

## EBR Systems Financial Results for FY2022

**Sunnyvale, California; 28 February 2023:** EBR Systems, Inc. (ASX: “EBR”, “EBR Systems”, or the “Company”), today released its Appendix 4E Preliminary Final Report for the full year ended 31 December 2022 and its audited consolidated financial statements, with accompanying notes.

### Operational milestones:

- Achieved major milestone of completing 183 patient interim enrolment in the pivotal SOLVE-CRT (“SOLVE”) trial, with headline results on track to be released in H1 2023
- Received US Food & Drug Administration (“FDA”) approval to include leadless pacemakers as a co-implant in the pivotal SOLVE trial
- Successfully executed an agreement for a 5 year \$US50m growth capital facility with leading venture debt provider, Runway Growth Capital, LLC
- Commercialisation expected to commence in H2 2024 with focus on established clinical partnerships and presence in US to drive initial sales growth
- Featured in several peer-reviewed publications and conferences including the 2022 Heart Rhythm Society (“HRS”) conference representing more than 7,000 health and science professionals

### Key financial details:

- Operational expenses of US\$34.0m during the twelve-month period ended 31 December 2022, an increase of US\$11.2m, compared to prior corresponding period driven by increased spending on research and development, clinical trial costs, and staffing costs.
- Net cash used in operating activities increased US\$8.3m to \$30.4m during the twelve-month period ended 31 December 2022.
- EBR holds cash, cash equivalents, and marketable securities of US\$64.5m at 31 December 2022

### Successfully completed SOLVE interim enrolment

EBR successfully completed interim enrolment of 183 patients in its pivotal SOLVE trial during the year. With enrolment completed in June 2022, final patients are currently undergoing their 6 month follow up which is expected to be completed in Q1 2023. Following final patient follow ups and statistical analysis, EBR expects to release the SOLVE headline data at the HRS conference in May 2023, followed by the submission of a pre-market approval (“PMA”) application to the FDA in H2 2023.

EBR’s SOLVE trial evaluates the safety and efficacy of the WiSE® system in patients with acute lead failures, chronic lead failures, high-risk upgrades and leadless upgrades. The primary efficacy endpoint for the trial is a greater than 9.3% improvement in heart function measured by a reduction in left ventricular end systolic volume, and the primary safety endpoint is less than 30% of patients with a device or procedure-related complication. EBR remains confident that both endpoints will be achieved given previous clinical trials of WiSE have exceeded both safety and efficacy endpoints set for the current pivotal SOLVE trial.

### Expanded market potential

In April, EBR received approval from the FDA to include leadless pacemakers as co-implants in its pivotal SOLVE trial, expanding the Company’s addressable market to US\$2.5bn in 2024, with further growth potential as more leadless pacemakers become available. EBR’s technology has the potential to address a significant unmet clinical need by providing a solution for physicians treating patients with limited upgrade options.

### Secured US\$50m growth capital facility

EBR executed an agreement for a 5-year US\$50m growth capital facility with a leading venture debt provider, Runway Growth Capital, LLC. The facility is structured such that US\$20m can be drawn immediately with the option to draw future tranches pending specific performance criteria. Runway Growth Capital's investment in EBR is a vote of confidence in the Company's unique and novel WiSE technology. Together with EBR's existing cash reserves, funds raised from the facility provide EBR with funding flexibility which will be used for the FDA approval process, growth and commercialisation activities. In an increasingly challenging economic environment, the debt facility provides EBR with balance sheet flexibility to protect shareholder value as the company progresses through its clinical and commercial milestones. Details regarding the facility and its terms can be found in the ASX announcement titled "EBR Systems secures US\$50m growth capital facility" released on 1 July 2022. At 31 December 2022, EBR had borrowed US\$20m. The remaining \$30M is available in two future tranches in 2023 and 2024 should EBR meet certain milestones.

### **Execution of commercialisation strategy**

EBR continued to execute on its commercialisation strategy during the year. The Company plans to leverage established partnerships with ~45 US sites that have participated in previous clinical trials to drive initial sales growth. Given the CRT market is highly concentrated, EBR intends to expand its reach to target the top 200-250 clinical sites in the US which represents >50% of the US CRT market. EBR has established a specialist sales force to help target these high-volume sites and aims to grow to 35 sales territories by end of 2025. Following initial adoption in the lucrative US market, EBR will expand its reach to high volume sites outside the US, following regulatory approvals and reimbursement coverage.

### **Clinical studies and publications**

EBR featured in multiple clinical studies, peer-reviewed publications, and leading global conferences during the year. A study demonstrating the feasibility of leadless left bundle branch area pacing using WiSE was published by the leading peer-reviewed journal Heart Rhythm. Heart Rhythm is the official journal of the Heart Rhythm Society, the Cardiac Electrophysiology Society and the Paediatric & Congenital Electrophysiology Society. Further details relating to the method and results of the study can be found in the ASX announcement titled "Clinical Study Demonstrating Feasibility of WiSE in Left Bundle Branch Area Pacing Published in Heart Rhythm Journal" released on 10 August 2022.

During the year, Andrew Shute, EBR's Senior Vice President of Global Field Operations, presented at the 2022 European Heart Rhythm Association. The presentation covered the feasibility of leadless left bundle branch pacing using WiSE in an animal model. The association is the leading network of European Cardiac Rhythm Management with over 3,500 members around the globe. EBR also attended the 2022 HRS conference in San Francisco. HRS is the leading conference on cardiac pacing and electrophysiology, representing more than 7,000 medical, allied health and science professionals from over 90 countries.

### **Outlook**

Final patient 6 month follow ups are expected to be completed in Q1 2023 and EBR will begin the process of data cleansing and analysis. EBR hopes to announce headline data for the trial at the HRS conference in May 2023, followed by a PMA application to the FDA in H2 2023.

In addition to engaging with regulatory authorities, EBR remains focused on supporting clinical sites and patient implants. EBR will continue to conduct business activities as well as present at distinguished cardiology conferences, investor conferences and publish in reputable medical journals.

**ENDS**

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

**For more information, please contact:**

**Company**

John McCutcheon

President & CEO

P: +1 408 720 1906

E: [info@ebrsystemsinc.com](mailto:info@ebrsystemsinc.com)

**Investors**

Dean Dribbin

Vesparum Capital

P: +61 3 8582 4800

E: [EBRSystems@vesparum.com](mailto:EBRSystems@vesparum.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, 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 (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.