ASX ANNOUNCEMENT **25 MARCH 2025**

2024 Activity Report and Form 10-K submission

Key Highlights:

- Successfully submitted the final module of Premarket Approval ("PMA") application for WiSE® CRT System ("WiSE") to the U.S. Food and Drug Administration ("FDA") in August 2024
- Subsequent to year end, the FDA completed the manufacturing Pre-Approval Inspection ("PAI") and EBR expects regulatory approval on or before 13 April 2025, with commercial launch anticipated in H2 2025
- Subsequent to year end, in January 2025 CMS notified EBR of the acceptance of WiSE into the inaugural year of the Transitional Coverage for Emerging Technologies ("TCET") reimbursement pathway
- Subsequent to year end, an 11-year lease was signed for a 51,000 square feet (4,751 sqm) manufacturing facility to increase scale and capabilities for future growth, with the transition expected to complete during H1 2026
- Appointment of Mr. Erik Strandberg as Chief Commercial Officer to drive U.S. commercialisation strategy, and Ms. Pharoah Garma as Chief Regulatory Officer.
- Successful US$34.0m / A$50.0m[1] capital raise completed in Q3 2024, with EBR well-capitalised through to initial commercialisation with cash and short-term investments of US$66.0m / A$106.1m[2]as of 31 December 2024

Sunnyvale, California; 25 March 2025: 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 release its Annual Activity Report and Form 10-K submission for the year ended 31 December 2024.

John McCutcheon, EBR Systems' President & Chief Executive Officer said:

"We are immensely proud of EBR's achievements in 2024, a transformative year for the company. We submitted and had our PMA application for the WiSE® CRT System accepted by the FDA, while recently also completing the FDA's Pre-Approval Inspection of our manufacturing facility. These accomplishments keep us on track for regulatory approval on or before 13 April 2025. Our acceptance into the TCET reimbursement pathway will support EBR's commercialisation strategy by improving patient access to this innovative technology and accelerate market adoption in the US.

The recent signing of a new lease on a 51,000 square foot (4,751 sqm) facility underscores our commitment to expanding manufacturing capabilities to accommodate growth and demand for WiSE. These milestones are a testament to the dedication of the EBR team as we continue our transition towards a commercial medical devices business."

Final module of FDA PMA application submitted and line of sight to final approval

In August 2024, EBR submitted the final module of its PMA application for the WiSE® CRT System to the U.S. FDA. This submission included an extensive technical and clinical data set, culminating in a comprehensive review of safety and effectiveness. In September 2024, the FDA completed the initial review of EBR's PMA application and formally accepted

[1] Assumes an A$:US$ 0.6804 exchange rate

[2] Assumes an A$:US$ 0.6214 exchange rate

the application for substantive review. This phase will involve a comprehensive evaluation process of the PMA application, further feedback and information requests prior to a decision on approval. A Day-100 Meeting was scheduled and completed with the FDA during December 2024, which helped to address any questions from the FDA and ensure alignment on any remaining steps to approval of the application.

Subsequent to year end in January 2025, the FDA conducted the PAI of EBR's existing manufacturing facilities to ensure the manufacturing procedures are compliant with Quality System regulations and that the Company can consistently produce medical devices that meet approved specifications. EBR is pleased to note that no Form FDA 483 observations were made (a Form FDA 483 notifies the company's management of observed deficiencies that need to be addressed before approval). This outcome underscores EBR's adherence to quality manufacturing practices. The successful completion of the PAI represents the PMA now being in its final phase. EBR believes that FDA regulatory approval should occur on or before 13 April 2025, based upon typical review times, paving the way for a commercial launch anticipated in H2 2025.

TCET Reimbursement Pathway

EBR announced in January 2025 that the WiSE System was accepted into the CMS' newly enacted TCET pathway. This new and highly selective pathway is designed to expedite Medicare explicit coverage for FDA-designated Breakthrough Devices. CMS has initiated an Evidence Preview process to assess potential benefits and harms. The benefits of the TCET pathway include early CMS engagement for an efficient review process and expedited Medicare coverage, alongside transitional Medicare coverage for up to five years. The TCET pathway offers EBR expanded optionality as we seek to optimize the various reimbursement programs available to the Company.

Commercialisation Readiness

Subsequent to year end, EBR signed a new 11-year commercial lease agreement for a new 51,000 square foot (4,751 sqm) facility to support anticipated growth as the Company begins commercialisation in H2 2025. This new facility significantly increases EBR's manufacturing footprint and will also be used for storage, distribution, and R&D. The agreement includes phased rent payments designed to allow for a gradual scale-up of operations. EBR will not be required to pay monthly rent on the new facility until January 2026 and will only pay rent on 20,000 square feet in the first year, incrementally increasing to the full 51,000 square feet by the fourth year. Additionally, approximately US$4m in tenant improvements will be financed by the landlord, alongside US$1.3m budgeted by EBR for furniture, equipment, and contingencies involved in the buildout. Following completion of the build out and installation of key equipment, the FDA will perform a manufacturing PAI akin to the recently completed inspection process for EBR's current facility.

The upgraded facility will bolster EBR's manufacturing scale and capabilities, ensuring the company is well-positioned to meet future demand. EBR plans to complete the move and qualification of the new facility by H1 2026, marking a significant milestone in its operational growth.

The Company is well positioned for the commercial launch of WiSE in H2 2025, targeting the significant U.S. market opportunity of US$3.6bn initially. Preparation is currently underway to support key commercialisation activities such as manufacturing scale-up (including initial tooling) and appointment of a strong commercial sales and marketing leadership team. EBR will leverage established partnerships and presence in the US to drive initial sales, targeting US sites that participated in the SOLVE-CRT trial and other high-volume sites.

Strengthened Management Team:

In early 2024, EBR appointed Mr. Erik Strandberg as Chief Commercial Officer ("CCO"). Mr. Strandberg brings over 20 years of medical device sales industry experience, with strong relationships built with a broad range of physician, C-suite hospital executives and medical professionals. Prior to joining EBR, Mr. Strandberg held key leadership roles with AtriCure (Nasdaq:ATRC), Boston Scientific (NYSE:BSX), St Jude Medical and Guidant Corporation. His appointment reflects EBR's commitment to building a robust commercial infrastructure in preparation for the anticipated FDA approval and market launch. Mr. Strandberg's strategic sales, operational oversight and leadership experience is instrumental in driving EBR's U.S. commercialisation strategy and overseeing WiSE's anticipated commercial launch in H2 2025.

Ms. Pharoah Garma was appointed as Chief Regulatory Officer ("CRO") in December 2024 and brings over 20 years of leadership experience in regulatory, clinical, quality, and R&D for innovative medical devices to EBR. She began her career at the FDA as a Senior Lead and Engineering Reviewer for cardiovascular implants and has since held key leadership roles in both start-ups and multinational corporations. Most recently, Ms Garma served as Chief Operating Officer at Boomerang Medical, where she led regulatory, clinical, and quality functions. Before that, she was Vice President of Regulatory and R&D at PQ Bypass, which was acquired by Endologix in 2021.

Active Media, Investor and Academic Engagement:

Throughout 2024, EBR maintained an active presence in the media and investment community. EBR's management presented at leading investor conferences such as the 2024 Emergence Conference in both Sydney and Singapore, the 18th Bioshares Biotech Summit, the AusBioInvest 2024 conference, Wilson's Drug & Device Conference and the Bell Potter Healthcare conference. Management also hosted investor roadshows across multiple cities in Australia, providing an opportunity for shareholders to directly engage with the Company. These engagements facilitated broad dissemination of EBR's pivotal research outcomes, strategic initiatives, and commercialisation strategy.

The WiSE CRT System featured in multiple peer-reviewed publications and leading scientific conferences during the year. In August 2024, SOLVE-CRT study results were published in the *Journal of the American Medical Associate (JAMA) Cardiology*, which reinforces the trial's clinical significance. *JAMA Cardiology* is a leading international peer-reviewed journal for clinical investigators, clinicians and trainees in cardiovascular medicine worldwide. The journal is highly selective, typically with ~10% of submissions accepted for publication. Throughout the year, multiple articles were also published in the Heart Rhythm Journal, the official journal of the Heart Rhythm Society (HRS). Global key opinion leaders also presented on WiSE at major scientific meetings including the European Heart Rhythm Association (EHRA) meeting, the Heart Rhythm meeting (HRS) and the Asia Pacific Heart Rhythm Society (APHRS).

Corporate Update

In March 2024, EBR achieved the significant milestone of admission into the S&P/ASX All Ordinaries Index. The inclusion in the index increases the Company's visibility amongst investors, validates the company's strong market performance, and effectively paves the way for increased liquidity and broader investment opportunities.

In September 2024, EBR launched a US$34.0m / A$50.0m[3]capital raise composed of a fully underwritten institutional placement and fully underwritten 1-for-20 accelerated non-renounceable pro-rata entitlement offer – composed of an accelerated institutional entitlement offer and a retail entitlement offer. The funds raised are being used to primarily support initial commercialisation activities, manufacturing scale-up (including initial tooling) and ongoing research and development. The institutional placement and accelerated institutional entitlement offer raised US$31.2m / A$45.8m[4], while the retail entitlement offer raised US$2.8m / A$4.2m[5].

During the year, EBR had net operating cash outflows of US$41.2m / A$66.3m[6], mostly relating to staff costs, clinical and regulatory costs, general and administrative costs, and interest expense. In addition to its cash balance of US$6.9m / A$11.1m[6] on 31 December 2024, EBR held US$59.1m / A$95.0m[6] in investments which will become cash or cash equivalents in the future. Investments are made in fixed income instruments, have a weighted average maturity of 5.9 months, and have a minimum credit rating of A-2/P-2/F2 by at least 2 of 3 Nationally Recognised Statistical Rating Organisations, specifically Standard & Poor's, Moody's, or Fitch.

ENDS

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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[4] Assumes an A$:US$ 0.6825 exchange rate
[5] Assumes an A$:US$ 0.6635 exchange rate
[6] Assumes an A$:US$ 0.6214 exchange rate

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About EBR Systems

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 applications 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.