

## EBR Systems Financial Results for FY2021

**Sunnyvale, California; 25 February 2022:** 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 2021 and its audited consolidated financial statements, with accompanying notes.

### Key financial details:

- Operational expenses of **US\$22.8m**, an increase of US\$2.2m compared to prior corresponding period (pcp) driven by an increase in field expenses to continue the final phase of the SOLVE-CRT pivotal clinical trial and to increase the number of sites participating in the trial
- **27%** increase in net cash used in operating activities, up from US\$17.5m to **US\$22.2m** in FY2021
- Strong cash position of **US\$78.2m** at 31 December 2021

### Operational milestones:

- Performed world’s first leadless left bundle branch area pacing implant utilizing WiSE CRT™ System
- Successful completion of a A\$110m initial public offering on the ASX in November 2021
- Advanced recruitment for SOLVE-CRT pivotal trial, with enrolment expected to complete in H1 2022
- Continued execution of commercial strategy and fostering relationships with US clinical sites
- Progressed planning activities for investigator-initiated studies in expanded indications: the Totally Leadless CRT (TLC) study and the Achieving Conduction System Activation with Left Ventricular Septal Endocardial Leadless Pacing (ACCESS-CRT) study
- Strengthened management team by the appointment of Mr Steve Sandweg as Chief Commercial Officer, Mr Michael Hendricksen as Chief Operating Officer and promotion of Ms Madhuri Bhat to Chief Regulatory Officer
- Featured clinical studies in several peer-reviewed publications, including results from part 1 of SOLVE-CRT in the Heart Rhythm Journal
- Appointed industry experts Dr Bronwyn Evans, Dr David Steinhaus and Ms Karen Drexler to the Board of Directors as Independent Non-Executive Directors

**World’s first leadless LBBAP:** Over the last 12 months, Professor Pascal Defaye, Head of Rhythmology and Cardiac Stimulation Unit, CHU de Grenoble-Alpes, France, performed the world’s first successful leadless Left Bundle Branch Area Pacing (LBBAP) implant utilizing the WiSE CRT System. The implant marks a significant achievement in the approach to physiological conduction system pacing. LBBAP pacing has been proposed as a strategy to achieve physiological pacing by utilizing the heart’s native conduction system, allowing faster left ventricular activation time. LBBAP has potential applications in both traditional bradycardia pacing and as an alternative approach to Cardiac Resynchronization Therapy (CRT). Until now, LBBAP has required use of a conventional pacing lead, driven deep into the ventricular septum, which can be technically challenging. Leadless LBBAP has the potential to provide superior resynchronization versus conventional CRT in select patients.

**Successful A\$110 million IPO on the ASX:** In November 2021, EBR Systems listed on the Australian Securities Exchange (ASX) following the successful completion of an initial public offering (“IPO”) that raised approximately A\$110 million through the offer of 101,851,851 CDIs at the offer price of A\$1.08. The IPO was strongly supported by institutional and sophisticated investors, including existing Australian shareholders such as M.H. Carnegie & Co, Brandon Capital and superfunds AustralianSuper, HESTA, Hostplus and Statewide Super, who collectively contributed more than A\$30 million, in addition to a broad range of new institutional and high net worth investors.

Proceeds raised will be primarily used to provide EBR with funding to support its growth strategies, including the clinical development of EBR's proprietary Wireless Stimulation Endocardially ("WiSE") device, expanding EBR's sales and marketing resources, manufacturing capacity, and investment into research and development to improve EBR's technologies.

**Progress in the SOLVE-CRT Pivotal trial:** The single-arm pivotal study assesses the safety and efficacy of the WiSE System in patients with acute lead failures, chronic lead failures and high-risk upgrades. EBR estimates that these indications have an initial addressable market of US\$2.1 billion in the Company's initial target markets of US, Germany, France, UK, Australia, Benelux and Scandinavia. 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 performance goal is less than 30% of patients with device or procedure-related complications. Such results were achieved and exceeded in a previous clinical study conducted by EBR, the SELECT-LV study, that was used to gain CE Mark approval. Recruitment for final efficacy and interim safety results in the SOLVE-CRT IDE trial is scheduled to complete in H1 2022 with headline results expected 3-4 months post follow-up completion.

**Advancement towards US Commercialisation:** Throughout 2021, EBR focused on advancing its pivotal trial to target US FDA PMAA submission in H1 2023. For its initial commercial launch, EBR will focus on driving adoption of WiSE at key, high-volume, luminary sites within the US followed by select, high-volume outside-of-US (OUS) sites. Initial adoption will be from sites who have participated in EBR's clinical trials, which is expected to involve up to 45 US sites. EBR has fostered strong relationships with these sites, all of which are leaders in cardiac medicine and will assist with promoting and building credibility for WiSE.

**Expansion of clinical portfolio and new indications:** During the 12 months, EBR continued its collaboration on two other, investigator-initiated clinical projects: Totally Leadless CRT (TLC) and Achieving Conduction System Activation with Left Ventricular Septal Endocardial Leadless Pacing (ACCESS-CRT). TLC is expected to add to EBR's already published experience of pairing the leadless WiSE with a leadless intracardiac pacemaker, which has previously demonstrated strong safety and efficacy results. ACCESS-CRT will evaluate the ability to activate the heart's native conduction system with WiSE. EBR hopes that these prospective, non-randomized studies could lead the way to expanded indications. The two studies are expected to commence in H1 2022 in Australia and Europe.

**Clinical studies in publications:** The Heart Rhythm Journal featured EBR's initial experience and results from part 1 of the SOLVE-CRT pivotal study (roll-in phase), which demonstrated favourable clinical responses in heart failure symptoms and significant left ventricle reverse remodelling, as well as a high success rate of WiSE endocardial placement in centres with no prior implanting experience. In addition, a smaller study which confirmed the technical feasibility of delivering leadless LBBAP using the WiSE-CRT system was published in the European Heart Journal. The European Society of Cardiology also published a paper which found that WiSE-CRT upgrades had high rates of procedural success and similar improvements compared to coronary sinus upgrades in clinical composite score and left ventricle remodelling.

**Corporate Update:** In 2021, EBR appointed Mr Michael Hendricksen as Chief Operating Officer ("COO") and Mr Steve Sandweg as Chief Commercial Officer ("CCO") and promoted Ms Madhuri Bhat to Chief Regulatory Officer ("CRO"). Michael has over 25 years of experience in product development and manufacturing of medical devices and previously served as COO at Ceterix Orthopaedics (Ceterix). Steve has 30 years of sales and commercialisation experience in Fortune 500 medical technology companies, having recently served as General Manager for Keystone Heart. Madhuri was promoted to CRO from her previous position as Senior Vice President of Regulatory & Compliance, Quality, and Clinical for EBR.

EBR also made several appointments to the Board following the departures of Mr Dave Stassen and Dr Leighton Reed. EBR welcomed Dr Bronwyn Evans, Dr David Steinhaus and Ms Karen Drexler to EBR's Board as independent Non-Executive Directors.

**Outlook:** EBR is in its final phase of recruitment for the SOLVE-CRT pivotal study, with completion of recruitment expected in H1 2022. EBR expects to announce headline data for the trial in H2 2022 and submit a PMA application in H1 2023 for U.S. FDA approval expected in H2 2023.

Pacing induced heart failure is an unresolved problem which results in poor patient outcomes and potentially severe heart complications. EBR provides the only leadless solution as it has been clinically tested to show effective synchronisation of the left ventricle to the pacing pulse of any pacing system. Overall, EBR faces an initial \$2.1 billion dollar market opportunity and is committed to expanding its reach globally to provide leadless CRT.

EBR remains focused on supporting clinical sites and patient implants and will continue its ongoing business activities including presentations at high profile cardiology conferences, investor conferences and multiple publications in medical & scientific journals.

**ENDS**

***This announcement has been authorised for release by EBR Systems 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 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.