

EBR passes tenth US commercial implant milestone

Key highlights:

- EBR's WiSE® System has been successfully implanted in the tenth commercial patient during the pilot launch phase
- There have been additional successful implants since this milestone
- These implants occurring ahead of reimbursement milestones are a testament to the clinical importance of WiSE to both patients and physicians
- EBR's limited market release (LMR) is on track to commence in October 2025, coinciding with initiation of the New Technology Add-On Payment (NTAP) and Transitional Pass-Through (TPT) reimbursement schemes.

Sunnyvale, California; 17 September 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 it has passed the tenth commercial implant of the WiSE System in the US.

Several of these procedures were performed by Dr. Rahul Doshi in HonorHealth, one of Arizona's largest nonprofit healthcare systems, serving a population of five million people. EBR's pilot launch strategy mirrors the planned LMR by focusing on fewer sites but obtaining a higher utilisation rate.

Rahul Doshi, M.D., Chief of Cardiovascular Medicine and Network Director for EP Services, HonorHealth said:

"The strong clinical evidence from the SOLVE-CRT study was no surprise, as left ventricular endocardial pacing is more physiological than the current epicardial CRT methods. Once reimbursement top-up payments begin, we would look to adopt WiSE immediately in patients who failed lead-based CRT and those considered high risk for a conventional upgrade. Physiologic, leadless pacing is the future!"

Following earlier disclosures regarding the US Centers for Medicare & Medicaid Service (CMS) reimbursement pathways for WiSE, the Company has received approval for the New Technology Add-On Payment (NTAP) targeting inpatients and preliminary approval for Transitional Pass-Through (TPT) targeting outpatients. Both programs will commence in October 2025, providing add-on payments intended to enable hospital adoption in both care settings and supporting EBR's commercialisation strategy.

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

"Passing the ten-case milestone so soon after FDA approval reflects strong clinical interest in leadless left-ventricular endocardial pacing and underscores the value EBR's novel WiSE System brings for patients who are not well served by conventional CRT. With reimbursement now confirmed for inpatients and preliminary approval received for outpatient settings from October 2025, we are well positioned to expand our footprint and commence our limited market release."

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 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 CHESSE 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.