

EBR Systems, Inc

Recommendation: Buy | Sector: Health Care Equipment

EBR Systems, Inc. develops implantable systems for wireless tissue stimulation. The company offers WiSE cardiac resynchronization therapy system that uses a proprietary wireless technology to deliver pacing stimulation directly to the inside of the left ventricle of the heart. Its products are used to eliminate lead complications, such as placement difficulty, unintended nerve stimulation, dislodgement, extraction, and repositioning. The company was incorporated in 2003 and is based in Sunnyvale, California.

Risk	Medium to High
Market Cap (\$)	291.145M
Shares Outstanding	308
Beta	0.76
EPS (TTM)	-0.1800
PE (TTM)	NA
Dividend Yield (%)	NA
52 Week Range (\$)	0.5350 - 1.3500
Target Price (\$)	1.30
Stop Loss (\$)	0.825

Stock Performance Profile:



Source: Trading View

Key Financial Highlights:

- Operational expenses of US\$34.5m/A\$55.6m, an increase of US\$0.5m/A\$0.8m compared to prior corresponding period (pcp) driven by increased research and development spending on product development and increased general and administrative spending on employee related expenses. These increases were offset by a reduction in sales and marketing expenses, and clinical and regulatory expenses, resulting from completing enrolment in the SOLVE-CRT trial in July of 2022.
- 7.71% increase in net cash used in operating activities compared to pcp, to US\$32.7m/A\$48.0m.
- EBR holds cash and short-term investments of US\$73.4m/A\$107.8m on 31 December 2023 and remains well funded through initial commercialization.

EBR achieved a transformative milestone during the year, announcing positive top-line data from its pivotal SOLVE-CRT trial. The trial met both primary endpoints, validating the ability of the WiSE CRT System to provide safe and effective cardiac resynchronization therapy and representing a significant breakthrough in the treatment of cardiac arrhythmia. Positive pivotal trial results pave the way to FDA approval and EBR is currently progressing its regulatory agenda targeting pre-market approval application (“PMAA”) submission to the FDA in Q3 2024 and FDA approval in Q1 2025.

In addition to the pivotal SOLVE-CRT trial results, EBR announced supporting positive data from its analysis of SOLVE-CRT’s randomized sub-study portion. The randomized phase consisted of 108 patients who all received the WiSE implant and were randomized in a 1:1 ratio to either the Treatment Group (WiSE-CRT System ON) or Control Group (WiSE-CRT System OFF). Results from the randomized sub-study support the conclusions of the primary study that the WiSE-CRT System is safe and efficacious in treating heart failure patients. With data from both the pivotal trial and randomized sub-study released, EBR has submitted a manuscript to a medical journal for peer-review and expect acceptance and publication in the near term.

Operational Milestones (FY 2023) met both primary endpoints in the pivotal SOLVE-CRT trial, paving the way to U.S. Food and Drug Administration (“FDA”) approval in Q1 2025

- Reported positive results from the SOLVE-CRT randomized sub-study, supporting conclusions from the primary study that the WiSE® CRT System is an effective treatment for heart failure patients
- Strengthened leadership team with appointment of Dr. Rick Kuntz as consulting Chief Scientific Officer, and Mr Gary Doherty as Chief Financial Officer
- Secured funding to support regulatory activities and initial commercial launch via a US\$21.6m capital raise and US\$20.0m drawdown from EBR’s growth capital facility with Runway Growth Capital
- Featured in scientific meetings, the media and investor conferences, including 2023 Heart Rhythm Society conferences in New Orleans and Hong Kong (Asia-Pacific)

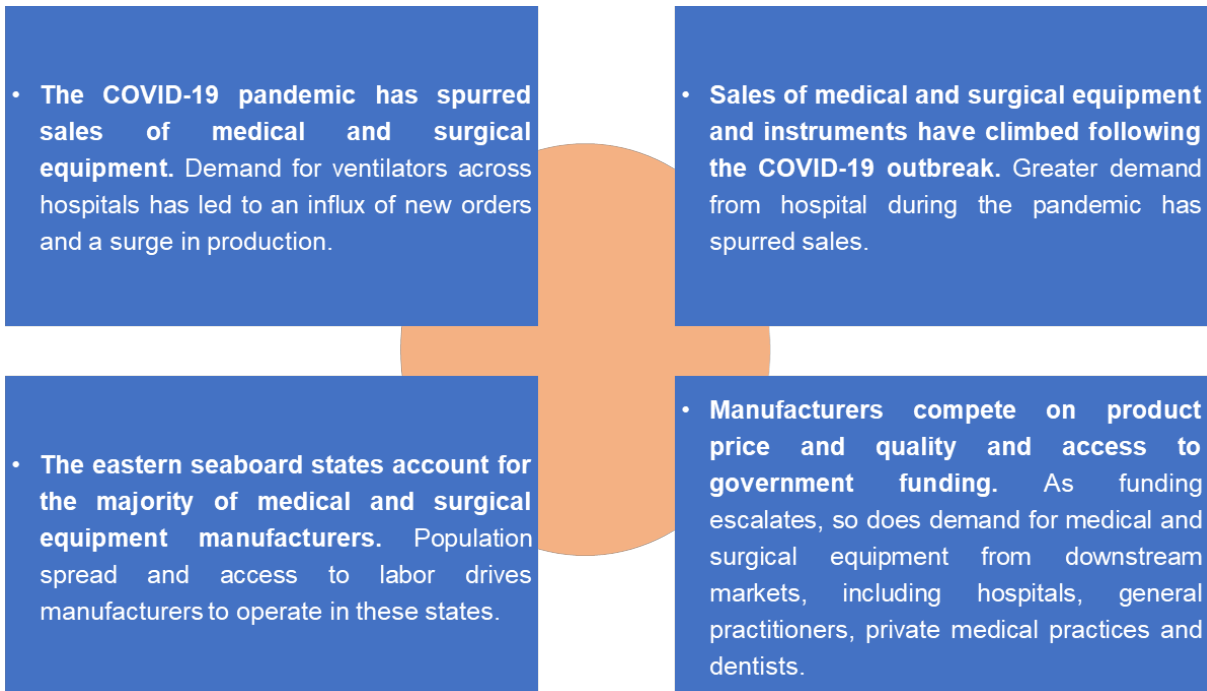
Source:

Company reports

Industry Overview

In contrast to most other manufacturing industries, which are declining due to increased production costs and intense competition from imports, makers of medical and surgical equipment are thriving. The growing healthcare industry and aging population in Australia have increased the country's need for surgical and medical supplies. Despite the fact that sales skyrocketed due to the COVID-19 outbreak, revenue increased by 31.9% in 2020–21. Due to the increased usage of ventilators, infusion systems, and renal care supplies in intensive care units to treat the virus, the pandemic increased demand for surgical and medical equipment in both public and private hospitals. Lockdowns and limitations on elective surgery hurt sales of other products including dental equipment and hearing aids, even as the need for these goods increased. Overall, it is projected that industry sales increased at an annualized.

Key Points:



Source: IBIS World

Risk Analysis

EBR Systems, Inc. faces several potential risks that could impact its operations and financial performance. One significant risk is technological disruption, as the company operates in the dynamic and rapidly evolving field of medical technology. Changes in industry standards, advancements in competing technologies, or regulatory hurdles could threaten the adoption and market acceptance of EBR Systems' innovative cardiac pacing technology. Additionally, market competition poses a risk, as the company competes with established players and emerging startups in the medical device market. Economic downturns, fluctuations in healthcare spending, and reimbursement challenges could also impact the company's revenue streams and growth prospects. Furthermore, as EBR Systems expands its operations globally, it faces risks related to geopolitical instability, regulatory compliance in different jurisdictions, and currency exchange fluctuations. Proactively addressing these risks through robust risk management strategies and maintaining agility in response to market dynamics will be crucial for EBR Systems to navigate successfully in its industry.

Outlook

EBR Systems, Inc. exhibits a promising outlook driven by its innovative medical technology and strategic positioning within the healthcare sector. As a leader in cardiac rhythm management, EBR Systems stands to benefit from increasing demand for advanced treatment options for patients with heart conditions. With a focus on developing and commercializing its Wireless Stimulation Endocardially (WiSE) technology, which offers a unique approach to cardiac pacing, the company has the potential to revolutionize the treatment landscape for heart failure patients. Moreover, EBR Systems' commitment to research and development, coupled with its partnerships with leading healthcare institutions, positions it favorably for future growth and market expansion. As the company continues to advance its technology and penetrate new markets, it is poised to capitalize on emerging opportunities and solidify its position as a key player in the cardiac healthcare industry.

Technical Analysis



Source: Trading View

Stock Binge's View:

The stock is moving in upwards manner marking higher top and higher bottom on the weekly charts, and has recently given an upside breakout of ascending triangle which is a bullish technical pattern. This event is likely to bring upside momentum in the coming few months and any dip here would be the opportunity to buy at lower levels. Momentum indicators e.g. RSI and MACD are gradually moving towards overbought levels along with that 100 days SMA is providing strong support levels in the recent past and only a close and sustain below this moving average would prices attract some more selling pressure but before that we can expect upside to remain intact in the coming months.

StockBinge recommends a "BUY" at current market around \$0.935 levels with stop loss of \$0.825 and a target will be \$1.30 which is around 40% of upside from present levels.

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