ASX ANNOUNCEMENT **29 August 2024**

EBR submits final PMA module to the U.S. FDA

Key Highlights:

- EBR has successfully completed and submitted the final Premarket Approval (PMA) application module for its WiSE® CRT System to the U.S. FDA.
- The PMA application is subject to an initial filing review period to ensure all necessary information has been completed for the FDA to conduct a substantive review.
- The Breakthrough Device designation for WiSE enables EBR to receive prioritised review and interactive communication with the FDA throughout the PMA process.
- Given the review cycle of a PMA application, EBR anticipates approval in Q1 CY2025 and remains on track for commercial launch in 2025.
- Subject to FDA approval, EBR is preparing for a 2025 launch readiness in the sizeable US market of US$3.6 billion.

Sunnyvale, California; 29 August 2024: 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 submission of its final PMA module to the U.S. Food & Drug Administration (FDA) for its WiSE CRT (Cardiac Resynchronization Therapy) System , marking a significant milestone in the Company's commercialisation pathway.

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

"We are delighted to have achieved this important milestone in our company's journey. This submission is the result of years of effort and collaboration between our clinical, regulatory, and engineering teams. With this application, we are now one step closer to making WiSE available to physicians for their patients across the United States. If approved, this PMA package will allow us to launch WiSE in 2025. We look forward to sharing further updates as we progress through the regulatory review process.

EBR's PMA application is subject to an initial FDA-mandated filing period to confirm that it is administratively complete and that technical elements of the application are adequate. Following completion of this stage, the FDA will notify the Company if their application has been accepted for substantive review.

The FDA's substantive review evaluates EBR's PMA application content, provides feedback and requests responses along the way, and eventually leads to a decision regarding the approvability of the WiSE System. The substantive review is a comprehensive evaluation process of the full PMA application, with key assessments including:

- A Bioresearch Monitoring (**BIMO**) audit: to ensure the quality and integrity of EBR's clinical trial study data, and to ensure test subjects that took part in investigations were protected from undue hazard or risk; and
- A Pre-Approval Inspection (**PAI**): to confirm EBR's manufacturing, processing and packing procedures comply with Quality System regulations, and that the facility can consistently produce devices that meet the approved specifications

Madhuri Bhat, EBR Systems' Chief Regulatory Officer said:

"This PMA application represents a pivotal step in EBR's clinical and regulatory process, highlighting our commitment to meeting all FDA requirements. EBR has maintained an open and collaborative discussion with the FDA consistently and throughout the application process to ensure that our submission adheres to the Agency's high standards. We are confident that any enquiries during the review period will continue in the same spirit of constructive dialogue to support a positive review."

EBR's PMA application includes extensive technical documentation and clinical data from all its clinical trials to date. This includes EBR's pivotal SOLVE-CRT trial, which successfully met its primary safety and efficacy endpoints. The Breakthrough Device designation for the WiSE System enables EBR to receive prioritised review and interactive communication with the FDA throughout the PMA process.

The submission of EBR's PMA application for the WiSE System represents a significant milestone for the Company and moves EBR closer to commercialising the world's first wireless pacemaker for the left ventricle in the United States. The WiSE System allows clinicians to address the needs of a patient population that currently has no other treatment options, and potentially improve the condition of millions of patients.

Subject to FDA approval, projected in Q1 CY2025, EBR is positioning for the commercial launch of WiSE in 2025 in the sizeable US market of US$3.6 billion. The commercial launch will focus initially on driving adoption of WiSE at key, high volume procedure sites within the U.S.

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

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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

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 submissions 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.