

EBR Systems Financial Results for 2023

Sunnyvale, California; 28 February 2024: 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 release its Appendix 4E Preliminary Final Report for the full year ended 31 December 2023.

Operational milestones:

- Achieved primary efficacy and safety endpoints in the pivotal SOLVE-CRT trial, paving the way to U.S. Food and Drug Administration (“FDA”) approval in Q1 2025
- Reported positive results from the SOLVE-CRT randomised sub-study, supporting conclusions from the primary study that the WiSE[®] CRT System is an effective treatment for heart failure patients
- Strengthened leadership team with appointment of Dr. Rick Kuntz as consulting Chief Scientific Officer, and Mr Gary Doherty as Chief Financial Officer
- Secured funding to support regulatory activities and initial commercial launch via a US\$21.6m capital raise and US\$20.0m drawdown from EBR’s growth capital facility with Runway Growth Capital
- Featured in scientific meetings, the media and investor conferences, including 2023 Heart Rhythm Society conferences in New Orleans and Hong Kong (Asia-Pacific)

Key financial details:

- Operational expenses of US\$34.5m/A\$55.6m¹, an increase of US\$0.5m/A\$0.8m¹ compared to prior corresponding period (pcp) driven by increased research and development spending on product development and increased general and administrative spending on employee related expenses. These increases were offset by a reduction in sales and marketing expenses, and clinical and regulatory expenses, resulting from completing enrolment in the SOLVE-CRT trial in July of 2022.
- 7.71% increase in net cash used in operating activities compared to pcp, to US\$32.7m/A\$48.0m².
- EBR holds cash and short-term investments of US\$73.4m/A\$107.8m² on 31 December 2023 and remains well funded through initial commercialisation

Achieved positive results in pivotal SOLVE-CRT trial and randomised sub-study

EBR achieved a transformative milestone during the year, announcing positive top-line data from its pivotal SOLVE-CRT trial. The trial met both primary endpoints, validating the ability of the WiSE CRT System to provide safe and effective cardiac resynchronisation therapy and representing a significant breakthrough in the treatment of cardiac arrhythmia. Positive pivotal trial results pave the way to FDA approval and EBR is currently progressing its regulatory agenda targeting pre-market approval application (“PMAA”) submission to the FDA in Q3 2024 and FDA approval in Q1 2025.

In addition to the pivotal SOLVE-CRT trial results, EBR announced supporting positive data from its analysis of SOLVE-CRT’s randomised sub-study portion. The randomised phase consisted of 108 patients who all received the WiSE implant and were randomised in a 1:1 ratio to either the Treatment Group (WiSE-CRT System ON) or Control Group (WiSE-CRT System OFF). Results from the randomised sub-study support the conclusions of the primary study that the WiSE-CRT System is safe and efficacious in treating heart failure patients. With data from both the pivotal trial and randomised sub-study released, EBR has submitted a manuscript to a medical journal for peer-review and expect acceptance and publication in the near term.

¹ Assumes an A\$:US\$0.6219 exchange rate

² Assumes a A\$:US\$0.68112 exchange rate

Strengthened leadership team

EBR strengthened its leadership team during the year with the appointment of both Dr. Rick Kuntz as consulting Chief Scientific Officer and Mr Gary Doherty as Chief Financial Officer. Dr Kuntz was appointed in February 2023 and brings over 15 years of experience in the healthcare sector, formerly occupying positions of Senior Vice President, Chief Medical and Scientific Officer of Medtronic and founding CEO of the Harvard Clinical Research Institute. During the year Dr. Kuntz provided valuable guidance and counsel during the final stages of the pivotal SOLVE-CRT trial and EBR looks forward to continuing to leverage his insights as the Company continues to execute on its regulatory and commercialisation strategy.

Mr Doherty was appointed as Chief Financial Officer in September 2023 and brings over 30-years of experience across technology, healthcare and finance to the role. Mr Doherty has a proven track record of developing high performing finance functions and medical device companies including his previous role as CFO of Acutus Medical (NASDAQ:AFIB), a medical technology company specialising in cardiac arrhythmia and atrial fibrillation treatment. EBR looks forward to leveraging Mr Doherty's experience as the Company prepares for initial commercialisation.

Funding secured to support regulatory agenda and initial commercial launch

EBR successfully raised US\$21.6m during the year, consisting of a US\$19.8m Placement and US\$1.8m Share Purchase Plan. The capital raise was strongly supported by EBR's existing CDI holders as well as new institutional and sophisticated investors. Separate to the capital raising proceeds, EBR announced that it had unlocked the second tranche of its growth capital facility with Runway Growth Capital. EBR executed the agreement with Runway Growth Capital on 1 July 2022 with the first US\$20m tranche drawn upon execution of the agreement. The second tranche unlocked on 6 June 2023 following announcement of the positive SOLVE-CRT trial data and EBR confirmed that the second tranche of US\$20m was drawn down. Funds from the capital raising and growth capital facility will be used to support regulatory approval activities and EBR's commercialisation strategy.

Featured in leading global conferences

EBR featured in multiple peer-reviewed publications and leading global conferences during the year. Positive results from the pivotal SOLVE-CRT study were presented at the Heart Rhythm Society Conference in New Orleans during the high profile late-breaking clinical trials session (19 – 21 May). Clinical data from the randomised arm was presented at the 16th Asia Pacific Heart Rhythm Society Scientific Session in Hong Kong (1 – 3 September). EBR also presented at numerous other leading global conferences including the German Cardiac Society (5 – 6 October) and the UK Heart Rhythm Congress (8 – 10 October), where the safety and effectiveness of the WiSE CRT System for cardiac rhythm management was highlighted.

EBR continued to feature at high-profile investor conferences during the year, including the 17th Bioshares Biotech Summit held in Hobart, Tasmania (24 – 25 July), Wilson's 2nd Annual Drug & Device Conference (26 – 27 October); the AusBioInvest 2023 Conference (30 October); and the Bell Potter Healthcare Conference (14 – 16 November 2023). EBR was also featured in The Capital Network's 'Emerging ASX Gems' webcast (3 November).

During the year, EBR's management team conducted several Australian investor roadshows taking place across several Australian states, providing shareholders with the opportunity to learn about the Company's activities and receive a hands-on demonstration with EBR's technology.

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This announcement has been authorised for release by the EBR Systems Finance 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, 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, 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. 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.