

ASX ANNOUNCEMENT

12 October 2026

Q3 2026 Commercial Update

Key Highlights

- EBR completed 40 WiSE® commercial implants during Q3 2026 (Q2 2026: 46), bringing total implants across the pilot phase and Limited Market Release to 157
- Q3 implant volumes were below the Company's prior forecast, particularly in September; the Company believes contributing factors included the commercial leadership transition, implementation of the refocused commercial execution strategy and additional field training requirements
- The correction in commercial strategy back to focus on deeper utilisation in accounts versus starting many new accounts has not yet shown up in current volumes but is expected to do so once fully implemented. EBR expects to report revenue in the range of US\$2.43M to US\$2.53M for Q3 2026 (Q2 2026: US\$2.6M), based on preliminary unaudited quarter-end results and subject to quarter-end closing adjustments
- FDA completed its pre-approval inspection of the new Santa Clara manufacturing facility, with only two observations noted; the facility also achieved ISO 13485 certification during the quarter
- The expanded facility has the potential to manufacture 9,600 systems annually, representing ~US\$607.6M in revenue
- The final tranche of the A\$150 million capital raising closed in August

Santa Clara, California; 12 October 2026: EBR Systems, Inc. (ASX: "EBR", "EBR Systems", or the "Company"), developer of the world's only wireless cardiac pacing device for heart failure, provides its preliminary commercial activity update for the quarter ended 30 September 2026.

Q3 commercial implant volumes were below the Company's prior quarters, as outlined below. During Q3, EBR advanced reimbursement, manufacturing scale-up and regulatory matters, including the U.S. Centers for Medicare & Medicaid Services (CMS) finalising increased Medicare inpatient reimbursement, completion of the U.S. Food and Drug Administration (FDA) inspection of the new Santa Clara manufacturing facility, ISO 13485 certification and commercial launch of the WiSE Coupler.

Commercial Update and Q4 Strategy

During the quarter, EBR commenced a realignment of its U.S. commercial organisation, with President & Chief Executive Officer John McCutcheon assuming responsibility for the commercial organisation. In that role, Mr. McCutcheon has made organisational changes to the commercial team, including the promotion of Michael Sot from Area Director to Director of U.S. Sales. The Company has numerous searches underway to bolster the commercial team, including recruitment of a Chief Commercial Officer.

EBR continues to refocus field management and activities around deeper utilisation within activated accounts, increased procedural frequency and strengthened field training and support.

These initiatives are intended to strengthen U.S. commercial execution, with benefits expected to build progressively as additional field training is completed and account activity increases.

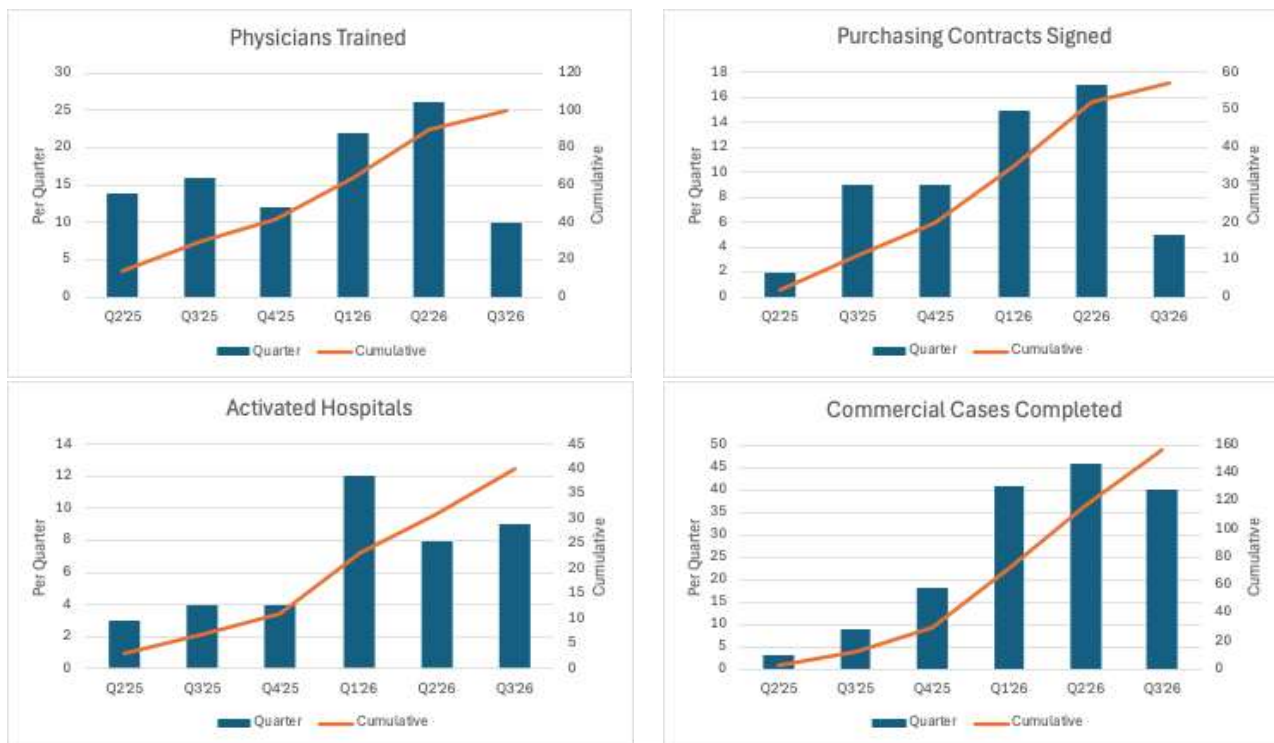
The WiSE System was implanted in 40 commercial patients during Q3 2026. September monthly cases were about half of the average July-August number, a direct consequence of the changes to strengthen the commercial organisation. Total implants across the pilot phase and Limited Market Release have reached 157.

An additional 5 purchasing contracts were signed during the quarter, bringing total purchasing contracts signed to 57.

A total of 100 physicians are now trained to implant the WiSE System, with 10 of these trained during Q3 2026.

As the limited market release continues, EBR is moderating the pace of new site activations and regaining focus on deeper utilisation within activated accounts, supporting repeat procedural experience, demonstration of use across a broader patient population, internal field capability and more consistent case scheduling.

At 30 September 2026, 40 hospitals had been activated, with 20 sites having completed three or more WiSE implants.



The Company recognizes that prior quarters growth was more dependent on new account startup rather than deeper utilisation within accounts. This was in direct contradiction to our stated strategy of the limited market release where the intent was to demonstrate utilisation of WiSE across a broader patient population within accounts before expanding to additional accounts.

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

"Q3 commercial implant volumes were below the prior two quarters. We believe the shortfall was due to commercial leadership transitions, which were done to correct the commercial execution. I take responsibility for that, and I believe these are temporary corrections that will put EBR on a stronger path to success."

"We made important progress in Q3 across reimbursement, manufacturing readiness and our U.S. commercial platform. We achieved ISO 13485 certification for our new manufacturing facility, the FDA completed its pre-approval inspection of that facility, we launched the WiSE Coupler and CMS finalised increased Medicare inpatient reimbursement for eligible WiSE procedures."

"I'll continue to lead the commercial organisation while we look for a new commercial leader. The team is focused on deeper utilisation within activated accounts, strengthening field training and support, and increasing procedural frequency. These changes take time to flow through to case volumes, but we believe they provide the right foundation for more consistent commercial execution as we move through Q4 and into 2027."

Funding and Reimbursement

During the quarter, EBR completed the final tranche of its A\$150 million capital raising. The completed raise strengthens the Company's balance sheet and supports continued investment in commercial expansion, manufacturing scale-up and its pathway toward cashflow breakeven.

During Q3, CMS finalised increased Medicare inpatient reimbursement for eligible WiSE procedures, effective 1 October 2026. Under the final FY2027 rates, base Medicare inpatient payments for eligible WiSE procedures increase by approximately 58% and 93% following their reassignment to higher-value Medicare Severity Diagnosis Related Groups (MS-DRGs) 228 and 229, respectively, which align with leadless pacemaker procedures. Assuming the maximum available New Technology Add-on Payment (NTAP) of US\$41,145, total Medicare payment may reach approximately US\$77,839 and US\$66,566, respectively supporting lessened financial hurdles within hospital contracting. Actual payments vary based on hospital- and case-specific factors and applicable CMS NTAP criteria (refer to ASX announcement dated 21 September 2026).

EBR expects to provide further detail in its Q3 2026 Quarterly Activity Report and Form 10-Q, to be lodged with the ASX on or about 10 November 2026 AEDT.

Operational and Regulatory Progress

EBR achieved operational milestones during the quarter that will support long-term product supply, manufacturing scale-up and the broader U.S. commercial rollout of WiSE.

The Company's new Santa Clara manufacturing facility achieved ISO 13485 certification during Q3. The FDA also completed its pre-approval inspection of the new facility in connection with EBR's Premarket Approval (PMA) supplement to add the facility as a manufacturing site for WiSE. At the close of the inspection, the FDA issued a Form 483 listing only two observations, and EBR responded "Promised to Correct" for both. The FDA's Center for Devices and Radiological Health will review the inspection record and make the final Agency determination regarding the inspection classification and the PMA supplement. EBR continues to anticipate PMA approval of the new site by the end of 2026 (refer to ASX announcement dated 28 September 2026).

During the quarter, EBR also advanced its engagement with the U.S. FDA regarding the previously disclosed echo-induced pacing issue and the cybersecurity incident.

Following its review of EBR's completed cybersecurity risk assessment, the FDA agreed that no immediate field corrective action or recall relating to the WiSE System is warranted (refer to ASX announcement dated 9 September 2026). EBR also met with the FDA regarding echo-induced pacing risk, and the FDA was aligned with EBR's plan to submit a Changes Being Effected (CBE) PMA supplement in Q4 2026 to update WiSE labelling to increase the visibility of this risk and its mitigations (refer to ASX announcement dated 16 September 2026).

EBR also commercially launched the WiSE Coupler during the quarter. The single-use accessory is designed to support positioning and stabilisation of the delivery catheter system during WiSE implantation by coupling the two delivery system handles together so that they work as one unit.

Looking ahead

EBR's priorities entering Q4 2026 are focused on strengthening commercial execution, expanding the US field team, completing field team training, increasing utilisation and procedural frequency within activated accounts, and progressing the transition to its new Santa Clara manufacturing facility.

The Company believes the refocused commercial strategy, expanded field team, increased Medicare inpatient reimbursement effective 1 October 2026, together with ongoing field training and, subject to FDA approval, its new manufacturing facility, will support the next phase of U.S. commercial adoption.

Preliminary Unaudited Financial Information

The Company has not yet completed its financial close process for the quarter ended 30 September 2026. Actual results may differ from those set forth in this release due to the risks and uncertainties inherent in EBR's business,

including, without limitation, audit adjustments and other developments that may arise between now and the completion of our quarter-end financial closing procedures and our independent registered public accounting firm's review of our consolidated financial statements for the quarter ended 30 September 2026. Such preliminary revenue results for quarter ended 30 September 2026, are subject to change, and should not be viewed as a substitute for financial information prepared in accordance with U.S. generally accepted accounting principles. Our independent registered public accounting firm has not audited, nor has it performed any review or other procedures with respect to the preliminary results set forth in this release, nor has it expressed any opinion or any other form of assurance on the preliminary revenue results for Q3 2026 set forth herein.

Investor Webinar

EBR's senior management team will host an investor webinar to discuss these results.

The webinar will be held on **Wednesday 14 October 2026 at 12:30pm AEDT (Tuesday 13 October at 6:30pm PDT)**.

Investors can register for the webinar via the following link:

<https://attendee.gotowebinar.com/register/2779759367686774870>

After registering, you will receive a confirmation email containing information about joining the webinar.

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

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

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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 in most markets and is currently only available for sale in the US.

EBR SYSTEMS, INC. (ARBN 654 147 127)

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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.