ASX ANNOUNCEMENT **22 May 2023**

EBR Reports Positive Results for its Pivotal SOLVE-CRT Trial, Paving the Way to FDA Approval

Key Highlights:

- EBR's pivotal SOLVE-CRT ("SOLVE") trial meets the primary efficacy and safety endpoints demonstrating statistically significant improvement against the benchmarks:
  - Efficacy endpoint: -16.4% (compared to -9.3% performance goal) (p = 0.003)
  - Safety endpoint: 80.9% (compared to 70% performance goal) (p < 0.001)
- Final PMA submission to the FDA targeted for Q1 2024, paving the way to FDA approval
- EBR remains well funded to progress its commercialisation strategy with a strong cash balance and access to the second tranche of its growth capital facility with Runway Growth Finance
- The positive results represent a major milestone on the path to addressing a significant unmet need in an annual addressable market worth US$2.5bn initially, with substantial upside potential
- EBR to hold webcast today at 9:15am AEST

Sunnyvale, California; 22 May 2023: 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 positive results from its pivotal SOLVE trial. Top-line data was released at the 2023 Heart Rhythm Society ("HRS") Conference during the high-profile late-breaking clinical trials session in New Orleans. The trial met its primary objectives, with the WiSE® device demonstrated to be safe, well tolerated, and efficacious.

Pivotal trial results

The study results demonstrated that patients implanted with the WiSE device saw a -16.4% reduction in heart volume, indicating improved heart function, with more than 80.9% of patients free from device or procedure-related complications, exceeding the pre-determined benchmarks as shown in Table 1. All other outcomes analysed to date have been concordant with these results showing significant improvement in reversing heart failure symptoms and improving physiology.

Table 1 – SOLVE trial results summary

	Result	Benchmark	p-value
Primary Efficacy Endpoint *Improvement in heart function measured by reduction in left ventricular end systolic volume*	**-16.4%**	**-9.3%**	**p = 0.003**
Primary Safety Endpoint *Freedom from device, or procedure-related complications*	**80.9%**	**70.0%**	**p < 0.001**

Allan Will, Chairman of EBR Systems commented:

"I am thrilled and immensely proud of the entire EBR team for achieving this positive trial result. This represents the culmination of decades of diligent research and development and teamwork, enabling us to deliver what we did today. The SOLVE trial not only demonstrates the ability of our device to provide safe and effective cardiac resynchronisation therapy but also validates EBR's technology as a key treatment for those suffering from cardiac arrhythmia. This breakthrough will significantly improve the lives of countless patients currently suffering from this disorder."

John McCutcheon, President and CEO of EBR Systems commented:

"I am incredibly encouraged by all aspects of the top-line data presented today, with the data exceeding our pre-specified regulatory primary efficacy and safety endpoints, paving the way for regulatory approval. The results validate our novel approach for delivering CRT and treating heart arrhythmia in heart failure patients. We are eager to advance our commercialisation strategy and will continue to work with the FDA to deliver a seamless pathway forward to approval. We look forward to leveraging our established partnerships and presence in the US to drive initial sales growth, targeting a US$2.5b market and improving patient outcomes for those with no other treatment options."

Next steps

This clinically significant outcome builds on successful previous trials and validates WiSE as a ground-breaking CRT treatment for patients who are unable to receive CRT from a traditional lead-based system. A manuscript will be submitted to a medical journal for peer-review and publication. The Company will continue to progress its regulatory agenda and is aiming to finalise its pre-market approval ("PMA") submission to the FDA in Q1 2024, paving the way for FDA approval. EBR has maintained significant engagement with the FDA, which includes gaining prior approval for the trial re-design to include a single-arm only treatment phase and the FDA granting the WiSE device a Breakthrough Device Designation. The Company looks forward to engaging with the regulatory body during the final stages of the approval process.

The Company is well funded to support its commercialisation objectives with substantial cash reserves of US$56.6/A$84.3[1] million as of March 2023 and a growth capital facility with Runway Growth Finance. In light of the positive trial results, EBR now has the option to draw down on the US$20m second tranche of this facility. EBR will now mobilise to execute its clear and targeted commercialisation strategy, focused on four patient groups in the US market (acute lead failure, high risk upgrades, leadless upgrades and chronic lead failure), which represent a combined market opportunity of US$2.5bn per annum. The Company looks forward to bringing this ground-breaking technology to patients, which in many cases have no other treatment option, providing a better quality of life for those suffering from heart failure.

Webcast

EBR will host a webcast at 9:15am (AEST) today to review the top line results as set out in an investor presentation released in a separate announcement to the ASX this morning.

Please click here to register for the briefing:

https://attendee.gotowebinar.com/register/1300636924960720992

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

[1] Assumes an A$:US$0.6695 exchange rate

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.