ASX ANNOUNCEMENT **16 October 2024**

EBR submits NTAP Application

Key Highlights:

- EBR has submitted the New Technology Add-On Payment (NTAP) application for its WiSE® CRT System to the Centers for Medicare & Medicaid Services (CMS)
- FDA breakthrough device designation means EBR's WiSE CRT System meets the new technology and substantial clinical improvement requirements, and EBR is confident in achieving the cost criterion
- This represents a significant milestone in EBR's commercialisation strategy to achieve US reimbursement, and underpins patient access to our unique technology and accelerating adoption in the US market
- EBR anticipates FDA regulatory approval in Q1 2025, with NTAP coverage expected to commence in Q4 2025

Sunnyvale, California; 16 October 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 the New Technology Add-On Payment (NTAP) application to the Centers for Medicare & Medicaid Services (CMS) for its WiSE CRT System.

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

"We are thrilled to have submitted our NTAP application to CMS, marking a significant milestone in our final regulatory phase as we move towards FDA approval early next year. This achievement brings us closer to delivering our unique technology to patients in need. We remain focused on executing our broader commercialisation strategy to accelerate market adoption and enable widespread access in the US."

The NTAP is designed to bridge the financial gap between the costs of innovative technologies and the standard Medicare Severity Diagnosis Related Groups (MS-DRG) payment structure in place, while encouraging early adoption of breakthrough medical advancements used in the inpatient setting for Medicare patients – with three specific criteria:

1. **Newness:** The medical service or technology must be new;
2. **Cost:** The medical service or technology must be sufficiently priced, such that the standard Medicare Severity Diagnosis Related Groups (MS-DRG) rate otherwise applicable is determined to be inadequate; and
3. **Substantial Clinical Improvement:** The medical service or technology must demonstrate a substantial clinical improvement over existing services or technologies.

EBR's FDA breakthrough device designation means that the WiSE CRT System automatically meets the Newness and Substantial Clinical Improvement criteria. EBR is confident that the Cost criteria will be met based on the expected pricing strategy to be implement for the WiSE CRT System.

Achieving NTAP designation would enable customers' reimbursement for in-patient procedures in the Medicare patient population. NTAP payments are limited to the lesser of 65% of the technology's costs or 65% of the amount by which the case costs exceed the standard MS-DRG payment. The NTAP reimbursement significantly reduces financial barriers for patients and supports EBR's overall commercialisation strategy by improving patient access to this innovative technology and accelerating market adoption in the US.

As previously disclosed, EBR anticipates receiving FDA approval for the WiSE CRT System in Q1 2025. This would be ahead of CMS's 1 May 2025 deadline and enable NTAP coverage to be effective from October 2025, the beginning of CMS's FY2026.

ENDS

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This announcement has been authorised for release by the 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.