ASX ANNOUNCEMENT **14 April 2025**

FDA Approval of WiSE® CRT System

Key highlights:

- EBR Systems has secured FDA approval for the WiSE CRT System—the world's first and only leadless solution for left ventricular endocardial pacing.
- For the first time, clinicians can deliver cardiac resynchronization therapy without leads
- EBR will initially target a US$3.6 billion addressable market across high-risk upgrade, lead failure, and leadless CRT expansion categories, with future opportunity to expand into other indications.
- A focused, limited market release will begin in late 2025. Full-scale commercial launch follows in early 2026.

Sunnyvale, California; 13 April 2025: EBR Systems, Inc. (ASX: **"EBR"**, **"EBR Systems"**, or the **"Company"**), developer of the world's only wireless cardiac pacing device for heart failure, is pleased to announce the US Food and Drug Administration (FDA) approval of EBR's WiSE cardiac resynchronisation therapy (**"CRT"**) System.

The FDA has issued an approval letter authorising the commercial marketing of EBR's WiSE CRT System in the US. The FDA approval of the WiSE CRT System was supported by the submission of five comprehensive modules as part of the Premarket Approval ("**PMA"**) application, the completion of a Pre-Approval Inspection (PAI) of EBR's manufacturing facilities in January 2025 with no form FDA 483 observations, and the resolution of any queries that arose from the FDA's review of the submitted modules.

John McCutcheon, EBR Systems' President & Chief Executive Officer said:

"We are thrilled to announce this major milestone for EBR and to share this achievement with our dedicated team, shareholders, partners and stakeholders who have supported us on this journey. Securing FDA approval for the WiSE CRT System is a transformative moment, marking our transition from clinical development to commercialisation.

With FDA approval in hand, EBR is well-positioned to bring our innovative solution to market, delivering real impact to patients and servicing a significant unmet need. We look forward to executing our commercial strategy and achieving our first revenue in late 2025, paving the way for sustained growth and long-term success."

CRT is a well-established treatment for heart failure and has been shown to improve clinical status and reduce heart failure hospitalisations and mortality. However, a material proportion of patients cannot be treated with a lead-based system. Hence, a significant unmet need exists to provide an alternative for stimulating the left ventricle for CRT.

The WiSE CRT System was designed to significantly expand the population of patients who could benefit from CRT. It was engineered specifically for patients left behind by conventional CRT. It's the only leadless solution for left ventricular pacing, designed to work seamlessly with existing pacemakers, defibrillators, or CRT devices that provide right ventricular pacing.

The FDA approved indications for use are as follows:

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."

These indications are consistent with EBR's estimated initial addressable market opportunity of ~US$3.6bn in the US. The indications for the WiSE CRT System focus on patients for whom conventional CRT is not an option.

- Acute lead failure patient: patients where attempts to place a left ventricular lead—typically via the coronary sinus—have failed due to anatomical or disease-related constraints.
- Chronic lead failure: patients with inactive or malfunctioning left-heart CRT leads
- High-risk upgrade: patients who have existing pacing systems, including leadless pacemakers*, who need an upgrade to biventricular pacing due to heart failure progression and are not candidates for CRT coronary sinus lead placement

*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.

The only contraindications are:

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.

The FDA approval letter was received by EBR via email at 10:47am PDT on 11 Apr 2025 (3:47am AEST on 12 Apr 2025) in line with the Company's expectation of obtaining approval on or before 13 Apr 2025. With FDA approval secured, EBR will launch the WiSE CRT System in phases. A limited market release is planned for 2025, with sales expected during the second half of the year, ramping towards full commercial distribution during 2026. The initial phase of the rollout will concentrate on high-volume centers, specifically those involved in previous clinical trials, aimed at gathering early user experience and facilitating wider adoption. The company will concurrently conduct a post-approval study, which is an FDA requirement as a condition of approval. EBR expects to enrol 320 patients in this study and will follow them for five years.

As a result of the FDA's Breakthrough Device Designation, EBR expects to qualify for two reimbursement schemes: New Technology Add-on Payment (NTAP – inpatients) and Transitional Pass-Through payment (TPT – outpatients). EBR expects both the NTAP and TPT reimbursement schemes to be effective from 1 October 2025, providing payment to cover EBR's selling price.

In parallel, EBR is expanding its team, strengthening training programs, and working with hospitals to simplify implant workflows—ensuring clinicians are well-prepared and supported from the start. This strategic rollout ensures the WiSE CRT System is introduced with the right clinical support, training, and infrastructure in place. As EBR moves toward full market launch, the goal remains clear: to expand access to a truly novel therapy and deliver meaningful improvement for heart failure patients who, until now, have had limited or no options. With WiSE, a new standard in cardiac resynchronization therapy is within reach.

Investor webinar

An investor webinar will be hosted on Monday, 14 April 2025 at 11:00 am AEST to discuss the FDA approval of EBR's WiSE CRT System and commercialisation plans.

Participants can register using the link or QR code below to access the online registration page:

http://ebrwebinar.com/4iey86n

ENDS

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

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About EBR Systems

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 in most markets and is currently only available for sale in the US.

Forward-Looking Statements

This announcement contains or may contain forward-looking statements that are based on management's beliefs, assumptions, and expectations and on information currently available to management. Forward-looking statements involve known and unknown risks, uncertainties, contingencies, and other factors, many of which are beyond the Company's control, subject to change without notice, and may involve significant elements of subjective judgment and assumptions as to future events which may or may not be correct.

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 applications and approvals; our expectations with respect to the integrity or capabilities of our intellectual property position.

Management believes that these forward-looking statements are reasonable as and when made. You should not place undue reliance on forward-looking statements because they speak only as of the date when made. EBR does not assume any obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. EBR may not actually achieve the plans, projections or expectations disclosed in forward-looking statements, and actual results, developments or events could differ materially from those disclosed in the forward-looking statements.

Foreign Ownership Restriction

EBR's CHESS Depositary Interests (CDIs) are issued in reliance on the exemption from registration contained in Regulation S of the US Securities Act of 1933 (Securities Act) for offers or sales which are made outside the US. Accordingly, the CDIs have not been, and will not be, registered under the Securities Act or the laws of any state or other jurisdiction in the US. The holders of EBR's CDIs are unable to sell the CDIs into the US or to a US person unless the re-sale of the CDIs is registered under the Securities Act or an exemption is available. Hedging transactions with regard to the CDIs may only be conducted in accordance with the Securities Act.