ASX ANNOUNCEMENT **30 September 2024**

FDA commences substantive review of EBR's PMA application

Key highlights:

- FDA has completed the initial filing review of EBR's PMA application, and determined the company's application contains all the information required to proceed to a substantive review
- The FDA's substantive review evaluates EBR's PMA application content to determine the effectiveness and safety of the WiSE® CRT System (WiSE)
- EBR anticipates FDA's regulatory approval in Q1 CY2025, with expected launch of WiSE in the US CRT market later in CY2025
- This announcement closely follows EBR's oversubscribed $50M financing. This funding provides the Company with cash runway through FDA approval and will support the Company through early commercialisation and revenue growth.

Sunnyvale, California; 30 September 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 U.S. Food & Drug Administration (**FDA**) has formally accepted its filing of their Pre-Market Approval (**PMA**) application for WiSE, with an effective date of 29 August 2024.

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

"We are delighted that our PMA application has progressed to substantive review by the FDA, effectively moving into the final stages of our regulatory timeline. The FDA moved quickly through this step, which could have taken up to 45 days. This significant milestone brings us even closer to U.S. commercialisation and to making available our life-changing WiSE technology to heart failure patients in need."

As previously announced[1], EBR's PMA application was subject to a FDA-mandated filing period of up to 45 days to confirm that it was administratively complete, and that technical elements of the application were adequate for the FDA to conduct a substantive review. Following acceptance, the FDA has notified EBR that it will now commence its substantive review over the content of EBR's PMA application. Other key milestones still pending include:

- 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;
- 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

During the substantive review, the FDA will provide feedback and request responses from the Company prior to a decision regarding the approvability of WiSE. EBR's PMA application includes extensive technical documentation and comprehensive clinical data from all clinical trials to date. This includes data from EBR's pivotal SOLVE-CRT trial, which successfully met its primary efficacy and safety endpoints. Separately, the Breakthrough Device designation for WiSE enables EBR to receive prioritised review and interactive communication with the FDA.

The Company anticipates FDA approval in Q1 CY2025 and remains on track for commercial launch in CY2025.

[1] EBR submits final PMA module to the U.S. FDA

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 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.