

ASX ANNOUNCEMENT

10 August 2022

## **Clinical Study Demonstrating Feasibility of WiSE™ in Left Bundle Branch Area Pacing Published in Heart Rhythm Journal**

**Sunnyvale, California; 10 August 2022:** EBR Systems, Inc. (ASX: “EBR”, “EBR Systems”, or the “Company”), developer of the world’s only wireless cardiac pacing system for heart failure, is pleased to announce that a scientific paper describing the use of leadless septal left ventricle (LV) pacing with the WiSE®-CRT system has been published in the leading peer-reviewed journal Heart Rhythm, the official journal of the Heart Rhythm Society, the Cardiac Electrophysiology Society and the Paediatric & Congenital Electrophysiology Society.

The paper, entitled “*Feasibility of leadless left ventricular septal pacing with the WiSE-CRT system to target the left bundle branch area: a porcine model and multi-centre patient experience*” summarises the results of studies led by Dr Mark Elliot, Clinical Research Fellow and Professor Aldo Rinaldi, Consultant Cardiologist and Head of Electrophysiology at Guy’s & St Thomas’ NHS Foundation Trust, and Professor of Electrophysiology & Devices at King’s College London, along with physicians from four countries. This paper has been published online on the Heart Rhythm website and will appear in the next print edition.

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

*“We are pleased to see this paper being published in a leading peer-reviewed journal. The studies conducted by Dr Mark Elliott, Professor Aldo Rinaldi and their international colleagues have generated important insights into feasibility and potential utility of WiSE in the treatment of heart failure through left bundle branch pacing. This further strengthens the body of data that we have built up in support of WiSE® over the past few years.”*

### **Summary**

The feasibility of leadless LV pacing via the WiSE®-CRT system was evaluated in two models: an observational human study and a porcine study, which is recognised as a clinically relevant and comparable model for human cardiac anatomy.

In the porcine model, two pigs underwent electrode implantation on the LV septum; in the human model, eight patients underwent implantation of WiSE®. The results were positive in both the porcine and human models, with successful deployment of the electrode on the LV septum. This demonstrates the feasibility of WiSE® in treating left bundle branch blockages in the heart, which is linked to a greater risk of heart attack induced death.

WiSE® was shown to enable more physiological ventricular activation, provide greater battery longevity through a minimised distance from the transmitter to the electrode and decrease the risk of perforation and pericardial effusion compared to conventional pacing.

The WiSE® CRT System is CE Mark-approved in Europe and the UK. In the U.S., it is an investigational device.

**ENDS**

***This announcement has been authorised for release by the EBR Systems Finance Disclosure Committee, a committee of the Board of Directors.***

**For more information, please contact:**

#### **Company**

Frank Hettmann  
Chief Financial Officer  
P: +1 408 720 1906  
E: [info@ebrsystemsinc.com](mailto:info@ebrsystemsinc.com)

#### **Investors**

Nina Lo  
Vesparum Capital  
P: +61 3 8582 4800  
E: [EBRSystems@vesparum.com](mailto:EBRSystems@vesparum.com)

**EBR SYSTEMS, INC.** (ARBN 654 147 127)

480 Oakmead Parkway, Sunnyvale CA 94085 USA T: +1 408 720 1906 W: <https://ebrsystemsinc.com/>

## 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 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 (including but not limited to the COVID-19 pandemic), 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. Given the current uncertainties regarding the impact of the COVID-19 on the trading conditions impacting the Company, the financial markets, and the health services world-wide, investors are cautioned not to place undue reliance on the current trading outlook.

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.