

ASX ANNOUNCEMENT

29 August 2022

EBR Half-Year Results 2022 and Securityholder Update

EBR Systems, INC (“**EBR Systems**”, “**EBR**”, “**The Company**”) is pleased to present the Company’s financial results for the half-year ending 30 June 2022, together with a securityholder update.

During the half-year, EBR:

- Achieved a major milestone of completing interim enrolment in the pivotal SOLVE-CRT (“SOLVE”) trial.
- Remains confident that it will achieve the 6-month primary endpoints, resulting in a successful pivotal trial and the basis for US Food and Drug Administration (“FDA”) approval. This is underpinned by outcomes from previous clinical trials of WiSE®, which have exceeded the performance endpoints set for the SOLVE trial.
- Announced it had executed an agreement for a 5-year \$US50m growth capital facility with a leading venture debt provider, Runway Growth Capital, LLC. Funds raised from the facility provide EBR with funding flexibility and will be used to support growth and commercialisation activities over the medium term.
- Maintained a strong cash position of US\$79.3m/A\$115.1m¹ at 30 June 2022

Operating and Financial Review

Financial performance

For the half-year ended 30 June 2022, the Company’s net loss before tax is US\$15.6m/A\$22.7m¹ (30 June 2021: US\$15.9m/A\$23.1¹).

Points to note on the Company’s financial position are:

- Operational expenses of US\$16.5m/A\$23.9m¹, an increase of US\$6.3m/A\$9.14m¹ compared to prior corresponding period (pcp) driven by an increase in research and development expenses and spending associated with resumption of the SOLVE clinical trial.
- 66% increase in net cash used in operating activities compared to pcp, to US\$15.4m/A\$22.4m¹.
- Strong cash position of US\$79.3m/A\$115.1m¹ at 30 June 2022.

To view the Half-Year Report, please click:

<https://www.asx.com.au/asxpdf/20220829/pdf/45ddz6c1mm8h86.pdf>.

¹Assumes an A\$:US\$0.689 exchange rate

Operational Update

During the half-year, EBR reached a significant milestone by successfully completing the 183-patient interim enrolment in its pivotal SOLVE trial of WiSE®. The clinical endpoints for the trial are determined at the 6-month follow-up, which is the last step required before submitting a Premarket Approval (PMA) submission to the FDA. The trial evaluates the safety and efficacy of WiSE® in heart failure patients who are classified as acute lead failures, chronic lead failures, high-risk upgrades, or leadless upgrades. The trial has been de-risked clinically, since previous trials of WiSE® exceeded the safety and efficacy endpoints set for the SOLVE trial, with over 450 patients treated with WiSE® to date. In addition, EBR has a clear and targeted pathway to commercialisation, leveraging its extensive engagement with the FDA, and Breakthrough Device Designation, which provides access to greater initial payment coverage in the U.S.

The initial global addressable market for WiSE® is US\$2.5bn in 2024, which increased from US\$2.1bn during the half-year after receiving FDA approval to include commercially available leadless pacemakers as co-implants for WiSE® in the pivotal SOLVE trial. The pivotal SOLVE trial was originally designed to only include patients with conventional pacemakers (pacemakers with a lead to the right ventricle), however this has since expanded to include patients with a leadless right ventricle pacemaker. WiSE® is the only device that can potentially support the upgrade of patients currently implanted with a leadless right ventricle pacemaker, which solves a significant unmet need by providing a solution to patients with no other upgrade options. The approval indicates that the FDA will consider whether to approve WiSE® for use with other leadless pacemakers as an on-label (FDA-approved) treatment option at the time of the PMA application.

The Company executed an agreement with leading venture debt provider, Runway Growth Capital, LLC, for a US\$50m growth capital facility that will span a period of 5 years. Funds from the facility provide EBR with access to non-dilutive capital and the funding flexibility to support growth endeavours and commercialisation activities for the medium term. The arrangement will involve a series of tranches with the initial payment of US\$20m drawn immediately and subsequent tranches being conditional upon significant milestones. Given current macroeconomic conditions globally including rising inflation, increasing interest rates, and plummeting market indices, additional funding provides EBR with considerable balance sheet flexibility and protection of securityholder value as the company progresses through to commercialisation. More details on the facility and terms can be found in the ASX announcement titled 'EBR Systems secures US\$50m growth capital facility', released on 1 July 2022.

In April, the world's first totally leadless LBBAP implant of Micra® and WiSE® was performed successfully by Professor Pascal Defaye, a leading cardiologist at the University Hospital of Grenoble, France. The implant is a milestone for EBR as it provides validation of EBR's additional clinical projects; the Totally Leadless CRT (TLC) and Achieving Conduction System Activation with Left Ventricular Septal Endocardial Leadless Pacing (ACCESS-CRT). The implant combines applications of both studies – as it combines WiSE® with a leadless right ventricle pacemaker, and it is also placed in the mid-septal position of the left ventricle of the heart. EBR hopes that these prospective studies could lead the way to expanded indications and WiSE® becoming a de-novo (first in line) treatment option for patients with heart failure.

During the Heart Rhythm Society conference in May, there were three significant presentations demonstrating the potential to either expand the clinical applications of WiSE® technology or success in treating a group of previously failed patients. Dr Jeffrey Alison, MonashHeart, presented on the Long-Term Efficacy Of The First Totally Leadless A-V Synchronous Biventricular Pacing System Implanted By Primary Intent. Dr Emad Aziz, Rutgers New Jersey Medical School, presented a case report on a Novel Pacing Technique for a Patient with Complete Heart Block and no Venous Access Utilizing the WiSE CRT System. Dr Mark Elliott, King's College London, presented on the Technical Feasibility of Septal Left Ventricular Pacing via the WiSE CRT System: An Initial Multi-Centre Experience.

ENDS

This securityholder update has been authorised for release by the EBR Systems Finance Disclosure Committee, a committee of the Board of Directors.

EBR SYSTEMS, INC. (ARBN 654 147 127)

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

For more information, please contact:

Company

Frank Hettmann
Chief Financial Officer

P: +1 408 720 1906

E: info@ebrsystemsinc.com

Investors

Nina Lo
Vesparum Capital

P: +61 3 8582 4800

E: EBRSystems@vesparum.com

EBR Systems: Company Overview and WiSE®

EBR Systems 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 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.

WiSE® 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® 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.

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 (including but not limited to the COVID-19 pandemic), 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 submissions 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. Given the current uncertainties regarding the impact of the COVID-19 on the trading conditions impacting the Company, the financial markets, and the health services world-wide, investors are cautioned not to place undue reliance on the current trading outlook.

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.