AFL supporter and his ability to attend Melbourne FC games was hampered by progressive heart failure symptoms.



Onset of heart failure

Heart failure materially impact the patient's quality of life

- **2009:** Brian collapsed with heart block and was inserted with a pacemaker, 5 months later he required an upgrade to an ICD
- **Post pacemaker and ICD:** Brian developed shortness of breath and reduced exercise tolerance over several years, even whilst lying flat in bed
- He experienced difficulty with daily activities

"I thought if I wanted to live longer then getting the WiSE CRT implant had to be done. That's it!"

Post WiSE CRT Implant

Post WiSE CRT implant, the patient has been able to enjoy everything he used to do

"9 months post WiSE implant and I am able to wash the cars readily and can now mow the lawns. I even went to the AFL game and could walk up multiple flights of stairs. I haven't been able to do that for years!"

"I would definitely recommend other patients consider the WiSE device if they were in a similar situation."





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