ASX ANNOUNCEMENT **27 August 2024**

EBR Half-Year Results 2024 and Securityholder Update

EBR Systems, INC (**"EBR Systems", "EBR", "The Company"**) is pleased to present the Company's financial results for the half-year ended 30 June 2024, together with a securityholder update.

During the half-year, EBR:

- Significantly progressed regulatory activities in preparation for the final submission of its Pre-Market Approval ("PMA") Application to the U.S. Food and Drug Administration ("FDA") – EBR plans to submit the final PMA application module for WiSE® subsequent to the half-year period
- Strengthened the management team with the appointment of Mr. Erik Strandberg as Chief Commercial Officer to drive EBR's US commercialisation strategy and oversee the launch of WiSE
- Progressed key commercialisation activities, including fostering relationships with high-volume CRT sites in the US ahead of FDA approval which is expected in Q1 2025
- Entered the S&P/ASX All Ordinaries Index, demonstrating EBR's growing company profile
- EBR's clinical data was presented at leading global scientific conferences, including the European Heart Rhythm Association (EHRA) congress and the Heart Rhythm Society (HRS) meeting
- EBR was invited to present at distinguished investor conferences including Emergence 2024 and the 18th Bioshares Biotech Summit
- Maintained a strong cash position and short-term investments of US$54.1m/ A$81.m[1] at 30 June 2024

Operating and Financial Review

Financial performance

For the half-year ended 30 June 2024, the Company's net loss before tax is US$20.6m/A$31.0m[1] (30 June 2023: US$15.6m/A$23.6m[2]). Key points to note on the Company's financial performance include:

- Operational expenses of US$19.3m/A$29.0m[1], an increase of US$3.7m/A$5.6m[1] compared to prior corresponding period (pcp) primarily driven by a US$2.2m/A$3.3m[1] increase in staff costs, and a US$1.2m/A$1.8m[1] increase in legal and accounting fees.
- 31% increase in net cash used in operating activities compared to pcp, to US$4.8m/A$7.2m[1].
- Cash and short-term investments of US$54.1m/ A$81.1m[1] at 30 June 2024

To view the Half-Year Report, please click:

https://announcements.asx.com.au/asxpdf/20240827/pdf/0672mv9rbj8mms.pdf

FDA review of PMA application underway

During the half-year, EBR made significant advancements in its regulatory programme and plans to submit the final PMA application module for its WiSE CRT System, subsequent to the half-year period. The Company utilised a modular submission approach which allowed the FDA to evaluate the contents of each information package and provide feedback dynamically. The modules submitted included information on biocompatibility testing, device verification testing, clinical trial data from all trials to date, post-market surveillance, proposed labelling, and other important data requested by the FDA.

[1]Assumes an exchange rate of A$:US$ 0.667
[2]Assumes an exchange rate of A$:US$ 0.662

Post submission, EBR's PMA application will undergo an initial filing review period to ensure all necessary information has been completed for the FDA to conduct a substantive review, after which the FDA will notify EBR whether its application has been accepted. The substantive review includes a comprehensive evaluation and audit on the content of EBR's PMA application. As part of the substantive review process, the FDA provides feedback and requests responses before making a final approval decision of the WiSE System. With the Breakthrough Device designation for WiSE, EBR receives prioritised review and retains interactive communication with the FDA throughout the PMA review process. The Company anticipates FDA approval in Q1 CY2025 and commercial launch later in 2025.

Chief Commercial Officer appointment

In April 2024, EBR strengthened its management team with the appointment of Mr. Erik Strandberg as Chief Commercial Officer. Mr. Strandberg brings more than 20 years of experience in the medical device sales industry and has developed a strong network including physicians, hospital executives, and medical professionals. Mr. Strandberg's skills in strategic sales planning, contract negotiation and operational oversight will be crucial in driving the success of EBR's US commercialisation strategy.

Commercial readiness

During the period, EBR continued to strengthen its relationships with high volume CRT procedure sites, who participated in the SOLVE-CRT trial. EBR plans to leverage these key partnerships, supported by a dedicated sales force to drive initial sales. The Company is strategically targeting four specific patient groups within the US market: acute lead failure, high risk upgrades, leadless upgrades, and chronic lead failure patients. With EBR's Breakthrough Device Designation, the Company automatically qualifies for the New Technology Add-On Payment ("NTAP") and Transition Pass-Through ("TPT") reimbursement programs, enabling EBR to establish an average selling price ("ASP") of ~US$45k upon commercialisation.

Investor and clinical awareness

During the period, EBR was included in the S&P/All Ordinaries index, increasing investor awareness and visibility for the Company. Inclusion in the index highlights EBR's growth in market value and increasing interest from the investment community in EBR's innovative WiSE solution.

The WiSE CRT System was featured in invited presentations by globally renowned physicians at both the European Heart Rhythm Association (EHRA) congress held in Germany, and the Heart Rhythm Society (HRS) meeting held in Boston, USA. These presentations highlighted the unique solution the WiSE CRT System offers by providing an alternative to cardiac pacing leads, historically the major source of complications and reliability issues in cardiac rhythm management.

EBR was invited to present at distinguished investor conferences including the 2024 Emergence Conference held in Singapore and the 18th Bioshares Biotech Summit held in Fremantle. At the Emergence Conference, EBR management presented to a network of 500 Asian-based high-net-worth investors, family offices and professional investors. The Bioshares Biotech Summit were one of 34 companies to present in front of over 220 delegates from the wider investment community. EBR management also conducted a series of investor roadshow, visiting Melbourne, Adelaide, Brisbane, and Sydney. John McCutcheon (President & CEO) and Andrew Shute (Senior Vice President) were able to meet with existing shareholders and new investors to provide an update on the Company's recent activities and offer a hands-on demonstration with EBR's technology.

Reclassification of Previously Released Financial Statements

The unaudited financial statements set forth in the Appendix 4D and released to ASX in conjunction with this announcement make certain reclassifications to the statement of operations for the six months ended 30 June 2024 that were previously released by the Company to ASX on 29 August 2023. These reclassifications had no impact on total operating expenses, net loss per share attributable to common stockholders, or total stockholders' equity.

The table below summarizes the effects of the reclassified statement of operations for the six months ended 30 June 2023:

	Consolidated Statements of Operations		
	As Originally Filed	Reclassification	As Revised
Operating expenses			
Research and development	$ 6,666,983	$ 5,608,844	$ 12,275,827
Sales and marketing	3,583,928	(3,583,928)	-
Clinical and regulatory	2,419,663	(2,419,663)	-
General and administrative	2,908,843	394,747	3,305,590
Total operating expenses	15,579,417	-	15,579,417
Loss from operations	(15,579,417)	-	(15,579,417)
Other (expense) income			
Interest expense	(1,464,316)	-	(1,464,316)
Interest income	-	1,150,982	1,150,982
Other income	1,500,022	(1,150,982)	349,040
(Loss) gain on foreign currency	(52,559)	-	(52,559)
Total other (expense) income	(16,853)	-	(16,853)
Loss before income tax	(15,596,270)	-	(15,596,270)
Income tax expense	-	-	-
Net loss	$ (15,596,270)	$ -	$ (15,596,270)

ENDS

This announcement has been authorised for release by General Disclosure Committee, a Committee of the 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, 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 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.