

ASX ANNOUNCEMENT

7 September 2026

New manufacturing facility achieves ISO certification milestone

Key highlights:

- EBR's new Santa Clara manufacturing facility achieves ISO certification following assessment by the British Standards Institution (BSI)
- Certification represents a key quality and operational milestone as EBR prepares to transition manufacturing into its expanded facility
- Additional manufacturing equipment has been installed into the new facility to support the transition from manual to automated assembly, increasing production capacity of the WiSE® System by approximately 500%
- Expanded facility supports EBR's long-term manufacturing capacity and U.S. commercial scale-up of the WiSE System
- FDA Pre-Approval Inspection of the new facility is scheduled to take place in September 2026 with anticipated FDA approval of the new facility by year end

Santa Clara, California; 7 Sep 2026: EBR Systems, Inc. (ASX: "EBR", "EBR Systems", or the "Company"), developer of the world's only wireless cardiac pacing device for heart failure, today announces that its new Santa Clara, California manufacturing facility has achieved ISO 13485 certification following assessment by global standards and certification body BSI.

ISO 13485 is the internationally recognised quality management standard for medical device manufacturing. It represents an important quality and operational milestone for EBR and supports the Company's transition to an expanded manufacturing facility with increased capacity for the continued U.S. commercial rollout of the WiSE System.

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

"Achieving ISO certification for our new Santa Clara facility is an important milestone in EBR's manufacturing scale-up strategy."

The certification, together with the move-in of additional manufacturing equipment including new, automated assembly machinery, supports our transition to a larger, more scalable manufacturing platform."

This expanded capability is an important part of EBR's broader commercial execution strategy as we continue the U.S. commercial rollout of the WiSE System."

EBR continues to install additional manufacturing equipment into the new facility, including new, automated assembly machinery. Once it receives FDA approval, the transition from manual to automated assembly of the WiSE System assembly process will be initiated, improving manufacturing efficiency and increasing production capacity by approximately 500%. This supports EBR's focus on cost reduction, yield improvement and production scale-up as commercial demand for WiSE grows.

The new Santa Clara facility expands EBR's manufacturing footprint and is expected to support an increase in overall production capacity as commercial demand for WiSE grows.

The FDA Pre-Approval Inspection for the new facility is expected to be completed in September 2026. Upon completion of the inspection and any remediation of potential observations, EBR expects the facility to be approved by FDA by year end.

For more information about EBR, please visit <https://www.ebrsystemsinc.com/>.

ENDS

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

For more information, please contact:

Company

Andrew Shute
Chief Corporate Development Officer
P: +44 7730 691421
E: investors@ebrwise.com

Investor Relations

Gabriella Hold
The Capital Network
P: +61 2 7257 7338
E: gaby@thecapitalnetwork.com.au

Julia Maguire
The Capital Network
P: +61 2 7257 7338
E: julia@thecapitalnetwork.com.au

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 in most markets and is currently only 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 and achieve broad market adoption including our estimates of potential revenues, costs, profitability and financial performance; our ability to develop and commercialize new products; our expectations with respect to our clinical trials, including enrollment 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. These forward-looking statements are based on EBR Systems' current expectations and inherently involve significant risks and uncertainties. EBR Systems' actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of certain risks and uncertainties including

those risks described in more detail in its most recently filed Annual Report on Form 10-K, Quarterly Report on Form 10-Q, and other documents on file with the SEC from time to time and available on the SEC's website at www.sec.gov.

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 ASX-traded (ASX: EBR) 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.