

## **Pivotal SOLVE-CRT Study Results Published in *JAMA Cardiology***

**Sunnyvale, California; 1 August 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 that results from its pivotal SOLVE-CRT (SOLVE) trial have been published in the peer-reviewed *Journal of the American Medical Association (JAMA) Cardiology*.

EBR announced positive top-line data from its pivotal SOLVE trial in May 2023 at the Heart Rhythm Society’s Late-Breaking Clinical Trials session, demonstrating that the WiSE® CRT System met its primary safety and efficacy endpoints for heart failure (HF) patients. Additionally, EBR released positive results from the SOLVE randomised sub-study in September 2023, further reinforcing conclusions from the primary study.

Results from the SOLVE trial have now been published in the peer-reviewed *JAMA Cardiology*, titled “Leadless Ultrasound-Based Cardiac Resynchronization System in Heart Failure” – <https://jamanetwork.com/journals/jamacardiology/fullarticle/2821182>

The authors concluded that, “The SOLVE-CRT study has demonstrated that leadless LV endocardial pacing with the WiSE CRT System is associated with a reduction in LVESV in HF patients. This is a novel technology that allows the delivery of CRT in HF patients who meet the standard criteria for CRT but who cannot be treated with conventional CRT.”

The publication of EBR’s SOLVE study in *JAMA Cardiology* reinforces the trial’s clinical significance and provides greater detail on the statistical analysis leading to the study enrolment stopping early for success. *JAMA Cardiology* is an international peer-reviewed journal and the leading journal for clinical investigators, clinicians, and trainees in cardiovascular medicine worldwide. The journal is highly selective, noting only 10% of submissions are accepted for publication.

**Dr Jagmeet P. Singh, Co-Principal Investigator said:**

*“The SOLVE-CRT study opens a window for the future care of patients who require CRT. By pacing endocardially in the LV, the WiSE CRT System allows us to potentially explore individual treatment strategies to provide more physiologic treatment of patients with heart failure. What I’m also really excited about is the potential to achieve totally leadless CRT by pairing WiSE with leadless pacemakers.”*

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

*“We are delighted to have the data from our successful SOLVE-CRT study published in the prestigious JAMA Cardiology journal. This reflects the quality of the clinical data supporting our WiSE CRT System and is a testament to the hard work of all involved. The academic and clinical interest in our work continues to grow and we welcome coverage in distinguished journals as we progress along our regulatory and commercialisation timelines.”*

***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 submissions 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.