

TGA grants Priority Review Determination for WiSE CRT System

Key highlights:

- The Therapeutic Goods Administration (TGA) has granted Priority Review Determination for EBR's WiSE® System
- Priority Review Determination provides an accelerated pathway toward inclusion on the Australian Register of Therapeutic Goods (ARTG) for the WiSE System
- EBR intends to submit its ARTG inclusion application in the near term
- Inclusion on the ARTG will support earlier access in Australia for heart failure patients with limited CRT options
- The Determination builds on strong recent momentum across EBR's regulatory, commercial and clinical programs, including FDA approval, growing U.S. commercial activity and early revenue generation

Sunnyvale, California; 24 April 2026: EBR Systems, Inc. (ASX: "EBR", "EBR Systems", or the "Company"), developer of the world's only wireless cardiac pacing device for heart failure, announces that the Therapeutic Goods Administration (TGA) has granted Priority Review Determination for the WiSE System.

The grant of the Determination represents a significant regulatory milestone and positions EBR to achieve market entry in Australia sooner than would otherwise be expected, complementing its existing U.S. commercialisation.

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

"Receiving Priority Review Determination from the TGA is an important step in expanding access to the WiSE System beyond the U.S. and reflects the potential of this technology to address a significant unmet need for heart failure patients in Australia. With FDA approval secured, early U.S. commercial momentum building and growing clinical validation, we believe WiSE is well positioned to offer a differentiated leadless CRT option for patients who cannot receive or do not respond to conventional lead-based therapy. We look forward to progressing our ARTG application and working with the TGA through the review process."

This follows U.S. Food and Drug Administration (FDA) approval for the WiSE System in April 2025. That approval provided a strong foundation for EBR's TGA Priority Review Determination submission, which was lodged on 12 March 2026.

The TGA's Priority Review pathway is designed to accelerate the evaluation of breakthrough medical devices that address life-threatening or seriously debilitating conditions where there is a high unmet clinical need. EBR's WiSE System is expected to be assessed within an accelerated timeframe, with the evaluation period reduced from the standard 225 working days to approximately 150 working days.

EBR intends to submit its application for inclusion on the ARTG within in the near future. Inclusion on the ARTG will support earlier access in Australia to a leadless pacing option for heart failure patients who have failed to benefit from conventional lead-based CRT.

ENDS

This announcement has been authorised for release by 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: info@ebrwise.com

Investor Relations

Gabriella Hold
The Capital Network
P: +61 2 8999 3699
E: gaby@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 SYSTEMS, INC. (ARBN 654 147 127)

480 Oakmead Parkway, Sunnyvale CA 94085 USA T: +1 408 720 1906 W: <https://ebrsystemsinc.com/>

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