

First US commercial implants of WiSE CRT System completed

Key highlights:

- EBR's WiSE® System has been successfully implanted in the first commercial patients in the US, following recent FDA approval
- Early implantations, in advance of reimbursement milestones, highlight the clinical importance of WiSE leadless left ventricular pacing for patients and clinicians
- EBR remains on track for initiation of its limited market release (LMR) and expected reimbursement add-on payments commencing October 2025.

Sunnyvale, California; 6 June 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 successful completion of the first commercial US implants of the WiSE cardiac resynchronization therapy ("CRT") system.

The procedures took place at St. David's Medical Centre and the Cleveland Clinic, two of several leading US institutions participating in this pilot release of the WiSE CRT System. These cases are representative of two of the main indications for WiSE – Previously Untreatable (CRT patient with non-functional CS lead) and High-Risk Upgrade (Micra® leadless pacemaker patient with pacing induced heart failure). This further supports our US\$3.6bn Total Available Market estimate as these are key elements of that projected market.

Reimbursement add-on payments for both inpatients (NTAP¹) and outpatients (TPT¹) are expected to commence in October 2025. This will coincide with the initiation of the LMR, which will concentrate on selected high-volume and strategically important institutions. The LMR which will run into 2026 is aimed developing clinician advocacy and facilitating wider adoption.

Dr. Robert Canby, St. David's Medical Centre said:

"Treating our first commercial patient was a powerful moment. We can now offer a leadless left ventricular endocardial pacing (LVEP) option for patients who were either unable to receive left ventricular pacing or whose prior therapies failed. Delivering pacing without navigating the coronary sinus is a major advancement. We're excited to continue building experience with the WiSE technology."

Dr. Niraj Varma, Cleveland Clinic said:

"Endocardial pacing is much closer to how the heart naturally activates. The WiSE System delivers this leadlessly. This can be achieved even when the CS and its tributaries are inadequate or unavailable. For many patients, this capability means better resynchronisation and improved outcomes."

¹ NTAP: New Technology Add-on Payment; TPT: Transitional Passthrough Payment

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

"Seeing the WiSE System in clinical use, helping heart failure patients with leadless LVEP, is truly gratifying. I'm incredibly proud of our team and honoured to be working with these incredible physicians to improve patients' lives."

ENDS

This announcement has been authorised for release by the Routine 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 has been approved by the FDA and is 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.

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