

ASX ANNOUNCEMENT

15 April 2025

## CMS Proposes Approval of NTAP Reimbursement

### Key Highlights:

- The Centers for Medicare & Medicaid Services (CMS) is proposing to approve the WiSE® CRT System for the New Technology Add-On Payment (NTAP) for FY 2026
- CMS has recommended WiSE receive the maximum add-on payment of 65% of the device cost, which is in addition to the normal MS-DRG payment. In combination, these are intended to fully cover the cost of the WiSE System.
- Award of NTAP is subject to the final rule and will be effective from 1 October 2025 and will remain in effect for three years once approved
- This represents a significant milestone in EBR's commercialisation strategy, moving one step closer to ensuring US reimbursement for Medicare inpatients
- An application for Transitional Pass-through (TPT) reimbursement to provide reimbursement for outpatients will be made shortly

**Sunnyvale, California; 14 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 Centers for Medicare & Medicaid Services (CMS) has proposed approval of the New Technology Add-On Payment (NTAP) for EBR's WiSE CRT System.

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

*"We are thrilled that CMS has proposed approval of NTAP reimbursement for the WiSE CRT System at the maximum rate of 65% of the device cost. This builds on today's exciting news of FDA approval and brings us closer to delivering our unique technology to patients being treated as inpatients. We are anticipating that this will be finalised in Q3 of this year, which would further our US 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. There are three specific criteria for a new technology to qualify:

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.

The newness and substantial clinical improvement criteria are automatically met for devices like WiSE CRT that have Breakthrough Device Designation in place. This proposed ruling establishes that WiSE CRT meets all the criteria and is eligible for NTAP. CMS routinely issues proposed rulings for public comment prior to finalising. The NTAP reimbursement will enable customer reimbursement for inpatient procedures in the Medicare patient population from 1 October 2025, subject to the CMS final rule expected in August 2025. Additionally, CMS has recommended the WiSE CRT System receive the maximum NTAP payment of 65% of the device's cost, in addition to the current DRG payment. 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. CMS recalibrates the relevant Medicare Severity Diagnosis-Related Groups

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(MS-DRGs) to account for the technology's costs based on claims data during the NTAP period, integrating them into the standard DRG payment rates. This transition typically occurs 2-3 years after the NTAP designation, ensuring payments align with the technology's utilization and costs.

## **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**

(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 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 CHES 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.