ASX ANNOUNCEMENT **21 October 2022**

WiSE® Device Update

Key Highlights:

- EBR has identified a potential increased rate of battery depletion caused by the transmitter in some WiSE® systems
- Affected devices have not impacted patient health or safety to date and EBR is working closely with relevant clinical sites and regulatory bodies to provide patient management recommendations
- EBR does not expect this development to materially impact the timing or data of headline results for the pivotal SOLVE trial, which remain on track for release in H1 2023
- The Company has engaged with the relevant regulatory bodies and expects resolution of this matter prior to final PMA submission to the FDA in H2 2023
- EBR does not expect the issue to have a material impact on funding requirements, with the Company's strong cash position (US$79.3m as of 30 June 2022) sufficient to support the pathway to FDA approval and commercialisation

Sunnyvale, California; 21 October 2022: EBR Systems, Inc. (ASX: **"EBR"**, **"EBR Systems"**, or the **"Company"**), developer of the world's only wireless cardiac pacing system for heart failure, today provides an update regarding the WiSE® system.

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

"As part of our ongoing technical assessments, we have identified a transmitter issue occurring in a small percentage of implanted systems that can cause the battery to deplete more rapidly than predicted. It is important to note that in these instances the system continues to function as designed and the device remains fully operational until battery depletion.

Given that patient care is core in everything we do at EBR, we are working diligently to implement the appropriate manufacturing solutions. We are closely collaborating with the relevant regulatory bodies, clinical sites, and partners to implement the required patient management protocols.

This development is not expected to impact previous trial results or timing of the pivotal SOLVE trial which is nearing completion. We remain highly confident in achieving the primary SOLVE endpoints and look forward to sharing headline results in H1 2023.

We remain focused on executing our commercialisation strategy, and do not expect any material changes to our funding requirements. We anticipate this matter to be resolved and expect any updates to be included within our PMA submission to the FDA in H2 2023."

Background

Following ongoing technical assessments, EBR has identified a potential increased rate of battery depletion affecting a small number of WiSE® systems. Preliminary analysis confirmed the cause as an insulation breach in the system's transmitter, which may result in the development of a leakage pathway, leading to the battery draining at a faster rate than normal. The issue has been clinically confirmed in 1 patient representing a device failure rate of 0.8%, with an additional 7 devices suspected of having a similar issue which could raise the failure rate to 6.3%. There have been no reported complications to patient health or safety as a result of this issue to date.

EBR continues to investigate the issue further, however the Company believes that this will not affect the outcomes of the pivotal SOLVE-CRT ("**SOLVE**") trial and said devices will continue to function normally and deliver biventricular pacing until the battery is depleted.

EBR remains committed to providing patients with the highest level of care and is working closely with the relevant regulatory bodies, physicians, clinical sites, and partner institutions to ensure that patient safety is maintained. In line with Company policy, EBR has issued a technical notification to customers highlighting patient management recommendations such as monitoring potential battery depletion and conducting routine tests for battery status. New patient implants have been paused until the issue has been rectified. The Company has already identified solutions involving manufacturing changes and is actively working to implement these changes.

Pivotal SOLVE trial unaffected

EBR does not expect this issue to impact headline data for the SOLVE trial, where the 183-patient interim enrolment was recently completed. EBR believes it will achieve the key primary endpoints of the SOLVE trial, as previous trials of WiSE exceeded the safety and efficacy endpoints required for SOLVE. As such, the Company remains confident it will release headline results in H1 2023.

EBR is currently engaged in consultation with relevant regulatory authorities across key markets. In the US, EBR expects final PMA submission to the FDA in H2 2023. This submission will include the necessary changes to design and manufacturing processes to resolve this matter.

The Company remains focused developing its unique and novel technology to help those suffering from heart failure, a major social and economic problem. EBR has a clear and targeted pathway to commercialisation in 2H 2024, with plans to initially target patients who cannot receive CRT from existing devices or are at high risk for conventional upgrades, with an initial annual addressable market of US$2.5 billion.

Impact on funding and other operations

The Company held cash of US$79.3m as of 30 June 2022. At this stage, EBR does not expect any material changes to cash requirements to resolve this issue and retains funding flexibility to execute on its clinical and commercialisation objectives. These include completing the SOLVE trial, implementing the relevant battery solution, securing relevant regulatory approvals for the WiSE® system, and longer-term commercialisation activities.

EBR continues to engage with other global regulatory bodies as part of its consultative approach. In Europe, the Company intends to reapply for CE Mark under the new MDR provisions, once the transmitter issue is resolved. European commercialization will commence following U.S. commercialization as planned.

Given EBR's decision to pause new patient implants, enrolment for other studies including the Totally Leadless CRT ("TLC") and Achieving Conduction System Activation with Left Ventricular Septal Endocardial Leadless Pacing ("ACCESS-CRT") studies, will be subject to the battery issue being resolved first. The Company will continue to update the market in line with its continuous disclosure obligations.

The Company entered into an ASX suspension so that it had adequate time to clarify the regulatory actions and communicate with all the physicians in the SOLVE study.

ENDS

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

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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 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 CHESS 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.